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Contents

Reviews

Viewpoints

Original Papers

Research Letter

Review

Digital Health Psychosocial Intervention in Adult Patients With Cancer and Their Families: Systematic Review and Meta-Analysis

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Abstract

Background: Patients with cancer and their families often experience significant distress and deterioration in their quality of life. Psychosocial interventions were used to address patients' and families' psychosocial needs. Digital technology is increasingly being used to deliver psychosocial interventions to patients with cancer and their families.

Objective: A systematic review and meta-analysis were conducted to review the characteristics and effectiveness of digital health interventions on psychosocial outcomes in adult patients with cancer and their family members.

Methods: Databases (PubMed, Cochrane Library, Web of Science, Embase, CINAHL, PsycINFO, ProQuest Dissertations and Theses Global, and ClinicalTrials.gov) were searched for randomized controlled trials (RCTs) or quasi-experimental studies that tested the effects of a digital intervention on psychosocial outcomes. The Joanna Briggs Institute's critical appraisal checklists for RCTs and quasi-experimental studies were used to assess quality. Standardized mean differences (ie, Hedges *g*) were calculated to compare intervention effectiveness. Subgroup analysis was planned to examine the effect of delivery mode, duration of the intervention, type of control, and dosage on outcomes using a random-effects modeling approach.

Results: A total of 65 studies involving 10,361 patients (mean 159, SD 166; range 9-803 patients per study) and 1045 caregivers or partners (mean 16, SD 54; range 9-244 caregivers or partners per study) were included in the systematic review. Of these, 32 studies were included in a meta-analysis of the effects of digital health interventions on quality of life, anxiety, depression, distress, and self-efficacy. Overall, the RCT studies' general quality was mixed (applicable scores: mean 0.61, SD 0.12; range 0.38-0.91). Quasi-experimental studies were generally of moderate to high quality (applicable scores: mean 0.75, SD 0.08; range 0.63-0.89). Psychoeducation and cognitive-behavioral strategies were commonly used. More than half (n=38, 59%) did not identify a conceptual or theoretical framework. Most interventions were delivered through the internet (n=40, 62%). The median number of intervention sessions was 6 (range 1-56). The frequency of the intervention was highly variable, with self-paced (n=26, 40%) being the most common. The median duration was 8 weeks. The meta-analysis results showed that digital psychosocial interventions were effective in improving patients' quality of life with a small effect size (Hedges g=0.05, 95% CI –0.01 to 0.10; I^2=42.7%; P=.01). The interventions effectively reduced anxiety and depression symptoms in patients, as shown by moderate effect sizes on Hospital Anxiety and Depression Scale total scores (Hedges g=–0.72, 95% CI –1.89 to 0.46; I^2=97.6%; P<.001).

Conclusions: This study demonstrated the effectiveness of digital health interventions on quality of life, anxiety, and depression in patients. Future research with a clear description of the methodology to enhance the ability to perform meta-analysis is needed. Moreover, this study provides preliminary evidence to support the integration of existing digital health psychosocial interventions in clinical practice.

Trial Registration: PROSPERO CRD42020189698; https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=189698

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KEYWORDS

cancer; anxiety; decision-making; depression; digital health; distress; family; mental health; mortality; psychosocial intervention; quality of life

Introduction

Cancer is often associated with psychological distress in patients and their family members. Emerging evidence shows that psychological distress contributes to cancer mortality [1,2]. Given that over 2 million new cancer cases are expected to be diagnosed in 2024 in the United States, psychosocial distress is a significant public health problem [3]. Psychosocial distress can be triggered by many challenges, such as decision-making regarding treatment, self-care challenges due to side effects from cancer treatment, maintaining work-life balance, and financial burden. A large body of research documents the negative influence of a cancer diagnosis and treatment on a patient's experience, including depression, anxiety, and decreased quality of life [4,5]. Cancer not only affects the patient but also imposes changes on the family [6]. Family members, who often assume caregiving roles to complement the roles of the health care team, often experience deteriorating quality of life and significant psychological distress [7,8]. For many years, researchers have examined psychosocial interventions addressing patients' and family members' needs to help maintain psychosocial well-being and quality of life during the cancer experience [9-12].

Increasingly, studies have used digital technology to deliver psychosocial interventions. In this report, we refer to digital health intervention as the use of digital, mobile, and wireless technologies to deliver an intervention. Digital health interventions have gained popularity due to their geographic accessibility, self-paced nature, user-friendly design, up-to-date information provision, and time-sensitive interaction with health care providers [13,14]. Further, digital interventions have significant potential for reaching people, mainly in rural areas or people with limited mobility [15]. There are various delivery modes for digital interventions, such as smartphone apps, websites, the internet, and virtual reality. There are also drawbacks, including concerns related to security and privacy and inaccessibility for people without smart device ownership. Psychosocial interventions may incorporate various components, such as communication skills training, cognitive behavioral therapy, patient education, peer support, and problem-solving training [16].

Despite the plethora of individual research studies, a synthesis of digital psychosocial interventions for patients with cancer and their families is needed to provide a summary of existing evidence regarding the effects of interventions and provide directions for future research and clinical practice. A range of systematic reviews have examined digital health psychosocial interventions for patients with cancer [17-22] and their family members [23,24]. However, these reviews have limitations. For example, some reviews primarily focused on a specific population, such as individuals with breast [17] or prostate cancer [19,20]; a particular delivery mode, such as internet-based [17,23,24]; or a specific psychosocial outcome, such as quality of life or psychological distress [21,22]. In addition, Slev et al [25] synthesized evidence from systematic reviews of interventions delivered through computers or the internet for patients with cancer and their caregivers; however, the authors failed to quantify the effectiveness of interventions across studies using advanced statistical techniques, such as a meta-analysis. To date, no studies have used meta-analytical strategies to quantify the impact of digital health interventions on psychosocial outcomes in patients with cancer and family members. To fill these gaps, we conducted a systematic review and meta-analysis to comprehensively review the characteristics and effectiveness of digital psychosocial interventions on psychosocial outcomes across different available delivery modes in adult patients with cancer and their family members.

The specific aims were to answer the following questions:

1. What are the characteristics of digital psychosocial interventions for adult patients and families living with cancer? (ie, intervention component, theoretical or conceptual framework, tailored or standardized, mode of delivery, prescribed dosage, duration of the intervention, and actual dosage)?
2. What is the efficacy of interventions on psychosocial outcomes for adult individuals diagnosed with cancer and their family members and associated factors (ie, delivery mode, control condition, and dosage, including the number of sessions, frequency, and duration)?

Methods

The review followed the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) checklist [26].

Study Identification

The medical librarian (DR) and first author (YZ) worked together to identify search terms to build a comprehensive search strategy (Multimedia Appendix 1). Using controlled vocabulary and keywords when available, the search strategy was executed in the following databases: PubMed, Cochrane Library, Web of Science, Embase, CINAHL, PsycINFO, ProQuest Dissertations and Theses Global, and ClinicalTrials.gov. The results were limited to the English language and those published from each resource's inception until March 2019, when the search was completed. An initial limited search of PubMed and CINAHL was undertaken, followed by an analysis of the text words in the abstract and the index terms used to describe the article. Relevancy was determined by the first author (YZ) and medical librarian (DR). A second search was undertaken across all included databases using all identified keywords and index terms.

Study Selection

The inclusion criteria were studies that (1) included adult patients (≥18 years of age with any cancer diagnosis) or their adult family members (eg, partner, caregiver, adult children, parent, or relative); (2) tested a digital health psychosocial intervention, which was defined as any nonpharmacological therapeutic intervention that addressed the psychological, social, personal, or relational adjustment needs associated with cancer through a digital health mechanism (eg, application and website); (3) measured at least 1 psychosocial outcome; and (4) used an experimental (randomized controlled trial [RCT]) or a quasi-experimental design. Studies were excluded if they enrolled pediatric patients with cancer; were review articles, letters to the editor, editorial reports, case reports, or commentaries; were published as abstracts only; and were not published in English. For meta-analysis, we excluded articles that did not provide data or when only a single study included the outcome measure.

After removing duplicates, the first author (YZ) read all titles and abstracts to identify articles based on inclusion and exclusion criteria. The full texts of all included articles were then screened independently by 2 reviewers (master's-level or above), and final decisions were made based on consensus. Finally, articles identified in the search were imported to Endnote X8 (Clarivate Analytics).

Data Extraction and Management

A Microsoft Excel (Microsoft Corporation) spreadsheet was used to record information [27], including the description of the interventions (eg, theory basis, mode of delivery, content, actual dosage, planned dosage, standardized, or tailored), study sample (eg, age, sex, education, race, ethnicity, and cancer diagnosis), study characteristics (eg, design, randomization method, and control condition), intervention outcome variables and measurements, follow-ups, and quantitative data (ie, mean, SD, and sample size). Dosage was described as the number of intervention sessions, frequency, and duration of access to intervention. A standardized intervention was defined as all participants receiving the same intervention, while a tailored intervention involved customization of the intervention based on individual characteristics or needs [28]. We defined the prescribed dosage as the intended treatment dose, including the number of intervention sessions, frequency, and total length according to the study protocol. A codebook was created for data extraction, and the team's decisions were tracked and recorded. All authors extracted data from 3 articles to pilot-test the spreadsheet. The research team discussed any ambiguity, resolved differences in interpretation, and modified the data extraction spreadsheet. Subsequently, each article underwent independent data extraction by YZ and another author (6 trained reviewers). The research team met throughout the study period every other week to resolve any discrepancies. A total of 15 original study authors were contacted to request missing information (eg, mean, SD, and sample size), and no additional data were received.

Assessment of Methodological Quality

The reviewers assessed the included studies for methodological rigor using standardized critical appraisal instruments from the 13-item Joanna Briggs Institute (JBI) Critical Appraisal Checklist for RCT and the 9-item JBI Critical Appraisal Checklist for quasi-experimental studies [29]. Reviewers answered each risk of bias item as "yes" (score=1), "no" (score=0), "unclear" (score=0), or "not applicable." Possible composite scores ranged from 0 to 9 for quasi-experimental studies and 0-13 for RCTs, with higher scores indicating less risk of bias and better study quality. The applicable score (range 0-1) was calculated by dividing the composite score by the maximum score possible after subtracting any "not applicable" responses [30]. All studies were double-coded, and any disagreements were resolved through discussion with the research team [26].

Data Synthesis and Meta-Analysis

Data Synthesis

Data synthesis was completed on all articles that met the inclusion criteria. Only primary study results were included if multiple articles were published from the same intervention study. Simple descriptive statistics (ie, mean, SD, frequency, and percentage) were used to summarize study characteristics (eg, study design and participant characteristics) and key features of interventions (ie, theory, mode of delivery, number of sessions, frequency, and total length). Intervention content was grouped and narratively summarized according to the description of the intervention components.

Meta-Analytical Procedure

An a priori decision was made to only include studies in the meta-analysis if at least 2 studies used the same instrument to assess the same psychosocial outcome [31]. Standardized mean differences (ie, Hedges *g*) were calculated to compare intervention effectiveness across studies that used different scales or measurements. Mean differences between the scores before the intervention and the follow-up assessment after the intervention were calculated for pre-post interventions. Similarly, for the RCT studies, the results from follow-up in each study were selected and analyzed using difference scores from before and after the intervention for both intervention and control groups, with the pooled SDs. We computed the overall effect size across different time points for studies with multiple follow-ups. By doing so, we captured the time-varying effect on intervention effectiveness [31]. The overall effect (including all information across all time points) and time-varying effects, including the interim effect (during the intervention period), immediate effect (after the intervention), short-term effect (follow-up ≤8 weeks after completion of the intervention), and long-term effect (follow-up >8 weeks after completion of the intervention), were calculated. A cutoff of 8 weeks was chosen because it was the median length of the follow-up period across the included studies.

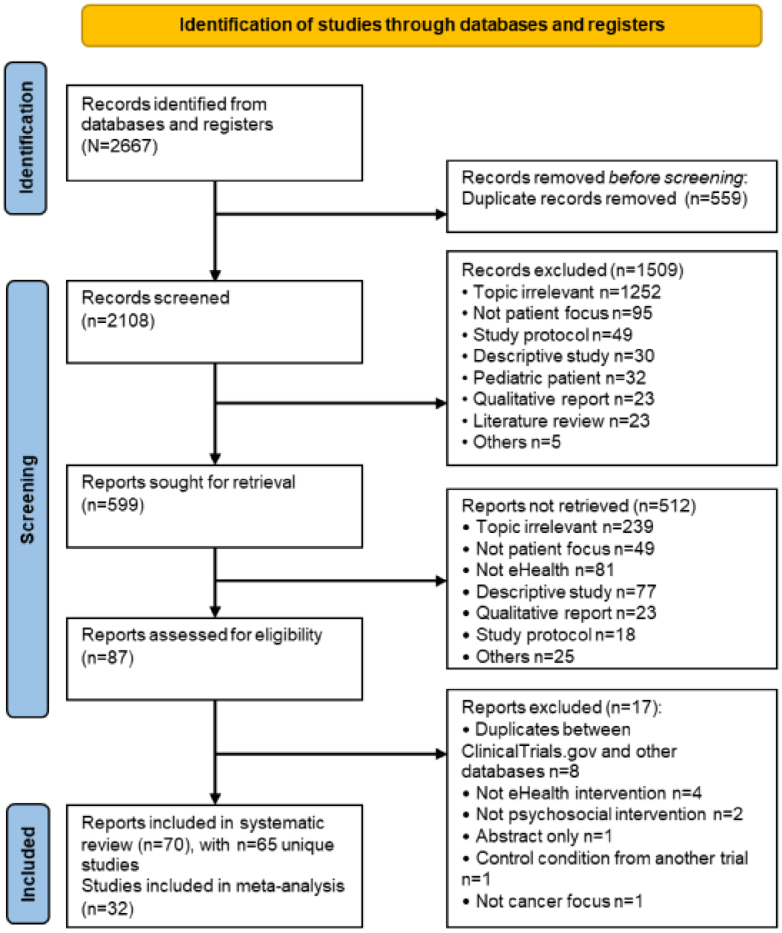
To assess study heterogeneity, the I^2 statistic was examined. The I^2 statistic quantifies the proportion of total variance across studies caused by a fundamental difference between trials rather than chance. An I^2 statistic of <25% indicates low heterogeneity, between 25% and 75% indicates moderate heterogeneity, and >75% indicates high heterogeneity [32]. Lower heterogeneity is better. Funnel plots (ie, to visually assess the asymmetry) and Egger test (ie, to test the asymmetry statistically) assessed publication bias [33]. In funnel plots, if points are distributed equally between positive and negative effects, bias is lacking; variability is expected to be greater near the bottom of the chart among smaller sample size studies. For the analysis of data from studies with more than 1 digital psychosocial intervention group, we compared each digital psychosocial intervention group to the control group separately. Additionally, subgroup analysis was planned based on the review's focus on examining the effect of delivery mode, type of control condition, and dosage on outcomes. Furthermore, we performed sensitivity analyses by including and excluding studies with extreme weights in the analyses. We used the DerSimonial-Laird random-effects model to weight and pool the individual estimates to capture variance across different studies, as all included studies were conducted in heterogeneous populations across various settings [34]. We performed all statistical and meta-analyses using STATA (version 17; StataCorp LLC).

Results

Search Results

After removing duplicates, a total of 2108 studies were identified. Figure 1 shows a flow diagram of studies identified, screened, included, and excluded from this systematic review and meta-analysis. After screening titles and abstracts and applying inclusion and exclusion criteria, a total of 70 records with 65 unique studies (for multiple manuscripts published from the same intervention study, only primary manuscripts were included) were included in the systematic review [35-99] and 32 studies [35,36,38,40,41,43,44,47,50,53-55,57,64,66,68-72, 74,77,80,82,83,86,88,91,93,95,96,99] with available data were included in the meta-analysis. A total of 33 studies were excluded from the meta-analysis because either data were unavailable to calculate the effect size (n=14) [42,46,51,62,73,76,78,79,81,84,87,89,94,98] or no other study used the same measure (n=19) [37,39,45,48,49,52, 56,58-61,63,65,67,75,85,90,92,97].

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram.



Study Characteristics

Overview

Of the 65 studies, 48 (74%) were RCTs [35-37, 39-50,52-57,59-65,72,73,76-82,85,89-91,93-99], and 17 (26%) were quasi-experimental [38,51,58,66-71,74,75,83,84,86-88,92].

More than half (n=37, 58%) of the studies were conducted in the United States [36-40,44,48-50,54,56-61,63, 65,67-69,71,72,74,77,79,80,83-85,87-90,94,97,98], and the rest were from the Netherlands (n=9, 14%) [35,41,43,47,64,70,91,92,96], Australia (n=5, 8%) [45,66,75,86,95], and other countries (eg, Denmark and Ireland). In total, 10,361 patients (mean 159, SD 166; range 9-803 patients per study) were included: 7098 female patients and 3263 male patients; 1045 caregivers or partners were enrolled (mean 16, SD 54; range 9-244 caregivers or partners per study), including 781 female individuals and 264 male individuals. The average age of patients ranged from 39.9 to 72 years, and the average age of caregivers or partners ranged from 51.5 to 58.8 years. In the 33 studies that provided information about race and ethnicity, most patients (n=3495, 90%) and family members (n=259, 97%) were described as “White” or “Caucasian.” The cancer diagnoses varied across studies, with the most prevalent being breast cancer (n=24, 37%) [35,37,38,42,44,52,54,58,60,61,64-66,70-72,74,76,80,82,84,91,93,95], mixed cancer diagnosis (n=19, 29%) [36,40,45,47,50,51,53,57,62,69,75,77,78,81,83,94,96,97,99], and prostate cancer (n=7, 11%) [39,48,56,67,85,88,98]. The attrition rate ranged from 0% to 76%, with a median of 16.8% (mean 20.4%, SD 13.7%). The recruitment rate ranged from 4.4% to 94.2%, with a median of 59.5% (mean 56%, SD 24.6%). Detailed information about the study and sample characteristics from the included studies is provided in Table S1 in Multimedia Appendix 2 [35-99].

Control Condition

Of the 48 RCTs, 29 (60%) studies included a usual care control group [35,36,39,41-44,46,47,52,54,55,62,64,65,73,76-80,82,85,91,93-96,99], and 19 (40%) included an active control [37,40,45,48-50,53,56,57,59-61,63,72,81,89,90,97,98]. Among the 17 quasi-experimental studies, 11 (65%) did not have a control group [38,51,67-71,74,86-88], and 6 (35%) studies included a usual care control group [58,66,75,83,84,92].

Outcome Assessment

A total of 21 studies had 1 follow-up assessment [22,38,45,47,48,50,51,57,68-70,72,74,76-78,88-90,98,99], 23 had 2 follow-up assessments [35,39,44,46,52-55,63-65,67,71,75,79,83,84,86,87,92,93,95,97], 11 had 3 follow-up assessments [37,40-43,60-62,66,80,91], and 7 had 4 or more follow-up assessments [49,56,58,59,73,81,85]. The timing of follow-up assessments varied, ranging from immediately to 6 months after the intervention. The commonly reported outcomes and relevant measures are reported below in *Aim 2: Effects on Patients' and Family Members' Psychosocial Outcomes*.

Quality Assessment (Risk of Bias)

The quality assessment scores of the included studies are summarized in Table S1 in Multimedia Appendix 2. Overall, the RCT studies' general quality was mixed, with applicable scores ranging from 0.38 to 0.91 (mean 0.61, SD 0.12). Quasi-experimental studies were generally of moderate to high quality, with applicable scores ranging from 0.63 to 0.89 (mean 0.75, SD 0.08) on the JBI Critical Appraisal Checklist for quasi-experimental studies. The publication year and applicable appraisal score were not significantly correlated in RCTs (r=0.12; P=.40) and quasi-experimental studies (r=–0.04; P=.88).

Aim 1: Intervention Characteristics

Overview

There was large heterogeneity in intervention components, theoretical or conceptual framework, type of intervention (ie, tailored or standardized), mode of delivery, prescribed dosage (ie, number of sessions, frequency, and length), and received dosage (Table S2 in Multimedia Appendix 2).

Intervention Components

A total of 37 (57%) out of 65 studies included a single intervention component [36,38-40,44,45,47,51,52,55-57,63-66,68,69,71-77,79,80,82-84,86,87,90,91,93,94,98], 13 (20%) studies included 2 intervention components [35,41,43,46,48,50,62,67,78,85,88,95,96], and 15 (23%) studies included 3-5 intervention components [37,42,49,53,54,58-61,70,81,89,92,97,99]. The most common intervention components were information and resources, or psychoeducation (n=29, 45%) [35,37,39-43,46,48,49,52-56,58-61,70,81,82,87-90,92,95,97], and cognitive-behavioral strategies (n=20, 31%) [44,45,47,50,54,57,63,64,67,68,71,74,75,80,85-87,89,91,98].

Theoretical or Conceptual Framework

More than half (n=38, 59%) of the included studies did not identify a conceptual or theoretical framework [37,41,42,45-47,51,52,54,55,57-63,66,69,71,73,75,76,78-81,85-90,92,93,95,97,98].

Standardized or Tailored Intervention

Of the 65 studies, 26 (40%) included both standardized and tailored interventions [37,39,42,43,46,47,49,53,55,59-61,64,68,70,73-75,77-79,81,85,89,92,94], 28 (43%) studies included only standardized interventions [36,38,41,44,50,51,54,56-58,63,65-67,69,71,72,76,80,82-84,87,88,91,93,95,98], and 11 (17%) studies had only tailored interventions [35,40,45,48,52,62,86,90,96,97,99].

Modes of Delivery

The majority of studies conducted interventions through an internet website (n=40, 62%) [35-37,39-50,53,55,59-62,64,67,68,70,72,75,77,81,82,85,88-91,93,95-99] or smart device app (n=8) [43,52,56,57,63,69,80,87]. A total of 7 (11%) studies conducted interventions through virtual reality [51,66,73,76,78,83,84], 3 (5%) studies through telehealth [54,74,79], and 2 (3%) studies through a computer program [38,65]. Electronic health information systems [92], interaction portals [58], and videoconferences [86] were each used in 1 study. Overall, 2 studies used multimodal interventions delivered through the combination of either telephone and videoconference [94] or internet and telephone [61].

Dosage

The dosage prescribed and received were highly variable. The number of intervention sessions ranged from 1 to 56, with a median of 6. A total of 27 (42%) studies did not specify the prescribed dose; 19 (29%) only stated the number of days participants had access to the intervention [35,36,42,49,56,59-62,67,70,80,81,85,87,89,92,95,99] and 8 (12%) did not provide information on the prescribed dosage [37,39,40,52,55,58,72,73]. Frequency was highly variable, with self-paced (n=26, 40%) as the most common [35,36,42,45,49,50,56,59-63,67,70,80,81,85,87-90,92,95-97,99], meaning no specific intervention frequency was defined and the intervention content was available throughout the study period. The other common frequencies of intervention sessions were weekly (n=17, 26%) [38,41,44,45,47,53,54,64,68,71,74,75,77,86,91,94,98] and 1-time intervention sessions (n=8, 12%) [48,65,66,76,78,82-84]. The median length of the intervention was 8 weeks, with the length ranging from 1 hour (ie, use of the intervention on an iPad for an hour) to 24 months. Received dosage was defined as the uptake of the intervention by the participants. A total of 18 (28%) studies did not report the received dosage [36,37,39,48,52,56,58,65,69,75,76,78,79,82,85,86,93,94]. Various information was reported, including attendance rate, number of times participants used the app, frequency with which participants logged into the website, number of website pages reviewed, skill practice time, and intervention session completion rate. Most of the interventions (n=43, 66%) were self-delivered without an interventionist, with self-paced being most common [35-37,39,40,42,44,45,48-53,55,57-60,62,63,67,69-73,75,76,78,80-84,87,88,91-93,95,96,99].

Aim 2: Effects on Patients’ and Family Members’ Psychosocial Outcomes

Patients’ Outcomes

Overview

A meta-analysis was conducted on 32 studies. Overall, 5 outcomes were examined. A summary of the interventions’ overall effect sizes; time-varying effect sizes for quality of life, anxiety, depression, distress, and self-efficacy; and heterogeneity statistics for each outcome is displayed in Table 1. The forest plots for overall effect sizes and time-varying effects are displayed in Multimedia Appendix 3. The funnel plots for overall effect sizes and time-varying effects are displayed in Multimedia Appendix 4.

Table 1. Summary of the meta-analysis.

Population, outcome, measure, and value	Effect at different time points				
	Overall[a]	Immediate	Interim	Short	Medium
Patient					
QOL[b]					
FACT-B[c]					
Pooled ES[d], Hedges *g* (95% CI)	0.13 (–0.05 to 0.31)	—[e]	—	—	—
I^2	62.3	—	—	—	—
Heterogeneity, χ^2 (*df*)	10.61 (4)	—	—	—	—
P value	.03	—	—	—	—
FACT-G[f]					
Pooled ES, Hedges *g* (95% CI)	–0.04 (–0.17 to 0.09)	—	—	—	—
I^2	0	—	—	—	—
Heterogeneity, χ^2 (*df*)	1.91 (4)	—	—	—	—
P value	.43	—	—	—	—
QLQ-30[g]					
Pooled ES, Hedges *g* (95% CI)	0.05 (–0.04 to 0.14)	—	—	—	—
I^2	58.4	—	—	—	—
Heterogeneity, χ^2 (*df*)	19.95 (6)	—	—	—	—
P value	.03	—	—	—	—
SF36[h]					
Pooled ES, Hedges *g* (95% CI)	0.03 (–0.10 to 0.15)	—	—	—	—
I^2	14.4	—	—	—	—
Heterogeneity, χ^2 (*df*)	8.41 (8)	—	—	—	—
P value	.31	—	—	—	—
Overall					
Pooled ES, Hedges *g* (95% CI)	0.05 (–0.01 to 0.10)	0.95 (–1.99 to 3.89)	–0.16 (–0.39 to 0.06)	2.25 (0.36 to 4.14)	0.18 (0 to 0.35)
I^2	42.7	100	70	98	18.3
Heterogeneity, χ^2 (*df*)	48.12 (20)	93227.62 (19)	3.34 (1)	203.50 (4)	7.35 (6)
P value	.01	<.001	.07	<.001	.29
Anxiety and depression					
HADS[i] total score					
Pooled ES, Hedges *g* (95% CI)	–0.72 (–1.89 to 0.46)	–0.04 (–0.23 to 0.16)	—	–0.22 (–0.54 to 0.10)	0.14 (–0.09 to 0.38)
I^2	97.6	0	—	0	0
Heterogeneity, χ^2 (*df*)	165.82 (14)	3.71 (4)	—	0.19 (1)	0.51 (1)
P value	<.001	.45	—	.66	.47
Depression					

Population, outcome, measure, and value	Effect at different time points				
	Overall[a]	Immediate	Interim	Short	Medium
HADS-depression					
Pooled ES, Hedges *g* (95% CI)	–0.13 (–0.23 to –0.02)	—	—	—	—
I^2	0	—	—	—	—
Heterogeneity, χ^2 (*df*)	4.17 (7)	—	—	—	—
P value	.73	—	—	—	—
CESD[j]					
Pooled ES, Hedges *g* (95% CI)	0.10 (–0.10 to 0.30)	—	—	—	—
I^2	0	—	—	—	—
Heterogeneity, χ^2 (*df*)	0.99 (4)	—	—	—	—
P value	.91	—	—	—	—
PHQ9[k]					
Pooled ES, Hedges *g* (95% CI)	–0.05 (–0.17 to 0.08)	—	—	—	—
I^2	0	—	—	—	—
Heterogeneity, χ^2 (*df*)	0.78 (1)	—	—	—	—
P value	.38	—	—	—	—
Multiple scales					
Pooled ES, Hedges *g* (95% CI)	0.32 (–0.35 to 0.99)	—	—	—	—
I^2	95	—	—	—	—
Heterogeneity, χ^2 (*df*)	19.86 (1)	—	—	—	—
P value	<.001	—	—	—	—
Overall					
Pooled ES, Hedges *g* (95% CI)	0.03 (–0.10 to 0.16)	0.06 (–0.10, 0.22)	-0.04 (–0.22, 0.14)	—	—
I^2	60.9	69.4	29.8	—	—
Heterogeneity, χ^2 (*df*)	40.77 (16)	58.85 (16)	4.27 (1)	—	—
P value	<.001	<.001	0.23	—	—
Anxiety					
HADS-anxiety					
Pooled ES, Hedges *g* (95% CI)	0.32 (–0.20 to 0.84)	—	—	—	—
I^2	94.3	—	—	—	—
Heterogeneity, χ^2 (*df*)	123.33 (7)	—	—	—	—
P value	<.001	—	—	—	—
SATI[l]					
Pooled ES, Hedges *g* (95% CI)	–0.19 (–0.41 to 0.04)	—	—	—	—
I^2	26.8	—	—	—	—

Population, outcome, measure, and value	Effect at different time points				
	Overall[a]	Immediate	Interim	Short	Medium
Heterogeneity, χ^2 (*df*)	5.46 (4)	—	—	—	—
P value	.24	—	—	—	—
Overall					
Pooled ES, Hedges *g* (95% CI)	0.12 (–0.19 to 0.43)	–0.10 (–0.19 to 0)	–0.04 (–0.19 to 0.12)	–0.13 (–0.43 to 0.17)	—
I^2	90.2	6.7	35.1	10.5	—
Heterogeneity, χ^2 (*df*)	132.99 (13)	13.94 (13)	6.16 (4)	1.12 (1)	—
P value	<.001	.38	.19	.29	—
Distress					
DT[m]					
Pooled ES, Hedges *g* (95% CI)	0.98 (–0.18 to 2.14)	0.51 (0.10 to 0.92)	—	—	—
I^2	98.5	54.2	—	—	—
Heterogeneity, χ^2 (*df*)	332.71 (2)	4.37 (2)	—	—	—
P value	<.001	.11	—	—	—
Self-efficacy					
CBI[n]					
Pooled ES, Hedges *g* (95% CI)	–1.41 (–4.02 to 1.20)	2.56 (–1.22 to 6.35)	—	—	—
I^2	99	98.2	—	—	—
Heterogeneity, χ^2 (*df*)	1.06 (1)	55.43 (1)	—	—	—
P value	.29	<.001	—	—	—
Family member					
Depression					
HADS-depression					
Pooled ES, Hedges *g* (95% CI)	–0.25 (–0.72 to 0.21)	—	—	—	—
I^2	0	—	—	—	—
Heterogeneity, χ^2 (*df*)	0.41 (1)	—	—	—	—
P value	.52	—	—	—	—
Anxiety					
HADS-anxiety					
Pooled ES, Hedges *g* (95% CI)	–0.23 (–0.70 to 0.23)	—	—	—	—
I^2	0	—	—	—	—
Heterogeneity, χ^2 (*df*)	0.65 (1)	—	—	—	—

Population, outcome, measure, and value	Effect at different time points				
	Overall[a]	Immediate	Interim	Short	Medium
P value	.42	—	—	—	—

[a] The overall effect accounts for time-varying effect across different time points.

[b] QOL: quality of life.

[c] FACT-B: Functional Assessment of Cancer Therapy–Breast.

[d] ES: effect size.

[e] Not applicable.

[f] FACT-G: Functional Assessment of Cancer Therapy–General.

[g] QLQ-30: Quality of Life Questionnaire, 30 items.

[h] SF36: Short Form Survey 36-item.

[i] HADS: Hospital Anxiety and Depression Scale.

[j] CESD: Center for Epidemiologic Studies Depression Scale.

[k] PHQ9: Patient Health Questionnaire-9.

[l] SATI: State-Trait Anxiety Inventory.

[m] DT: Distress Thermometer.

[n] CBI: Coping Behaviors Inventory.

Quality of Life

Quality of life was measured by the Functional Assessment of Cancer Therapy–Breast [44,54,80,93,95], Functional Assessment of Cancer Therapy–General [38,53,57,86,88], European Organization for Research and Treatment of Cancer Quality of Life Questionnaire, 30-items [35,40,43,74,91,96,99], and 36-item Short Form Survey [41,54,64,70,71]. Overall, a total of 21 studies with 1847 participants in the intervention groups showed an increase in quality of life, with a mean difference between groups of Hedges g=0.05 (95% CI –0.01 to 0.10). The impact of heterogeneity within the studies was significant (I^2=42.7%; P=.01). With respect to publication bias, the funnel plot displayed a greater number of studies toward the top of the mean (Egger test, P<.001). The time-varying effects were as follows: Hedges g=–0.16 (95% CI –0.39 to 0.06) for the interim effect; Hedges g=0.95 (95% CI –1.99 to 3.89) for the immediate effect; Hedges g=2.25 (95% CI 0.36-4.14) for the short-term effect; and Hedges g=0.18 (95% CI 0-0.35) for the long-term effect. The statistical heterogeneity among studies was I^2=70% (P=.07) for the interim effect; I^2=100% (P<.001) for the immediate effect; I^2=98% (P<.001) for the short-term effect; and I^2=18.3% (P=.29) for the long-term effect.

Anxiety and Depression

Hospital Anxiety and Depression Scale (HADS) total scores (without subscale scores reported) were reported in 5 studies with 338 participants in the intervention groups [43,47,64,86,91]. Overall, participants receiving interventions reported decreased anxiety and depression with a standardized mean difference of Hedges g=–0.72 (95% CI –1.89 to 0.46). The heterogeneity within the studies was significant (I^2=97.6%; P<.001). The funnel plot was found to be asymmetric, and Egger test was found to be not statistically significant (P=.77). The time-varying effects were as follows: Hedges g=–0.04 (95% CI –0.23 to 0.16) for the immediate effect; Hedges g=–0.22 (95% CI –0.54 to 0.10) for the short-term effect; and Hedges g=0.14 (95% CI –0.09 to 0.38) for the medium-term effect. The statistical heterogeneity among studies was I^2=0% across all time-varying effects.

Depression

Depression was assessed by the HADS-depression subscale [50,69,74,86,95,96,99], Center for Epidemiologic Studies Depression Scale [41,68,71,77], Patient Health Questionnaire-9 (PHQ-9) [40,53], and a combination of the PHQ-9 and HADS-anxiety [43,57] in 1509 participants in the intervention groups. Overall, interventions were not more effective than control conditions for reducing depression (Hedges g=0.03, 95% CI –0.10 to 0.16), with a high heterogeneity of 60.9% (P<.001). With respect to publication bias, the funnel plot displayed a greater number of studies toward the top of the mean (Egger test, P=.25). The time-varying effects were as follows: Hedges g=0.06 (95% CI –0.10 to 0.22) for the immediate effect and Hedges g=–0.04 (95% CI –0.22 to 0.14) for the interim effect. The statistical heterogeneity among studies was I^2=69.4% for the immediate effect and I^2=29.8% for the interim effect.

Anxiety

Anxiety was assessed by the HADS-anxiety subscale [57,64,69,74,86,95,96,99], State-Trait Anxiety Inventory (STAI) [66,71,72,82,83], and a combination of the STAI and HADS-anxiety [43] in 1075 participants in the intervention groups. Overall, interventions were not more effective than control conditions for reducing anxiety (Hedges g=0.12, 95% CI –0.19 to 0.43), with high heterogeneity of 90.2% (P<.001). The funnel plot displayed a greater number of studies toward the top of the mean (Egger test, P=.46). The interim effect was Hedges g=–0.04 (95% CI –0.19 to 0.12), and the immediate effect was Hedges g=–0.10 (95% CI –0.19 to 0), and the short-term effect was Hedges g=–0.13 (95% CI –0.43 to 0.17). The statistical heterogeneity among studies was I^2=35.1% for the interim effect, I^2=6.7% for the immediate effect, and I^2=10.5% for the short-term effect.

Distress

Psychological distress was assessed in 182 participants in the intervention groups using the distress thermometer [35,69,91]. Overall, participants in the intervention groups showed no reduction in distress, with a mean difference between groups of Hedges *g*=0.98 (95% CI –0.18 to 2.14). The impact of heterogeneity within the studies was significant (I^2=98.5%; *P*<.001). Regarding publication bias, the funnel plot displayed a symmetric distribution around the mean effect (Egger test, *P*=.46). The immediate effect was Hedges *g*=0.51 (95% CI 0.10-0.92), with statistical heterogeneity I^2=54.2%.

Self-Efficacy

Self-efficacy was measured by the Coping Behaviors Inventory in 174 participants in the intervention groups [44,55]. Overall, participants in the intervention groups did not report improvement in self-efficacy, with a standardized mean difference of Hedges *g*=–1.41 (95% CI –4.02 to 1.20). However, the impact of heterogeneity within studies was significant (I^2=99%; *P*<.001). Regarding the publication bias, the funnel plot displayed a symmetric distribution around the mean effect (Egger test, *P*=.22). The immediate effect was Hedges *g*=2.56 (95% CI –1.22 to 6.35) with high heterogeneity (I^2=98.2%; *P*<.001).

Subgroup Analyses

Given the heterogeneity of reporting on dosage information and limited data, the subgroup analysis of dosage on intervention effect was not conducted. Table 2 includes the results of the subgroup analysis on the effect on quality of life, depression and anxiety, and distress. Overall, the associations between delivery mode and control condition with patient outcomes were not statistically significant (*P*>.05).

Table 2. Subgroup analyses on the effect of delivery mode (internet vs noninternet) and control condition (usual care vs active control) on patient outcomes.

Outcome and moderators	Effect size, Hedges *g* (95% CI)	SE	*P* value
Quality of life (27 studies)			
Delivery mode	0.04 (–0.06 to 0.14)	0.05	.45
Control condition	–0.01 (–0.99 to 0.06)	0.04	.78
HADS[a] total (6 studies)			
Delivery mode	0.16 (–0.30 to 0.62)	0.24	.50
Control condition	N/A[b]	N/A	N/A
Depression (21 studies)			
Delivery mode	0.10 (–0.09 to 0.29)	0.10	.31
Control condition	–0.04 (–0.17 to 0.09)	0.07	.55
Anxiety (15 studies)			
Delivery mode	0.01 (–0.07 to 0.09)	0.04	.79
Control condition	–0.06 (–0.34 to 0.22)	0.14	.67
Distress (8 studies)			
Delivery mode	N/A	N/A	N/A
Control condition	–0.03 (–0.34 to 0.28)	0.15	.86

[a] HADS: Hospital Anxiety and Depression Scale.

[b] N/A: not applicable.

Family Members' Outcomes

The forest plots for overall effect sizes are displayed in Multimedia Appendix 5. The funnel plots for overall effect sizes are displayed in Multimedia Appendix 6. For family members' data, we pooled 2 studies [36,69] on anxiety and depression for the meta-analysis with 68 participants in the intervention groups. Due to the small sample size, no time-varying effect or subgroup analysis was calculated. The overall effect on anxiety was Hedges *g*=–0.23 (95% CI –0.70 to 0.23), with heterogeneity of I^2=0% (*P*=.42). The overall effect on depression was Hedges *g*=–0.25 (95% CI –0.72 to 0.21), with heterogeneity of I^2=0% (*P*=.52). Regarding publication bias, the funnel plot displayed asymmetrical scattered points with statistical significance (Egger test, *P*<.001).

Discussion

Overview

This systematic review and meta-analysis of 65 unique digital psychosocial intervention studies for patients with cancer and their family members provides strong evidence that psychosocial interventions delivered through digital health significantly improve psychosocial outcomes. There were 3 major findings. First, this review included a large group of participants with various cancer diagnoses; however, underrepresented populations affected by cancer were not included, and the results predominantly focused on White patients. Second, we found that various intervention modes and components were used. There is a lack of specificity with respect to the description of interventions or theoretical basis for interventions, which may hinder future replication or refinement of the interventions and understanding of underlying mechanisms. Third, despite high heterogeneity across studies, the available data suggest that digital psychosocial interventions effectively improve some psychosocial outcomes, including patients' quality of life, anxiety, and depression.

Principal Findings

First, the majority of participants in the included studies were White and female, which does not reflect the broader patient population with cancer, including non-White ethno-racial groups (ie, African American or Black, American Indian and Alaska Native, Asian, Native Hawaiian or other Pacific Islander, and Hispanic or Latino populations). It is well documented in the literature that the impact of cancer on psychological distress and quality of life is worse for racial and ethnic minority groups [100-102]. Therefore, future trials should include more participants from underrepresented groups to reduce health care disparities and improve generalizability in diverse populations [103]. Family members and caregivers were rarely included in the studies reviewed. However, there is ample evidence that family members and caregivers experience significant caregiver burden, worsening quality of life, and difficulty with psychological adjustment, therefore needing support [104,105]. Previous systematic reviews suggest that interventions targeting problem-solving and communication skills may ease the burden related to patient care and improve caregivers' quality of life [106]. Many reviews focus on the evaluation of nondigital interventions targeting the psychosocial experience in family members and caregivers, including several reviews of caregiver interventions [9,107-109]. Therefore, with growing technology usage, more digital interventions are needed to address family members' or caregivers' needs.

Few RCTs met all quality criteria, including blinding, analysis by treatment assignment, and standardized outcome assessment [110]. While concealing assignments from participants and those delivering interventions is not always possible, single blinding of assessors should occur in well-designed research. Few studies used power calculations for sample size, making it difficult to determine whether sample sizes were adequate [111]. Generally, results from group sizes <20 are questionable. There are several effective strategies known to increase the retention rate, such as adding monetary incentives and using an open trial design [112,113]. The critical appraisal also depends on comprehensive reporting of study details, which were limited in the identified studies. Although attempts have been made to improve reporting using the CONSORT (Consolidated Standards of Reporting Trials) statement for RCTs and the Transparent Reporting of Evaluations with Nonrandomized Designs (TREND) statement for nonrandomized intervention studies in the early 2000s [114,115], we did not see improvement in appraisal scores over time. The main limitations of the results include underpowered and methodologically weaker studies. These highlight the need for improved methodologies in future research, as the overall methodological quality was moderate.

Second, this study identified various intervention modes and components, which is consistent with a previous systematic review of psychosocial interventions for patients with advanced cancer, which identified similar intervention components, including psychoeducation and CBT-based intervention, as 2 of the most common [11]. However, more than half of the included studies did not use theoretical or conceptual frameworks to guide the development of intervention components or selection of outcomes. The lack of a theoretical framework leads to a lack of clarity about the mechanisms through which intervention components impact psychosocial outcomes [116]. In future research, theories or conceptual frameworks need to be incorporated to help us better understand the mechanisms that explain the changes in psychosocial outcomes when using digital health interventions.

In addition, the prescribed dosage information (ie, the number of sessions, duration, and frequency) was inconsistently reported, making it difficult to estimate an efficacious intervention dose. Most of the interventions were self-paced, without the involvement of an interventionist, which gives the patient autonomy to choose which intervention component or module they would like to focus on and how much time to allocate. However, there is a lack of information on intervention uptake, which may have influenced the effectiveness of interventions. Approaches that tackle barriers to adherence at various levels (eg, individual, family, clinician, agency, and environment) and improve engagement should be implemented [117]. For example, a scoping review about engagement strategies in digital interventions for mental health promotion recommended personalized feedback, e-coaching to guide content and individual progress, social platforms and interaction with peers, content gamification, reminders, and ease of use [118].

Third, we found some significant improvement in the patient's quality of life. Some studies with a smaller number of participants or with a focus on internet-based interventions reported an improvement, but the results from these studies were not consistent [21,119]. This meta-analysis, including 21 studies, revealed a small effect size for overall effectiveness of digital health interventions in improving patients' quality of life (Hedges *g*=0.05, 95% CI –0.01 to 0.10), with time-varying effects shown as promising. Another meta-analysis that pooled 16 studies demonstrated a larger positive effect of mHealth interventions on the quality of life of patients with cancer (standardized mean difference 0.28, 95% CI 0.03-0.53) [21]. Another meta-analysis that included 6 internet-based psychoeducational interventions for patients with cancer showed no significant improvement in quality of life (mean difference 1.10, 95% CI –4.42 to 6.63) [119]. Importantly, our analyses found the largest improvements in quality of life occurred from post intervention to 8 weeks (Hedges *g*=2.25, 95% CI 0.36-4.14). The effect of psychosocial interventions decreased after 8 weeks of follow-up, suggesting that interventions may need booster sessions or tailoring to time-sensitive needs in order to maintain effectiveness in the long term. This result was limited by substantial inconsistency across studies in all evaluation periods except the medium-term effect [32]. In addition, given the heterogeneity of follow-up periods in selected studies, the time-varying effect was only tested with a small number of studies, not in the 21 studies we used to calculate the overall effect.

This meta-analysis was able to demonstrate the effectiveness of digital health interventions on both anxiety and depression (measured by HADS: Hedges *g*=–0.72, 95% CI –1.89 to 0.46). Our finding was partially consistent with the other meta-analyses. One study showed that internet-based psychoeducational interventions had a significant effect on decreasing depression (standardized mean difference −0.58, 95% CI −1.12 to −0.03), but found no evidence for effects on distress (standardized mean difference −1.03, 95% CI −2.63 to 0.57) [119]. However, there was considerable heterogeneity in measurements among the studies included in the review by Wang et al [119]; it is difficult to determine how meaningful it is to make direct comparisons between the studies included in this meta-analysis and past reports. Possible ways to address this problem could be using similar outcome measures and a standardized study report.

Our meta-analysis demonstrated that the interventions were effective in reducing anxiety and depression in family caregivers. However, the effect size was small, perhaps due to the limited number of studies. This is partially consistent with findings from another meta-analysis, which found depressive symptoms decreased from baseline to post intervention (Hedges *g*=–0.44, 95% CI –1.03 to 0.15) [120], while anxiety remained relatively stable when comparing intervention to control either at postintervention (Hedges *g*=0.12, 95% CI –0.16 to 0.44) or during follow-up (Hedges *g*=–0.08, 95% CI –0.34 to 0.19).

Strengths and Limitations

This review’s strength lies in its rigorous design, sophisticated data synthesis, and enduring empirical contributions. We acknowledge that our literature search was conducted 4 years before manuscript submission. The findings and contributions from our research remain pertinent and enduring. This is because, as digital psychosocial interventions continue to evolve, the core intervention content and outcomes have remained relatively consistent over the past 4 years. It would be valuable to conduct a reassessment of the evolving body of evidence concerning digital psychosocial interventions that have emerged since the onset of the COVID-19 pandemic. Moreover, this study was conducted in line with best practices by double-coding and following the PRISMA guidelines. The meta-analysis, including subgroup analysis, was conducted using appropriate methods for combining studies across various follow-up periods. Although we did an extensive search at the start of this review, we may have missed some critical studies, unreported, or unfinished studies. If all data were available, the meta-analysis could have reduced the chances of inflated type-1 error for both observed and unobserved effects that were available for assessment [121]. There was not enough data to perform post hoc analyses to examine the effect of factors such as intervention components and length of intervention on outcomes due to insufficient data.

Conclusions

Patients with cancer and their family members need high-quality psychosocial interventions throughout the cancer trajectory. Digital technologies provide a platform to deliver evidence-based psychosocial interventions from a distance, without the heightened risk of contracting viruses, especially for patients with cancer whose immune systems are compromised. This study comprehensively synthesized the effects of digital psychosocial interventions for people affected by cancer. Our findings suggest that digital health interventions are effective for adult patients with cancer and their family members. Further research development in this area needs to include large, high-quality studies with a clear description of the methodology, theoretical foundations, and standardized tools to permit inclusion in meta-analyses to inform the effectiveness of interventions for a better understanding of the mechanisms.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Literature search strategy.
[DOCX File , 16 KB - cancer_v10i1e46116_app1.docx]

Multimedia Appendix 2
Summary tables.
[DOCX File , 53 KB - cancer_v10i1e46116_app2.docx]

Multimedia Appendix 3
Forest plots of studies reported on intervention effect on patient outcomes.
[DOCX File , 1723 KB - cancer_v10i1e46116_app3.docx]

Multimedia Appendix 4
Funnel plots of studies reported on intervention effect on patient outcomes.
[DOCX File , 91 KB - cancer_v10i1e46116_app4.docx]

Multimedia Appendix 5
Forest plots of studies reported on intervention effect on family member outcomes.
[DOCX File , 110 KB - cancer_v10i1e46116_app5.docx]

Multimedia Appendix 6
Funnel plots of studies reported on intervention effect on family member outcomes.
[DOCX File , 23 KB - cancer_v10i1e46116_app6.docx]

Multimedia Appendix 7
PRISMA checklist.
[PDF File (Adobe PDF File), 72 KB - cancer_v10i1e46116_app7.pdf]

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Abbreviations

CONSORT: Consolidated Standards of Reporting Trials
HADS: Hospital Anxiety and Depression Scale
JBI: Joanna Briggs Institute
PHQ-9: Patient Health Questionnaire-9
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT: randomized controlled trial
STAI: State-Trait Anxiety Inventory
TREND: Transparent Reporting of Evaluations with Nonrandomized Designs

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Review

Machine Learning Approaches to Predict Symptoms in People With Cancer: Systematic Review

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Abstract

Background: People with cancer frequently experience severe and distressing symptoms associated with cancer and its treatments. Predicting symptoms in patients with cancer continues to be a significant challenge for both clinicians and researchers. The rapid evolution of machine learning (ML) highlights the need for a current systematic review to improve cancer symptom prediction.

Objective: This systematic review aims to synthesize the literature that has used ML algorithms to predict the development of cancer symptoms and to identify the predictors of these symptoms. This is essential for integrating new developments and identifying gaps in existing literature.

Methods: We conducted this systematic review in accordance with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) checklist. We conducted a systematic search of CINAHL, Embase, and PubMed for English records published from 1984 to August 11, 2023, using the following search terms: *cancer*, *neoplasm*, *specific symptoms*, *neural networks*, *machine learning*, *specific algorithm names*, and *deep learning*. All records that met the eligibility criteria were individually reviewed by 2 coauthors, and key findings were extracted and synthesized. We focused on studies using ML algorithms to predict cancer symptoms, excluding nonhuman research, technical reports, reviews, book chapters, conference proceedings, and inaccessible full texts.

Results: A total of 42 studies were included, the majority of which were published after 2017. Most studies were conducted in North America (18/42, 43%) and Asia (16/42, 38%). The sample sizes in most studies (27/42, 64%) typically ranged from 100 to 1000 participants. The most prevalent category of algorithms was supervised ML, accounting for 39 (93%) of the 42 studies. Each of the methods—deep learning, ensemble classifiers, and unsupervised ML—constituted 3 (3%) of the 42 studies. The ML algorithms with the best performance were logistic regression (9/42, 17%), random forest (7/42, 13%), artificial neural networks (5/42, 9%), and decision trees (5/42, 9%). The most commonly included primary cancer sites were the head and neck (9/42, 22%) and breast (8/42, 19%), with 17 (41%) of the 42 studies not specifying the site. The most frequently studied symptoms were xerostomia (9/42, 14%), depression (8/42, 13%), pain (8/42, 13%), and fatigue (6/42, 10%). The significant predictors were age, gender, treatment type, treatment number, cancer site, cancer stage, chemotherapy, radiotherapy, chronic diseases, comorbidities, physical factors, and psychological factors.

Conclusions: This review outlines the algorithms used for predicting symptoms in individuals with cancer. Given the diversity of symptoms people with cancer experience, analytic approaches that can handle complex and nonlinear relationships are critical. This knowledge can pave the way for crafting algorithms tailored to a specific symptom. In addition, to improve prediction precision, future research should compare cutting-edge ML strategies such as deep learning and ensemble methods with traditional statistical models.

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KEYWORDS

machine learning; ML; deep learning; DL; cancer symptoms; prediction model

Introduction

Background

Cancer poses considerable physical and psychological challenges for those diagnosed with the disease. The Global Cancer Observatory estimated that there were 19.3 million new cancer cases and 43.8 million individuals living with cancer within 5 years of diagnosis globally in 2020 [1]. Symptoms such as fatigue, pain, nausea, vomiting, depression, and anxiety often persist beyond treatment [2-5], detrimentally affecting individuals' quality of life [6]. Moreover, people with cancer frequently grapple with multiple intertwined symptoms [7], intensifying their distress [8]. Unmanaged cancer symptoms can lead to increased health care use, including emergency department visits and unscheduled hospitalizations to address these symptoms; a decline in the quality of life [9]; and even a reduced life expectancy. Providing precision symptom management tailored to the individual at the right moment has the potential to significantly improve outcomes, which is crucial for both people with cancer and their health care providers. Accurately predicting and addressing these symptoms is fundamental to providing such precision in symptom management.

Artificial intelligence, incorporating machine learning (ML) and deep learning (DL) models, excels in handling complex, high-dimensional, and noisy data. It has demonstrated effectiveness in disease diagnosis, predicting disease recurrence, enhancing quality of life, and symptom management [10-16]. There is a growing interest in ML in the emerging field of predictive analytics for cancer symptoms. ML contributes to the development of robust clinical decision systems, enhancing overall health care delivery [17]. ML algorithms can be broadly categorized into supervised learning, unsupervised learning, semisupervised learning, and reinforcement learning. DL, a subset of ML, addresses complex tasks such as speech recognition, image identification, and natural language processing [18].

Objectives

This study seeks to offer a comprehensive and systematic review of the literature on the application of ML algorithms in predicting symptoms for people with cancer. Conducting this review of a rapidly expanding body of literature is imperative to understand the current state of the science for ML models in symptom prediction for cancer and to guide future research. This research aims to provide a comprehensive understanding of the current state of research; identify areas for improvement; and understand the limitations and gaps in the current literature, such as a lack of specific focus on ML models for patients with cancer. By comparing model performances across diverse symptom prediction tasks, we can identify the best practices, highlight areas for improvement, and offer informed recommendations that will propel the field of predictive analytics in cancer symptom research forward.

Methods

Search Strategy and Data Sources

This study was conducted in accordance with the PRISMA (Preferred Reporting Items for Systematic Review and Meta-Analyses) protocol [19] and involved a comprehensive database search spanning from 1984 to August 11, 2023, including the PubMed, Embase, CINAHL, and Google Scholar databases. The search terms encompassed *cancer*, *neoplasm*, *signs and symptoms*, *neural networks*, *machine learning*, and *specific algorithm names*. In our study, we used Boolean expressions, using specific combinations of keywords and phrases, acknowledging the variability in terminology across studies. Search results were compiled using EndNote 20 (Clarivate Analytics). The detailed search strategy, which uses Boolean expressions, and the PRISMA checklist can be found in Multimedia Appendices 1 and 2.

Inclusion and Exclusion Criteria

To identify relevant research focusing on the application of ML methods in predicting cancer symptoms, we applied the following inclusion criteria: (1) papers published in English, (2) studies that used ML algorithms, and (3) research specifically aimed at predicting cancer symptoms. The exclusion criteria were as follows: (1) nonhuman studies, (2) technical reports, (3) review papers, (4) book chapters or series, (5) conference proceedings, and (6) studies for which full texts were unavailable. Two authors, NZ and NY, independently screened and cross-checked the candidate records. During the screening process, conducted using EndNote 20, any disagreements were resolved by consulting a third reviewer (SGW). The screening process involved an initial review of titles and abstracts, followed by a full-text examination to determine the study's eligibility for inclusion in the review.

Data Extraction and Analysis

In our study, we implemented a systematic, multistep process for data synthesis. Initially, relevant studies were identified and selected based on the predefined inclusion and exclusion criteria. Two independent researchers, NZ and NY, extracted data from 42 selected studies. They worked independently to mitigate bias and enhance the accuracy of the data extraction process. In cases of discrepancies, these were resolved through discussion or consultation with a third reviewer, SGW. The extracted data were aggregated, involving the collation of study characteristics such as research location, sample size, study design, types of ML algorithms, validation metrics, identified significant predictors, cancer types, and the specific symptoms focused on. This comprehensive approach enabled us to reduce the bias and increase the reliability of our findings. For the analysis, we used both quantitative and qualitative methods. Quantitative data, such as frequencies and percentages, were compiled and analyzed using Python. This included the creation of insightful plots and heat maps to identify patterns and trends, illustrating relationships among variables and highlighting key findings in an easily digestible format. Qualitative aspects, such as algorithm implementation or study design, were explored through narrative synthesis. This allowed for a deeper understanding of the context and nuances in the application of ML algorithms for cancer symptom prediction.

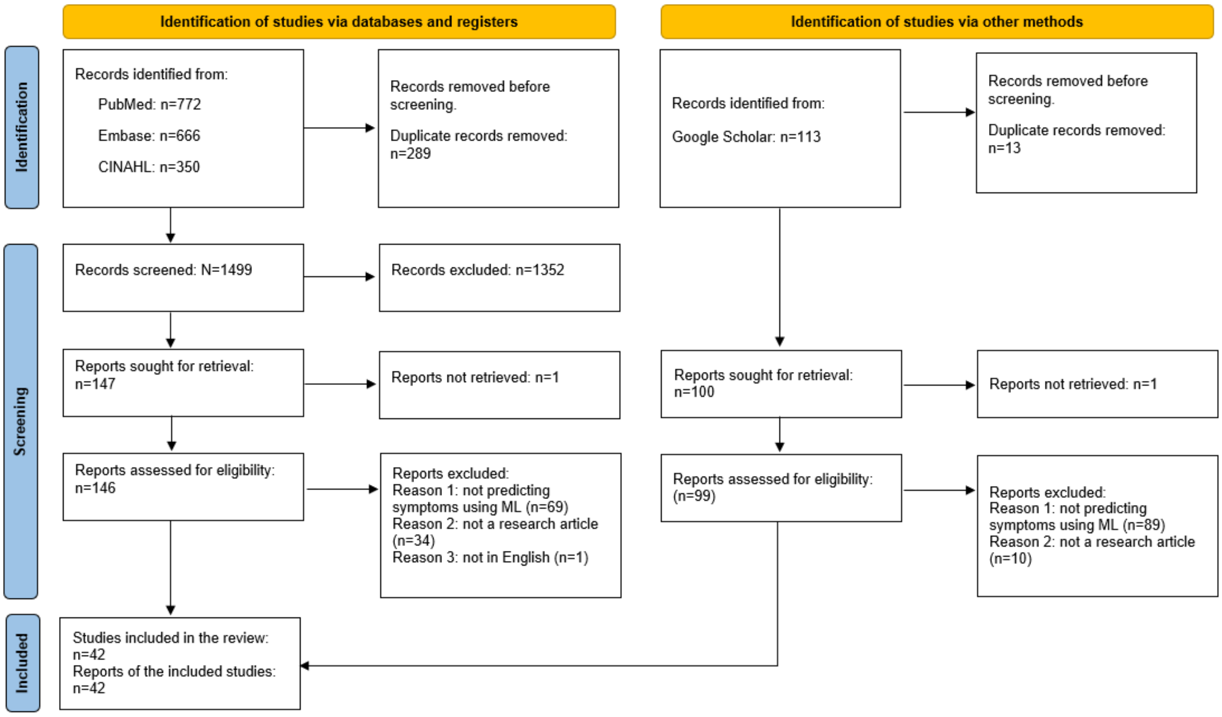
We conducted a cross-analysis to compare findings from different studies, assessing the effectiveness of various ML algorithms across different cancer types and symptoms and identifying common predictors of success and the challenges faced. Finally, we interpreted the findings in the context of the existing literature. We discussed how our results align with or differ from previous studies and what new insights our synthesis brings to the field of ML in cancer symptom prediction.

Results

Overall Results

A search across the 3 databases produced 1788 papers. After removing 289 duplicates, we screened the records for titles and abstracts, excluding another 1352 irrelevant records. However, 1 study was not retrieved. We reviewed the full text of the remaining 146 records, omitting 105 due to the absence of ML application in predicting cancer symptoms (69/146, 47.3%), not being a research article (34/146, 23.3%), and not being an English article (1/146, 1%). In the second phase, we intend to include Google Scholar in our research methodology to capture an additional 113 articles not found in our main databases, although 1 study was not retrieved. We reviewed the full text of the remaining 99 records, ultimately excluding all of them for reasons such as the lack of ML applications in cancer symptom prediction (89/99, 90%) and not being a research articles (10/99, 10%). Eventually, 42 studies met the inclusion criteria, as depicted in Figure 1.

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flowchart. ML: machine learning.



Of the 42 studies, 42 (100%) is listed in PubMed, Embase covers 37 (88%) studies, and CINAHL includes 18 (43%) studies. The distribution and overlap of these research articles across the databases are illustrated in Multimedia Appendix 3.

The data extracted from these studies, which include the reference number, research location, year, data type, cancer site, symptoms, significant predictors, ML algorithms, and validation methods, are detailed in Table 1 and in Multimedia Appendix 4.

Table 1. Details of the included studies (n=42).

Study	Country, year	Data type; number of data	Population	Cancer symptoms	Significant predictors	Algorithms	Validation methods
Sun et al [20]	China, 2023	Clinical data; 1152	People with breast cancer	Pain	Postmenopausal status, urban medical insurance, history of at least 1one operation, underwent general anesthesia with fentanyl and sevoflurane, and received axillary lymph node dissection.	*LR*[a,b], *RF*[c], *GBDT*[d], and *XGB*[e]	Random
Xinran et al [21]	China, 2023	Clinical data; 494	People with advanced cancer	Cognitive impairment	Cancer course, anxiety, and age	LR and *ANN*[f]	Random
Shaikh et al [22]	United States, 2023	Clinical data; 1152	Survivors of cancer with osteoarthritis	Depression	Age, education, care fragmentation, polypharmacy, and zip code–level poverty	*XGB*	10-fold CV[g]
Kober et al [23]	United States, 2023	Clinical data; 1217	People with cancer receiving chemotherapy	Morning fatigue	13 individual Li-Fraumeni syndrome items	*EN*[h], RF, LASSO[i], LR (filtered/unfiltered), RPAR[j], and SVM[k]	Random
Du et al [24]	China, 2023	Clinical data; 565	People with cancer	Fatigue	Pain score, Eastern Cooperative Oncology Group score, platelet distribution width, and continuous erythropoiesis receptor activator	LR, *RF*, NB[l], and XGB	5-fold CV
Moscato et al [25]	Italy, 2022	Clinical data; 21	People with cancer	Pain	N/A[m]	SVM, RF, *MP*[n], LR, and AdaBoost[o]	10-fold CV
Masukawa et al [26]	Japan, 2022	Clinical data; 808	People with cancer	Social distress, spiritual pain, pain, dyspnea, nausea, and insomnia	N/A	*LR, RF, light GBM*[p]*, SVM,* and *ensemble*	5-fold CV
Fanizzi et al [27]	Italy, 2022	CT[q] image data; 61	People with oropharyngeal cancer receiving radiotherapy	Xerostomia	Weight preradiotherapy, induction chemotherapy, sex, platinum-based chemotherapy, current chemotherapy, alcohol history, age at diagnosis, smoking history, surgery, clinical tumor, and clinical node	SVM and *CNN*[r]	10-fold CV
Ueno et al [28]	Japan, 2022	Clinical data; 284	People with breast cancer	Insomnia	General fatigue, physical fatigue, and cognitive fatigue	*L2 penalized LR* and *XGB*	8-fold CV
On et al [29]	Korea, 2022	Clinical data; 935	People with cancer receiving chemotherapy	Nausea-vomiting, fatigue-anorexia, diarrhea, hypersensitivity, stomatitis, hand-foot syndrome, peripheral neuropathy, and constipation	Earlier history of adverse drug reaction, comorbidity, cancer site and type of chemotherapy, demographics, and antineoplastic therapy–related features	*LR, DT*[s], and *ANN*	3-fold CV

Study	Country, year	Data type; number of data	Population	Cancer symptoms	Significant predictors	Algorithms	Validation methods
Li et al [30]	China, 2022	Clinical data and CT image data; 365	People with cancer receiving radiotherapy	Xerostomia	Hypertension, age, total radiotherapy dose, dose at 50% of the left parotid volume, mean dose to right parotid gland, mean dose to oral cavity, and course of induction chemotherapy	*RF*, DT and XGB	External validation
Kurisu et al [31]	Japan, 2022	Clinical data; 668	People with advanced cancer receiving pharmacological interventions	Delirium	The baseline Delirium Rating Scale-R98 severity score (cutoff of 15), hypoxia, and dehydration	*DT*	5-fold CV
Guo et al [32]	China, 2022	Clinical data; 80	People with lung cancer receiving chemotherapy	Lung infection	Age ≥60 years, length of stay ≥14 days, surgery history, combined chemotherapy, myelosuppression, diabetes, and hormone application	LR and *ANN*	Random
Baglione et al [33]	United States, 2022	Clinical data; 40	People with breast cancer	Depressed mood and anxiety	Connectedness, receive support, frequency and duration use of mobile app, and physical pain	*RF* and XGB	LOOCV[t]
Chao et al [34]	United States, 2022	Clinical data and CT image data; 155	People with HNC[u] receiving radiotherapy	Xerostomia	N/A	SVM, *KNN*[v], NB, and RF	Nested
Wakabayashi et al [35]	Japan, 2021	Clinical data and CT image data; 69	People with cancer receiving radiotherapy	Pain	Age, numeric rating scale, and biological effective dose 10	*RF*	LOOCV
Zhou et al [36]	China, 2021	Clinical data; 386	People with colorectal cancer after chemotherapy	Cognitive impairment	Age, BMI, colostomy, treatment complications, cancer-related anemia, depression, diabetes, Quality of Life Questionnaire Core 30 score, exercise, hypercholesterolemia, diet, marital status, education level, and pathological stage	RF, *LR*, and SVM	Random
Xuyi et al [37]	Canada, 2021	Clinical data; 46,104	Specific cancer site or treatment not mentioned	Pain, depression, and well-being	Lung cancer, late-stage cancer, existing chronic conditions such as osteoarthritis, mood disorder, hypertension, diabetes, and coronary disease	*ANN*	Random
Xu et al [38]	China, 2021	Clinical data; 598	People with gastrointestinal tumors after surgery	Postoperative fatigue	Age, higher degree of education, lower personal monthly income, advanced cancer, hypoproteinemia, preoperative anxiety or depression, and limited social support	LR, *ANN*, CART[w]	Random
Wei et al [39]	China, 2021	Clinical data; 533	People with breast cancer	Lymphedema	N/A	ANN, *LR*, C5.0, RF, SVM, CART	10-fold CV
Wang et al [40]	United States, 2021	Clinical data; 823	People with HNC	Pain, taste, and general activity	N/A	SVM, KNN, and RF; Gaussian NB and MLP[x]; and ARIMA[y] and *LSTM*[z]	Random

Study	Country, year	Data type; number of data	Population	Cancer symptoms	Significant predictors	Algorithms	Validation methods
Wang et al [41]	United States, 2021	Clinical data and CT image data; 138	Specific cancer site or treatment not mentioned	Depression	N/A	*Fine tree*, *medium tree*, coarse tree, linear-discriminant, quadratic discriminant, LR, Gaussian NB, kernel NB, linear SVM, quadratic SVM, cubic SVM, Fine Gaussian SVM, Medium Gaussian SVM, Coarse Gaussian SVM, Fine KNN, Medium KNN, Coarse KNN, Cosine KNN, Cubic KNN, Weighted KNN, boosted trees, bagged trees, subspace discriminant, subspace KNN, and random undersampling boosted trees	5-fold CV
Mosa et al [17]	United States, 2021	Clinical data; 6124	People with cancer receiving chemotherapy	Nausea-vomiting	Smoking, alcohol status, sex, age, and BMI	NB, LR, ANN, SVR[aa], and *DT*	10-fold CV
Low et al [42]	United States, 2021	Clinical data; 44	People with pancreatic cancer after surgery	Diarrhea, fatigue, and pain	Physical activity bouts, sleep, heart rate, and location	LR, KNN, SVM, RF, GB[ab], XGB, and *LightGBM*	3-fold CV and LOOCV
Kourou et al [43]	Greece, 2021	Clinical data; 609	People with breast cancer	Depression	A set of psychological traits (optimism, perceived ability to cope with trauma, resilience as a trait, and ability to understand the illness) and subjective perceptions of personal functionality (physical, social, and cognitive)	RF, *SVM*, and GB	5-fold CV
Kober et al [44]	United States, 2021	Clinical data; 1217	People with cancer receiving chemotherapy	Evening fatigue	Morning fatigue, lower evening energy, and sleep disturbance	*RF*, LR (filtered or unfiltered), RPAR, and SVM	10-fold CV
Hu et al [45]	China, 2021	Clinical data; 238	People with non-Hodgkin lymphoma receiving chemotherapy	Depression	Education level, sex, age, marital status, medical insurance, per capita monthly household income, pathological stage, Suicide Severity Rating Scale, Pittsburgh Sleep Quality Index, and Quality of Life Questionnaire Core 30	SVM, RF, and *LASSO+LR*	Random
Haun et al [46]	Germany, 2021	Clinical data; 496	People with cancer seen in primary care	Anxiety	Fatigue or weakness, insomnia, and pain appeared	OLS[ac], RR[ad], *LASSO*, ENR[ae], RF, and XGB	10-fold CV

Study	Country, year	Data type; number of data	Population	Cancer symptoms	Significant predictors	Algorithms	Validation methods
Lee et al [47]	United States, 2020	Clinical data and CT Images data; 388	People with lung cancer after intensity-modulated radiation therapy	Weight loss	Joint Gross tumor volume L1+L2+L3 radiomics, Gross tumor volume, and esophagus L3 dosiomic	SVM, DNN[af], and *ensemble classifier*	Nested CV
Juwara et al [48]	Canada, 2020	Clinical data; 204	People with breast cancer after surgery	NP[aj]	Anxiety, type of surgery, and acute pain	LS[ah], *RR*, *ENR*, RF, *GB*, and ANN	10-fold CV
Men et al [49]	United States, 2019	Clinical data and CT image data; 784	People with HNC receiving radiotherapy	Xerostomia	Feature map visualization	LR and *3D-RC-NN*[ai]	Random
Jiang et al [50]	United States, 2019	Clinical data and CT images data; 427	People with HNC	Xerostomia	The patient has human papillomavirus, completed chemotherapy, their baseline xerostomia grade, tumor site, N stage, and use of feeding tube	*RR*, LASSO, and RF	10-fold CV
Sheikh et al [51]	United States, 2019	CT images data; 266	People with HNC	Xerostomia	N/A	*Generalized linear model*	10-fold CV
Papachristou et al [52]	United States, 2019	Clinical data; 799	People with cancer receiving chemotherapy	Sleep disturbance, anxiety, and depression	Age, gender, cancer site, the number of prior cancer treatment, and initial diagnosis	*SVR* (linear, polynomial, and radial Sigma) and n-CCA[aj]	10-fold CV and bootstrap
Zhang et al [53]	China, 2018	Clinical data; 375	People with cancer receiving radiotherapy	Weight loss	Head and neck tumor location and total radiation dose of ≥70 Gray, and without postsurgery	*DT* and LR	Random
Olling et al [54]	Denmark;2018	Clinical and CT image; 131	People with lung cancer receiving radiotherapy	Odynophagia (painful swallowing)	N/A	*Multivariable LR*, Lasso and elastic net regularized generalized linear models, and *SVM*	10-fold CV
Gabryś et al [55]	Germany;2018	Clinical and CT image; 153	People with HNC after radiotherapy	Xerostomia	The parotid gland volume, the spread of the contralateral dose-volume histogram, and the parotid gland eccentricity, and sex	LRL1[ak], LRL2[al], LR-EN[am], *KNN*, SVM, *ET*[an], and *GTB*[ao]	Single and nested CV
Lötsch et al [56]	Germany;2018	Clinical data; 1000	People with breast cancer after surgery	Pain	Age, chronic pain of any type, number of previous operations, BMI, preoperative pain in the area to be operated on, smoking and psychological factors	*Unsupervised ML*[ap]	Random
Abdollahi et al [57]	Iran;2018	Clinical and CT image; 47	People with HNC receiving chemotherapy	Hearing loss	10 of the 490 radiomic features selected as the associated features with significant sensorineural hearing loss status	Decision stump, Hoeffding, C4.5, NB, AdaBoost, bootstrap aggregating, and LR	10-fold CV
van Dijk et al [58]	United States;2018	Clinical data and CT image; 68	People with HNC	Xerostomia	N/A	*LR*	External validation
Cvetković [59]	Serbia;2017	Clinical data; 84	People with breast cancer	Depression	N/A	*ELM*[aq], ANN, and Fuzzy Genetic Algorithm	Random

Study	Country, year	Data type; number of data	Population	Cancer symptoms	Significant predictors	Algorithms	Validation methods
van Dijk et al [60]	United States;2017	CT image features; 249	People with HNC	Xerostomia	N/A	*LR*	10-fold CV

[a] LR: logistic regression.

[b] Italic text in this column indicates the best results used in the study.

[c] RF: random forest.

[d] GBDT: gradient boosting decision tree.

[e] XGB: extreme gradient boosting.

[f] ANN: artificial neural network.

[g] CV: cross-validation.

[h] EN: elastic net.

[i] LASSO: Least absolute shrinkage and selection operator.

[j] RPAR: recursive partitioning and regression trees.

[k] SVM: support vector machine.

[l] NB: Naïve bayes.

[m] N/A: not applicable.

[n] MP: multiple perceptron.

[o] AdaBoost: Adaptive boosting.

[p] GBM: light gradient boosting machine.

[q] CT: computed tomography.

[r] CNN: convolutional neural network.

[s] DT: decision tree.

[t] LOOCV: leave-one-out-cross-validation.

[u] HNC: head and neck cancer.

[v] KNN: k-nearest neighbor.

[w] CART: classification and regression tree.

[x] MLP: multilayer perceptron.

[y] ARIMA: autoregressive integrated moving average.

[z] LSTM: long short-term memory neural network.

[aa] SVR: support vector regression.

[ab] GB: gradient boosting.

[ac] OLS: ordinary least square.

[ad] RR: ridge regression.

[ae] ENR: elastic net regression.

[af] DNN: deep neural network.

[ag] NP: neuropathic pain.

[ah] LS: least squares.

[ai] 3D-RCNN: 3D region-based convolutional neural network.

[aj] n-CCA: nonlinear canonical correlation analysis.

[ak] LRL1: L1 penalized logistic regression.

[al] LRL2: L2 penalized logistic regression.

[am] LR-EN: logistic regression-elastic net.

[an] ET: extra tree.

[ao] GTB: gradient tree boosting.

[ap] ML: machine learning.

[aq] ELM: extreme linear machine.

A total of 2 individual researchers (NZ and NY) separately extracted data from each study, working independently of each other. This approach is used to reduce bias and increase the accuracy of the data extraction process. If discrepancies arise between the 2 independent authors, they are usually resolved through discussion or by consulting a third reviewer (SGW).

Primary Database Information

The studies selected were published between 2017 and 2023 and were conducted in North America (18/42, 43%), Asia (16/42, 38%), and Europe (8/42, 19%). Methods of data collection varied, with studies originating from individual centers (23/42, 55%) and multiple centers (19/42, 45%). The average sample size was 1686, and the studies varied in sample size: <100 participants (8/42, 19%), between 100 and 1000 participants (27/42, 64%), and >1000 participants (7/42, 17%). Most studies relied on clinical data (28/42, 67%), although some integrated clinical data with computed tomography (CT) images (14/42, 33%). The study designs were diverse, including retrospective (18/42, 43%), cross-sectional (15/42, 38%), prospective (5/42, 12%), and longitudinal (4/42, 10%) approaches.

Cancer Primary Sites and Predicted Symptoms

Various primary cancer sites were studied, with head and neck cancers being the most prevalent (9/42, 21%). Breast cancer was the focus of 19% (8/42) of the studies, and lung cancer was studied in 17% (3/42) of the cases. The included studies included participants undergoing a range of treatments, including chemotherapy (9/42, 21%), radiotherapy (9/42, 21%), surgery (4/42, 10%), and investigations of posttreatment survivors (2/42, 5%). Of the 42 included studies, 10 unique symptoms were reported as outcome variables in the predictions. Those included were xerostomia (9/42, 14%) [27,30,34,49-51,55,58,60], depression (8/42, 13%) [22,33,37,41,43,45,52,59], pain (8/42, 13%) [20,25,26,35,37,40,42,56], fatigue (6/42, 10%) [23,24,29,38,42,44], anxiety (3/42, 5%) [33,46,52], sleep disturbance or insomnia (3/42, 5%) [26,28,52], nausea or vomiting (3/42, 5%) [17,26,29], weight loss (2/42, 3%) [47,53], cognitive impairment (2/42, 3%) [21,36], and diarrhea (2/42, 3%) [29,42].

One study reported multiple symptoms, including hypersensitivity [29], stomatitis [29], hand-foot syndrome [29], peripheral neuropathy [29], and constipation [29]. Another study delved into taste and general activity [40]. Individual studies were dedicated to each of the following symptoms: delirium [31], lung infection [32], lymphedema [39], well-being [37], odynophagia [54], social distress [26], spiritual pain [26], dyspnea [26], and hearing loss [57]. The distribution of these symptoms is depicted in Multimedia Appendix 5.

Significant Candidate Predictors of Symptoms

Numerous predictors were frequently used for predicting symptoms, which can be grouped into demographic features and clinical characteristics.

Demographic Features

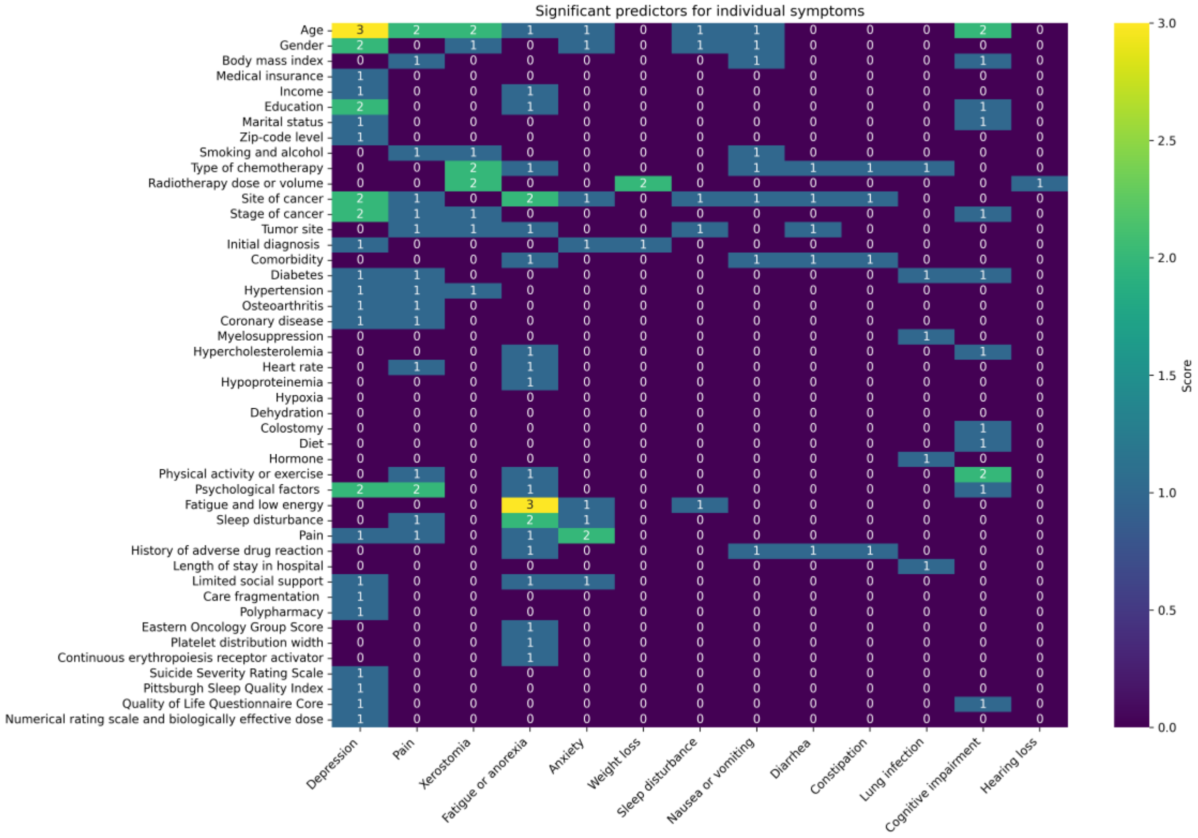
The demographic features include age, sex, BMI, income, medical insurance, education, marital status, and zip code–level poverty.

Clinical Characteristics

The clinical characteristics include smoking and alcohol use, initial diagnosis, presence of cancer, stage of cancer, cancer course, tumor site, type and number of prior treatments, chemotherapy type, and radiotherapy dose and volume. Health conditions such as comorbidity, diabetes, hypertension, osteoarthritis, and coronary disease also play a significant role. In addition, psychological factors such as depression and anxiety, fatigue, sleep disturbance, and pain are considered. Other influential predictors encompass care fragmentation, polypharmacy, hormone levels, physical activity, diet, heart rate, and social support factors.

In our comprehensive analysis of 42 studies, all the detailed findings on common cancer symptoms are compiled in Figure 2. We provide a detailed analysis of the predictors for the 4 most frequently reported cancer symptoms identified in this study: xerostomia, pain, depression, and fatigue. In a detailed analysis of 42 studies, various predictors for 4 common cancer symptoms—xerostomia, pain, depression, and fatigue—have been identified, each with its distinct set of influencing factors.

Figure 2. Significant predictors of individual symptoms.



Significant predictors for individual symptoms

	Depression	Pain	Xerostomia	Fatigue or anorexia	Anxiety	Weight loss	Sleep disturbance	Nausea or vomiting	Diarrhea	Constipation	Lung infection	Cognitive impairment	Hearing loss
Age	3	2	2	1	1	0	1	1	0	0	0	2	0
Gender	2	0	1	0	1	0	1	1	0	0	0	0	0
Body mass index	0	1	0	0	0	0	0	1	0	0	0	1	0
Medical insurance	1	0	0	0	0	0	0	0	0	0	0	0	0
Income	1	0	0	1	0	0	0	0	0	0	0	0	0
Education	2	0	0	1	0	0	0	0	0	0	0	1	0
Marital status	1	0	0	0	0	0	0	0	0	0	0	1	0
Zip-code level	1	0	0	0	0	0	0	0	0	0	0	0	0
Smoking and alcohol	0	1	1	0	0	0	0	1	0	0	0	0	0
Type of chemotherapy	0	0	2	1	0	0	0	1	1	1	1	0	0
Radiotherapy dose or volume	0	0	2	0	0	2	0	0	0	0	0	0	1
Site of cancer	2	1	0	2	1	0	1	1	1	1	0	0	0
Stage of cancer	2	1	1	0	0	0	0	0	0	0	0	1	0
Tumor site	0	1	1	1	0	0	1	0	1	0	0	0	0
Initial diagnosis	1	0	0	0	1	1	0	0	0	0	0	0	0
Comorbidity	0	0	0	1	0	0	0	1	1	1	0	0	0
Diabetes	1	1	0	0	0	0	0	0	0	0	1	1	0
Hypertension	1	1	1	0	0	0	0	0	0	0	0	0	0
Osteoarthritis	1	1	0	0	0	0	0	0	0	0	0	0	0
Coronary disease	1	1	0	0	0	0	0	0	0	0	0	0	0
Myelosuppression	0	0	0	0	0	0	0	0	0	0	1	0	0
Hypercholesterolemia	0	0	0	1	0	0	0	0	0	0	0	1	0
Heart rate	0	1	0	1	0	0	0	0	0	0	0	0	0
Hypoproteinemia	0	0	0	1	0	0	0	0	0	0	0	0	0
Hypoxia	0	0	0	0	0	0	0	0	0	0	0	0	0
Dehydration	0	0	0	0	0	0	0	0	0	0	0	0	0
Colostomy	0	0	0	0	0	0	0	0	0	0	0	1	0
Diet	0	0	0	0	0	0	0	0	0	0	0	1	0
Hormone	0	0	0	0	0	0	0	0	0	0	1	0	0
Physical activity or exercise	0	1	0	1	0	0	0	0	0	0	0	2	0
Psychological factors	2	2	0	1	0	0	0	0	0	0	0	1	0
Fatigue and low energy	0	0	0	3	1	0	1	0	0	0	0	0	0
Sleep disturbance	0	1	0	2	1	0	0	0	0	0	0	0	0
Pain	1	1	0	1	2	0	0	0	0	0	0	0	0
History of adverse drug reaction	0	0	0	1	0	0	0	1	1	1	0	0	0
Length of stay in hospital	0	0	0	0	0	0	0	0	0	0	1	0	0
Limited social support	1	0	0	1	1	0	0	0	0	0	0	0	0
Care fragmentation	1	0	0	0	0	0	0	0	0	0	0	0	0
Polypharmacy	1	0	0	0	0	0	0	0	0	0	0	0	0
Eastern Oncology Group Score	0	0	0	1	0	0	0	0	0	0	0	0	0
Platelet distribution width	0	0	0	1	0	0	0	0	0	0	0	0	0
Continuous erythropoiesis receptor activator	0	0	0	1	0	0	0	0	0	0	0	0	0
Suicide Severity Rating Scale	1	0	0	0	0	0	0	0	0	0	0	0	0
Pittsburgh Sleep Quality Index	1	0	0	0	0	0	0	0	0	0	0	0	0
Quality of Life Questionnaire Core	1	0	0	0	0	0	0	0	0	0	0	1	0
Numerical rating scale and biologically effective dose	1	0	0	0	0	0	0	0	0	0	0	0	0

For xerostomia, age, gender, chemotherapy type, radiotherapy dose and volume, cancer stage, tumor site, and hypertension are crucial predictors. In the case of pain, factors such as age, BMI, smoking and alcohol habits, cancer site and stage, tumor site, diabetes, hypertension, osteoarthritis, coronary disease, physical activity, psychological factors, sleep disorders, and existing pain conditions emerge as significant. Significant predictors for depression include age; gender; education; cancer site and stage; economic factors such as insurance, income, and poverty level; marital status; initial diagnosis impact; comorbidities (diabetes, hypertension, osteoarthritis, and coronary disease); pain; social support; care fragmentation; polypharmacy; and various scale scores. Finally, for fatigue, the key predictors are existing fatigue and low energy, cancer site, sleep disturbances, age, income, education, chemotherapy type, tumor site, comorbidities, hypercholesterolemia, heart rate, hypoproteinemia, physical and psychological factors, pain, adverse drug reaction history, limited social support, Eastern Cooperative Oncology Group score, platelet distribution width, and erythropoiesis.

When examining the commonalities across these predictors for xerostomia, pain, depression, and fatigue, several factors stand out as particularly influential across multiple symptoms: age; gender; cancer site and stage; treatment-related factors such as the type of chemotherapy and radiotherapy; comorbidities such as diabetes, hypertension, and coronary disease; physical and psychological factors; and socioeconomic factors such as income and education level, demonstrating the impact of cancer treatments on symptom development. These common predictors underscore the complex, multifactorial nature of symptom manifestation in patients with cancer, necessitating a comprehensive approach to their management and care.

ML Algorithms and Validation Metrics

Of the 42 studies analyzed, 7 (17%) used a single ML algorithm, whereas 35 (83%) used multiple algorithms. The most effective models, in terms of performance, were logistic regression (LR; 9/42, 17%), random forest (7/42, 13%), artificial neural networks (5/42, 9%), decision trees (DTs; 5/42, 9%), and extreme gradient boosting (3/42, 6%). For validation methods, 10-fold cross-validation was the most used (14/42, 31%), followed by 5-fold cross-validation (5/42, 11%), 3-fold cross-validation (2/42, 4%), and 8-fold cross-validation (1/42, 2%). The primary evaluation metric across these studies was the area under the curve, which was adopted in 24% (26/42) of the studies. A visual representation of the leading ML models along with the validation and evaluation metrics used in the study presents in Multimedia Appendix 6.

Discussion

Principal Findings

In this review, we present the first systematic analysis of ML applications for predicting the development of cancer symptoms. We explore the most frequently studied cancer sites and delve into the intricacies of ML procedures. Breast, head or neck, and lung cancers are the most frequently studied sites in current research, with xerostomia, depression, pain, and fatigue being the most prominent symptoms. The application of various ML techniques is on the rise, with data acquisition and preprocessing being pivotal for successful ML models. While a range of algorithms, from traditional methods such as LR and DT to advanced ones such as DL, are used, there is a growing emphasis on data quality, external validation, and a standardized approach to model evaluation. The future of ML in cancer symptom prediction looks promising, with a need for collaborative efforts among oncologists, data scientists, and patient groups, combined with more comprehensive research on lesser-studied cancer sites and standardized methodologies.

Regarding the cancer sites covered in the studies, breast, head or neck, and lung cancers emerged as the most frequently researched primary cancer sites. The range of symptoms and side effects that patients experienced varied from one study to another. Some symptoms depended on the specific cancer site and the treatments patients received. For example, xerostomia, which can either arise from the tumor itself or manifest as a treatment side effect, has a significant impact on patients' dental health and compromises antimicrobial functions [61]. However, most symptoms were not directly attributed to a particular cancer site or treatment.

Our review revealed a notable emphasis on predicting xerostomia in 14% (9/42) of the studies, despite head and neck cancers being less prevalent. The notable emphasis on predicting xerostomia in ML research, despite the lower prevalence of head and neck cancers, is likely due to advancements in integrating ML with CT imaging. CT imaging is a pivotal tool in the diagnosis and treatment planning of head and neck cancers. The integration of ML with CT imaging has opened new possibilities for more accurately predicting side effects such as xerostomia. ML techniques, when applied to CT images, can potentially identify patterns and indicators that are not easily discernible by human observers. This capability can lead to earlier and more precise predictions of xerostomia, thereby enabling better preventive measures and treatment planning to mitigate this side effect. Therefore, the focus on xerostomia in ML research, in the context of head and neck cancers, is likely driven by the opportunities presented by combining ML with advanced imaging techniques.

Depression, a widespread emotional challenge for people with cancer [62,63], was the focus of prediction in many studies (8/24, 13%). Similarly, pain, a recurrent concern for palliative care patients [64] and survivors of cancer [65,66], was the subject of prediction in >13% (8/24) of the studies. Fatigue, prevalent across all age groups with cancer [67,68], was highlighted in 6 (10%) of the 42 studies reviewed.

In terms of the ML approaches used in the studies, a plethora of techniques were used to construct these predictive models, spanning all phases of the ML process, from data collection and preprocessing to feature and algorithm selection, model training, testing, and evaluation. The process of data acquisition is pivotal for the development of ML models, thereby emphasizing the importance of an adequate sample size. Upon reviewing 42 studies, we discerned that the most frequent sample sizes for ML applications ranged between 100 and 1000 samples. More advanced ML techniques necessitate larger data sets to bolster robustness and mitigate the risk of overfitting. Alarmingly, certain studies in our review used ML with comparably smaller data sets, introducing the risk of model overfitting and potential biases in the subsequent performance metrics [69]. Challenges tied to sample size might impede the creation of sturdy and trustworthy ML models [70]. Data preprocessing is indispensable to yield clean and interpretable data, which is a cornerstone for proficient ML models. Data cleaning approaches encompass addressing missing values, tackling data noise, and data normalization. Within health care data sets, noisy or absent data are frequently a by-product of inaccuracies in manual entries or instrument recordings made by medical personnel or ancillary staff [71]. However, most of the reviewed studies lacked comprehensive descriptions of their data cleaning methodologies or strategies for handling noisy data and normalization, constrained by word or page limits in publications.

Given the crucial importance of data quality in developing ML models, it is essential for researchers to focus equally on effective data preparation and choosing suitable algorithms. Future endeavors would benefit from exhaustive procedural documentation made available on public platforms such as GitHub. In a research context, GitHub can be used for sharing and collaborating on various aspects of a research project, including but not limited to code. It allows researchers to maintain version control of their scripts, data analysis procedures, and even documentation. This feature is particularly beneficial for replicating studies and verifying results, as it provides a transparent view of the methodologies and analyses used.

Overloading an ML model with excessive features can undermine its ability to differentiate between pertinent data and superfluous noise, leading to the challenge often referred to as the "curse of dimensionality." The goal of feature engineering is to mitigate model complexity, expedite the training process, reduce the data's dimensionality, and avert overfitting [72]. By streamlining the model with a curated set of predictors, it becomes more accessible and transparent, emphasizing the importance of feature selection during data preparation. Our review pinpointed the most frequently used significant predictors in cancer symptom prediction. The efficacy of prediction models is heavily influenced by the number and interplay of the relevant predictors. Factors such as age, gender, type and number of previous treatments, cancer location, cancer stage, chemotherapy type, dosage and volume of radiotherapy; chronic conditions such as diabetes and hypertension; concurrent diseases; and symptoms including depression, anxiety, fatigue, pain, and sleep disturbances have consistently featured as determinants in numerous predictive frameworks. Our review of cancer symptom prediction underscored age as a pivotal factor, associated with predominant symptoms such as depression, pain, xerostomia, and fatigue. While numerous elements, from gender to type of treatment and cancer stage, influence the predictive models, it is the prominence of age that consistently emerges as a cornerstone predictor. As we delve deeper into this field, even with the introduction of newer determinants and correlations, the centrality of age in these frameworks remains indisputable.

Regarding algorithm selection, traditional methods often struggle with handling high-dimensional data and processing extensive information. To tackle these challenges, researchers have increasingly shifted toward innovative ML algorithms that are renowned for their robust predictive power and strong generalization capacities. These sophisticated algorithms excel at delving deep into data and discerning intricate interrelationships among variables. To navigate the multifaceted landscape of modeling challenges, it is advantageous for researchers to leverage a diverse array of ML algorithms. Most studies used multiple predictive models, with techniques such as LR, RF, ANN, and DT consistently delivering stellar results. The introduction of advanced ML techniques, such as DL and ensemble classifiers, provides promising opportunities to elevate prediction accuracy in future research.

After their design, the ML models undergo training and testing on different data sets. However, these models can grapple with issues such as overfitting and underfitting. Overfitting occurs when a model becomes overly complex, which leads to increased variance and reduced clarity. In contrast, underfitting results from an oversimplified model, causing it to overlook key data patterns and diminish its predictive capacity. Therefore, the ideal learning model should strike a balance between the optimal variance and justifiable bias. To mitigate these issues, the common strategy is to divide the data set into training and testing subsets, followed by internal or external validation. While most studies in our review used internal validation, only 1 study reported external validation [58], which was demonstrated on a small cohort of 25 patients with head and neck cancer. Although its performance is typically lower than evaluations using the original data sets, external validation remains crucial for gauging ML models [72]. It is a crucial step in ensuring that the model's performance is not just limited to the conditions and data it was originally trained on but also applicable and reliable in broader, real-world clinical settings. This approach serves to verify the model's efficacy and generalizability across different patient populations and settings.

Understanding and interpreting ML models continue to pose challenges. Determining the variables that significantly impact symptom prediction can be elusive due to the intricate prediction processes. Many studies gauge the performance of ML models using metrics that examine their ability to distinguish between 2 classes. From our systematic review of 42 studies, the area under the curve emerged as the predominant metric for the prediction models. Other metrics included accuracy, sensitivity, specificity, positive predictive value, root mean square error, and negative predictive value. These metrics provide a holistic view of a model's efficacy, facilitating its refinement and enabling more precise predictions. However, the diverse emphasis on distinct metrics in numerous studies underscores the need for a uniform approach to evaluating ML models in cancer symptom prediction.

As interest grows in using ML for predicting cancer symptoms, there are several areas that merit deeper investigation. A crucial area is broadening the range of studied cancer sites and more comprehensively correlating symptoms with various treatment methods. To fully understand symptom prediction, it is essential that future studies delve into lesser-explored or infrequently studied cancer sites. Furthermore, the methodologies used for data preprocessing and cleaning should be documented more thoroughly, focusing on best practices to ensure data integrity. As data are foundational to ML models, transparent and detailed preprocessing can improve the reliability and repeatability of these models. Although our analysis highlighted common predictors for symptom forecasting, examining potentially underrepresented or emerging indicators could refine these models further. On the algorithmic front, exploring hybrid ML methods that merge the strengths of multiple algorithms might be particularly beneficial for cancer symptom prediction. Standardizing evaluation metrics across studies would also provide clarity and facilitate a more accurate comparison of various ML techniques. To genuinely progress, collaborations among oncologists, data scientists, and patient advocacy groups are vital to ensure that the developed models are technically robust and clinically pertinent. With these insights, ML stands poised to transform cancer care, creating treatment plans based on patient-focused and accurate symptom prediction models.

Limitations

This review is not without its limitations. Although we established clear inclusion and exclusion criteria, potential biases in the studies we analyzed could inherently limit our review. We might have missed or excluded relevant studies due to inadequate information or the absence of keywords in their titles or abstracts. Many of the studies we reviewed did not specify the cancer site, potentially limiting the accuracy and applicability of our findings to specific cancer types. The broad range of predictors used across the studies also made it difficult to draw definitive conclusions about the most influential factors in predicting cancer symptoms using ML algorithms. As such, readers should interpret these results cautiously, given this variability.

Conclusions

ML offers an intriguing potential for predicting cancer symptoms, thereby preemptively mitigating the associated challenges. Predicting the symptoms that people with cancer might experience and determining their onset throughout their treatment journey is a pivotal clinical issue that can enhance patients' quality of life. Notably, all studies in our review were published after 2017, highlighting the nascent nature of this research area. Our investigation primarily sought to outline the ML methodologies harnessed for symptom prediction in people with cancer. While ML techniques hold an edge over traditional statistical approaches by virtue of their prowess in analyzing vast data sets and gauging the efficacy of diverse prediction models, certain impediments such as a limited pool of symptoms; suboptimal data preparation; challenges in feature engineering; and complexities in ML algorithm design, validation, and evaluation can constrain the broad applicability of these predictive models. Future research should pivot toward amplifying the efficacy of ML strategies. This enhancement can be achieved by harnessing expansive, high-caliber data sets; tapping into innovative technologies for data refinement; and sculpting refined models. Harnessing ML can potentially free health care practitioners—including doctors, nurses, and clinic personnel—to accentuate the human touch in managing cancer symptoms.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
The detailed search strategy for the databases and the Boolean expressions used.
[DOCX File , 30 KB - cancer_v10i1e52322_app1.docx]

Multimedia Appendix 2
PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) 2020 checklist.
[PDF File (Adobe PDF File), 942 KB - cancer_v10i1e52322_app2.pdf]

Multimedia Appendix 3
The distribution and overlap of 42 studies across the databases.
[PNG File , 88 KB - cancer_v10i1e52322_app3.png]

Multimedia Appendix 4
The data extracted from 42 studies.
[DOCX File , 31 KB - cancer_v10i1e52322_app4.docx]

Multimedia Appendix 5
Number of studies per cancer symptoms.
[PNG File , 62 KB - cancer_v10i1e52322_app5.png]

Multimedia Appendix 6
Visual overview of the machine learning models and metrics.
[PNG File , 74 KB - cancer_v10i1e52322_app6.png]

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Abbreviations

CT: computed tomography
DL: deep learning
DT: decision tree
LR: logistic regression
ML: machine learning
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

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Review

Telemedicine Applications for Cancer Rehabilitation: Scoping Review

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Abstract

Background: Cancer is a significant public health issue worldwide. Treatments such as surgery, chemotherapy, and radiation therapy often cause psychological and physiological side effects, affecting patients' ability to function and their quality of life (QoL). Physical activity is crucial to cancer rehabilitation, improving physical function and QoL and reducing cancer-related fatigue. However, many patients face barriers to accessing cancer rehabilitation due to socioeconomic factors, transportation issues, and time constraints. Telerehabilitation can potentially overcome these barriers by delivering rehabilitation remotely.

Objective: The aim of the study is to identify how telemedicine is used for the rehabilitation of patients with cancer.

Methods: This scoping review followed recognized frameworks. We conducted an electronic literature search on PubMed for studies published between January 2015 and May 2023. Inclusion criteria were studies reporting physical therapy telerehabilitation interventions for patients with cancer, including randomized and nonrandomized controlled trials, feasibility studies, and usability studies. In total, 21 studies met the criteria and were included in the final review.

Results: Our search yielded 37 papers, with 21 included in the final review. Randomized controlled trials comprised 47% (n=10) of the studies, with feasibility studies at 33% (n=7) and usability studies at 19% (n=4). Sample sizes were typically 50 or fewer participants in 57% (n=12) of the reports. Participants were generally aged 65 years or younger (n=17, 81%), with a balanced gender distribution. Organ-specific cancers were the focus of 66% (n=14) of the papers, while 28% (n=6) included patients who were in the posttreatment period. Web-based systems were the most used technology (n=13, 61%), followed by phone call or SMS text messaging–based systems (n=9, 42%) and mobile apps (n=5, 23%). Exercise programs were mainly home based (n=19, 90%) and included aerobic (n=19, 90%), resistance (n=13, 61%), and flexibility training (n=7, 33%). Outcomes included improvements in functional capacity, cognitive functioning, and QoL (n=10, 47%); reductions in pain and hospital length of stay; and enhancements in fatigue, physical and emotional well-being, and anxiety. Positive effects on feasibility (n=3, 14%), acceptability (n=8, 38%), and cost-effectiveness (n=2, 9%) were also noted. Functional outcomes were frequently assessed (n=19, 71%) with tools like the 6-minute walk test and grip strength tests.

Conclusions: Telerehabilitation for patients with cancer is beneficial and feasible, with diverse approaches in study design, technologies, exercises, and outcomes. Future research should focus on developing standardized methodologies, incorporating objective measures, and exploring emerging technologies like virtual reality, wearable or noncontact sensors, and artificial intelligence to optimize telerehabilitation interventions. Addressing these areas can enhance clinical practice and improve outcomes for remote rehabilitation with patients.

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KEYWORDS

telerehabilitation; telemedicine; rehabilitation; cancer; exercise; physical therapy; telehealth; remote care; digital medicine; oncology; oncologist; metastases; exercising; scoping review; scoping reviews; PubMed

Introduction

Cancer is a worldwide public health problem and is the second leading cause of death in the United States [1]. Treatments for cancer, such as surgery, chemotherapy, radiation therapy, and hormone therapy, often result in psychological and physiological sequelae and side effects that interfere with treatment completion, the ability to function and perform essential daily activities, and quality of life (QoL) [2]. Physical activity is an essential component of cancer rehabilitation and effectively reduces the burden of several specific cancers, including benefits related to physical function, QoL, and cancer-related fatigue [3].

The American College of Sports Medicine concluded that exercise training is safe during and after cancer treatments and improves the QoL in several survivor groups of cancer [3]. Based on these findings, individualized and personalized programs are needed for patients with cancer depending on the type of cancer, stage of the disease, and patient goals to avoid inactivity, disability, and worsening of their QoL. Rehabilitation is a standard part of cancer care and can have the potential to reduce the burden on the health care system [4].

Unfortunately, many patients do not have access to all the cancer rehabilitation therapy due to problems related to social economics; transportation; and several other factors that impact the treatment, like work, costs, and time [5,6]. All these factors can seriously impact the patient's access to cancer rehabilitation services in medical facilities. Conversely, technology has been growing, and treatment nowadays can be delivered to patients without the need for a face-to-face consultation [7]. This convergence of circumstances has led to the emergence of telerehabilitation, a subfield of telemedicine that uses information and communication technologies (ICTs) to develop systems capable of managing and delivering rehabilitation remotely and has been suggested as one mechanism that can reduce some barriers to accessing and providing rehabilitation [8].

Telerehabilitation has been implemented across various diseases with promising results [9-15] and was considered highly cost-effective [16,17]. Nonetheless, there is a noticeable shortage of studies evaluating the use of physical therapy in telerehabilitation for patients with cancer broadly. A review of reviews on telemedicine and digital health in patients with cancer did not uncover any documents related explicitly to rehabilitation [18]. Furthermore, the available literature reviews tend to focus on specific types of cancer [19-21], lack a systematic approach to guide the review process [22-24], target pediatric populations [25], or focus exclusively on cognitive or behavioral rehabilitation [26].

For these reasons, this scoping review aimed to identify studies regarding physical therapy telerehabilitation for survivors of cancer and understand the technology used, exercises, and outcomes of this type of treatment that has the potential to grow.

Methods

Study Design

This scoping review was conducted using the methodological framework of Arksey and O'Malley [27], with five major steps: (1) identify research question, (2) identify relevant studies, (3) evaluate and select studies to be included, (4) chart the data, and (5) collect, summarize, and report the results. We report this study following the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews) 2020 guidelines (Multimedia Appendix 1) [28]. The protocol was registered on the Open Science Framework [29].

Research Question

Based on our aim, we formulated the following research question: "How are telemedicine approaches used for cancer rehabilitation?"

Search Strategy

An electronic literature search was conducted using the PubMed database to identify relevant studies for inclusion in this scoping review. The following Boolean search terms were used: (telerehabilitation) AND (cancer) AND ("physical therapy" OR "exercise" OR "cancer rehabilitation"). No language restrictions were applied. The studies included were published between January 2015 and May 2023. This time frame was selected because, starting in 2015, global regulatory frameworks were established that promoted the use of telemedicine technologies. These frameworks provided standards and best practices, coinciding with the increased adoption of ICTs in the health care sector, thereby fostering research in this area. The literature search was reviewed and validated by an expert in telemedicine.

Study Selection

We included studies that reported physical therapy exercises and telerehabilitation interventions for patients with cancer. Eligible designs included randomized controlled trials (RCTs) and nonrandomized controlled trials, controlled and noncontrolled before-after studies, and feasibility and usability studies that reported the intervention treatment. Exclusion criteria comprise systematic review studies and meta-analysis, no physical therapy treatment mentioned, and studies with only psychological treatment. Two reviewers (PGLR and CMR-R) conducted the selection process independently and in duplicate. Any disagreements were solved through discussion, and if consensus could not be reached, a third reviewer (JF) made the final decision.

Data Extraction

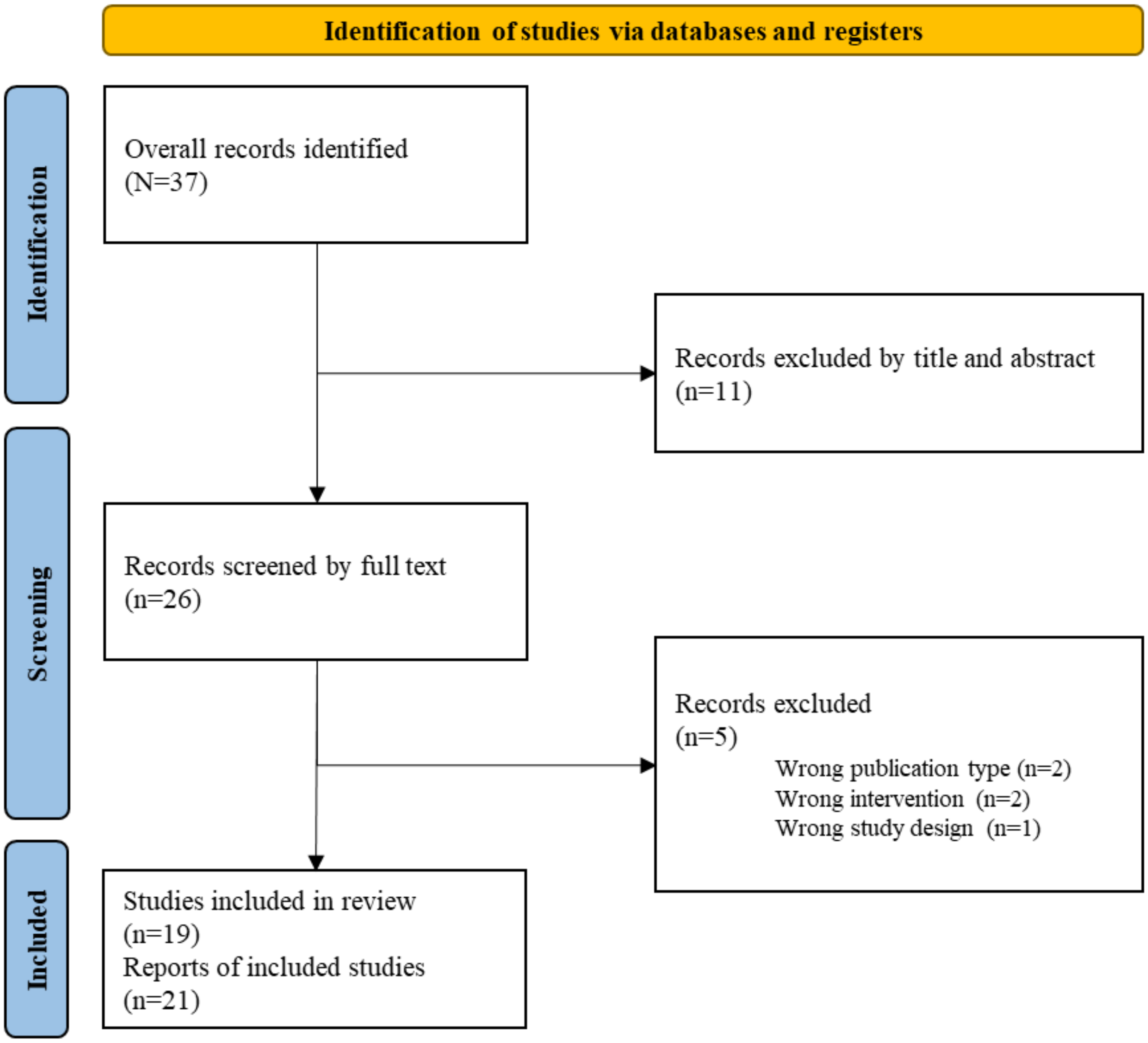
One reviewer (CMR-R) collected the data from the documents using a predefined collection form in a Microsoft Excel spreadsheet. The other reviewer (PGLR) then double-checked the resulting form to ensure comprehensive data extraction. The data included in the study comprised the following: first author and year for each publication, type of study, specific design, sample size, sociodemographic characteristics (sex, age, race, and ethnicity), stage of cancer, and other special characteristics. Additionally, the specific technology used to deliver exercise programs or monitor each study, the type of exercise program, the description, duration, frequency, time per session, intensity of the program, and the monitoring of performance and the outcomes were charted. We synthesized findings by reporting frequencies and percentages for the abovementioned main characteristics. Furthermore, we chart the studies' geographic location, publication date, and type of study performed in a bubble plot.

Results

Selection Process

Our research query provided 37 potential papers to be included in the study. After reviewing the title and abstract, we found 26 relevant documents to the research question. All these studies were then read in detail and reviewed, resulting in 21 papers to be included in the final study. This process is detailed in Figure 1.

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flowchart of the study search and exclusion process.



General Characteristics

Overall, 21 studies were included in this scoping review, spanning from 2015 to 2023 and representing a diverse range of countries and study designs. As illustrated in Figure 2, most of the papers were conducted in the United States (n=5, 24%), Spain (n=4, 19%), and South Korea (n=3, 14%). The distribution of study types across these regions shows a higher concentration of RCTs in the United States and Spain. In contrast, feasibility and usability studies were more evenly distributed across various countries.

Figure 2. Studies by geographic location, type of study, and year of publication. RCT: randomized controlled trial.

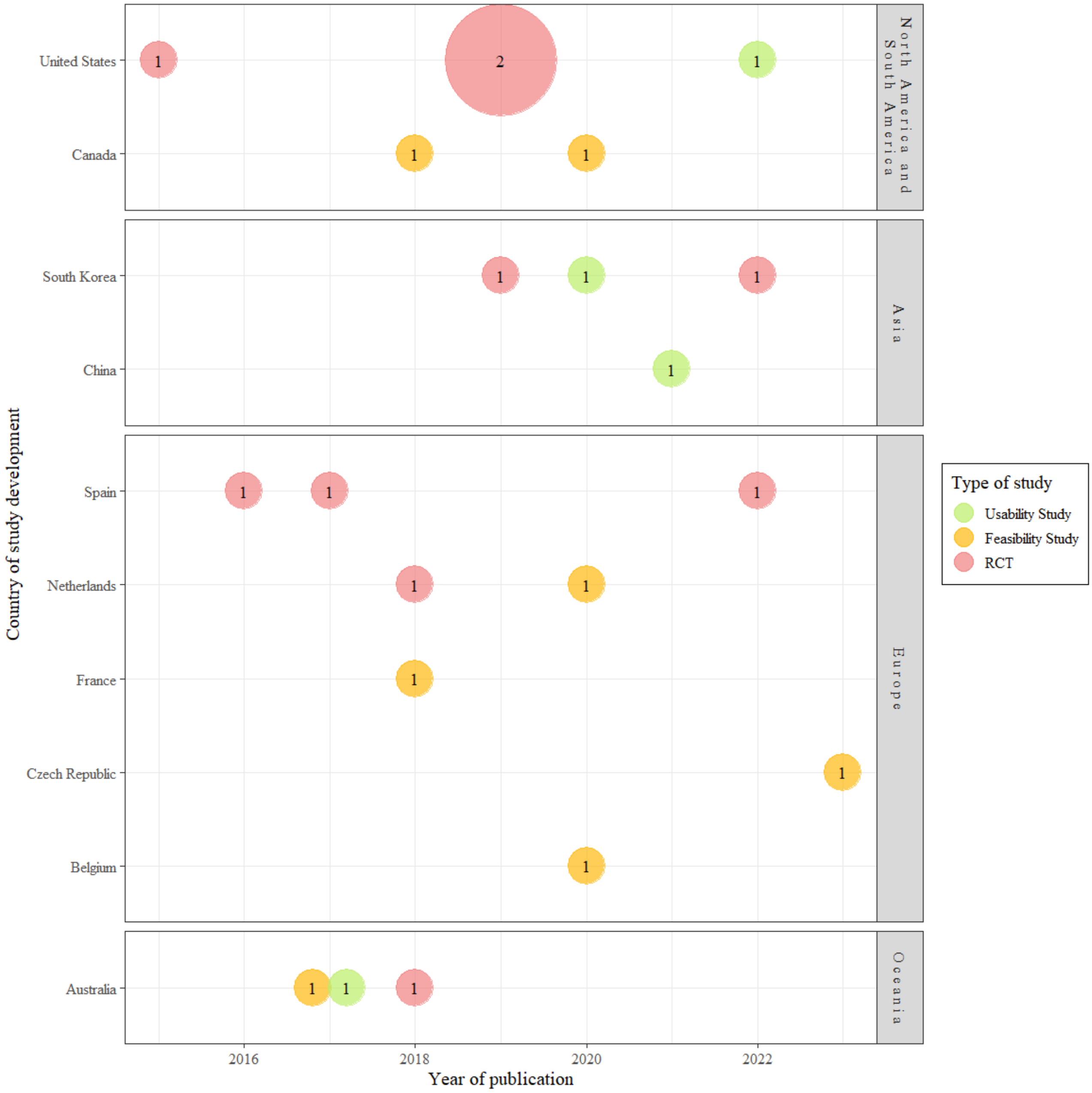


Table 1 shows that the most common type of study was the RCT, accounting for 48% (n=10) of the included studies. Feasibility studies constituted 33% (n=7) of the studies, while usability studies comprised the remaining 19% (n=4). The specific designs of these papers varied, with many adopting a prospective approach, and evaluations were often conducted at multiple time points, typically before and after intervention. Regarding sample sizes, the total sample size for most studies was 50 or fewer, representing 57% (n=12) of the studies. Studies with sample sizes ranging from 51 to 100 comprised 33% (n=7), and only 10% (n=2) had more than 100 participants. When examining the sample size per group, 48% (n=10) of the studies had 30 or fewer participants per group, 43% (n=9) had between 31 and 50 participants per group, and only 10% (n=2) had more than 50 participants per group.

Table 1. Study design and participants characteristics.

Paper	Type of study	Specific design	Sample size	Participants sociodemographic characteristics	State of cancer, other special characteristics
Schwartz et al (2015) [30]	RCT[a]	Prospective, randomized, 2 arms, in a parallel group, 2-time point evaluation (pre-post)	Total=50, T[b]=25, C[c]=25	• Sex: 76% (38/50) female • Age: mean 52.4 (SD 12.9) years	Cancer under or after chemotherapy or radiotherapy
Galiano-Castillo et al (2016) [31]	RCT	Prospective, randomized, 2 arms, in a parallel group, 3-time point evaluation (pre-post)	Total=81, T=40, C=41	• Sex: 100% female • Age: T: mean 47.4 (SD 9.6) years, C: mean 49.2 (SD 7.9) years	Stage I-IIIA breast cancer after adjuvant therapy without conditions that limit exercise
Collins et al (2017) [32]	Feasibility study	Prospective, nonrandomized, 2 arms, in a parallel group, multiple time point evaluation (each appointment)	Total=30, T=15, C=15	• Sex: 33.3% (10/30) female • Age: T: mean 57 (range 47-77) years, C: mean 65 (range 37-72) years	Head and neck cancer under curative-intent chemotherapy or radiotherapy
Galiano-Castillo et al (2017) [33]	RCT	Prospective, randomized, 2 arms, in a parallel group, 2-time point evaluation (pre-post)	Total=81, T=40, C=41	• Sex: 100% female • Age: T: mean 47.4 (SD 9.6) years, C: mean 49.2 (SD 7.9) years	Stage I-IIIA breast cancer after adjuvant therapy and without conditions that limit physical exercise
Wall et al (2017) [34]	Usability study	Prospective, single-arm, 2-time point evaluation (pre-post)	Total=15	• Sex: 100% male • Age: mean 58.7 (range 46-70) years	Oropharyngeal squamous cell carcinoma planned for curative-intent chemotherapy without physical impairments that limit exercise
Frensham et al (2018) [35]	RCT	Prospective, randomized, 2 arms, in a parallel group, 2-time point evaluation (pre-post)	Total=91, T=46, C=45	• Sex: 51.6% (47/91) female • Age: T: mean 65.2 (SD 9.3) years, C: mean 66.1 (SD 9.4) years • Race: White=87, Asian=2, ATSI[d]=2	Survivors of cancer who were not receiving treatment without contraindications for exercise
Gehring et al (2018) [36]	RCT	Prospective, randomized, 2 arms, in a parallel group, 2-time point evaluation (pre-post)	Total=34, T=23, C=11	• Sex: 55.9% (19/34) female • Age: T: mean 48.0 (SD 9.4) years, C: mean 48.0 (SD 11.9) years	Stage II-III glioma without contraindications for exercise
Vallerand et al (2018) [37]	Feasibility study	Prospective, randomized, 2 arms, in a parallel group, 2-time point evaluation (pre-post)	Total=51, T=26, C=25	• Sex: 60.8% (31/51) female • Age: mean 52.6 (SD 13.7) years	Leukemia, non-Hodgkin or Hodgkin lymphoma with the ability to perform exercise
Villaron et al (2018) [38]	Feasibility study	Prospective, randomized, 2 arms, in a parallel group, 2-time point evaluation (pre-post)	Total=43, T=21, C=22	• Sex: 72.1% (31/43) female • Age: mean 49.7 (SD 13.7) years	Cancer under chemotherapy or systemic treatment with the ability to perform exercise
Cheville et al (2019) [39]	RCT	Prospective, randomized, 3 arms, in a parallel group, 2-time point evaluation (pre-post)	Total=516, T1=72, T2=72, C=72	• Sex: 49.8% (257/516) female • Age: mean 65.6 (SD 11.1) years • Race: White=492, non-White=24 • Ethnicity: Hispanic or Latino=28	Stage IIIC or IV solid or hematologic cancer and low to moderate functional impairment that limits ambulation
Ji et al (2019) [40]	RCT	Prospective, randomized, 2 arms, in a parallel group, 2-time point evaluation (pre-post)	Total=64, T=32, C=32	• Sex: 29.7% (19/64) female • Age: T: mean 60.5 (SD 10.1) years, C: mean 57.9 (SD 9.8) years	Nonsmall cell lung cancer, ability to walk more than 150 m in a 6-minute walk test

Paper	Type of study	Specific design	Sample size	Participants sociodemographic characteristics	State of cancer, other special characteristics
Longacre et al (2019) [41]	RCT	Prospective, randomized, 3 arms, in a parallel group, 2-time point evaluation (pre-post)	Total=516, T1=172, T2=172, C=172	• Sex: 49.8% (257/516) female • Age: mean 65.6 (SD 11.1) years • Race: White=492, non-White=24 • Ethnicity: Hispanic or Latino=28	Stage IIIC or IV solid or hematologic cancer and low to moderate functional impairment that limits ambulation
van Egmond et al (2020) [42]	Feasibility study	Ambispective, 2 arms, 2-time point evaluation (pre-post)	Total=45, T=15, C=30	• Sex: 26.7% (12/45) female • Age: T: mean 62.8 (SD 6.9) years, C: mean 60.3 (SD 7.0) years	Esophageal or gastric cancer after surgery and with postoperative complications, with impairments that limit mobility, were assigned to in-person therapy
Kim et al (2020) [43]	Usability study	Prospective, single-arm, 3-time point evaluation (pre-during-post)	Total=31	• Sex: 16.1% (5/31) female • Age: mean 56.7 (SD 7.7) years	Stage I-II hepatocellular carcinoma, who could walk independently for more than 30 minutes
MacDonald et al (2020) [44]	Feasibility study	Prospective, single-arm, 2-time point evaluation (pre-post)	Total=35	• Sex: 62.9% (22/35) female • Age: mean 55 (SD 15.9) years	Survivors of cancer with a moderate-high disability received clearance from a physiatrist to participate in exercise
Piraux et al (2020) [45]	Feasibility study	Prospective, single-arm, 2-time point evaluation (pre-post)	Total=23	• Sex: 30.4% (7/23) female • Age: mean 61.7 (SD 10.6) years	Esophageal or gastric cancer planned for surgery without conditions that contraindicate or limit exercise
Zhou et al (2021) [46]	Usability study	Cross-sectional, single-arm, 1-time point evaluation (post)	Total=15	• Sex: 100% female • Age: mean 54.7 (SD 7.78) years	Stage I-III breast cancer after surgery, able to perform whole-body physical activity
Finkelstein et al (2022) [47]	Usability study	Cross-sectional, single-arm, 1-time point evaluation (post)	Total=11	• Sex: 100% male • Age: mean 68.1 (SD 11.2) years	Metastatic urogenital cancer receiving outpatient care
Lozano-Lozano et al (2020) [48]	RCT	Prospective, randomized, 2 arms, in a parallel group, 2-time point evaluation (pre-post)	Total=80, T=40, C=40	• Sex: 100% female • Age: T: mean 49.7 (SD 8.42) years, C: mean 53.4 (SD 8.66) years	Stage I-IIIA breast cancer, some range of ROM[e] limitation, and overweight
Park et al (2023) [49]	RCT	Prospective, randomized, 2 arms, in a parallel group, 2-time point evaluation (pre-post)	Total=100, T=50, C=50	• Sex: 100% female • Age: T: mean 42.5 (SD 9.06) years, C: mean 47.3 (SD 8.55) years	Breast cancer after surgery, with limited ROM in the affected shoulder but able to perform exercise
Filakova et al (2023) [50]	Feasibility study	Prospective, single-arm, 2-time point evaluation (pre-post)	Total=11	• Sex: 72.3% (8/11) female • Age: mean 60.3 (SD 10) years	Lymphoma after chemotherapy with the ability to perform exercise

[a] RCT: randomized controlled trial.

[b] T=treatment group.

[c] C=control group.

[d] ATSI: Aboriginal or Torres Strait Islander.

[e] ROM: range of motion.

Participants Characteristics

Table 1 reveals that the gender distribution among the studies was varied. Only 2 (10%) studies included all men, whereas 7 (33%) studies had more men than women. Similarly, 7 (33%) studies had more women than men, and 5 (24%) studies included all women participants. Most of the studies involved participants aged 65 years or younger, accounting for 81% (n=17) of the studies. Only 19% (n=4) of the studies included participants who were older than 65 years.

The studies encompassed a wide range of cancer types and stages of cancer treatment (Table 1). Organ-specific cancers were the focus of 67% (n=14) of the studies, including breast cancer, head and neck cancer, lung cancer, and various others. The remaining 33% (n=7) of the studies did not specify the type of cancer, focusing instead on survivors of cancer or patients with cancer undergoing chemotherapy or radiotherapy. In total, 6 (29%) studies included participants who were in the posttreatment, while 3 (14%) studies involved participants undergoing treatment. Only 2 (10%) studies included participants before the start of the treatment, and 10 (48%) studies had unclear stages of treatment.

Technology Used

As shown in Table 2, the papers included in this scoping review used various technologies to deliver exercise programs or monitor participants, highlighting the diverse approaches to telerehabilitation for patients with cancer. Most studies (n=13, 62%) used web-based systems, such as Retwise, e-CUIDATE, and SwallowIT, to facilitate patient and provider interactions. Mobile apps were used in 24% (n=5) of the studies, with apps like Physitrack (Physitrack PLC), Second Wind (Mediplus Solution), and the BENECA mobile health (mHealth) app (Mixed University Sport and Health Institute) being notable examples.

Table 2. Intervention characteristics.

Paper	Technology used to deliver exercise programs or monitoring	Type of exercise program	Exercise program description	Duration, frequency, time per session, and intensity of the program	Monitoring of performance	Outcomes measured
Schwartz et al (2015) [30]	Web-based system (Retwise website) for patient+pulse oximeter	In-person clinic-based rehabilitation+self-directed home-based tailored exercise program	Aerobic and resistance training.	12 weeks, 3-4 sessions per week, 20 minutes of aerobic exercise at an intensity of 60%-70% of aerobic capacity, and 3-5 resistance exercises with unclear time per session, neither intensity.	• Self-monitoring using digital tools and web system	6MWT[a], 1-repetition maximum of lower and upper body strength.
Galiano-Castillo et al (2016) [31]	Web-based system (e-CUIDATE website) for patient and provider+phone call	Home-based remote real-time guidance provided by CUIDATE research staff	(1) Warm - up, (2) resistance and aerobic exercise training, and (3) cool - down.	8 weeks, 3 sessions per week, 90 minutes per session. Intensity and volume of exercise according to guidelines of the American College of Sports Medicine for survivors of cancer.	• Remote asynchronous and synchronous monitoring via web system, videoconferencing, or phone calls, on-demand by CUIDATE research staff	QoL[b], Brief Pain Inventory, handgrip dynamometer, isometric abdominal test, back dynamometer, multiple sit - to - stand test, and the Piper Fatigue Scale.
Collins et al (2017) [32]	Web-based system (unspecified website) for patient and provider	Home-based remote real-time guidance provided by clinic staff	Rehabilitation of swallowing and communication function, nutritional management, and review of post-treatment symptoms.	8 months, unclear frequency, neither time per session, and these were requested on-demand. Unclear intensity.	• Unclear	Service outcomes, costs, and consumer satisfaction.
Galiano-Castillo et al (2017) [33]	Web-based system (e-CUIDATE website) for patient and provider+phone calls	Web system–guided home-based tailored exercise program	(1) Warm - up, (2) resistance and aerobic exercise training, and (3) cool - down.	8 weeks, 3 sessions per week, 90 minutes per session. Intensity and volume of exercise according to guidelines of the American College of Sports Medicine for survivors of cancer.	• Remote asynchronous and synchronous monitoring via web system, videoconferencing, or phone calls, on-demand by CUIDATE research staff	6MWT, Auditory Consonant Trigrams, and Trail Making Test.
Wall et al (2017) [34]	Web-based system (SwallowIT website) for patient and provider	Web system–guided home-based tailored exercise program	Swallowing exercises based on the “Pharyngocise” protocol.	6 weeks, daily, 45 minutes per session. Unclear intensity.	• Remote asynchronous monitoring after exercise via web system, unclear frequency by the speech pathologist	Perceptions were evaluated via structured questionnaires and phone interviews. Patients’ perceptions toward using SwallowIT (4 questions), the functionality of the system (2 questions), the efficacy of the system (4 questions), and preferences for other service-delivery models (2 questions).

Paper	Technology used to deliver exercise programs or monitoring	Type of exercise program	Exercise program description	Duration, frequency, time per session, and intensity of the program	Monitoring of performance	Outcomes measured
Frensham et al (2018) [35]	Web-based system (STRIDE website) for patient+pedometer	Self-directed home-based tailored exercise program	Individual target steps per day program.	Unclear.	- Self-monitoring via web system, daily	Measures of physiology, physical fitness, QoL, and 6MWT.
Gehring et al (2018) [36]	Web-based system (unspecified website) for patient and provider+HR[c] monitor watch+phone calls	Self-directed home-based tailored exercise program	The intervention comprised 3 home-based aerobic training sessions per week for 6 months.	6 months, 3 sessions per week, unclear time per session. Intensity of 60%-85% of maxHR.	- Remote asynchronous monitoring after exercise via the system weekly by the physiotherapist	Feasibility (accrual, attrition, adherence, and safety), satisfaction, patient-reported physical activity, VO_2 peak[d], and BMI.
Vallerand et al (2018) [37]	Phone call–based system for both patients and providers	Self-directed home-based regular progressing exercise program	Aerobic exercises.	12 weeks, unclear frequency, recommended 60-300 minutes per week time per session. Unclear intensity.	- Remote synchronous monitoring or coaching via phone call weekly by research staff	Self-reported aerobic exercise behavior, QoL, fatigue, and program satisfaction. Feasibility metrics (recruitment, adherence, adverse events, retention, follow-up, and acceptability metrics).
Villaron et al (2018) [38]	Pedometer+SMS text messaging	Self-directed home-based standard exercise program	Walking program with a pedometer.	8 weeks, unclear frequency, time per session, neither intensity.	- Remote asynchronous coaching, weekly by research staff	Level of physical activity (pedometer), fatigue (MFI-20[e]), and EORTC-QLQ-C30[f].
Cheville et al (2019) [39]	Web-based system (unspecified website) for both patient and providers+pedometer+phone call	Self-directed home-based tailored exercise program	The physical therapists instructed patients in an incremental pedometer–based walking program and a resistive exercise program.	6 months, recommended at least 4 sessions per week, unclear time per session, neither intensity.	- Remote synchronous monitoring after exercise via phone call, on demand by physiotherapist - Remote asynchronous monitoring via web system, weekly by physiotherapist	Activity measure (computer adaptive test), pain interference and average intensity (Brief Pain Inventory), and QoL (EQ-5D-3L).
Ji et al (2019) [40]	Mobile app (efil breath) for patients+wearable pulse oximeter+web-based system for providers	Mobile app–guided home-based tailored or fixed exercise program	Walking distance exercise program mainly and resistance exercises guidance videos.	12 weeks, unclear frequency, time per session, neither intensity.	- Remote asynchronous monitoring after exercise via web system, unclear frequency by lung cancer specialists and nurses	6MWT, dyspnea (mMRC[g]), QoL (EQ-5D), and service satisfaction.
Longacre et al (2019) [41]	Web-based system (unspecified website) for both patient and providers+pedometer+phone call	Self-directed home-based tailored exercise program	Pedometer-based walking program and a resistive exercise program.	6 months, recommended at least 4 sessions per week, unclear time per session, neither intensity.	- Remote synchronous monitoring after exercise via phone call, on demand by physiotherapist - Remote asynchronous monitoring via web system, weekly by physiotherapist	QoL (EQ-5D-3L) and intervention costs.

Paper	Technology used to deliver exercise programs or monitoring	Type of exercise program	Exercise program description	Duration, frequency, time per session, and intensity of the program	Monitoring of performance	Outcomes measured
van Egmond et al (2020) [42]	Mobile app (Physitrack) for patients	Web system–guided home-based tailored exercise program	Muscle strength, coordination, range of joint motion, and stamina.	12 weeks, at least 2 sessions per week, unclear time per session. The intensity and frequency of the functional exercises were determined according to the guidelines of the American College of Sports Medicine.	- Remote synchronous monitoring after exercise via phone call, SMS text messaging, or videoconference weekly by physiotherapist	Willingness, adherence, refusal rate, treatment duration, occurrence of adverse events, patient satisfaction. Musculoskeletal and cardiovascular functions and activities.
Kim et al (2020) [43]	Mobile app (Second Wind) for patients and providers+IoT[h] track device (HR, steps, calorie expenditure, and exercise time)	Mobile app–guided home-based tailored exercise program	Warm-up, stretching, aerobic, and muscle-strengthening exercises for the upper and lower extremities.	12 weeks, unclear frequency, neither time per session. Intensity and target HR for the aerobic exercise were set from the results of the 6MWT.	- Self-monitoring using digital tools and on-demand remote asynchronous monitoring by the study coordinator	6MWT, grip strength test, 30-second chair stand test, IPAQ-SF[i], body composition, biochemical profiles, and QoL (C30).
MacDonald et al (2020) [44]	Mobile app (Physitrack) for patients and providers+Fitbit+phone calls	Mobile app–guided home-based tailored exercise program	Aerobic exercise for 150 minutes per week, 2-3 days of resistance training, and routine large muscle group flexibility training.	8 weeks, 2-3 sessions per week, unclear time per session, neither intensity.	- Self-monitoring via mHealth[j] app and remote asynchronous monitoring via web system and feedback provided via phone call weekly by kinesiologist	Feasibility, acceptability. Physical symptoms, social functioning, distress, physical activity, work function, and physiological factors.
Piraux et al (2020) [45]	Web-based system (Virtuagym website) for patients and provider+phone calls	Digital tool–guided home-based tailored exercise program	Tele-prehabilitation, including aerobic, resistance, and inspiratory muscle training.	2-4 weeks, 3-5 sessions per week, 75 minutes per session. Intensity of 65%-74% of maximum HR for aerobic exercises.	- Remote synchronous monitoring after exercise via phone call by physiotherapist	Feasibility (recruitment rate, retention rate, attendance to exercise sessions, exercise-related adverse events, and patient satisfaction), 6MWT, fatigue, QoL, anxiety, and depression.
Zhou et al (2021) [46]	Virtual reality–based system	By design, digital tool–guided home-based tailored program	(1) Fist clenching, (2) wrist twisting, (3) elbow bending, (4) lifting, (5) shoulder circling, (6) ear touching, (7) wall climbing, (8) backhanding, (9) head holding, (10) abduction.	1 session.	- Unclear	General information questionnaire, usability surveys: System Usability Scale (SUS), SSQ[k], and PQ[l].
Finkelstein et al (2022) [47]	Web-based system (HAT system website) for patients	By design, web system–guided home-based tailored program	Individuality: specific exercises based on patients' needs.	1 session.	- Remote asynchronous monitoring after exercise via system by the health provider	Surveys: sociodemographic form, the Rapid Estimate of Adult Literacy in Medicine, SUS; semistructured qualitative exit interview.

Paper	Technology used to deliver exercise programs or monitoring	Type of exercise program	Exercise program description	Duration, frequency, time per session, and intensity of the program	Monitoring of performance	Outcomes measured
Lozano-Lozano et al (2020) [48]	Mobile app (BENECA mHealth app) for patients	In-person clinic-based rehabilitation	Individualized AROM[m] session.	8 weeks, 3 sessions per week, 75-95 minutes per session. Unclear intensity.	• Self-monitoring via mHealth app	QoL (EORTC QLQ-C30 and EORTC QLQ-BR23[n]), Disabilities of the Arm, Shoulder, and Hand (DASH), a self-reported questionnaire that measures symptoms and physical function (disability) for any upper-limb region.
Park et al (2023) [49]	Virtual reality–based system (Kinnect motion capture via Xbox [UINCARE Home+rehabilitation system])	Digital tool–guided home-based tailored exercise program	Each exercise level was composed of warm-up (deep breathing+trunk twist), main workouts (different degrees of motion and variations of passive or active flexion, rotation, and abduction exercises with or without dumbbells were used), and cool-down (deep breathing) components. The exercise level was determined according to the results obtained over the first 4 weeks. Passive and active ROM[o] of shoulder exercises were included.	12 weeks, daily, unclear time per session, neither intensity.	• Remote asynchronous monitoring after exercise via a system by the physician	ROM of the affected shoulder, pain in the affected shoulder (Numerical Rating Scale), functional outcomes (Quick DASH score), and QoL (Functional Assessment of Cancer Therapy-Breast and EQ-5D-5L).
Filakova et al (2023) [50]	Web-based system (PolarFlow website) for patient+HR monitor sync to website+phone call	Self-directed home-based tailored exercise program	Modality of walking, Nordic walking, or cycling dependent on patient preference.	12 weeks, 3 sessions per week, 30-50 minutes per session. Intensity of 60%-85% HRmax and 11-13 on the Borg rating of RPE[p].	• Remote synchronous monitoring after exercise via phone call weekly by the physiotherapist • Remote asynchronous monitoring via web system, unclear frequency by physiotherapist	Weight, body composition, cardiopulmonary exercise test.

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[a] 6MWT: 6-minute walking test.

[b] QoL: quality of life.

[c] HR: heart rate.

[d] VO_2 peak: peak oxygen uptake.

[e] MFI-20: Multidimensional Fatigue Inventory.

[f] EORTC QLQ-C30: European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30.

[g] mMRC: modified Medical Research Council Dyspnea Scale.

[h] IoT: Internet of Things.

[i] IPAQ-SF: International Physical Activity Questionnaire-Short Form.

[j] mHealth: mobile health.

[k] SSQ: Simulator Sickness Questionnaire.

[l] PQ: Presence Questionnaire.

[m] AROM: active range of motion.

[n] EORTC QLQ-BR23: European Organization for Research and Treatment of Cancer Quality of Life Questionnaire and Breast Module.

[o] ROM: range of motion.

[p] RPE: rate of perceived exertion.

Phone call or SMS text messaging–based systems were used in 43% (n=9) of the studies, either as stand-alone methods or in conjunction with other technologies. For instance, Vallerand et al [37] and Villaron et al [38] used phone calls and SMS text messaging, respectively, to deliver and monitor exercise programs. Additionally, medical devices were integrated into 24% (n=5) of the studies, often paired with other technologies. Examples include pulse oximeters, pedometers, and heart rate monitor watches.

Immersive technologies, such as virtual reality (VR), were used in 10% (n=2) of the studies. These included systems like the Kinect motion capture via Xbox and other VR-based approaches.

The studies varied in the number of technologies used. Approximately 48% (n=10) of the studies used only 1 type of ICT to deliver their programs. In contrast, 9 (43%) studies used 2 types of ICT, combining methods like web-based systems with phone calls or medical devices. A smaller portion (n=2, 10%) used 3 types of ICT.

Several studies combined different technologies to enhance the delivery and monitoring of exercise programs. For example, Ji et al [40] used a combination of a mobile app (efil breath; LifeSemantics Corp), a wearable pulse oximeter, and a web-based system for providers. Similarly, MacDonald et al [44] integrated a mobile app (Physitrack), a Fitbit device, and phone calls to provide comprehensive patient support. Other studies focused on leveraging the strengths of specific technologies. For instance, van Egmond et al [42] used the mobile app Physitrack for patient engagement, while Finkelstein et al [47] used the Home Automated Telemanagement website to facilitate patient interactions.

Exercise Program Details

Most physical rehabilitation programs (n=7, 33%) were self-directed, home-based tailored exercise programs, where patients followed individualized exercise plans independently. Web system–guided programs accounted for 24% (n=5) of the studies, using digital platforms to provide real-time or asynchronous guidance. Mobile app–guided programs comprised 14% (n=3) of the studies, leveraging mHealth apps to deliver and monitor exercise routines. Additionally, 14% (n=3) of the programs were directly guided by health providers, and digital tools guided 10% (n=2).

Most exercise programs (n=19, 90%) were home-based, enabling patients to perform their routines in a familiar environment. Only 1 (5%) study included clinic-based rehabilitation, and another (n=1, 5%) combined home and clinic-based exercises. The types of exercises predominantly included aerobic (n=19, 90%), resistance (n=13, 62%), and flexibility training (n=7, 33%). Only 2 (10%) studies focused explicitly on swallowing exercises, addressing particular needs of patients with oropharyngeal cancer.

The duration of the exercise programs varied, with 11 (52%) of the papers reporting interventions extending beyond 2 months and 7 (33%) lasting 2 months or less. The frequency of exercise sessions was less than daily in 48% (n=10) of the studies, while daily exercise was prescribed in 14% (n=3). However, the exercise frequency was unclear in 29% (n=6) of the studies. The time per session was varied, with 24% (n=5) of the studies specifying sessions of 1 hour or less and 10% (n=2) indicating sessions longer than 1 hour. The time per session was unclear in 57% (n=12) of the studies. The exercise intensity was explicitly defined in 38% (n=8) of the studies, while it remained unclear in 52% (n=11).

Monitoring methods were diverse, reflecting the integration of various technologies and approaches. Remote asynchronous monitoring was common, with many studies using web systems, phone calls, or mobile apps to track patient progress. For instance, Galiano-Castillo et al [31,33] used both synchronous and asynchronous monitoring via web systems and videoconferencing, while MacDonald et al [44] combined self-monitoring via a mHealth app with weekly feedback from a kinesiologist. Self-monitoring was also a key component in several programs. Schwartz et al [30] and Kim et al [43] implemented self-monitoring using digital tools, allowing patients to track their own progress and report it to health care providers as needed.

Outcomes Measured

The outcomes measured in the studies included in this scoping review highlight the multifaceted approach to assessing the effectiveness and feasibility of physical telerehabilitation programs for patients with cancer. These outcomes can be broadly categorized into QoL, usability, feasibility, and functional outcomes, with some studies measuring additional specific outcomes.

QoL was a key outcome measured in 48% (n=10) of the studies. Instruments such as the EQ-5D-3L, Brief Pain Inventory, Piper Fatigue Scale, and various cancer-specific QoL questionnaires like the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 were commonly used. For instance, Galiano-Castillo et al [31] and Cheville et al [39] used these tools to evaluate participants' overall well-being and health status, while van Egmond et al [42] assessed musculoskeletal and cardiovascular functions and activities alongside patient satisfaction.

Usability outcomes were assessed in 38% (n=9) of the studies, focusing on the practicality and user-friendliness of the telerehabilitation interventions. Studies like those by Wall et al [34] and Finkelstein et al [47] used structured questionnaires and surveys, including the System Usability Scale, to gather feedback on participants' experiences and satisfaction with the technological platforms used.

Feasibility outcomes, measured in 14% (n=3) of the studies, included metrics such as recruitment rates, adherence, retention, and safety. The studies by Gehring et al [36] and MacDonald et al [44] focused on these aspects to determine the practicality and acceptability of the interventions.

Functional outcomes were the most frequently assessed, with 71% (n=15) of the studies measuring various aspects of physical performance. Commonly used measures included the 6-minute walk test, grip strength tests, and body composition assessments. Studies like those by Schwartz et al [30] and Kim et al [43] used these tests to evaluate improvements in physical fitness and functional capacity. Additionally, specific functional outcomes related to cancer treatment, such as the Disabilities of the Arm, Shoulder, and Hand questionnaire used by Lozano-Lozano et al [48], were also assessed.

Other outcomes measured in 33% (n=7) of the studies included service outcomes, costs, and consumer satisfaction, as seen in the study by Collins et al [32]. Additionally, some studies measured unique outcomes specific to the intervention or population, such as weight and body composition, as in the study by Filakova et al [50].

Most studies (n=11, 52%) measured 2 outcomes, integrating assessments of functional performance and QoL or usability. For example, Ji et al [40] evaluated the 6-minute walk test, dyspnea, QoL, and service satisfaction, providing a comprehensive overview of the intervention's impact. A smaller portion of studies (n=5, 24%) measured 3 or more types of outcomes, offering a detailed evaluation across multiple dimensions.

Discussion

Principal Results and Comparison With Other Studies

This scoping review aimed to explore the existing telerehabilitation studies for patients with cancer. We included 21 papers that met our criteria. The major findings indicated that physical therapy delivered via telehealth for patients with cancer can improve functional capacity, cognitive functioning, and QoL [33,48]; reduce pain and hospital length of stay [39]; and improve fatigue, physical well-being, emotional well-being, and anxiety [45]. Additionally, improvements in absolute peak oxygen uptake and BMI [36,50]; handgrip strength of affected and nonaffected sides; abdominal, back, and lower body strength [31]; physical fitness, systolic blood pressure, diastolic blood pressure, waist girth, mental health, social functioning, and general health [35]; and strength and endurance were observed [30]. Positive effects on feasibility [32,36,37,42,44-47], acceptability [30,34,44], and cost-effectiveness were also noted [41].

These findings align with previous studies demonstrating the feasibility of physiotherapy with telerehabilitation. For instance, a systematic review with meta-analysis by van Egmond et al [51] showed that telerehabilitation in surgical populations is feasible and can enhance QoL. Given that the effectiveness of telerehabilitation is at least equal to usual care for physical outcomes, it presents a viable alternative for physical therapy [51]. The improvement of QoL was a major outcome across most studies; similarly, a systematic review by Bártolo et al [52] found a trend toward improved QoL among patients with cancer who were exposed to telecare interventions.

This review included 10 RCTs, 7 feasibility studies, and 4 usability studies. Consequently, there is a need for more robust studies on cancer telerehabilitation, with greater uniformity in clinical trial reports. Developing clinical practice guidelines and integrating exercise and rehabilitation services into the cancer care delivery system are essential steps forward [53].

Research indicates that exercise is advantageous before, during, and after cancer treatment, applicable to all cancer types and various cancer-related impairments [53]. Engaging in moderate to vigorous exercise is particularly effective for enhancing physical function and alleviating cancer-related impairments. Supervised exercise programs have been shown to provide greater benefits than unsupervised ones, with serious adverse events being rare [53]. In our review, the exercises included aerobic routines, resistance training, swallowing exercises, and walking programs, all supervised via web-based systems, mobile apps, and telephone calls.

However, our review also reveals gaps in the current literature, particularly in the underreporting of exercise intensity and frequency, which are crucial for understanding the full impact of these programs. Future studies should provide more detailed descriptions of these parameters to enhance the reproducibility and comparability of findings. Moreover, while our review indicates overall positive outcomes, the variability in study designs and sample sizes suggests a need for more standardized methodologies to strengthen the evidence base.

A recent systematic review on the effectiveness of exercise-based telerehabilitation for patients with cancer demonstrated significant improvements in cardiorespiratory fitness (standardized mean difference=0.34; 95% CI 0.20-0.49) and physical activity (standardized mean difference=0.34; 95% CI 0.17-0.51) [54]. However, the review did not find significant changes in other outcomes, such as QoL, fatigue, or mental health. These findings underscore specific areas of measurable improvement while highlighting gaps in other critical domains of patient well-being. Complementarily, our scoping review uniquely contributes to this field by offering a more comprehensive examination of telerehabilitation interventions. Unlike the systematic review, we included quasi-experimental studies and assessed feasibility and usability outcomes, providing a broader understanding of the preliminary research landscape. This inclusive approach not only explores the outcomes evaluated by the interventions but also evaluates their practical implementation and user experience. By detailing the various components and methodologies of telerehabilitation programs, our review extends the current knowledge base, emphasizing the multifaceted benefits and challenges of implementing these interventions for patients with cancer. This holistic perspective is crucial for developing more effective and user-centered telerehabilitation strategies in oncology care.

We only found 2 papers using immersive technologies, such as VR, with 1 RCT reporting beneficial outcomes for patients. This finding aligns with recent evidence suggesting that VR is feasible for telerehabilitation in other chronic conditions, such as chronic obstructive pulmonary disease and orthopedic diseases [55,56]. Given the recent increase in research on immersive technologies, VR in telerehabilitation is a promising area for future exploration [57].

Another noteworthy aspect of our review is that only 5 papers referenced the use of wearable devices to provide patients with objective measures of progress during their rehabilitation. Although limited in our review, wearable devices offer significant potential for remote monitoring. A systematic review found that wearables significantly increased physical activity levels in patients with cardiovascular diseases [58]. This suggests that wearable or noncontact sensors [52] could be effectively integrated into telerehabilitation programs to enhance patient monitoring and outcomes.

Finally, using artificial intelligence (AI) in telerehabilitation is a technological trend worth observing. Our review did not find any papers referencing the use of AI. Still, the recent exponential growth in AI applications in health care suggests this trend could be explored in future studies. AI has the potential to significantly impact telerehabilitation by providing personalized and adaptive interventions based on patient data [59,60]. Exploring AI integration could open new avenues for improving the effectiveness and efficiency of telerehabilitation programs.

Limitations

This scoping review has some limitations that should be acknowledged. First, the heterogeneity of the included studies presents a challenge in synthesizing the findings. The studies varied widely in terms of their design, participant characteristics, types of cancer, interventions, and outcomes measured. This variability makes it difficult to draw definitive conclusions about the overall effectiveness of telerehabilitation for patients with cancer. Despite this, the diversity of studies also highlights the flexibility and adaptability of telerehabilitation interventions, which is a strength in addressing the varied needs of patients with cancer. Second, the reliance on self-reported data for some outcomes may introduce reporting bias and affect the accuracy of the findings. While self-reported measures are valuable for assessing subjective outcomes like QoL, they are susceptible to inaccuracies. Objective measures such as wearable devices to monitor physical activity and physiological parameters can help validate self-reported data and provide a more comprehensive assessment. Third, many of the included studies had relatively small sample sizes, limiting the statistical power and generalizability of the results. Conducting larger, multicenter studies would increase sample sizes and enhance the representativeness of the findings, providing more robust statistical power to detect significant effects. Fourth, the technological variability across studies, with different platforms used for delivering and monitoring telerehabilitation, adds another layer of complexity and affects the comparability of the results. Standardizing the technological platforms used in interventions could reduce variability and improve comparability. Fifth, our review did not include a formal risk of bias evaluation, which could affect the reliability of our conclusions. While we included RCTs and quasi-experimental studies, which generally have higher quality, and ensured that all studies came from peer-reviewed journals, future studies should incorporate a formal risk of bias assessment to further enhance the rigor and reliability of the findings. Finally, we acknowledge that this is a rapidly evolving field, and more recent studies or those published before 2015 may have been missed. Moreover, while we conducted a thorough search, the exclusive use of PubMed as the database and the specific term “telerehabilitation” may have limited the identification of some relevant papers. The term “telerehabilitation” is relatively recent and might not be uniformly used across different regions and research contexts, potentially omitting some studies that use alternative terminology. Future reviews could benefit from including multiple databases and a broader range of search terms to capture the full scope of the literature. Despite these limitations, our review provides a comprehensive overview of the current state of research in telerehabilitation for patients with cancer, highlighting important trends and gaps that can inform future studies and clinical practice.

Conclusions

This scoping review demonstrates that telerehabilitation exercises for patients with cancer are beneficial and feasible, with various approaches used in study design, technology, exercises, and outcomes. The evidence indicates that telerehabilitation can improve functional capacity, cognitive functioning, QoL, and other health metrics while being cost-effective and acceptable to patients. However, the review also highlights significant variability in study designs and a need for more detailed reporting on exercise intensity and frequency. Future research should focus on developing standardized methodologies, incorporating objective measures, and exploring emerging technologies such as VR and AI to optimize telerehabilitation interventions for patients with cancer. By addressing these areas, we can enhance clinical practice and improve outcomes for remote rehabilitation with patients.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews) checklist.
[PDF File (Adobe PDF File), 68 KB - cancer_v10i1e56969_app1.pdf]

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Abbreviations

AI: artificial intelligence
ICT: information and communication technology
mHealth: mobile health
PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews
QoL: quality of life
RCT: randomized controlled trial
VR: virtual reality

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Viewpoint

Need for Culturally Competent and Responsive Cancer Education for African Immigrant Families and Youth Living in the United States

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Abstract

Cancer prevalence data for Black Americans is monolithic and fails to consider the diverse cultures and backgrounds within that community. For instance, African immigrants constitute a meaningful proportion of the foreign-born Black immigrants in the United States (42%), but the prevalence of cancer in the African immigrant community itself is unknown. Therefore, without accurate cancer prevalence data, it is impossible to identify trends and other key factors that are needed to support the health of African immigrants and their children. Moreover, it is impossible to understand how the culture and language of subgroups influence their cancer-related health behavior. While research in this area is limited, the existing literature articulates the need for culturally responsive and culturally tailored cancer education for African immigrants and their adolescent children, which is what we advocate for in this viewpoint paper. Existing projects demonstrate the feasibility of culturally responsive programming for adults; however, few projects include or focus on adolescents or children born to African immigrants. To best meet the needs of this understudied community, researchers must use culturally competent interventions alongside familiar, usable media. For adolescents, technology is ubiquitous thus, the creation of a culturally tailored digital intervention has immense potential to improve cancer awareness and prevention for youth and their community. More research is needed to address many of the existing research gaps and develop a rich understanding of the unique experience of cancer among African immigrant families that can be used to inform intervention development. Through this viewpoint, we review the current state of cancer-related research among African immigrant families in the United States. In this paper, we acknowledge the current knowledge gaps and issues surrounding measurement and then discuss the factors relevant to designing an educational intervention targeted at African immigrants and the role of African immigrant youth.

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KEYWORDS

African immigrant; youth; adolescent; adolescents; teen; teens; teenager; teenagers; cancer awareness; health disparities; culturally competent education; African; Black; immigrant; cultural; culturally; cancer; oncology; patient education; awareness; prevention; disparity; disparities

Introduction

Cancer has a profound impact on the experience of health for many in the United States that only continues to grow. Research has demonstrated the escalating rates of early-onset cancer diagnosis among women and the alarming decreasing rates for men and Black people; most commonly in breast, thyroid, and colorectal cancer [1]. Early diagnosis and prompt treatment of cancer are critical to improved public health. The decreasing rate of early cancer detection and response is introducing a significant health inequity among Black people in the United States. African-born immigrants and their children comprise a meaningful portion of the US population. The paper aims to describe the existing research gaps and experiences of cancer among African immigrant families and highlight the need to design and tailor cancer education for African immigrant families.

There was a surge in the African immigrant population between 1970 and 2015 [2]. This migration pattern has continued, with the African immigrant population growing from 881,000 in 2000 to 2.0 million in 2019, comprising 42% of the US foreign-born Black population. African immigrants have tended to settle in 4 main cities in the United States: Washington DC, New York City, Minneapolis or St Paul, and Atlanta [3]. Prior research has established that most African immigrants come from Western (35.7%) and Eastern Africa (29.6%) [4]: from Nigeria (13.7%), Ethiopia (10.8%), Ghana (7.8%), and Kenya (5.5%) [5]. Therefore, Nigeria and Ethiopia constitute the top birthplaces of African immigrants in the United States.

In 2011, one of the first peer-reviewed papers on African immigrant health was published. It highlighted the growing population of African immigrants in the United States and the need to study their health care needs and practices since chronic diseases, including cancer, were poorly understood [3]. There is a growing research interest in African immigrant health, especially by researchers who are first- and second-generation African immigrants themselves, especially in light of the myriad of factors that impact African immigrants' health, and that of their families, including the trauma of immigration, conflicting cultural contexts between African family dynamics and those common in the United States, diet and lifestyles, culture, religion, and spirituality. These constructs make up the richness of immigrants' lives and continue to impact their health behaviors, health care experiences, and decision-making about their health practices after they move to the United States. Therefore, attention must be given to these factors. These factors also influence how African immigrants interact with and navigate the health care system, making it essential to understand how these factors can negatively impact health care system involvement.

The number of health-related areas influenced by immigration only grows as their length of stay in the United States increases [6]. Given the unique health experiences of African immigrants, the need to better understand the cancer-related health of African immigrants is imperative. The United States has begun to address disparities in immigrant health, such as affordances of health care following the implementation of the Affordable Care Act or state-level legislation allowing immigrants (especially the young, pregnant persons, and older people) to be eligible for state Medicare. States that have expanded care for immigrant children have seen reductions in no-insurance rates and rates of families forgoing medical care [7]. However, there is a current dearth of initiatives directly designed for African immigrants. With a deeper understanding of cancer in the African immigrant community, we can create novel, innovative, and culturally specific educational tools to support African immigrant families and improve current and future African immigrant community cancer health.

Discerning Cancer Prevalence Among African Immigrants

Overview

Uncovering cancer prevalence and awareness among African immigrants is challenging. Racial and ethnic minority groups are underrepresented in health research overall, contributing to persistent health disparities in the United States [8]. Cancer death rates among Black people continue to increase and so does the risk of developing cancers [9]. In the past few decades, there have been focused efforts to conduct research and draft policies to address health disparities within immigrant communities. However, there is a discernable lack of research on African immigrants' (and their children's) health related to cancer prevention and awareness in the United States. The challenge is due to limited resources allocated to minority issues and a lack of effort to distinguish the population as different and unique from other minority populations [10,11].

Issues With Measurement

Most research on immigrant health in the United States has focused on Latinos and Asian Americans [12-15]. Similarly, most cancer-related research in the United States has used race, and Hispanic or Latino ethnic affinity, regardless of the differing histories of migration, as the basis of categorizing research participants. Therefore, there is limited knowledge about African immigrant health in the United States, especially on cancer awareness, cancer care, and overall health outcomes. Accurate prevalence of cancer among African immigrants is unknown, available literature mostly focuses on databases that have combined data for African-born immigrants and US-born Black people. This makes it difficult to identify African immigrants and to provide accurate evidence of the extent and impact of cancer within their communities [16]. This practice facilitates a monolithic view of people with African heritage; therefore, it discourages granularity of analysis and limits health services' researchers' ability to address African immigrant-specific health challenges and examine related research questions.

Some researchers have started to address the overgeneralization of categorizing all African immigrants as "Black" by focusing on their country of origin or time since immigration or assimilation or acculturation [17,18]. Assimilation allows immigrants to integrate into the social, linguistic, and cultural fabric of the host society. However, acculturation experience differs across immigrant groups. The Hispanics, specifically Mexican Americans, constitute an immigrant group in the United States with a robust acculturation. Safran Williams in his classification of diasporas describes Mexican American as "not true diaspora" [19]. This is because of their immigration history with the United States [19]. Further, Spanish is the dominant language of the Mexicans and is also the most popular foreign language in the United States. As a result, acculturation for Mexican immigrants is steady and impacts the strength of research and health interventions for this immigrant group [20-22]. Contrarily, the cultural and linguistic significance of African immigrant identities do not share the same history and recognition both in the United States social milieu and in the US health care system especially those relating to cancer education and research. African immigrants have an existing cultural identification from their homeland and their languages do not have the same recognition as that of Hispanic Americans. Nonetheless, the effort to acculturate among African immigrants accounts for the experiences such as changes in diet, modified language practices, and using the health care services for access to information, treatment, and care. The acculturation process is also layered with the African immigrants' spirituality and how it influences their reception of health care treatment. Careful attention to the cultural practices of African immigrants and their relevance to health intervention will largely impact the outcomes in cancer awareness and education.

The issue of having a monolithic "Black" category affects the extraction of research data on African immigrants [16]. Some progress is being made in this area. For instance, 1 study promoted awareness and accessibility to screening for chronic diseases among African immigrants living in Georgia [17]. Other research has discussed African immigrants' health and allostatic load score as it relates to cardiovascular, metabolic, and immune systems [18]. Finally, a scoping review identified additional socio-ecological challenges faced including the lack of culturally competent health care, distrust of the health care system, challenges navigating the US health system, and the burdensome cost of care [16].

What We Do Know About African Immigrants and Cancer

Accurate prevalence rates of cancer in African immigrants in the United States are lacking. Evidence suggests high cancer prevalence in their countries of origin, especially breast and cervical cancer for women and prostate cancer for men [23-25]. More research is needed to understand the prevalence of cancer within immigrant families and how their immigration may influence cancer prevalence.

The experiences and needs of African immigrants are unique [17,26-32]. Sociocultural factors underlie the experience of cancer in the African immigrant community. The stigma of being diagnosed with cancer, lack of cancer awareness, limited or no screening (especially among African immigrant women), and limited familiarity with prevention strategies and treatment technologies available may be contributing to the high prevalence of cancer [24,30]. These factors lead to late-stage diagnoses because of a lack of access to health care, lower education levels, and cultural and religious beliefs regarding cancer [33,34]. Studies also found that African-born women have limited knowledge and exposure to breast cancer screening information before their arrival in the United States [30,34,35], which can impact their preventative and cancer screening behaviors. Existing research has also explored cancer mortality among adults across different Black ethnic groups—African, African American, and Caribbean—showing some mortality and prevalence differences between these groups [36].

Further, 1 study has found that income, among other factors, plays a significant role in the population's understanding of colorectal cancer [37]. With a focus on breast and cervical cancer screening, other studies examined the knowledge and perspectives of African immigrants [38,39]. Their findings underscore significant factors impacting the decision to seek preventative screening measures among African immigrants, including fatalism, lack of cancer knowledge, stigma, length of stay in the United States, provider gender, and privacy concerns [40-43]. Another study examined prostate cancer risk experiences among West African men and shed light on the modifiable risk factors implicated in prostate cancer mortality and morbidity [44]. A study of cervical cancer awareness among African immigrant women in Iowa City highlighted factors such as fear, languages spoken, and education as barriers to preventative treatment [45]. Considering the available research and prevalent factors that limit cancer prevention knowledge and behavior it is imperative to develop culturally, and linguistically appropriate cancer education programs aimed at increasing awareness and screening of cancer. In summary, while research has begun to address differences in African immigrant health, the differences are many which will require further study and consensus.

Lack of Cancer Awareness Among Youth and African Immigrants

In 2008, it was estimated that the 82% of the US population increase between 2005 and 2050 would be attributed to immigrants and their descendants [26]. Despite an increase of African immigrants' offspring in the United States, little is known about these second-generation individuals born and raised in the United States (with at least 1 foreign-born parent), regarding their health beliefs, perceptions, and practices. This is understandable as little is known about their parents regarding these factors. A study that explored beliefs and lifestyle behaviors relating to healthy living and diet among middle-aged adults in the immigrant population indicated that little is known about the beliefs, perceptions, and practices of diet and exercise among young African immigrants [46]. Young adults of African immigrant descent are part of the future, and attention needs to be paid to their well-being.

It is unknown if children of African immigrants are being educated about cancer by their parents, their communities, their health care providers, or in schools. Cancer is often termed as a taboo subject in most African homes and communities. This is further compounded by other barriers such as access to care, quality of care, communication gaps, lack of education, lack of affordable health care, lack of transportation, socioeconomic status, shame and stigma, and cultural and religious beliefs [47]. Nonetheless, some children of African immigrants become aware of cancer when close family members or friends are diagnosed. With limited cancer awareness and the vulnerability of African immigrants regarding cancer, youth, and their parents must be educated using culturally competent, tailored, and responsive family-oriented cancer education initiatives that build on the strengths of these immigrant cultures as well as address the barriers to cancer prevention behaviors.

Although the limited research reviewed above examines cancer among Black immigrant men and women, there is no substantial body of research that addresses cancer education and awareness among first and second-generation African immigrant adolescents in the United States. A lack of knowledge about youth immigrants and second-generation African immigrants can put this population at a disadvantage as compared to their peers. Cancer awareness among African immigrants and youth studies, including older and younger Somali women, use age as a factor for examining standardized prevalence of cardiovascular disease risk factors among both African immigrants and African Americans [47,48]. Although age is an important factor to consider, this work does not focus on youth. Another study, rather than age, used the year of residence in the United States to examine self-reported health problems among African immigrant adults [49].

While several studies have begun to address cancer research among the African population broadly, the significant paucity of research that focuses on the youth of African immigrant families in the United States leaves a critical gap in cancer awareness and prevalence research. To our knowledge, no studies have sought to examine or address cancer awareness among the youth of African immigrant families, nor interventions for cancer awareness and education. The youth of African immigrant families in the United States constitute an important population that is instrumental in creating awareness about the prevalence of cancer within their community. To access the youth groups of African immigrant descent in the United States, it is expedient to identify cultural and age-relevant educational tools for creating awareness about the prevalence of cancer disease.

Existing Studies on the Promotion of Cancer Awareness and Education Among African Immigrants

Overview

There is evidence of studies that promote cancer health education among African immigrants and other minority groups using various culturally tailored approaches and technologies. The success of a community-academic partnership model at community faith-based centers is effective for immigrant women in learning about breast cancer [50]. Moreover, health education programs in community-based settings have indicated strong potential. Further, 2 studies involving interpreters and culturally targeted communication, showed increased breast cancer knowledge and an improvement in screening for breast cancer for immigrant and multicultural women [51,52].

Study findings have demonstrated the importance of culturally tailored educational tools and different approaches to reduce cancer-related disparities. These studies provide strong evidence supporting the use of culturally relevant educational materials, patient navigation programs, peer-to-peer education, education programs, videos, and cofacilitated health promotion forums in promoting preventative and cancer screening behaviors [33,53-62]. Together these projects shed light on some of the few, yet variable opportunities for successful community-engaged research with African immigrant families.

Furthermore, some studies have demonstrated the potential of technology in promoting cancer awareness and education among African immigrants. Mobile devices, tablets, and computers have been used to address common cultural and linguistic barriers to cancer screening. Mobile health initiatives, culturally tailored messaging, language support, mobile apps, short message services, and text messages have all proven effective in impacting cancer screening behaviors [18,63-65]. Some of these initiatives could be adapted into family-based programs where young African immigrants could learn in familiar spaces using ubiquitous and widely acceptable technologies such as serious games.

Global Health Perspectives and Solutions for Culturally Competent Care Among African Immigrants

Health care approaches for immigrant populations require adaptation and cultural competence to serve diverse communities effectively. Parallel analysis of the US health care models with those of other nations like Canada and Australia offers a framework to evaluate and refine strategies to address health disparities among African immigrants. Canada and Australia have made strides in fostering inclusive health strategies that can inform US health care practices, particularly in providing culturally competent care to African immigrants.

For example, in Canada, health care delivery to immigrant populations acknowledges the necessity of cultural competence. Canada’s universal health care system actively integrates culturally tailored interventions. The Canadian government has pushed for strategies that involve community engagement and representation in health decision-making, enhancing the cultural appropriateness of health care services [66]. Using community health workers who share the same cultural background as immigrants has been a breakthrough, acting as a bridge between health care providers and immigrant communities [67]. These community health workers facilitate communication, understanding, and trust—essential elements in promoting the health and well-being of immigrant populations [68].

Further, Australia's approach to immigrant health pivots on inclusivity and health equity to deliver services that are respectful of and responsive to diverse patients' health beliefs, practices, and needs [69]. A notable instance is the Victorian Immigrant and Refugee Women's Coalition's efforts, which engage women directly to educate about health issues, including cancer awareness [70]. Australian health policies aim to address the language barriers and the diverse cultural contexts that can influence health care usage and outcomes. In contrast, the United States continues to grapple with creating a standardized approach for culturally competent care throughout its health care system.

While there are pockets of exemplary practices, such as using patient navigators in cancer care to assist patients from minority backgrounds, there is not a universal health care mandate specifically aimed at immigrant health [67]. Instead, the United States relies on a patchwork of local initiatives and federal guidelines, such as those by the Office of Minority Health which established the National Standards for Culturally and Linguistically Appropriate Services in health and health care [71]. In conclusion, both the Canadian and Australian models underscore the importance of cultural competence and systemic support in improving immigrant health outcomes. They demonstrate that effective immigrant health strategies require the integration of culturally informed practices across all stages of health care—from preventive education to treatment. This implies adopting multifaceted approaches that can cater to the unique cultural, linguistic, and religious elements that define African immigrant communities.

Youth: the Bridge for Culturally Tailored Cancer Education

Given their positionality, first through second-generation African immigrant youth are at a unique nexus from which they can bridge health gaps related to cancer that arise from their heritage and sociocultural contexts. Cultural tailoring acknowledges the broad culture but identifies specific strategies for reaching specific individuals. These groups of individuals have insights into the linguistic and cultural practices of their families as well as those of the society they live in. Due to their positionality, the youth are motivated to embrace language awareness, which emphasizes the interrelatedness of language, culture, and social structures [72]. The interrelatedness of cultural meanings and linguistic signs allows for the tailoring of educational content that addresses distinctive groups. The adolescents of African immigrant families are a product of the diverse linguistic and cultural interactions that occur through transnational migration and globalization.

To engage with youth and form a robust bridge between coexisting sociocultural systems to improve African immigrant community health, research should focus on methods that are familiar and usable for adolescents. A ubiquitous facet of adolescent life is technology. There is increasing interest in serious games (ie, games that serve an educational or developmental purpose aside from pure entertainment) as a learning medium. Although innovative interventions including serious games are becoming popular, they are not traditionally designed and tailored to meet the cultural and health needs of minoritized populations such as African immigrant families. Systemic reviews of serious games indicate limitations that need to be addressed [73-76]. It will be beneficial for health services' researchers to use a participatory design approach when designing cancer education and intervention tools for African immigrant families. Such a collaborative approach will allow African immigrant families to partner in the co-design of technologies such as serious games and facilitate the creation of a culturally competent and responsive learning medium. Youth from African immigrant families typically have a hybrid of identities which necessitate the use of education technologies such as serious games in ways that speak to their lived experiences and families' cultural heritage and realities. Therefore, there is a need to tailor educational resources using technology platforms that would engage the linguistic and sociocultural realities of the African immigrant population. Interventions to improve cancer outcomes in African immigrants, especially among youth, are necessary.

Youth and community members from other minority populations in the Northwest Arctic region of Alaska participated in community-based participatory action research honoring indigenous ways, creating a Sharing Circle used to understand community priorities and develop culturally relevant cancer education that could be incorporated into school curriculum. It is an opportunity for youth involvement in culturally relevant health promotion efforts to address health disparities in cancer [77].

Culturally Tailored Education for African Immigrant Youth

Overview

Developing educational resources for African immigrant youth brings into focus the question of curricular content and pedagogical approaches that fit this group. The connection of educational content with cultural identities is espoused in the framework of culturally relevant pedagogy (CRP) [78]. CRP encompasses multiple concepts related to students' academic achievements and social inequalities, but its central tenet is the interconnection of theories and cultures in manners that will "empower students intellectually, socially, emotionally, and politically by using cultural referents to impart knowledge, skills, and attitudes [79]." African immigrants and people of historically marginalized cultures are unique and deserving of an educational approach that is aligned with their needs. It offers liberatory education which inspires the learners to become social commentators, advocates, and critical consumers of knowledge while empowering control over one's health. The use of such an approach will be beneficial in disseminating and promoting cancer education in the community.

The pedagogical approaches to achieving culturally tailored education may derive from CRP and adopt effective strategies that will merge critical consciousness and cultural connections in the learning content. CRP proposes three components that must be integrated to achieve learning: (1) a focus on youth learning and academic success, (2) developing youth's cultural competence to assist them in developing positive ethnic and social identities, and (3) supporting youth's critical consciousness or their ability to recognize and critique societal inequalities.

Researchers have described examples of targeted and tailored strategies, techniques, and procedures for successful intervention with a variety of populations [80]. These researchers identified linguistic, community-engaged, and sociocultural strategies as important to reaching a particular community. Building on this knowledge, we identify four approaches that a cancer education intervention that the youth of African immigrant heritage can draw on, namely: (1) linguistic and cultural markers, (2) belief system and religious affiliation, (3) hybrid nationality, and (4) age-related learning preferences. With a deeper understanding of how these factors, concerning cancer health, shape the identities, beliefs, and behaviors of African immigrant youth in the United States, we may be able to create culturally competent educational tools for cancer awareness and prevention.

Linguistic and Cultural Markers

African immigrants, having come from different countries with diverse colonial histories, have distinct languages. The native languages of African immigrants play an important part in their identity. The youth of African immigrants assimilate the language and cultures of the host society while leveraging their cultural and linguistic heritage for optimum survival, a process that yields linguistic and cultural hybridity.

The complexity that underlies the African immigrants' linguistic and cultural identities in the United States should inform approaches to developing culturally competent education for youth and their families to improve overall health outcomes. It is expedient to target cancer-awareness information by incorporating aspects of the home languages of African immigrants—especially Western and Eastern Africa [5]. For example, the Swahili language would be accessible to immigrant families of East African origin, and Pidgin English for families with West African heritage. Appropriate learning mediums for cancer awareness for African immigrant youth should intersect with the linguistic and cultural practices of the African immigrant population.

Belief System and Religious Affiliation

In a 2021 report, the Pew Research Center stated that African immigrants in the United States are more religious than other Black Americans, even though Black Americans are more religious than Americans of other races [81]. Further broken down into specific practices, the report noted that African immigrants value attending religious services weekly, more than other Black Americans: "around half of the African immigrants living in the United States (54%) say they attend religious services at least weekly, compared with about 3-in-10 United States-born (32%) and Caribbean-born (30%) Black adults."

Similar to language, culture, and national consciousness, the belief systems and religiosity of African immigrants will have a major imprint on their young children. Health information tailored specifically to religiosity will not only be responsive to African immigrants' cultural perspectives, but it may also improve engagement with pedagogical materials. Moreover, studies are scarce on the intersection of African immigrants' religious practices and responses to health care education about cancer, thereby illustrating another gap in research that may ultimately improve the approach to cancer education among distinctive ethnic and racial groups. Additionally, there is a shortage of research on the religious practices of African immigrants, highlighting another research gap that could ultimately enhance approaches to cancer education among distinct ethnic and racial groups.

Hybrid Nationality and Afropolitanism

African immigrants in the United States, have diverse origins from one of the 54 nations of Africa, many of which are multiethnic. These diverse ethnic identities house unique cultural and linguistic features within and outside the individual nation's borders. While African immigrants actively engage with the dominant Western traditions of the society they reside in, they also maintain their cultural customs. As a result, youth from African immigrant families often exhibit hybrid language use, blending the host language with elements of African culture, including specific exclamation and colloquial forms rooted in African cultural beliefs. This linguistic and cultural hybridity is significant in addressing the existing gap in cancer awareness research among African immigrant families and fosters a sense of community within the African immigrant population in the United States.

The concept of Afropolitanism defines Africans as an integral part of the global community rather than separate from it. This concept refers to the empowerment associated with a blended, polyethnic, and cosmopolitan identity [80]. Afropolitanism iterates Africans' awareness of their origins and the consciousness of the cultural ambiguities that occur because of their integration into the host society. This understanding impacts African immigrants' response to cancer education and approaches to accessing health care for cancer treatment. Their cultural and spiritual beliefs are still very much prominent in their perspective on cancer disease. This consciousness could, however, be tapped into for possible changes and adaptations among this immigrant group. The summary of the African immigrants' complex experience is iterated in the term, "Afropolitan." Afropolitan describes an individual whose identities are deeply rooted in their diverse, transcultural experiences, reflecting youth linguistic and cultural practices within African immigrant families [68,69]. African immigrants' hybrid language and cultural identities necessitate the development of health educational tools and technologies that integrate African cultural perspectives and engage these youth in learning and retaining health information in a culturally responsive manner.

Age-Related Learning Preferences

Consideration for age-appropriateness in technology is not unique to African immigrant youth; however, the connection of this factor to digital literacy, access, and equity makes it critical to examine further and worthy of discussion. A report by the Migration Policy Institute on immigrant learning with digital technology has identified uneven access to digital resources for youth aged between 15 and 17 years who are either immigrants themselves or have at least one immigrant parent [82]. Research suggests that factors like work, language, and familial influence affect how immigrant youth use technology for learning [83]. Given the versatility of the adolescent age group with technology, they have increased access to vital information on health issues and diseases that are prevalent within their community. More important is their access to their heritage culture as well as the culture of their residing society. As a result, youth play a vital role as intermediaries, connecting with their families to promote cancer awareness within their communities.

Further Research Needed

Overview

A robust foundation of data and associated knowledge surrounding cancer in the communities of African immigrants is needed to truly understand the impact of cancer on this group and appropriate approaches to intervention to reduce cancer risk and improve cancer treatment. Several priorities are highlighted throughout this paper and an overview is presented in Textbox 1.

Textbox 1. Summary of key main areas for future research.

Priorities for future cancer prevention and control research focused on African immigrant populations

- Disaggregate study populations according to country or region of origin to improve cultural tailoring and knowledge.
- Develop family-oriented educational initiatives including programs for children.
- Use community-engaged approaches including partnerships with faith-based organizations.
- Leverage emerging technology for recruiting study participants and delivering educational messages while accounting for barriers to access.
- Align cancer awareness information with language and cultural markers specific to the population.
- Consider the global African community and hybrid African and American cultural practices.
- Incorporate relevant religious and spiritual beliefs and practices to enhance cancer education effectiveness.
- Consider youth and adolescents as intermediaries for increasing cancer awareness among family members.
- Explore the potential for interagency collaboration (Centers for Disease Control and Prevention, Centers for Medicare & Medicaid Services, Health Resources and Services Administration, and National Institutes of Health) to address cancer-related health challenges for African immigrant families.

To achieve the goal of increasing cancer awareness among African immigrant families, 1 strategy involves creating a culturally tailored serious game. Serious games offer opportunities to build upon the research base of effective approaches to reduce the cancer burden by focusing on youth and leveraging technology. Research is crucial that examines the language use of youth from African immigrants in the United States. Previous research has already categorized most African immigrants living in the United States into Western (35.71%) and Eastern Africa (29.61%) groups, which could serve as a basis for examining youth cancer awareness within each group [5]. Open-ended ethnographic interviews could be used to identify the nuanced cultural and linguistic practices of the youth of African immigrant families. The heterogeneity of Africa’s cultural identities could result in a new monolithic idea of Black subgroups in the United States, the importance of beginning this inquiry cannot be delayed. Detailed demographic questionnaires and open response forms can allow for flexibility in how studies aggregate and allow for new divisions and aggregations of African immigrants. However, it is noted that immigration by African countries is unequal with many African immigrants arriving from Western and Eastern African countries [5].

Additionally, recruitment strategies are particularly important in the success of this line of research and will need to be evaluated. As immigrant populations are “Hard-to Reach,” using innovative ways to reach a target population is also important [84]. During the COVID-19 pandemic, online recruitment using Facebook (Meta), Instagram (Meta Platforms), and WhatsApp (WhatsApp LLC) was an effective recruitment strategy especially because it built on existing communication and information-sharing norms within the African immigrant community. Further research should use and evaluate multiple recruitment streams.

Findings from such research endeavors will have a meaningful impact on the strategies for developing culturally tailored educational content such as a serious game, to create awareness about cancer among African immigrant families in the United States. A culturally adapted serious game has immense potential to be instrumental in improving awareness and cancer prevention strategies in African immigrant families.

Conclusion

The importance of culturally tailored cancer education for African immigrants is underscored by uncertainty. Issues surrounding the measurement of cancer prevalence in African immigrant populations exacerbate the uncertainty of how cancer affects the African immigrant population in the United States. The existing, yet limited research on the topic suggests that African immigrants, especially adolescents, have unique experiences that lie at the nexus of their traditional culture and the complex novelty of the US health care system for immigrants. Research demonstrates the impact of cultural beliefs (such as fatalism and stigmatization of cancer diagnoses among African cultures) and lack of knowledge about cancer and cancer screening compounds to affect access to screening and care for African immigrants. Further research specifically targeting African immigrants and their youth can not only disentangle the unique struggles of African immigrants but also allow for the tailoring of education to provide maximal impact to vulnerable populations.

While recognizing our lack of knowledge and the uncertainty around the experience of cancer in the United States for African immigrants and advocating that increased research is the needed foundation for alleviating health disparities, more difficult work is ahead. It is integral for health scientists, health care providers, African culture scholars, and communities of African immigrants to come together for sustained research activity. These transdisciplinary associations will aid in the collection of data specific to African immigrants, but also the community engagement needed to co-design a culturally sensitive educational intervention. This will be no small task and require the dedicated work of many experts alongside and within the African immigrant community to forge long-term relationships that can facilitate recruitment, retention, and meaningful knowledge generation for the African immigrant community in the context of cancer experience.

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Authors' Contributions

OA conceptualized the original idea for this paper, led the gathering of data and team expertise, and contributed to drafting and leading the revising of the final paper. All coauthors contributed to the literature review and drafting of this paper.

Conflicts of Interest

None declared.

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Abbreviations

CRP: culturally relevant pedagogy

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Viewpoint

An Introduction to the OutSMART Cancer Serious Game: Current and Future Directions

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Abstract

Given that cancer is a challenging disease that plagues millions of individuals of all age groups and socioeconomic statuses globally, developmentally appropriate education is often lacking for young people, particularly adolescents. Increasing cancer awareness and prevention education among adolescents using innovative strategies, such as game-based learning, is critical in reducing the burden of this disease. Adolescents are understudied in the field of cancer prevention and control, yet vulnerable as they tackle creating life-long health behavior patterns. Targeting cancer prevention education for adolescents has the potential to support long-term healthy behavior and reduce their risk of cancer. This paper provides an overview of the Collaborative Research on MEdication use and family health (CRoME) Lab's novel game-based cancer prevention education tool. OutSMART Cancer is an innovative, novel educational intervention in the form of a serious game. Serious games are educational tools that seek to impart knowledge and improve behaviors in their players. This game covers information related to breast cancer, colon cancer, and lung cancer. This viewpoint is a summary of the developmental process for the OutSMART Cancer game. We describe in detail the work preceding initial game development, the current version of the game, future directions for the game, and its educational potential. The long-term goal of OutSMART Cancer is to improve cancer awareness and knowledge regarding prevention behaviors in adolescents and support a lifetime of health and wellness.

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KEYWORDS

serious game; cancer; health education; adolescents; health behavior; United States; young people; adolescent; teenager; teenagers; cancer prevention; education; cancer risk; tool; OutSMART Cancer; innovative; game development; cancer awareness; prevention; wellness

Introduction

The ubiquity of cancer in the United States denotes both the immense burden of the disease and the countless individuals devoted to spreading awareness. Although preventative and treatment-based measures have improved outcomes and reduced cancer deaths, the incidence of some of the most common cancers is on the rise [1]. Some studies have suggested that people in the United States lack the necessary knowledge and awareness of cancer, particularly those of lower socioeconomic status [2,3]. Similar results have been indicated in adolescents in the United Kingdom and the United States [4-7]. Thus, despite the prevalence of cancer awareness, there is still a salient and critical need to encourage cancer awareness and knowledge from a young age so that individuals can better understand the basic biological etiology of this disease and support life-long prevention behaviors.

For educational interventions to be successful, especially those involving complex and emotionally charged chronic conditions, they must be tailored to the intended audience. The Collaborative Research on MEdication use and family health (CRoME) Lab has a history of engaging with and educating adolescents and parents on health topics, such as cancer prevention, medication safety, and vaping prevention [8]. The CRoME Lab has co-designed serious games for adolescents and parents around prescription opioid medication safety [9]. Serious games are games designed with the characteristic purpose of imparting knowledge to the player, rather than merely providing a recreational experience [10]. In this viewpoint, we detail the work leading to the development of a cancer education serious game named OutSMART Cancer, the current state of the game, and future directions.

Early Work With Youth Stakeholders

In 2020, our team began research in Wisconsin with middle and high schools, holding focus groups with 327 students and conducting a further survey with 235 students [11-13]. In one study, the CRoME Lab held 25 focus groups with 188 middle and high school students between the ages of 12 and 18 years [11]. Through exploring adolescent perceptions, we found that many adolescents were interested in learning about cancer, specifically, cancer prevention. Middle and high school students in this study recounted familiarity with basic cancer biology but indicated unfamiliarity with how to assess cancer risk and what behaviors they can institute to prevent cancer.

One survey study examined adolescent's knowledge and attitudes toward cancer as well as the acceptability of a game-based learning approach for cancer education in homes, health care settings, and schools [12]. The survey responses reiterated the findings from the initial previous focus groups. Although most students expressed basic cancer knowledge, only 66% knew that individuals have some level of control over their cancer risk. Moreover, only 37.3% reported knowing how to lower their cancer risk, while 50% suggested they try to make healthy choices to reduce their risk. Study findings provided further evidence for the need to educate youth on cancer and its prevention. Most adolescents (82%) reported that they would accept the use of a game to help them learn about cancer.

These initial studies with adolescents informed the CRoME Lab's design of the OutSMART Cancer gameplay book, which was further assessed through focus groups with adolescents. This gameplay book showed adolescents the initial conceptualization of OutSMART Cancer informed by the Cancer Clear and Simple Curriculum [14]. A total of 18 focus groups, comprising 139 adolescents, provided in-depth feedback on the playbook [13]. Adolescents indicated that they preferred a serious game over educational modalities, such as websites and videos. Our cumulative research to date has shown that a serious game that focuses on cancer knowledge and prevention and is tailored to the preferences of adolescents could be integral in improving adolescent cancer prevention behavior.

In 2023, OutSMART began early evaluation by adolescents and parents. This demonstration is currently unavailable to the public, as it is evaluated among key stakeholders—adolescents and parents. Informed consent has been collected from participants in each study related to the development and testing of this game. Findings from this study will result in an adapted version of the game, which will be used to evaluate efficacy and implementation.

The OutSMART Cancer Game

OutSMART is a web-based, computer videogame that presents 3 familiar, cancer-related scenarios in a narrative, choice-based format (Figures 1-5) [15]. It is built upon the Unity WebGL game engine and is currently optimized for browser gameplay on laptops and computers [16]. Within this game, players interact with the environment through a first-person perspective, taking the role of an adolescent. Players are faced with 3 scenarios that cover information related to breast, colon, and lung cancers. In each scene, players progress by clicking on pop-up bubbles, giving the player choices that move the storyline along. Players progress from one scene to the next once they have completed that scene's storyline. After completion of a scene, players are taken to a map to choose the next available scene.

In the first scene, the player heads downstairs for a day at school to see their mother on the couch. After asking why she had not left for work, the mother tells the player that she is experiencing a painful lump in her breast alongside fatigue and will be going to her doctor that day. As the player offers to attend the appointment with her, the scene switches to the car ride to the doctor's office. During this ride, the mother shares her family history of breast cancer and her anxiety. Later, in the doctor's office, the player and their mother learn that the lump is cancerous. This level espouses key information, such as early warning signs of breast cancer, screening tools, basic cancer biology, and cancer stages.

In the second scene, the player brings mail inside for their father and discovers a letter from his doctor's clinic encouraging him to schedule a colonoscopy. During this scene, the player tells their father about the letter and encourages him to schedule an appointment. However, at first, their father is apprehensive and talks of anxiety after his previous colonoscopy, which had uncovered polyps. After some conversation with their father, his attitude changes, and he decides to schedule a visit. This scene introduces colon cancer and screening strategies; it also introduces the player to the types of emotions that can act as barriers to screening.

In the final scene, the player goes to school and learns about cancer in a simulated classroom environment. Following class, their friend introduces them to a new person, who, when left alone with the player offers them a vape (electronic cigarette). Although peer pressure is evident, the player must refuse, articulating their own reasoning why they are choosing to protect their own health. This scene introduces players to the power of personal choice and how everyday choices can influence cancer risk.

Figure 1. OutSMART Cancer gameplay.

Figure 2. Screenshot of mom lying ill on the couch.

Figure 3. Screenshot of the doctor’s office scene.

Figure 4. Colon cancer scene with father.

Dad

Can you bring in the mail?_

Figure 5. Peer offering vape to the player.

Kevin

Well, I got my hands on some Polar Breeze cartridges on sale. It might help you take your mind off things. You want to give it a try?

The Future of the OutSMART Cancer Game

Although preliminary evaluation and targeted adaptation of this game are ongoing, a simultaneous endeavor has begun to create a more adapted cancer-education game. This adaptation of OutSMART Cancer will emphasize the need for cancer awareness and targeted education among Black Americans and African immigrant youth and parents (OutSMART Cancer: Africana). The creation of OutSMART Cancer: Africana is responsive to the need for culturally competent cancer education for youth and African immigrant families living in the United States using culturally familiar language and imagery. Black Americans and African immigrants experience cancer and health care uniquely, requiring a tailored educational approach [17].

The initial intention is to widely disseminate this serious game through clinical settings, such as community pharmacies, primary care offices, and cancer clinics, as well as community settings, such as schools and community health organizations. Researchers aim for this intervention to be taken up by adolescents and their families across the United States. We expect that this game will eventually be publicly available on the internet for play on computers and mobile devices. The long-term goal of the OutSMART Cancer games is to facilitate family communication about cancer prevention, associated healthy behaviors, early detection, and cancer screening.

Authors' Contributions

OA conceptualized and supervised the study and was in charge of writing the original draft as well as reviewing and editing the manuscript. TJM contributed to the writing of the original draft as well as reviewing and editing it.

Conflicts of Interest

None declared.

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Abbreviations

CRoME: Collaborative Research on MEdication use and family health

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Viewpoint

Using a Mobile Messenger Service as a Digital Diary to Capture Patients' Experiences Along Their Interorganizational Treatment Path in Gynecologic Oncology: Lessons Learned

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Abstract

A digital diary in the form of a mobile messenger service offers a novel method for data collection in cancer research. Little is known about the things to consider when using this data collection method in clinical research for patients with cancer. In this Viewpoint paper, we discuss the lessons we learned from using a qualitative digital diary method via a mobile messenger service for data collection in oncology care. The lessons learned focus on three main topics: (1) data quality, (2) practical aspects, and (3) data protection. We hope to provide useful information to other researchers who consider this method for their research with patients. First, in this paper, we argue that the interactive nature of a digital diary via a messenger service is very well suited for the phenomenological approach and produces high-quality data. Second, we discuss practical issues of data collection with a mobile messenger service, including participant and researcher interaction. Third, we highlight corresponding aspects around technicalities, particularly those regarding data security. Our views on data privacy and information security are summarized in a comprehensive checklist to inform fellow researchers on the selection of a suitable messenger service for different scenarios. In our opinion, a digital diary via a mobile messenger service can provide high-quality data almost in real time and from participants' daily lives. However, some considerations must be made to ensure that patient data are sufficiently protected. The lessons we learned can guide future qualitative research using this relatively novel method for data collection in cancer research.

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KEYWORDS

mobile apps; computer security; confidentiality; data collection; oncology; breast neoplasms; mobile phone

Current Perspectives on Digital Diaries in Cancer Research

Overview

Asking research participants to write their experiences down in a diary generates different data from those that might be obtained from qualitative interviews. Using ambulatory assessment (AA) methods in the form of diary writing allows for the collection of rich data during the patient's daily life almost in real time [1,2]. AA is a research tool that has grown dramatically in popularity, particularly in the last decade [2,3]. AA refers to an array of assessment approaches that include the experience sampling method (such as paper-pencil diaries) or ecological momentary assessment (EMA; such as digital diaries on mobile phones) [3,4]. AA ensures that data collection occurs within the patient's individual natural environment and context. This improves data validity as opposed to more traditional assessment methods that often take place in artificial environments [2,5]. Moreover, data collection methods such as the experience sampling method or EMA have the potential to reduce recall bias [6,7].

AA has commonly been used to collect structured quantitative data, for instance, using software to support clinical research projects, such as REDCap (Research Electronic Data Capture; Vanderbilt University) [8]. In cancer research, AA techniques have been applied using specifically developed mobile applications functioning as diaries, for instance, to track clinical symptoms [9] or to assess self-report physical activity [10,11]. In addition, AA or EMA in oncology research holds promise to improve the understanding of patients' symptoms and quality of life by taking their natural environment into consideration [12].

However, such techniques can also be a useful data collection tool for qualitative research [4]. Applying AA in mental health research is well established. However, less is known about its feasibility and added value for oncology research [12].

Diaries in digital format can offer a variety of data, such as videos, audios, and photos, which can be recorded [13]. More specifically, digital diaries in the form of a mobile messenger service or application enable remote data collection with the possibility of real-time feedback on participant activity, thereby improving collaboration between members of the research team and participants. Telling a patient's story with the help of mobile digital devices in the research context encourages a detailed description [14] and holds promise as a participatory research practice [15,16]. Capturing patients' stories is especially useful in qualitative research to explore participants' lived experiences with health care [17]. Moreover, the treatment of gynecological and breast cancer is multiprofessional and interorganizational, as it mostly includes a combination of surgery, chemotherapy, radiation, and targeted therapies. Patients have numerous appointments, often in several different locations, with their experiences potentially getting lost in retrospective interviews.

Background on the Original Study

This viewpoint paper was inspired by the experiences we acquired in an original study with the aim of examining the meaning of trust, interprofessional collaboration, and the role of the advanced practice nurse in gynecological oncology in the treatment path of women with gynecological cancer. Detailed study procedures and results will be provided elsewhere and are not the focus of this viewpoint. We conducted a mixed methods study [18] and chose for the qualitative part an interpretive phenomenological approach in accordance with van Manen [19]. A total of 12 women (aged 27 to 61 years) were recruited in 2 oncology clinics by 2 advanced practice nurses. Most participants had a higher qualification (n=9, 75%) and were in the cancer stage IA (n=4, 33%), followed by stage IIA (n=3, 25%), according to the Union for International Cancer Control.

We asked participants to share their experiences using a mobile messenger service installed on a tablet as a digital diary from diagnosis to follow-up. The mean study duration among the 12 participants was 10.5 (SD 4.1, range 2-16) months.

The diary was unstructured to reflect participants' individual experiences and perceptions around the phenomena of trust and interdisciplinarity. This meant the participants did not receive specific questions from the research team but sent us their perceptions on trust and interdisciplinarity at varying time intervals and with varying subjective content depending on their circumstances and differing treatment paths. The participants were informed that they should view and use Threema (Threema GmbH) similarly to an actual paper-based diary, writing down their inner reflections and perceptions. This also meant that participants did not necessarily expect any response to their diary entries or prompts from the research team on a regular basis. However, we found that this flexible approach met recommendations for the successful integration of EMA techniques, such as permitting continuous researcher and patient interaction, sending questions, reacting to responses, and debriefing after the completion of treatment phases [20].

Along with the digital diary, we conducted repeated semistructured interviews, and participants filled in a structured questionnaire at each treatment phase (ie, diagnosis, surgery, chemotherapy, radiation, and follow-up). Through this triangulation of methods, we were able to generate richer data [21].

Ethical Considerations

The study was approved by the responsible ethics committee of northwest and central Switzerland (registration number 2021-00730). All patients provided written informed consent before enrollment in the study. Participants were informed that participation in the study was completely voluntary and that nonparticipation or withdrawal was possible at any time once participation had begun without any consequences concerning further care and treatment or employment. Texts sent via the messenger service were encrypted before data analysis to ensure confidentiality. The encryption key was kept in the Institute of Applied Nursing Science, separate from other data. Participant data were stored on a password-protected drive. The patients received no compensation for participation. However, each patient received a tablet to be used as a digital diary. The tablet was given to the patients as a gift. With regard to our digital diary approach, the ethics committee deemed it important for us to report in detail how the data were encrypted and stored to ensure data protection.

Rationale for Using Digital Diaries in Cancer Research

For the original study, we chose the digital diary method via a mobile messenger service mainly for 3 reasons [22]. First, cancer treatment may impair physical and cognitive function. Therefore, we tried to keep patient burden as low as possible and minimize the time between women's experiences and their reporting. Accurate reporting is particularly important in view of the complex treatment that involves numerous appointments with several health care professionals [23]. By solely relying on interviews conducted retrospectively and in light of any potential impairment of cognitive function due to the treatment, the accuracy of the women's reports may else have been compromised. Second, trust is highly subjective by nature. It takes time to develop, may change with time, and is influenced by previous collaboration experiences [24]. To reflect the participants' lived experience and the phenomenon of trust over time, the diary method using mobile messenger services, such as the ones many people already use on their mobile phones, appeared particularly appropriate [25]. It seemed to fit the phenomenological methodology, as mobile messenger services are already part of our day-to-day experience, as opposed to additional diary applications or software. Using specific digital diary software with structured prompts could be viewed as an added hurdle to be part of participants' daily lives. Therefore, messenger services show promise in capturing nuances of patients' lived experiences along the illness and treatment journey [26].

The digital diary method also allows participants' testimonies of their lives to shape the direction of the research, thereby addressing power imbalance [27]. Third, the technical solution provided advantages such as responsive and transparent data collection and password protection, which would prevent reading by others and contribute to data security. However, research has also found pitfalls when using mobile messenger services in the context of health care in the past. A recent scoping review on the use of the WhatsApp (Meta Platforms Inc) messenger found research ethics were not considered adequately. The authors deemed this to be concerning, given the controversies WhatsApp has faced regarding data protection in detail end-to-end encryption [28]. In addition, for health researchers, technical solutions such as end-to-end encryption might not be obvious, and the need for technical support might be underestimated. Data security policies and regulations are constantly adapted in Switzerland and other countries in Europe. Digital modes of data collection add new aspects to consider when protecting the sensitive data of study participants. From a practical point of view, the interface of digital applications on electronic mobile devices requires other practical skills and preparations of the researchers than classical data collection methods. For example, IT support is needed for planning and maintaining the running systems and for troubleshooting when problems occur.

In summary, using a mobile messenger service for qualitative data collection seems an opportune way to collect data nowadays. However, it poses some questions, particularly with regard to data quality, practical aspects, and data protection, that need to be considered when choosing this option for clinical studies.

Aim

The purpose of this viewpoint paper is to discuss the lessons we learned from applying a digital diary as a data collection method by sharing our experiences, some solutions, and questions that we encountered while using this method. We aimed to provide useful information to other researchers who consider digital diary methods for their research, especially in the context of oncology care.

Methods

The paper covers our experiences on three main topics: (1) data quality, (2) practical aspects, and (3) data protection. Our initial considerations around these 3 topics and how we approached them are described in the following sections.

Data Quality

In terms of data quality, we paid particular attention to the extent to which the data collected with the mobile messenger service conformed to the paradigm of phenomenological methodology. In doing so, we held continuous team meetings, recorded the discussions, and analyzed them for this paper. As a more universal approach to data quality, we used the quality criteria of Lincoln and Guba [21], namely credibility, transferability, dependability, and confirmability. In addition, we considered the criteria of authenticity [29]: fairness, ontological authenticity, educative authenticity, catalytic authenticity, and tactical authenticity. How we incorporated these criteria into our research method is elaborated in the Key Lessons Learned section.

Practical Aspects

Practical aspects of planning, setting up, and maintaining the mobile devices as well as the software were continuously recorded by the research team in a field protocol. Practical solutions and questions that were addressed are reported in this manuscript. The analysis of the protocols and data security was carried out in joint discussions with the primary team (experienced researchers with a clinical nursing background), including an IT expert.

Data Protection

Because of the interactive nature of the messenger service, we had to consider the privacy protection of both parties, the patients and the research staff. Essential requirements for messenger services were derived from the European Union (EU) data protection legislation. The introduction of the EU General Data Protection Regulation (GDPR) has an impact on everyone who moves on the web. Although this is an EU regulation, it nevertheless has an extraterritorial effect, as companies from nonmember states are also obliged to implement it under certain circumstances. Switzerland's revised data protection act entered into force on September 1, 2023, and approximates the GDPR.

Key Lessons Learned

Overview

We compared certain evaluation criteria for each messenger to then selected a suitable messenger service. The three main areas of focus namely (1) data quality, (2) practical aspects, and (3) data protection (including data privacy and information security), were interrelated, and decisions in one area most often needed some considerations for one of the others. For instance, it was considered practical by some research team members to text patients from their personal mobile devices, but this led to new data protection issues.

Data Quality

We ensured *credibility* by interacting with our participants on a regular basis through the messenger service over a lengthy period, from the phase of cancer diagnosis to follow-up several months later. The interactive nature of the messenger service allowed us to enrich the content the participants posted nearly in real time, thereby largely circumventing any recall bias. However, we found that this bias could not be completely omitted. During data collection, several participants forgot to send us their messages, especially in the last phase of data collection during follow-up, or were simply too burdened by the side effects of the treatment to update us regularly. However, we felt these missing data could be mitigated through data triangulation. For instance, when we conducted the semistructured interviews at each treatment phase, we could inquire about information that had potentially gone missing in the diary. Moreover, we paid particular attention to the aspect of *social desirability* In our experience, we found this possible bias to be rather negligible, as all participants felt comfortable sharing positive and negative information around their experiences. The interaction with the patients on the mobile messenger service allowed us to inquire what was meant if a certain message was ambiguous. We entered probing questions into the messenger service to delve deeper when certain information that touched upon our research question was provided. In addition, during the interviews, we gave respondents the opportunity to correct misinterpretations we might have made of their digital diary messages, thereby triangulating and cross-checking the data. We ensured *transferability* by encouraging participants to share their narrative with us. However, sometimes, individual requirements called for the application of pragmatic decisions. For instance, we allowed one of the participants to send us photos of handwritten messages, as she mentioned feeling less comfortable typing a lot of information into the tablet. However, she used this option only twice before switching to email. We considered *dependability* and *confirmability* by, for example, noting down common responses of the research team in a separate file. (For example, “Dear participant, thank you for your detailed descriptions. We will consider them carefully.”) By archiving our responses and discussing them among ourselves, we ensured that our reactions were similar across patients in case of comparable situations. Exchanges with study participants outside of the messenger service (including quick telephone calls for technical reasons or setting an interview date) were recorded. To limit researcher bias, we avoided steering the participant’s narrative too strongly to capture the participant’s lived experience. This was particularly relevant for probing questions that we entered into the messenger service. In this regard, we found it particularly helpful that each participant chat group was supervised by 3 researchers and that responses could, therefore, be discussed.

Moving on to the 5 dimensions of authenticity according to Lincoln and Guba [29,30], we aimed at achieving *fairness* through our prolonged engagement with participants and regular peer debriefings with fellow researchers who were in the chat groups. We established *ontological and educative authenticity* by allowing ourselves as researchers to be “educated” by our participants, taking on an emic perspective. The ongoing dialogue with participants helped achieve a sense of familiarity in the researcher-participant relationship and led to an effective hermeneutic circle. Regarding *catalytic authenticity*, we discussed and defined how we interacted with study participants throughout the research process, especially how we communicated over the messenger. When situations that we had not fully anticipated beforehand arose, for instance, certain technical difficulties of participants, we found solutions through discussion and joint decision-making in the research team. To ensure *tactical authenticity*, we spoke to participants over their personal telephone before every initial interview, inquiring whether they felt empowered to fully communicate and share their experiences with us over the mobile messenger service. Participants could also exercise control on how frequently they interacted with us, when they sent us messages, and what content they decided to share with us.

Overall, we found that the use of a mobile messenger service for the digital diaries fully met our expectations in view of data quality. The richness and authenticity of data that were generated via this method were exceptionally high and ensured the credibility of the data. We felt that this method yielded a feasible and personal way to accompany a woman directly after her gynecological or breast cancer diagnosis and get to know her lived experience during her treatment almost in real time. In our study, the digital diary data complemented the semistructured interviews most favorably. We found that the contact via the mobile messenger service moved the starting point in each interview much closer to the focus of our primary research question on trust and interdisciplinarity, as the researcher already knew eminent details of the participants’ lived experience. This was especially relevant in the initial study phases, when participants experienced more uncertainty and emotions.

Practical Aspects

Field protocols mainly yielded 2 practical interrelated groups of things to consider when using digital diary data collection: technical aspects and the interactive nature of the messenger service.

Technical Aspects

In our research context, it was important that the selected messenger service was flexible, was popular in terms of its recognition value, and had the greatest possible compatibility with common operating systems, such as Android (Google LLC) or iOS (Apple Inc). The messenger service needed to be compatible with not only the tablets provided but also the user’s smartphone. Data security played a major role when choosing a messenger service, and the most important criteria are described later in this paper in the Data Protection section. Costs also guided our decision because tailored mobile diary apps can be expensive compared to more affordable messenger services. Finally, we selected the Swiss mobile messenger service Threema.

As tablets were gifted to the participants during recruitment, all participants chose to use the tablet instead of their mobile phone. One of the participants mentioned that she wanted to keep the “disease and her private life separate.” Another reason for patients not choosing their own mobile device for posting messages might have been that the research assistants in both settings did not emphasize this possibility sufficiently. The tablets were provided fully set up and preinstalled. However, the tablets were not as much part of patients’ everyday life experience as we had hoped. Notably, at the end of data collection, some participants mentioned not wanting to continue to use the gifted tablet for other purposes because they associated it with their disease. Indeed, one of the participants mentioned having given the tablet to a relative. None of the tablets were returned to the research team.

During data collection, patients sometimes forgot to bring the tablet with them to certain appointments (eg, radiation appointments) to document their experiences. Had they been using their smartphones to communicate with us, we assume this would have happened less frequently. In some cases, the research team had difficulties reaching participants (1) when the first contact was problematic (refer to the subsequent discussion about Wi-Fi connection) or (2) when the participants had not recorded their experiences for some time. According to the study protocol, contact should be held solely via the mobile messenger service. However, as some participants did not boot their tablet regularly, this way of communication was not always reliable. Instead, we established an initiating phone call as well as email contact in individual cases for first and ongoing contact. If messages were not sent to the research team via the messenger service for >3 weeks, the research team tried to contact the participant via the messenger service and then via the contact person in the respective setting, and if this did not suffice, the research team tried to establish contact via phone or email. However, we discussed how often or in which intervals phone calls might be appropriate if patients did not send us a message for a while.

This way, we were able to keep in contact with all participants and, at the same time, respect their personal life as much as possible. No participant dropped out of the study, despite the longitudinal character with a mean study duration of 10.5 months and no financial incentive. All in all, this confirms a high level of feasibility of the data collection method from the participants’ side.

Some decisions entailed situations that were not anticipated by the research team. For example, as the chosen mobile messenger service was distributed via a common mobile app store, a new account for each tablet needed to be created by the team, which affected complex password management, among other things. The payment method needed to be compatible with the standards of the project’s financial control. In addition, the used mobile app store account and payment method had to be safe from fraud and unlawful use by subsequent app users. As a solution, mobile app store vouchers were used instead of entering the details of a credit card.

The selected messenger service stores data on each mobile device rather than in the cloud. In one instance, a message was not received by one of the research staff due to synchronization problems in the messenger service. As we had regular team discussions and chats were hosted by 3 members of the research team, this problem was soon discovered, and the message could be retrieved. Another time, we encountered a synchronization problem related to the decentralized data backup on participants’ mobile devices: some messages were received with the incorrect date and time stamp. Research team members in the chat quickly realized this issue when messages were sent in the wrong sequence. Having several researchers present in each chat was a definitive advantage. Once we realized the discrepancy, the administrator of the chats synchronized chat groups regularly, and we no longer encountered this issue.

Although generally not a problem, establishing a Wi-Fi connection on the tablet did require some basic technical knowledge. In one situation, initial Threema messages after recruitment were not recorded via the messenger service on the tablet until the participant had her husband connect the tablet to her home Wi-Fi. Some data from the early treatment phases were lost due to this technical issue. The research team could not offer remote support for this kind of problem, as each Wi-Fi router might be different. However, as connecting mobile devices to home Wi-Fi was a known task for most participants, this was not problematic and could be solved without much burden for the participant.

Another practical technical issue that was not fully anticipated by the team was the practicability of producing and sending text messages on a tablet. For example, participants frequently mentioned that the autocorrection feature wrote “odd” words, and they were not always capable of disabling the function. As a result, they needed to recheck each message and correct mistakes manually, which increased time and effort for data generation and caused frustration for one of the participants. We would recommend disabling the autocorrection mode before handing out the device to participants or providing a guide regarding how to do this manually. In addition, the handling can differ between mobile devices. For example, a participant suggested changing to writing emails from her private laptop instead of using the messenger service on the tablet because she could not become used to the tablet swipe function compared to the keyboard on her laptop. We decided that she can send her emails to a protected server of a research team member.

Surprisingly, the time-saving method of sending voice notes via Threema was hardly ever used, even though research assistants suggested this method in the supporting phone calls. Therefore, we assume that this method of messaging posed a greater barrier to participants than text messaging. As a result, data generated by Threema consisted mostly of written text messages. One of the participants elaborated on her dislike of sending voice notes. She mentioned that it was important for her to reread the text she had written before sending it to us.

The Interactive Nature of the Messenger Service

The interactive nature of the messenger service triggered our hypothesis that participants might expect some feedback on their posts. In the study protocol, the team planned to ensure so-called impartial feedback to balance the abovementioned “steering” of the data with the amount of data that were derived. We ensured timely feedback by building teams of 3 researchers for each chat. One person per chat was in charge of answering in an impartial manner. In this context, impartial meant that the responses did not reinforce emotional topics and used the participant's own words whenever possible. A common answer to a post was, for example, "Thank you for this interesting message. I am curious how xyz will turn out." During data collection, we repeatedly discussed how our answers may influence the participants' posts. We also considered whether certain replies may be used to direct posts intentionally to generate more data that focused on the research question. After consulting an external expert for phenomenology, we decided on a mode of intentionally "steering" participants' posts to generate richer data in view of the research question.

For the Swiss context, we needed to choose the teams according to their language-speaking abilities, as the study sites were from 2 different language regions (Swiss German and French). As the chats were backed up regularly on local servers, a person in charge was chosen to oversee this task. This team member had to be extra careful not to miss any messages; otherwise, some messages might not have been included in the transcript (refer to the Technical Aspects section). In addition, participants had to be informed regarding who was able to read their posts and why 3 team members were part of the chat group. As some participants inquired whether the other participants were able to read their posts in the messenger, we realized that confidentiality needed to be explained in more detail. As is standard in qualitative clinical studies, we informed patients that the research team was not giving any medical advice. Some discussions were necessary to balance the neutrality of the answers and responsiveness when some participants revealed that they had acute health problems. We stored standard answers with emergency numbers of the treating departments for each study site, for which we coordinated with the on-site contact persons.

Another aspect of the personal attendance of the chat groups was discussed frequently in the team: some patients posted mainly in the evening and late at night. Some research team members used distinct ringtones; others muted the messenger service to avoid receiving potentially upsetting messages in their spare time. This was possible, as some researchers did not use Threema in their personal life at the time of the study. However, if message notifications were not muted, posts reached us outside of working hours. Balancing the pros and cons, most of us stuck to our choice to use our personal mobile phone for chat supervision. This seemed more convenient and allowed the team members to report in a timely manner, becoming somewhat part of patients' lived experience.

Data Protection

In view of data protection, we found that several aspects of data privacy and information security had to be considered for the selection of the mobile messenger service [31-33]. The criteria in Textbox 1 indicate when a messenger service may be suitable for exchanging sensitive health-related data on a more general level.

Textbox 1. General criteria when choosing a messenger service for data collection.

General criteria

- Privacy by design—data security and metadata sparing are already considered in the development phase of the messenger. Where there are no data, there can be no misuse of it.
- Open source—the app's source code is publicly available and can be viewed by third parties.
- End-to-end encryption—only the chat participants can view the exchanged information. Even the service operator has no way of decrypting it.
- Self-hosting—the messenger is run on the institution's own server (on premises) to meet its own security requirements and retain sole data sovereignty. In the context of temporary research projects at universities, self-hosting and administrability are not always possible. In that case, at least the operation of the solution (server) should be subject to the respective country-specific data protection legislation.
- Data protection conformity—the messenger's functionality fully complies with the strict regulations of the General Data Protection Regulation, which means that the misuse of confidential health care data can be ruled out.
- User-friendliness and intuitive handling—if the requirements of user-friendliness and functional scope are not met, even the most secure messenger service is worthless and may promote the emergence of applications and services without explicit IT department approval.

These generic requirements lead to a comprehensive checklist that can be used to evaluate current and future messengers in terms of their suitability for handling sensitive health data. The checklist and the definitions of the different criteria are provided in the Multimedia Appendix 1. The Messenger Evaluation Checklist is applied to 5 publicly available messenger services in the Multimedia Appendix 2, allowing for comparisons of different technical aspects.

According to this evaluation, various messengers could have been used for the application scenario of our study (or similar studies handling sensitive data). It is also to be expected that more suitable messengers will be developed or that existing providers will close their weak points regarding data protection and the security of customer data. In the context of this study, which was conducted in Switzerland, we selected the Swiss app Threema from the suitable messengers for three main reasons:

1. Threema was the first major messenger service to commit to data protection and privacy.
2. Threema does not require personal data (data sparseness).
3. The messenger offers a number of similar functions to those offered by WhatsApp, such as sending voice notes or photos, which also catered to different communication preferences of patients.

First, as an important mechanism for data protection, Threema uses secure "end-to-end" encryption. This is comparable to specific AA applications, such as movisens. This was relevant to our study because we did not provide a SIM card, and we found that transmission via Wi-Fi would suffice. Participants were able to type their posts in the messenger service offline, which were sent as soon as the tablet was connected to Wi-Fi. We left it to the participants to decide which Wi-Fi they used. However, we could not ensure data security for open-access Wi-Fi, such as hospital Wi-Fi or restaurant Wi-Fi. One solution might have been a virtual private network connection. However, as we had to balance technical skills and usability with data protection, the end-to-end encryption of the messenger service was considered safe enough.

Second, in terms of data sparseness, Threema does not ask for any data when registering and adheres to strict data protection guidelines. Moreover, as the application was preinstalled on the tablets by the research team, participants did not need to register using their private phone number. The address book is not by default synchronized and matched with existing messenger users. If data are collected, they are deleted again immediately. Text messages and media are stored only on the end devices unless the user chooses the backup function. The servers then only have the function of a relay station: messages and data are forwarded but not permanently stored. As Threema cannot view or process messages, users retain control over their messages.

Third, fortunately, Threema not only meets the functional requirements in our study but also adequately protects the personal data of all chat group participants (study participants and research staff). Moreover, according to the terms of service, Threema does not store any metadata that could be used to identify the message content. Threema uses data only to provide the necessary service, emphasizes data privacy, and minimizes data collection. There is no evidence that Threema uses data for modeling or other purposes.

In addition to the 3 reasons that led to its selection, Threema fulfills many other requirements, as listed in the Multimedia Appendix 1 and evaluated in the Multimedia Appendix 2.

Discussion

Principal Findings

In this viewpoint paper, we intended to report the lessons we learned using a mobile messenger service to generate data for digital diaries in an oncology setting. Overall, we found that using a mobile messenger service such as Threema as a digital diary was feasible and highly valuable for data collection, and we never regretted our decision. The flexibility around diary content and timing of messages was a major strength of the study, particularly for this patient population facing significant challenges. Although we did not send regular prompts, the diary generated rich data. The challenges that we met during our study showed us that technical support needs to be carefully considered while planning and conducting such research. Technical aspects should entail software and hardware in view of the suitability of the backend and the usability of the front end. These considerations might include not only the choice of the software and means of data protection but also practical front-end considerations, such as technical support if a device is not working or the practicality of writing long, emotional messages with a touchscreen keyboard.

Data Quality

In our study, it was particularly important for us to collect high-quality data that ensured we could take part in participants' lived experiences. Using a mobile messenger service provided us with rich descriptions that participants did not necessarily share with us during the interviews. Researchers in another study came to similar conclusions, where they introduced a chatbot for patients with breast cancer. They found that patients revealed more intimate information and shared thoughts about sexuality and hair loss [34]. In another study, the authors confirmed that participants felt more at ease sharing private information over the messenger because of anonymity and privacy considerations. The authors concluded that messenger services also have the potential to facilitate trust and, therefore, the collection of more in-depth data, especially in longitudinal studies [35], which we also observed in our study. We found in our study that interacting regularly with participants over the messenger service made the exchange more personal. We felt as though we were taking part firsthand in the participants' experiences almost in real time. On the one hand, participants at times forgot to update us via the tablet, and some participants expressed a wish to keep their private life and the disease separate, particularly in the follow-up phase. However, we still felt that this method achieved a level of nearness we could not have achieved through interviews or questionnaires only. In addition, we felt that the mobile messenger service aided us in circumventing the issue of recall bias, which can be an issue for other methods of data collection [6]. This is especially important for cancer research, considering chemotherapy-related cognitive impairment, such as memory deficits [36,37].

Furthermore, and in line with findings from the study by Herron et al [38], the digital diary entries gave us clues as to how the interviews could further deepen the participants' accounts of their experiences. In addition, we informed the participants which member of the team was primarily responsible for interacting with them within the messenger. This team member usually also conducted all interviews, which additionally fostered trust between the researcher and participant.

Practical Aspects

In our study, we reflected on technical aspects as well as researcher and participant interaction. Participants were eager to send us Threema messages at the start of the study, but at certain points in their treatment path, especially during radiation and follow-up, engagement was an issue. Other research suggests that a high attrition rate and continuous engagement are key challenges in health care studies that rely on mobile applications [39]. However, researchers found that personal contact, such as receiving response messages from researchers, made participants feel valued, and they were more likely to complete data collection [40]. It was paramount in our study to be able to interact with participants and to use other mediums when Threema communication declined or came to a halt. As we had very little missing data and no dropouts, this somewhat laborious method paid off in our study. We think that this may also be the reason why we had no dropouts. This is particularly worth mentioning, as the study took place over a long period during which several patients did not feel well. The low dropout rate coincides with the strengths highlighted by Trull and Ebner-Priemer [3] on self-report AA. The authors argued that patients with severe illness have demonstrated good compliance in AA studies and are willing to share honest reports of their experiences.

Data Protection

Data protection was one of our main considerations when we selected the messenger service Threema. Weis et al [41] found in their qualitative study that an important concern for patients with cancer was data security as well as confidentiality. We made sure that study participants were well aware of all relevant data protection aspects. Interestingly, none of the patients with cancer expressed any unease or worry in this direction when communicating with us over the messenger service.

One concern for the researchers of this study, however, was the data security for open-access Wi-Fi, as we did not provide patients with a SIM card. Cyber security and issues of cyber security vulnerability among Android devices have also been reflected upon in other health care research [32,42]. Mierzwa et al [43], for instance, recommend considering the cyber-risk likelihood and a consequence analysis when using a certain technology in health care. They found that WhatsApp is not an adequate tool to share clinical information due to its noncompliance with the GDPR and Health Insurance Portability and Accountability Act rules. In their opinion, health care organizations and physicians should abandon WhatsApp, moving toward secure messaging apps that are able to maintain the confidentiality and security of patient data. However, these works mostly considered tools for communication within health care organizations and for communication between their employees.

Potential Pitfalls

Several different mobile messenger services could have been used in our study. We did not conduct an in-depth analysis of all available applications beforehand but instead selected Threema out of 3 main publicly known applications based on the 3 reasons mentioned in the Data Protection section.

We did not encounter any major pitfalls in the process of ethical clearance that diverged from our previous non–digital diary studies with patients with cancer. However, it is important to note that ethical clearance requirements may differ greatly, even within the same country. The mobile messenger service used in this study is based in Switzerland, the same country where the study was conducted. This may have influenced the process.

We cannot rule out the possibility that the technical nature of the digital diary might have resulted in a slightly biased sampling, with technically affine persons feeling more inclined to participate in this kind of study. However, we found that age and educational level showed a certain diversity.

The research team of this study did not have a professional background or expert IT knowledge. Study participants also did not receive any specific training to use the mobile application, as recommended by Daniëls et al [44]. We could only provide remote support via phone when the study participants experienced technical difficulties. In such cases, we referred participants to the recruiting nurse, who also lacked the technical expertise to help with participants' mobile devices. Mostly, we could solve the problems. However, if not, we indeed jointly found individual pragmatic solutions, such as allowing the use of pictures of handwritten messages or using a keyboard and emailing diary messages. One might argue that the different modes of data collection as well as the unstructured setup of the diary in comparison to more conventional AA applications led to a slight imbalance in data quality. We checked whether a certain amount of "closeness" to the patient's lived experience might have been lost due to this decision. In this particular case, for example, the switch to email was successful, as the participant immediately started sending us more detailed reports more frequently. It remains unclear whether the data collection method described here was superior or inferior to other data collection methods. However, we found that it led to a certain amount of "felt proximity" to participants' lived experiences. As this was precisely the goal of our study, we found that using the digital diary method served our purpose quite adequately.

Conclusions

We recommend using a mobile messenger service for digital diaries in studies because they can generate timely and rich data that represent patients' lived experiences. This data collection method also shows promise for generating high-quality data over a longer period. Interacting and engaging with patients regularly over the messenger service may not only facilitate patients' truthful responses but also greatly aid participant retention. We consider the digital diary method to be suitable for cancer research because it allows researchers to closely follow patients and partake in their experiences in each treatment phase in a timely manner. Last but not least, the combination of methods contributed to the 100% retention rate.

The choice of a high-quality messenger service is particularly important for researchers. We believe that our insights on data quality, practical aspects, and data protection provide details on how researchers may use this method to its best potential. We feel that more work may be needed to answer the questions that remained unsolved in our study.

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Data Availability

The relevant data are in the paper or in the Multimedia Appendices 1 and 2.

Authors' Contributions

The study was conceptualized by A Kobleder, A Koller, DB, RE, and EB. Data were curated by EB, DB, and RE. Formal analysis was performed by EB, A Koller, DB, RE, CM, and CT. A Kobleder, A Koller, RE, and DB were involved in funding acquisition. Investigation was conducted by EB, DB, RE, CM, A Kobleder, and A Koller. Methodology, supervision, and validation were performed by A Kobleder, CM, and A Koller. Visualization was performed by CT. The original draft was written by EB, A Koller, and CT, and reviewing and editing were done by A Kobleder, DB, CM, and RE. Generative artificial intelligence was not used in any portion of the manuscript writing.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Messenger evaluation checklist.
[DOCX File , 36 KB - cancer_v10i1e52985_app1.docx]

Multimedia Appendix 2
Exemplary analysis of 5 messengers.
[DOCX File , 37 KB - cancer_v10i1e52985_app2.docx]

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Abbreviations

AA: ambulatory assessment
EMA: ecological momentary assessment
EU: European Union
GDPR: General Data Protection Regulation
REDCap: Research Electronic Data Capture

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Demographics and Health Characteristics Associated With the Likelihood of Participating in Digitally Delivered Exercise Rehabilitation for Improving Heart Health Among Breast Cancer Survivors: Cross-Sectional Survey Study

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Abstract

Background: Strong evidence supports the benefits of exercise following both cardiovascular disease and cancer diagnoses. However, less than one-third of Australians who are referred to exercise rehabilitation complete a program following a cardiac diagnosis. Technological advances make it increasingly possible to embed real-time supervision, tailored exercise prescription, behavior change, and social support into home-based programs.

Objective: This study aimed to explore demographic and health characteristics associated with the likelihood of breast cancer survivors uptaking a digitally delivered cardiac exercise rehabilitation program and to determine whether this differed according to intervention timing (ie, offered generally, before, during, or after treatment). Secondary aims were to explore the knowledge of cardiac-related treatment side-effects, exercise behavior, additional intervention interests (eg, diet, fatigue management), and service fee capabilities.

Methods: This cross-sectional study involved a convenience sample of breast cancer survivors recruited via social media. A self-reported questionnaire was used to collect outcomes of interests, including the likelihood of uptaking a digitally delivered cardiac exercise rehabilitation program, and demographic and health characteristics. Descriptive statistics were used to summarize sample characteristics and outcomes. Ordered logistic regression models were used to examine associations between demographic and health characteristics and likelihood of intervention uptake generally, before, during, and after treatment, with odds ratios (ORs) <0.67 or >1.5 defined as clinically meaningful and statistical significance a priori set at $P \leq .05$.

Results: A high proportion (194/208, 93%) of the sample (mean age 57, SD 11 years; median BMI=26, IQR 23‑31 kg/m^2) met recommended physical activity levels at the time of the survey. Living in an outer regional area (compared with living in a major city) was associated with higher odds of uptake in each model (OR 3.86‑8.57, 95% CI 1.04-68.47; P=.01‑.04). Receiving more cardiotoxic treatments was also associated with higher odds of general uptake (OR 1.42, 95% CI 1.02-1.96; P=.04). There was some evidence that a higher BMI, more comorbid conditions, and lower education (compared with university education) were associated with lower odds of intervention uptake, but findings differed according to intervention timing. Respondents identified the need for better education about the cardiotoxic effects of breast cancer treatment, and the desire for multifaceted rehabilitation interventions that are free or low cost (median Aus $10, IQR 10-15 per session; Aus $1=US $0.69 at time of study).

Conclusions: These findings can be used to better inform future research and the development of intervention techniques that are critical to improving the delivery of a digital service model that is effective, equitable, and accessible, specifically, by enhancing digital inclusion, addressing general exercise barriers experienced by chronic disease populations, incorporating multidisciplinary care, and developing affordable delivery models.

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KEYWORDS

digital health; breast cancer; exercise; rehabilitation; cardiotoxicity; demographic; cancer survivor; exercise rehabilitation; home-based program; pathologic process; radiation; physical phenomena; heart care; cardiovascular disease; diagnosis; cross-sectional study; chronic disease; statistics

Introduction

Advances in cancer treatment and care have contributed to improved breast cancer–specific survival rates and a growing population of long-term breast cancer survivors [1,2]. Among this group, the late effects of specific cardiotoxic cancer therapeutics can adversely impact cardiovascular health and, consequently, both quality of life and survival [1]. Cardiovascular disease is now the leading cause of morbidity and mortality among long-term breast cancer survivors [1,3]. Notably, cardiovascular mortality rates are higher in women with breast cancer compared with the general population (hazard ratio 1.3, 95% CI 1.0-1.7) [3]. The development of cardiotoxicity is further exacerbated by the shared underlying risk factors for developing both cancer and cardiovascular disease, such as obesity and physical inactivity [4].

Participating in exercise rehabilitation may help to improve cardiovascular health among breast cancer survivors. Obesity, lower levels of cardiorespiratory fitness, and lower physical activity levels are known risk factors for cardiovascular disease and cancer [5-7]. There is strong evidence to support that exercise rehabilitation following cardiovascular disease can reduce morbidity and mortality [8,9]. The evidence supporting the benefits of exercise following breast cancer is also strong, with improvements in fitness, quality of life, and physical functioning well established from randomized controlled trials [6,10]. Despite the exacerbated risk of cardiovascular disease as a consequence of breast cancer treatment and the clear potential for exercise rehabilitation in this context, providing comprehensive exercise support to people with breast cancer in a safe, feasible, and effective way remains a major service delivery challenge [11,12].

Historically, clinic-based, face-to-face delivery of exercise therapy or prescription has been considered the gold standard and has been the delivery mode most commonly assessed in exercise oncology trials [10,13]. However, lessons from exercise rehabilitation in the cardiac setting highlight uptake and retention issues that come with clinic-based, face-to-face exercise delivery. Specifically, fewer than one-third of Australians who are referred to exercise rehabilitation complete a program following a cardiac diagnosis [14].

Technological advances make it increasingly possible to embed real-time supervision, tailored exercise prescriptions, behavior change, and social support into home-based programs [15]. These techniques may lead to higher exercise adherence, which is a key determinant of efficacy [15]. Remote monitoring and personalized feedback have also been reported by participants with breast cancer to be preferred attributes of technology-supported interventions [16]. A recent randomized controlled trial involving participants with coronary heart disease demonstrated the non-deidentified inferiority of a remotely-delivered cardiac rehabilitation intervention compared with standard face-to-face rehabilitation [17]. Furthermore, those in the remotely-delivered group demonstrated greater improvements in longer-term behavior change and the intervention cost significantly less to deliver [17]. It seems plausible this delivery approach could prove beneficial in an exercise oncology setting.

There is, however, a risk that those who are least likely to uptake digital rehabilitation interventions may include those who could benefit the most. Specifically, while a digital-delivery approach could address cost and access barriers (which are of particular concern for those with lower income or who live in regional/rural areas [18]), these benefits may be counterbalanced by poor internet availability and digital literacy for these same groups [18]. Digital literacy refers to “the capabilities and resources required for individuals to use and benefit from digital health resources” [19]. Digital literacy is, therefore, an interaction between systemic and individual factors, and is inclusive of several domains, including “the ability to actively engage with digital services”, “digital services that suit individual needs”, “access to systems that work,” and “engagement in our own health”. Additionally, barriers to uptaking digitally delivered exercise rehabilitation may also be reflective of general exercise barriers experienced by other chronic disease populations. A greater understanding of the individual characteristics likely to predict uptake is needed to proactively address potential inequalities or barriers that the use of this delivery model may bring.

Therefore, the aim of the current study was to explore individual demographic and health characteristics associated with the likelihood of uptake of a digitally delivered exercise rehabilitation intervention among breast cancer survivors, and to explore whether uptake differs according to intervention timing, that is, whether it is offered (1) generally, (2) before, (3) during, and (4) after treatment. Secondary aims were to explore the knowledge of cardiac-related treatment side-effects, the use of and interest in fitness trackers and apps, exercise behavior, additional intervention topics of interest, and service capabilities.

Methods

Ethical Considerations

This cross-sectional study involved the completion of a web-based survey between March and December 2020 in Australia. Ethics approval was sought and obtained from the University of Melbourne Human Research Ethics Committee (1955472). Informed consent was obtained from all subjects involved in the trial and all data were deidentified for privacy and confidentiality. Participants had the opportunity to leave contact details if they wished to receive a Aus $5 gift card for completing the survey (Aus $1=US $0.69 at the time of study).

Participants and Procedure

Participants were recruited via paid Facebook advertisements (run during March and June 2020) and cancer-specific research registries (ie, Breast Cancer Network Australia membership list July 2020; National Breast Cancer Foundation Register4 December 2020). Participants were eligible if they were diagnosed with breast cancer in the past 5 years, were aged 18 years and older, able to answer the survey in English, and resided in Australia. All potentially eligible participants were directed to a web-based survey where they could read the study information sheet, confirm eligibility, provide informed consent, and complete the survey. At the end of the survey, participants could leave contact details if they wished to receive the Aus $5 gift card (US $3.45) [20], receive a summary of the results, or be contacted for future research opportunities. The survey was conducted via Qualtrics and survey items were informed and reviewed by 2 women with breast cancer and the multidisciplinary research team, including physiotherapists, behavioral scientists, a dietitian, a cardiologist, and a medical oncologist.

Outcomes of Interest

Primary Outcome of Interest

Overview

The primary outcome of interest was the likelihood of uptake of a digitally delivered exercise rehabilitation intervention among breast cancer survivors, and to explore associated demographic and health characteristics. Assessment methods are described below.

Likelihood of Uptake of Digitally Delivered Cardiac Exercise Rehabilitation

The likelihood of uptake was assessed using purpose-built survey items on a 5-point Likert scale ranging from “not at all likely” to “extremely likely.” Participants were asked to rate how likely they would be to participate in a program generally, and before, during, and after treatment. The question stem included contextual information, including possible design features and anticipated benefits (Document S1 in Multimedia Appendix 1).

Demographics and Health Information

Participants reported their age, height, weight, postcode (remoteness determined based on Australian Statistical Geography Standard [21]), marital status, education, employment, if they were of Aboriginal or Torres Strait islander origin, and languages spoken at home. Participants rated their general health (poor to excellent) and whether they had been diagnosed with high cholesterol, high blood pressure, diabetes, congestive heart failure, heart attack, stroke or transient ischemic attack, depression or anxiety, or another health condition (used to calculate a study-specific comorbidity index; range=0 - 8). Breast cancer history information was self-reported, including stage at diagnosis, treatments received, time since diagnosis, and current disease state. Participants who had received a treatment associated with cardiotoxicity (chemotherapy, radiotherapy, or human epidermal growth factor receptor 2 [HER-2] therapy), had ≥2 risk factors for cardiovascular disease (ie, age>60 years, BMI>30, hypertension, diabetes), or self-reported compromised cardiac function were categorized as having a high risk of cardiotoxicity based on the American Society of Clinical Oncology Guidelines [1].

Secondary Outcomes of Interest

Overview

Secondary outcomes of interest included knowledge of cardiac-related treatment side-effects, use of and interest in fitness trackers and apps, exercise behavior, additional intervention topics of interest, and service capabilities. Assessment methods are described below.

Knowledge of Cardiac-Related Treatment Side Effects

Self-reported knowledge of cardiac-related side effects from cancer treatment was assessed using a single item on a 5-point Likert scale (“not at all knowledgeable” to “extremely knowledgeable”).

Use of and Interest in Fitness Trackers and Apps

Participants were asked whether they had used a fitness tracker or smartphone app to monitor exercise or other health behaviors. Where participants reported having previously used a smartphone app, they were prompted to specify which apps they had used.

Exercise Behavior

Exercise behavior was assessed using the Godin Leisure Time Exercise Questionnaire (GLTEQ) [22] and a purpose-built resistance-training item using the same format. For the GLTEQ, participants indicated how many times on average they spent doing strenuous, moderate, and mild or light exercise for ≥15 minutes during a 7-day period. Activity frequencies were multiplied by 9, 5, and 3 metabolic equivalents, respectively, and summed to create a total activity score. Participants were considered sufficiently active to obtain health benefits if they had a total activity score ≥24. Scores between 14 and 23 units were considered moderately active, and those <14 units as insufficiently active [23]. Using the same question stem, participants indicated how many times per week they spent doing resistance (strength) activities (eg, weights, yoga). Participants were classified as meeting the guidelines if they reported doing ≥2 sessions during a typical 7-day period [24].

Additional Intervention Interests

A single survey item assessed interest in 12 other intervention topics of interest relating to health behaviors and symptom management.

Service Capabilities

The dollar amount (Aus $) participants would be willing or able to pay per session was assessed with a single survey item.

Data Analyses

Descriptive statistics were calculated for all survey items. Ordered logistic regression models were used to examine associations between demographic and health characteristics and the likelihood of intervention uptake. Four models were estimated: uptake generally, uptake before treatment, uptake during treatment, and uptake after treatment. Given prior research acknowledging the potential importance of demographics and health status in explaining health service–related inequalities [25], all collected demographic and health status variables were screened for inclusion. Variable selection was refined based on bivariate analyses, with the outcome variable regressed on each demographic and health variable using all available data. Variables that were statistically significant ($P \leq .05$) or those of potential theoretical importance to digitally delivered services (eg, location) were selected for inclusion in the multivariate model [26,27]. The potential for multicollinearity was assessed by examining associations between remaining variables (using χ^2 tests, correlation matrices, and regression analyses as appropriate) to determine variables to be retained in the final model. At each step, variables were retained if they were statistically significant ($P \leq .05$) or clinically relevant (odds ratio [OR] <0.67 or >1.5) [28,29]. The variable with the highest *P* value was removed from the model (assuming it satisfied the elimination criterion, ie, a $P > .05$ or OR <0.67 or >1.5). The procedure ceased when there were no variables in the model that satisfied the elimination criterion (ie, all variables in the model had a $P \leq .05$ or OR <0.67 or >1.5). All analyses were complete case analyses and conducted using SPSS Statistics for Windows (version 28.0; BMI).

Results

Participant Flow

Overall, 250 eligible individuals started completing the survey, with 87% (n=218) completing outcomes of interest (ie, the likelihood of participating in a remotely-delivered exercise intervention generally, and at different time points) and 83% (n=208) completing all demographic and health variables. There were no significant differences in likelihood ratings between individuals with and without missing data for patient characteristics. All analyses were performed on a complete case basis (N=208).

Participant Characteristics

Participant characteristics are presented in Table 1. Participants had a mean age of 57 (SD 11) years and a median BMI of 26 (IQR 23-31) kg/m^2. Approximately two-thirds resided in a major city (132/208, 64%) and 3 in 4 participants were married or living with a partner (153/208, 74%). The majority of participants had a university degree (137/208, 66%) and engaged in regular exercise (194/208; 93%). Over half of the participants surveyed (120/208, 58%) reported “little” to “no” knowledge of potential cardiotoxic effects of treatment, with just under half (94/208, 45%) being classified as being at high risk of cardiotoxicity. In terms of use of and interest in technology for fitness, 62% (129/208) of participants reported having previously used a fitness tracker and a further 30% (63/208) expressed an interest in trying one. Fewer participants had previously used a smartphone app (87/208, 42%), and of the participants who had not used a smartphone app, three-quarters (92/208, 76%) were open to trying. The types of apps most commonly reported as having previously been used included in-built health apps (Apple health and Samsung health), apps linked to specific fitness trackers (eg, Fitbit and Garmin Connect), popular fitness apps (Map My Walk, My Fitness Pal, Strava, and Run Keeper) and mindfulness apps (insight timer and smiling mind).

Table . Participant characteristics (N=208).

Characteristics	Values
Demographic and health information	
Age (years), mean (SD)	57.4 (10.8)
BMI (kg/m^2), median (IQR)	26.0 (23.2 - 30.75)
Comorbidity index, median (IQR)	1.0 (0.0 - 1.0)
Location, n (%)	
Major cities in Australia	132 (63.5)
Inner regional	59 (28.4)
Outer regional/remote Australia	17 (8.2)
Marital status, n (%)	
Married, de facto, or living with partner	153 (73.6)
Separated, divorced, widowed, or single	53 (25.5)
Prefer not to say	2 (1)
Education, n (%)	
High school (Year 10 or 12)	16 (7.7)
Certificate or diploma (eg, TAFE or college)	55 (26.4)
University degree	137 (65.9)
Employment, n (%)	
Employed	103 (49.5)
Retired	66 (31.7)
Other	39 (18.8)
Aboriginal or Torres Strait Islander, n (%)	
No	206 (99)[a]
Language spoken at home, n (%)	
English	201 (96.6)
Other	7 (3.4)
Disease information	
Time since diagnosis (years), mean (SD)	2.2 (1.6)
Number of cardiotoxic treatments, median (IQR)	1.0 (1.0 - 2.0)
Stage of disease, n (%)	
Stage I-II	148 (71.2)
Stage III-IV	57 (27.4)
Unsure	3 (1.4)
Treatment stage, n (%)	
Not yet started active treatment for cancer	2 (1)
Currently undergoing curative treatment	38 (18.3)
Completed curative treatment and in remission	119 (57.2)
Ongoing treatment to manage the disease	45 (21.6)
Other	4 (1.9)
Cardiotoxicity risk, n (%)	
High-risk[b]	94 (45.2)
Does not meet high-risk criteria	114 (54.8)

Characteristics	Values
Knowledge of cardiac-related treatment side-effects, n (%)	
A little or not at all	120 (57.7)
Extremely or somewhat knowledgeable	88 (42.3)
Behavioral variables	
GLTEQ[c] score (units), median (IQR)	45.0 (33.3 - 62.0)
Resistance training (sessions per week), median (IQR)	2.0 (1.0 - 4.0)
GLTEQ, n (%)	
Moderately active (<24 units)	14 (6.7)
Active (≥24 units)	194 (93.3)
Resistance training categories, n (%)	
Not meeting guidelines (<2 sessions per week)	117 (56.3)
Meeting guidelines (≥2 sessions per week)	91 (43.8)
Fitness tracker use, n (%)	
No, this does not interest me	16 (7.7)
No, but I would be open to trying	63 (30.3)
Yes, I have used a fitness tracker	129 (62)
Smartphone app use, n (%)	
No, this does not interest me	29 (13.9)
No, but I would be open to trying	92 (44.2)
Yes, I have used a fitness tracker	87 (41.8)

[a] No (n=1); Prefer not to say (n=1).

[b] Participants who had received a treatment associated with cardiotoxicity, had ≥2 risk factors for cardiovascular disease, or self-reported compromised cardiac function (see *Outcomes of Interest* section for additional detail).

[c] GLTEQ: Godin Leisure Time Exercise Questionnaire

Likelihood of Participating in a Digitally Delivered Exercise Rehabilitation Program

Over 80% of participants reported being “extremely” or “quite a bit likely” to participate in a digitally delivered exercise program as part of their cancer treatment and recovery plan. When asked about specific timepoints, the majority of participants (>70%) were interested at any time, but particularly so in the after-treatment period (193/208, 93%) (Table 2).

Table . Likelihood of participating in a digitally delivered exercise rehabilitation program (N=208).

Timepoint	Not at all, n (%)	A little, n (%)	Somewhat, n (%)	Quite a bit, n (%)	Extremely, n (%)
In general – How likely is it that you would participate in a program like this if it was offered to you as part of your cancer treatment and recovery plan?	3 (1.4)	11 (5.3)	23 (11.1)	57 (27.4)	114 (54.8)
Before treatment – Exercising at this stage can help to prepare your body for treatment. It may also help you to stay more active during treatment.	12 (5.8)	14 (6.7)	34 (16.3)	38 (18.3)	110 (52.9)
During treatment – Exercising at this stage can help people to tolerate treatments and maintain quality of life.	6 (2.9)	15 (7.2)	36 (17.3)	68 (32.7)	83 (39.9)
After treatment – Exercising at this stage can help to overcome treatment side-effects, maintain quality of life and reduce risk of other health conditions.	1 (0.5)	2 (1.0)	12 (5.8)	47 (22.6)	146 (70.2)

Characteristics Associated With Likelihood of Participating in a Digitally Delivered Exercise Rehabilitation Program

Results of the bivariate analyses are reported in Table S1 in Multimedia Appendix 2 and associations between demographic and health characteristics are reported in Table S2 in Multimedia Appendix 3. The demographic and health variables included in the final multivariate models were as follows: general uptake (BMI, education, number of cardiotoxic treatments, and location due to its potential theoretical importance in relation to digitally delivered services [age and employment were removed due to collinearity]); before (BMI, location, and education); during (comorbidity index and location [BMI was removed due to collinearity]); and after treatment (BMI, education, and location).

Results of the ordered logistic regression models are presented in Table 3. In the general uptake model, those living in an outer regional area reported higher odds for having a higher likelihood of participating in a digitally delivered exercise rehabilitation program, compared with those living in a major city (OR 4.05; 95% CI 1.04-15.81, *P*=.04). Having been treated with a higher number of cardiotoxic treatments was also associated with higher odds of being in a higher likelihood category (OR 1.42; 95% CI 1.02-1.96, *P*=.04). Whereas a higher BMI and a lower level of education (compared with university education) were associated with lower odds of reporting higher likelihood of uptake.

Table . Associations between participant characteristics and a higher category of likelihood to participate (N=208).

	General		Before		During		After	
	OR[a] (95% CI)	*P* values	OR (95% CI)	*P* values	OR (95% CI)	*P* values	OR (95% CI)	*P* values
BMI	0.95 (0.91-0.99)	.02[b]	0.93 (0.89-0.98)	.003[b]	—[c]	—	0.94 (0.89-0.99)	.01[b]
Cardiotoxic treatments	1.42 (1.02-1.96)	.04[b]	—	—	—	—	—	—
Comorbidity index	—	—	—	—	0.65 (0.50-0.83)[d]	<.001[b]	—	—
Education								
University (n=137)	Ref[e]	Ref	Ref	Ref	—	—	Ref	Ref
Diploma (n=55)	0.37 (0.20-0.69)[d]	.002[b]	0.42 (0.23-0.78)[d]	.005[b]	—	—	0.30 (0.15-0.60)[d]	<.001[b]
High school (n=16)	0.52 (0.19-1.45)[d]	.21	0.48 (0.18-1.27)[d]	.14	—	—	0.38 (0.12-1.14)[d]	.085
Location								
Major city (n=132)	Ref	Ref	Ref	Ref	Ref	Ref	Ref	Ref
Inner regional (n=59)	1.01 (0.56-1.85)	.97	1.08 (0.60-1.98)	.79	0.76 (0.44-1.34)	.35	1.10 (0.55-2.19)	.79
Outer regional (n=17)	4.05 (1.04-15.81)[d]	.04[b]	4.84 (1.29-18.08)[d]	.02[b]	3.86 (1.39-10.73)[d]	.01[b]	8.57 (1.07-68.47)[d]	.04[b]

[a] OR: odds ratio

[b] Statistically significant: *P*<.05.

[c] N/A: not applicable; denotes variables that were not included in the multivariate models (see *Data Analyses* section for variable selection methods).

[d] Clinically relevant: OR<0.67 or >1.5.

[e] Ref: reference category.

Being from an outer regional area was associated with higher odds of reporting a higher likelihood of uptake before, during, and after treatment. However, ORs were not consistent across treatment phases. A higher BMI and a lower level of education (compared with university education) were associated with lower odds of being in a higher likelihood category both before and after treatment. As was a higher number of comorbid conditions during treatment.

Other Intervention Topics of Interest

Participants were interested in a range of other topics to support their recovery or ongoing management of cancer. Table 4 lists interest in each topic, with weight maintenance, sleep, managing fatigue, and diet of interest to ≥50% of the sample. Mindfulness and stress reduction were also popular topics, with over one-third of participants reporting interest.

Table . Participant interest in other intervention topics as part of cancer treatment and recovery (N=208).

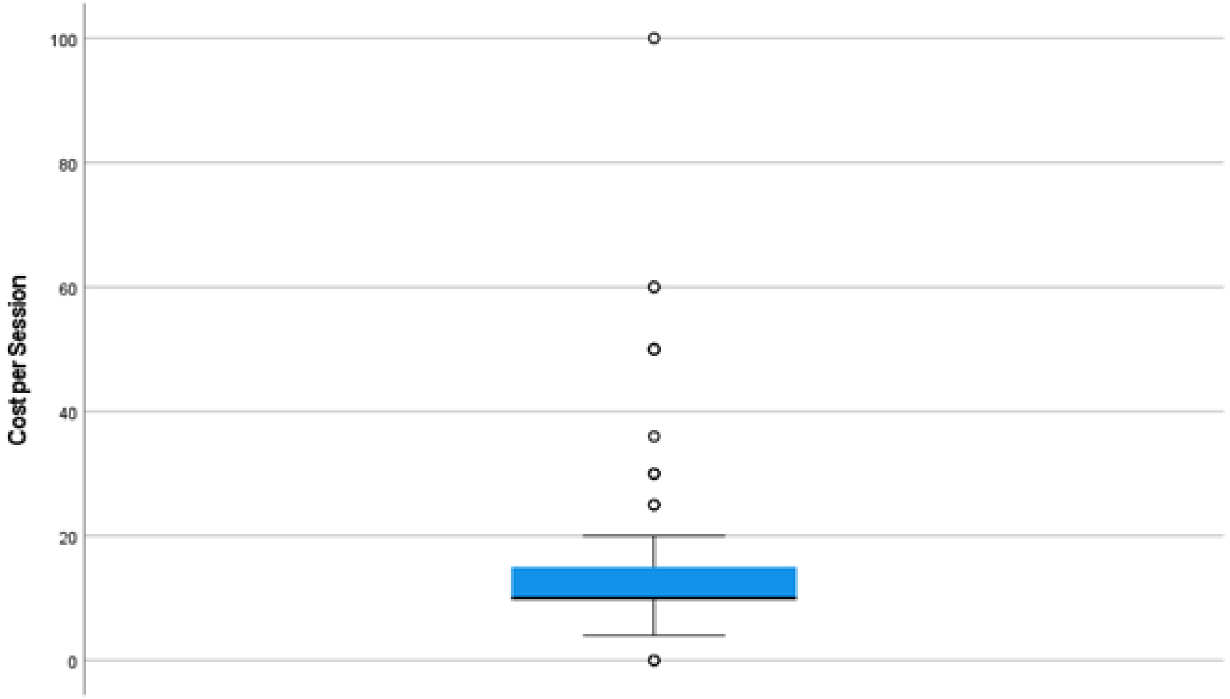
Topic	Values, n (%)
Diet	106 (51)
Weight maintenance	124 (59.6)
Smoking	0 (0)
Alcohol	23 (11.1)
Sleep	113 (54.3)
Falls prevention	18 (8.7)
Medication adherence	7 (3.4)
Stress	87 (41.8)
Memory	60 (28.8)
Managing fatigue	109 (52.4)
Mindfulness	95 (45.7)
Other[a]	18 (8.7)

[a] Other included mental health, lymphoedema massage, pain management, bone density management, self-examination, hot flushes, and chemo brain.

Cost per Session

The distribution of participant responses regarding the amount willing or able to pay for an exercise program per session is displayed in Figure 1. The median amount was Aus $10 (US $6.9) per session (IQR Aus $10 - 15). Few participants (21/208, 10%) could afford or were willing to pay over Aus $25 (US $17.25) per session, with most participants (163/208, 78%) reporting an amount of ≤Aus $15 (≤US $10.35).

Figure 1. Amount willing or able to pay per session for an exercise program (n=206).



Discussion

Principal Findings

This study examined the characteristics of breast cancer survivors associated with the likelihood of uptake of a digitally delivered cardiac exercise rehabilitation intervention. There was a high level of interest in uptake among the majority of participants across the treatment trajectory. There was also some evidence to support that living in an outer regional area and receiving more cardiotoxic treatments increased the likelihood of uptake further. Conversely, there was some evidence to suggest that patients with a higher BMI, more comorbid conditions, and lower education levels may be less likely to uptake the proposed intervention. Further investigation into these factors is critical for the delivery of a digital service model that is both effective and accessible.

The current findings are promising in that they suggest that the majority of breast cancer survivors are interested in uptaking a digitally delivered exercise rehabilitation intervention to improve cardiovascular fitness. This aligns with similar research in the area, with a high proportion of breast cancer survivors having reported an interest in participating in an exercise program or receiving physical activity counseling [30-32]. Breast cancer survivors have also reported high levels of interest (68% - 85%) in technology-supported exercise interventions specifically [16]. However, despite these promising levels of interest, physical activity levels typically decline following breast cancer diagnosis and remain low [33,34], thus suggesting that there is a need to develop intervention strategies and service delivery models that support breast cancer survivors to adopt and maintain regular activity.

The findings of this study provide some suggestions as to which patients (ie, those with a higher BMI, more comorbid conditions, and lower levels of education) may be less likely to uptake the proposed intervention. Recent research examining issues of digital health technology implementation in cancer care suggests that digital literacy may partially explain the current results [25]. Previous research has demonstrated that those with a lower education have lower digital literacy [35], which may impact the ability of this group to effectively engage in a digitally delivered intervention. Efforts to work collaboratively with those who may have lower digital literacy should be made to enhance the service delivery model for these groups, including its uptake, safety, feasibility, and effect [25]. Future research involving co-design processes and consumer involvement might be particularly beneficial for enhancing digital inclusion, which refers to the “access, affordability, usage, skills and relevance of digital technologies to individuals or groups” [25].

These results may also be reflective of general exercise barriers experienced by chronic disease populations (eg, those with risk factors of cardiotoxicity, such as a high BMI) [36]. Specifically, systematic review level evidence suggests that the primary barriers to participating in physical activity among people with a higher BMI include a lack of self-discipline or motivation, pain or discomfort, and a lack of access to equipment [36], all of which would also impact capabilities and resources for participating in a remotely-delivered intervention. Similarly, the presence of comorbidities has been identified as a barrier to physical activity among multiple cancer populations [37-39]. As such, the findings of the current study may be reflective of general barriers in this population, and so engagement with a digital intervention needs to address these barriers. This may be of particular importance among long-term breast cancer survivors, as a higher BMI and comorbidities such as high cholesterol, high blood pressure, diabetes, and previous cardiovascular disease are among the main risk factors for cardiotoxicity [40-42].

The secondary aim of this study was to evaluate other aspects of intervention delivery that would be useful for informing exercise oncology interventions among breast cancer survivors more broadly. Overall, the findings suggest the need for (1) multifaceted rehabilitation interventions that address multiple health behaviors (ie, diet and sleep as well as exercise), as well as mental health and symptom management, (2) better education for patients about potential cardiotoxic effects of treatment, and (3) interventions that are free or low cost for patients. Our findings relating to the need for multifaceted rehabilitation interventions mirror others [43]. In particular, the need for rehabilitation services to include multidisciplinary care that addresses not only physical well-being, but nutritional and psychological well-being and managing post-treatment challenges (eg, fatigue), as well as education regarding the potential heart-related side-effects of treatment [43].

Our findings in relation to service fees are novel, particularly considering the current chronic disease management plan in Australia and the affordability of private sessions. In Australia, the Chronic Disease Management initiative offers 5 government-rebated sessions with an allied health professional each year [44]. However, the current rebate (85% of the minimum service fee of ≈Aus $60 [≈US $41.4] [45,46]) leaves a payment gap above what has been reported as an acceptable cost per session by the current sample. Further, previous research suggests that those who are arguably the most disadvantaged (ie, those with a health care card or from a low socioeconomic or non-English speaking background) are less likely to be referred to physiotherapy services [47] and report being unable or unwilling to cover the payment gap attached to accessing allied health services [48,49]. In addition to continued advocacy at a government level to generate policies and funding models that support these services for people with chronic conditions, future research should aim to develop and evaluate service models that can provide effective, affordable, and equitable access to allied health services.

Limitations

Several limitations should be considered alongside the results of the present analysis. First, the survey items posed to participants regarding their likelihood of uptake referred to their hypothetical interest and participation in digitally delivered cardiac exercise rehabilitation. As such, participant responses and findings of this analysis may or may not reflect real-life uptake. The cross-sectional design also precludes the exploration of longitudinal trajectories of the likelihood of uptake, and characteristics that may impact such trajectories. Additionally, considering that over half the sample had completed treatment at the time of the survey, items relating to participation pre- and during-treatment were collected retrospectively and as such, may be impacted by recall bias. The sample was also highly active (no sedentary participants and few insufficiently active), which may have biased the results and contributed to the high likelihood ratings across the cancer continuum and may not be representative of the broader breast cancer population. The recruitment strategy (web-based advertising) and study research questions resulted in it being more likely to appeal to women who were already active or who valued exercise. Web-based recruitment also limited participation to those with internet access (possibly excluding remote participants in areas without internet access) and those with sufficient digital literacy to complete a web-based survey (possibly excluding those who would be unable or unwilling to engage in digital services). This is of particular importance considering that the likelihood of participating in digital interventions was the primary outcome. Despite these limitations, a key strength of this analysis is its novelty in addressing the major service delivery challenges that have been observed in the cardiac rehabilitation setting, prior to developing an exercise rehabilitation intervention for cardiotoxicity following breast cancer treatment. Participants were also representative of the Australian breast cancer population in terms of age, geographical location, marital status, and health-related variables (eg, BMI) [50,51]. Further, this study investigated preferences regarding multidisciplinary rehabilitation topics and cost.

Findings from this research highlight several areas that warrant future investigation. Specifically, future research should explore the likelihood of uptake among a sample of sedentary or insufficiently active breast cancer survivors. This could provide valuable insight from those who potentially face the greatest barriers to exercise participation, as well as inform the development of more acceptable digital interventions. Additionally, findings suggest that patients with risk factors for cardiotoxicity (ie, those with a higher BMI and more comorbid conditions) may be less likely to uptake a digital exercise intervention. It would be of interest to investigate the likelihood of uptake for in-person programs in this subsample, to determine whether this is a delivery model issue or a more general exercise experience, and subsequently, what could a delivery model offer that would increase the likelihood of uptake.

Conclusion

The findings of this study provide valuable knowledge regarding factors that influence the likelihood of uptake of a digitally delivered cardiac exercise rehabilitation intervention. These findings can inform future research and the development of intervention techniques that are critical to improving the delivery of a digital service model that is effective, equitable, and accessible to those at risk of cardiotoxicity following breast cancer treatment. Specifically, future research should aim to (1) enhance digital inclusion by collaboratively developing interventions that can be effectively engaged with by those who have lower digital literacy, (2) enhance engagement through the inclusion of techniques that address general barriers experienced by chronic disease populations, (3) incorporate multidisciplinary intervention topics that address multiple health behaviors, and (4) develop and evaluate the affordability of digital service delivery models.

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Authors' Contributions

TJ was responsible for formal analysis, writing the original draft, creating visualizations, and project administration. LE, JCR, LD, SH, RM, ALS, and BK contributed to the methodology and reviewed and edited the manuscript. NK also participated in the methodology and manuscript review process. CES oversaw the conceptualization of the study, contributed to the original draft, and provided supervision.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Supplementary Document 1.
[DOCX File, 244 KB - cancer_v10i1e51536_app1.docx]

Multimedia Appendix 2
Supplementary Table 1.
[DOCX File, 22 KB - cancer_v10i1e51536_app2.docx]

Multimedia Appendix 3
Supplementary Table 2.
[DOCX File, 23 KB - cancer_v10i1e51536_app3.docx]

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Abbreviations

GLTEQ: Godin Leisure Time Exercise Questionnaire
HER-2: human epidermal growth factor receptor 2
OR: odds ratio

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Original Paper

Iterative Patient Testing of a Stimuli-Responsive Swallowing Activity Sensor to Promote Extended User Engagement During the First Year After Radiation: Multiphase Remote and In-Person Observational Cohort Study

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Abstract

Background: Frequent sensor-assisted monitoring of changes in swallowing function may help improve detection of radiation-associated dysphagia before it becomes permanent. While our group has prototyped an epidermal strain/surface electromyography sensor that can detect minute changes in swallowing muscle movement, it is unknown whether patients with head and neck cancer would be willing to wear such a device at home after radiation for several months.

Objective: We iteratively assessed patients’ design preferences and perceived barriers to long-term use of the prototype sensor.

Methods: In study 1 (questionnaire only), survivors of pharyngeal cancer who were 3-5 years post treatment and part of a larger prospective study were asked their design preferences for a hypothetical throat sensor and rated their willingness to use the sensor at home during the first year after radiation. In studies 2 and 3 (iterative user testing), patients with and survivors of head and neck cancer attending visits at MD Anderson’s Head and Neck Cancer Center were recruited for two rounds of on-throat testing with prototype sensors while completing a series of swallowing tasks. Afterward, participants were asked about their willingness to use the sensor during the first year post radiation. In study 2, patients also rated the sensor’s ease of use and comfort, whereas in study 3, preferences were elicited regarding haptic feedback.

Results: The majority of respondents in study 1 (116/138, 84%) were willing to wear the sensor 9 months after radiation, and participant willingness rates were similar in studies 2 (10/14, 71.4%) and 3 (12/14, 85.7%). The most prevalent reasons for participants’ unwillingness to wear the sensor were 9 months being excessive, unwanted increase in responsibility, and feeling self-conscious. Across all three studies, the sensor’s ability to detect developing dysphagia increased willingness the most compared to its appearance and ability to increase adherence to preventive speech pathology exercises. Direct haptic signaling was also rated highly, especially to indicate correct sensor placement and swallowing exercise performance.

Conclusions: Patients and survivors were receptive to the idea of wearing a personalized risk sensor for an extended period during the first year after radiation, although this may have been limited to well-educated non-Hispanic participants. A significant minority of patients expressed concern with various aspects of the sensor's burden and its appearance.

Trial Registration: ClinicalTrials.gov NCT03010150; https://clinicaltrials.gov/study/NCT03010150

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KEYWORDS

user-centered design; patients with head and neck cancer; dysphagia throat sensor

Introduction

Background

In 2021, approximately 32,000 Americans developed laryngeal or pharyngeal cancer, which has a 5-year survival rate of 61% for all stages combined [1]. Management of these cancers often includes high-dose intensity-modulated radiation therapy (IMRT) designed to spare pharyngeal muscles and reduce the incidence of radiation-associated dysphagia (swallowing difficulty) [2]. Still, a range of studies have reported that roughly 60% of patients receiving IMRT developed long-term swallowing problems within 2 years after radiation had ended, ranging in intensity from inability to swallow solid food without compensatory strategies to being completely feeding tube dependent [3-10].

As with most chronic conditions, early detection and intensive swallowing therapies are key to preventing long-term dysphagia [11-26], especially if patients are adherent to swallowing therapy instructions [27]. However, noninvasive screening procedures for early detection of radiation-associated fibrosis do not yet exist in the United States. Instead, gold standard modified barium swallow (MBS) and fiberoptic endoscopic evaluation of swallowing tests are typically ordered after the patient begins to complain of difficulties with swallowing [12]. Furthermore, preventive swallowing therapies are not always prescribed prior to the development of radiation-associated dysphagia [28-30]. Unfortunately, once radiation-associated dysphagia is clinically detected, there is little hope of fully restoring normal function [11,31,32].

To detect radiation-associated dysphagia before it becomes permanent, it is necessary to monitor changes in swallowing function much more frequently than is currently possible in the clinical setting. Subclinical change in swallowing activity or risk for dysphagia could be assessed during standard cancer surveillance visits, but increasing the periodicity of these visits would increase patient burden by requiring more frequent travel to the medical center for swallowing imaging and tests. Frequent at-home monitoring with wearable sensors between scheduled surveillance visits could address this gap in monitoring, especially if the sensors were designed to support decision-making regarding initiation of intensive speech language therapies [33]. To this end, researchers have developed myriad devices that can be worn on the skin and measure a range of mechanical, optical, biochemical, electrical, or acoustic signals with high fidelity [34-39].

However, sensor performance alone is not sufficient for improving health outcomes as patient engagement is also important [40]. Within the specific context of preventing dysphagia in survivors of head and neck cancer, repeated at-home monitoring over a period of months if not years is necessary to demonstrate a clinical advantage over current treatment paradigms. Unfortunately, most mobile technologies fail to engage patients over sustained durations, with most mobile health (mHealth) interventions for chronic disease reporting steep declines in use, some as high as 95% within the first few weeks, depending on the technology and context [41-43]. The most frequently cited reasons for discontinued use are decreased interest in the technology after its novelty abates, perceived lack of usefulness relative to burden, poor implementation of user experience, and frustration with technical issues [44-47].

To counter these barriers, it is widely agreed that user-centered testing be conducted in a sustained and iterative fashion during the design and development of new health technology. User-centered testing assesses the human technology interface by evaluating how well the technology incorporates into end users' daily routines, habits, and capabilities, known loosely as user acceptability [40,48]. Beyond acceptability, technologies should be designed to maximize their potential to effect changes in patients' attitudes and health behaviors. Oinas-Kukkonen and Harjumaa's [49] persuasive system design model describes four categories of persuasive design principles that optimize the likelihood of health behavior change: task support (personalized design features that make it easier for users to achieve their goals), social support (leveraging interpersonal learning, eg, via online community forums), dialogue support (providing feedback to the user in a manner that helps the user move toward their goal, eg, with praise and rewards), and system credibility (the perceived clinical expertise embedded within the sensor output) [49]. Relatively few mHealth interventions conduct user-centered testing during technology development, which may be one reason for diminishing patient engagement and eventual abandonment [50-53]. In the US market, the user abandonment rate of fitness trackers is 50% within 6-12 months [44,54]. Patient abandonment rates are higher for those 70 years and older; one study found that 43% of their sample had abandoned their sleep and activity trackers within the first 2 weeks of use [55].

A recent review of 51 mHealth intervention studies targeting chronic diabetes, cardiovascular, or pulmonary diseases noted that diminished patient engagement was prevalent and posed a significant threat to effective use of the technology. Accordingly, nonsignificant effects on clinical markers outweighed significant findings two-to-one [42]. Therefore, our study explicitly addressed the design of a wearable sensor with the future intended use of home-based assessment for 9 months, starting with the third month after radiation to the 12th month. All design preferences and opinions were solicited within the context of sustaining engagement with the sensor for 9 months during the first year since repeated measurements over time would be needed to detect patterns of developing dysphagia in posttreatment patients.

Goal of This Study

We assessed patient needs and preferred characteristics regarding the design of a wearable sensor to deliver personalized risk of dysphagia. Specifically, we assessed perceived barriers to wearing the sensor for 9 months, starting from the third month after the end of radiation treatment (to allow for healing from radiation skin burn) until the 12th month post treatment, and the impact of proposed design features on willingness to wear the sensor. In the first of three iterative user-centered tests, we surveyed a large cohort of survivors of head and neck cancer who were 4-5 years past radiation treatment to assess the perceived need for the sensor and desired design features for future prototypes. In study 2, we assessed user acceptability for a wired prototype sensor within a small sample of long-term survivors, oversampled for radiation-associated dysphagia. Finally, in the third user test, we tested a revised prototype on a sample of patients with head and neck cancer undergoing active treatment to get a better sense of competing priorities during a fraught time in their lives. The revised prototype included more elastic and comfortable materials for the strain sensor and custom-made dry electromyography (EMG) sensors, as opposed to commercial sensors. During the third test, we repeated our questions about user acceptability and willingness to wear the sensor for 9 months, as well as new questions about bidirectional feedback in the form of haptic (vibration) signaling.

Methods

Study 1

Design and Eligibility

Survivors of head and neck cancer who were still alive and who were already enrolled in a psychosocial parent study were asked to answer a questionnaire about a hypothetical throat sensor. Men and women were eligible for the parent study if they had received radiation with curative intent for oropharyngeal (stage II-IVb), laryngeal (II-IVb), hypopharyngeal (I-IVb), or nasopharyngeal cancer (I-IVb), or an unknown primary cancer with cervical metastases; were at least 2 years post treatment; were 18 years or older; and spoke English. Men and women were excluded if they had treatment for previous head and neck cancer; a history of previous head and neck surgery (previous biopsy, tonsillectomy, or tracheotomy were allowed); other cancer diagnoses, except nonmelanoma skin cancer; or a history of current oropharyngeal dysphagia unrelated to cancer diagnosis (eg, dysphagia due to underlying neurogenic disorder).

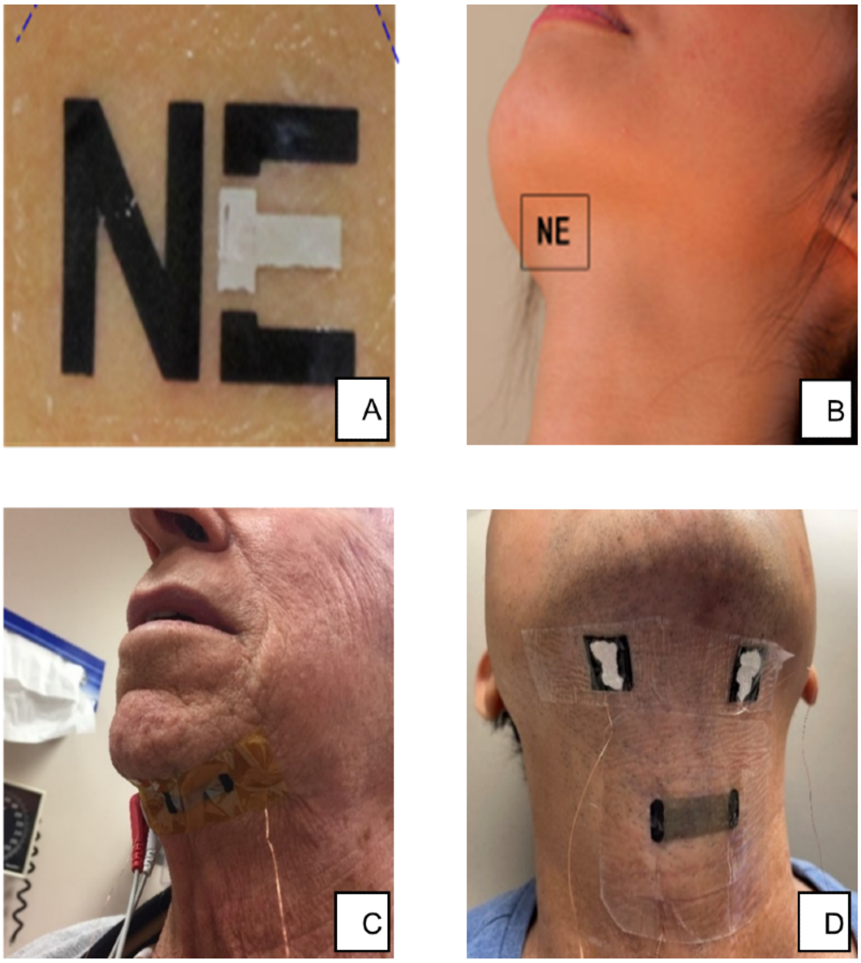
Recruitment and Data Collection Procedures

For the psychosocial parent study, all eligible patients were approached for recruitment at the radiation clinic's radiation education class after being identified at the weekly multidisciplinary tumor board conference. The accrual rate for entry into the original parent study was 77%; demographic and disease information was collected at baseline. Those patients who were already enrolled in the psychosocial parent study and still alive (n=234) were contacted by phone to determine if they would answer optional questions about a hypothetical sensor to be worn on the throat. Patients who did not return calls after 5 attempts or did not have working phone numbers were not approached further for enrollment into study 1. After obtaining informed consent, participants completed the optional questionnaire administered either by REDCap, telephone, or mail at a single time point [56]. For mailed questionnaires, a research staff's phone number was provided if the patient had any questions about the questionnaire.

Measures

Demographic information regarding age, race/ethnicity, employment, income, and marital status were obtained by questionnaire. Disease stage was abstracted from the medical record. Participants then completed a questionnaire. The first page of the questionnaire showed a photograph of the proposed sensor (Figure 1A) and a diagram of the sensor's placement on the neck (Figure 1B), a brief description of the sensor's purpose, and the proposed timeline of wearing the sensor every weekend from the third month post radiation to the 12th month post radiation for a total of 9 months.

Figure 1. Appearance of the hypothetical and actual sensor prototypes. (A) Study 1 respondents were shown a photograph of the proposed sensor and (B) its proposed location on the neck. (C) Study 2's graphene strain sensor prototype, supported on 13-μm-thick polyimide tape (the contact surface is silicone) and placed on the submental region probing muscle contraction. (D) Study 3's soft polymer strain sensor, now placed under the laryngeal prominence to capture movement during swallowing.



Main Outcome: Willingness to Wear the Sensor

For studies 1-3, the study questionnaire asked whether the patient would have been willing to wear the sensor for 9 months during the first year after radiation, starting in month 3 post treatment. This time point was asked about since it would give sufficient time for the skin on their neck to have healed from radiation skin burn. Participants were then asked whether they would have been willing to wear the sensor for the entire 9 months, every other week, or every weekend during the 9-month period, and then a series of branched logic true-false questions about reasons for willingness versus unwillingness to wear the sensor. Next, using a 3-point Likert scale response format, all participants rated whether changes in the sensor design (either unobtrusive appearance or the ability to receive feedback about risk for dysphagia) would change the individual's willingness or unwillingness to wear the sensor every weekend for 9 months. Additional comments or suggestions were also solicited as free text.

Study 2

Design and Eligibility

A second sample of survivors of head and neck cancer who were 2 to 10 years post radiation and attending surveillance visits at MD Anderson gave informed consent and enrolled into the study during a 1-week period; testing was constrained to a 1-week period in which visiting graduate engineering students from the University of California San Diego traveled to MD Anderson for on-patient equipment testing. The eligibility criteria for study 2 were the same as for study 1; however, we oversampled for patients with a Dynamic Imaging Grade of Swallowing Toxicity score >0, indicating radiation-associated dysphagia that had been verified with MBS [57]. The oversampling was done to gauge the accuracy of the prototype sensor in distinguishing between dysphagic survivors and survivors without dysphagia [58]. For every dysphagic participant, we recruited a nondysphagic patient matched for age and sex. For patients who declined participation, deidentified disease information, demographics, and reason for refusal were noted in the study record.

Procedure and Assessment

A wired prototype graphene strain sensor coupled with a wired surface EMG sensor was placed on the patient to obtain muscle movement measurements during a series of swallowing tasks of various bolus textures, as described previously (Figure 1C) [58]. Immediately after the on-throat sensor test, patients were asked to answer six questions about the sensor's discomfort, ease of use, and associated embarrassment using a 5-point Likert scale ranging from strongly disagree to strongly agree. Patients were again asked whether they would be willing to wear the sensor for 9 months (but now for once a month on the weekends) with branching questions asking for reasons for willingness versus unwillingness. Patients were again asked to rate the impact of sensor unobtrusiveness and predictive dysphagic feedback on willingness to wear the sensor for extended periods. Finally, demographic information regarding age, race, and marital status were abstracted from the medical record. All testing sessions were conducted at the Head and Neck Cancer Center at MD Anderson.

Study 3

Design and Eligibility

Similar eligibility, consent, and testing procedures were used in study 3. However, eligible patients were more likely to be approached during active treatment for throat cancer, whereas studies 1 and 2 recruited long-term survivors. Study 3's sensor (Figure 1D) was revised to have better skin conformation and comfort; standard surface EMG electrodes were now replaced with flexible custom dry electrodes, whereas the strain sensor was supported on a silicon substrate [59].

Assessment Procedures

After completion of the on-throat sensor test, patients were also asked the same questions used in study 1 regarding willingness to wear the sensor for 9 months and whether changes in the sensor's appearance and feedback capability would change their minds about their willingness to wear the sensor. In addition, participants were interviewed regarding the helpfulness of future capability of the sensor itself to give immediate haptic feedback in three different scenarios: to indicate correct placement of the sensor, to indicate correct performance of a particular swallowing exercise, and to indicate quality of swallowing during at-home testing of various bolus textures. Their answers were transcribed, categorized, and coded into three categories (0: not helpful; 1: helpful under certain conditions; 2: helpful).

Analysis

Descriptive statistics (eg, proportions, means, ranges, and SDs) were computed for the process evaluation and participant satisfaction data, together with 95% CIs. To assess the external validity of the study, demographic and disease information was compared between respondents and nonrespondents in study 1 (Table 1) and between participants and refusers in studies 2 and 3 (data not shown; available data for participants in studies 2 and 3 is shown in Table 2). All questionnaire responses were analyzed with SPSS (version 26; IBM Corp).

Table 1. Demographic/disease comparisons between willing and unwilling participants (study 1).

Characteristic	Potentially eligible survivors (from parent study)				Survivors who completed the questionnaire			
	Total (N=234)	Nonrespondent (did not participate)	Respondent	*P* value	Total (n=138)	Willing to wear for 9 mo	Unwilling	*P* value
What is your age? (years)				.28				.15
Participants, n (%)	234	96 (41.0)	138 (58.9)		138	22 (15.9)	116 (84.1)	
Mean (SD)	57.4 (10.0)	56.6 (9.8)	58 (10.1)		58 (10.1)	55.2 (9.4)	58.5 (10.1)	
Median (min-max)	58 (18-83)	56 (30-79)	59 (18-83)		59 (18-83)	56.5 (35-75)	59 (18-83)	
What is your ethnic background? n (%)				.003				.59
Hispanic or Latino	21 (9.1)	15 (16.0)	6 (4.4)		6 (4.4)	0 (0.0)	6 (5.2)	
Not Hispanic or Latino	210 (90.9)	79 (84.0)	131 (95.6)		131 (95.6)	22 (100.0)	109 (94.8)	
Race, n (%)				.23				.53
African American	10 (4.3)	6 (6.4)	4 (2.9)		4 (2.9)	1 (4.5)	3 (2.6)	
American Indian or Alaska Native	1 (0.4)	1 (1.1)	0 (0.0)		0 (0.0)	0 (0.0)	0 (0.0)	
Asian	6 (2.6)	1 (1.1)	5 (3.64)		5 (3.6)	1 (4.5)	4 (3.5)	
Native Hawaiian or Pacific Islander	1 (0.4)	0 (0.0)	1 (0.7)		1 (0.7)	0 (0.0)	1 (0.9)	
Non-Hispanic White	213 (92.2)	86 (91.5)	127 (92.7)		127 (92.7)	20 (90.9)	107 (93.0)	
Education, n (%)				.02				.26
Some college and lower	112 (48.9)	54 (58.1)	58 (42.6)		58 (42.6)	7 (31.8)	51 (44.7)	
Bachelor’s degree or higher	117 (51.1)	39 (41.9)	78 (57.4)		78 (57.4)	15 (68.2)	63 (55.3)	
Employment status, n (%)				.60				.18
Full-time/part-time	145 (63.3)	57 (61.3)	88 (64.7)		88 (64.7)	17 (77.3)	71 (62.3)	
Not employed	84 (36.7)	36 (38.7)	48 (35.3)		48 (35.3)	5 (22.7)	43 (37.7)	
Marital status, n (%)				.50				>.99
Single living alone/married but living apart/separated/divorced/widow	46 (20.0)	21 (22.1)	25 (18.5)		25 (18.5)	4 (18.2)	21 (18.6)	
Single but living with significant other/married living with spouse	184 (80.0)	74 (77.9)	110 (81.5)		110 (81.5)	18 (81.8)	92 (81.4)	
Occupation, n (%)				.07				.54
Professional/managerial	143 (71.9)	51 (63.0)	92 (78.0)		92 (78.0)	16 (88.9)	76 (76.0)	
Retail/service/labor	44 (22.1)	24 (29.6)	20 (16.9)		20 (16.9)	2 (11.1)	18 (18.0)	
Student/unemployed	12 (6.0)	6 (7.4)	6 (5.1)		6 (5.1)	0 (0.0)	6 (6.0)	
What is your income before taxes? (US $), n (%)				.007				.22
<30,000	38 (18.9)	24 (30.4)	14 (11.5)		14 (11.5)	0 (0.0)	14 (13.6)	
30,000-50,000	31 (15.4)	13 (16.5)	18 (14.8)		18 (14.8)	2 (10.5)	16 (15.5)	
50,000-75,000	28 (13.9)	9 (11.4)	19 (15.6)		19 (15.6)	2 (10.5)	17 (16.5)	
>75,000	104 (51.7)	33 (41.8)	71 (58.2)		71 (58.2)	15 (78.9)	56 (54.4)	
Stage of disease, n (%)				.24				.70
Stages I or II	76 (32.5)	27 (28.1)	49 (35.5)		49 (35.5)	7 (31.8)	42 (36.2)	
Stages III or IV	158 (67.5)	69 (71.9)	89 (64.5)		89 (64.5)	15 (68.2)	74 (63.8)	

Table 2. Demographic/disease comparisons between willing and unwilling participants (studies 2 and 3).

Characteristic	Study 2				Study 3			
	Total sample (n=14)	Willing to wear for 9 mo (n=10)	Unwilling (n=4)	*P* value	Total sample (n=14)	Willing to wear for 9 mo (n=12)	Unwilling (n=2)	*P* value
Age (years), mean (SD)	61.6 (11.5)	61.2 (12.3)	62.8 (11.0)	.83	62.4 (12.3)	61.0 (11.9)	70.5 (16.3)	.33
Race, n (%)				.55				.57
African American	0 (0)	0 (0)	0 (0)		0 (0)	0 (0)	0 (0)	
American Indian or Alaskan Native	0 (0)	0 (0)	0 (0)		0 (0)	0 (0)	0 (0)	
Asian	0 (0)	0 (0)	0 (0)		2 (14)	2 (17)	0 (0)	
Native Hawaiian or Pacific Islander	0 (0)	0 (0)	0 (0)		0 (0)	0 (0)	0 (0)	
Non-Hispanic White	13 (92.9)	9 (90)	4 (100)		12 (86)	10 (83)	2 (100)	
More than one race	1 (7.1)	1 (10)	0 (0)		0 (0)	0 (0)	0 (0)	
What is your ethnic background? n (%)				.85				.70
Hispanic or Latino	3 (21.4)	2 (20)	1 (25)		1 (7)	1 (8)	0 (0)	
Not Hispanic or Latino	11 (78.6)	8 (80)	3 (75)		13 (93)	11 (92)	2 (100)	
Occupation, n (%)				.52				.87
Managerial/professional	2 (14)	2 (20)	0 (0)		7 (50)	6 (50)	1 (50)	
Retail, service, operator	9 (64)	6 (60)	3 (75)		6 (43)	5 (42)	1 (50)	
Student or unemployed	3 (21)	2 (20)	1 (25)		1 (7)	1 (8)	0 (0)	
Marital status, n (%)				.37				.01
Married/living with significant other	12 (86)	8 (80)	4 (100)		12 (86)	12 (100)	0 (0)	
Single/divorced/widowed/separated	2 (14)	2 (20)	0 (0)		2 (14)	1 (50)	1 (50)	
Dysphagic status, n (%)	14			.27				
Dysphagic (DIGEST[a]>0)	7 (50)	5 (50)	2 (50)	>.99	7 (50)	6 (50)	1 (50)	>.99
Not dysphagic (DIGEST=0)	7 (50)	5 (50)	2 (50)	N/A[b]	7 (50)	6 (50)	1 (50)	N/A
Disease stage, n (%)				.14				.70
I-II	1 (8)	0 (0)	1 (25)		1 (7)	1 (8)	0 (0)	
III-IV	12 (92)	9 (90)	3 (75)		13 (93)	11 (92)	2 (100)	

[a] DIGEST: Dynamic Imaging Grade of Swallowing Toxicity.

[b] N/A: not applicable.

Ethical Considerations

All study materials and procedures were approved by the institutional review board at MD Anderson Cancer Center's institutional review board (protocol 2016-0597). All enrolled participants signed informed consent forms before testing began. All study data were deidentified, and no compensation was provided for participation.

Results

Overview

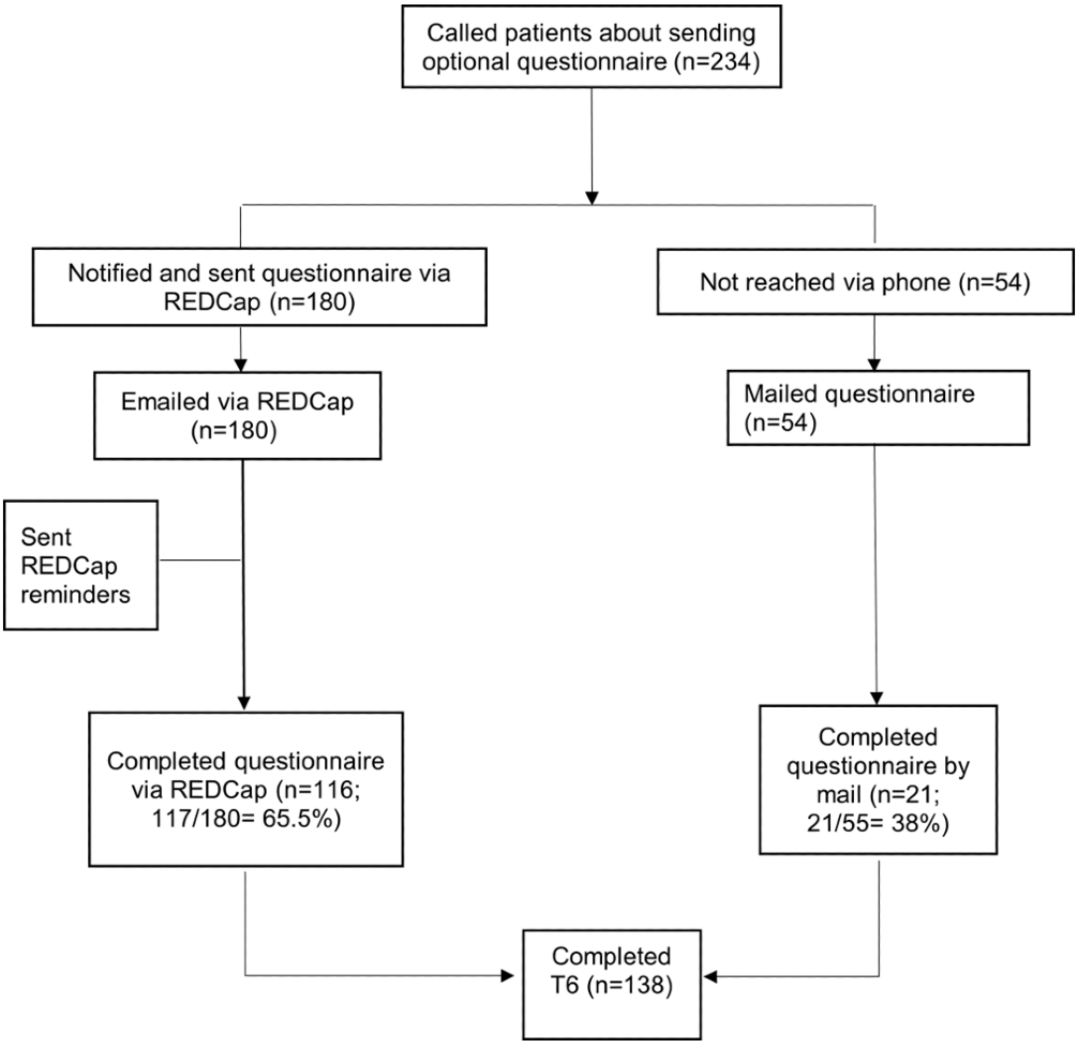
Prior to patient user testing, our study incorporated design input from multiple disciplines, including behavioral scientists, speech pathologists, radiation oncologists, and engineers. Initially, our primary concerns were to develop a wearable device that would not injure skin sensitized by radiation and have an uncomplicated application and removal procedure. Various invasive sensors, such as those worn inside the mouth, were dropped from consideration after it was realized that patients would possibly need to use the device during radiation and later at home during the first year post treatment. During study 1, we gathered patient reactions to a photograph of a sensor (Figure 1), whereas in studies 2 and 3, prototype versions were tested on survivors and patients in the clinic (Figure 1). The racial breakdown of the overall study sample (N=234) was non-Hispanic White (n=213, 92.2%), African American (n=10, 4.3%), Asian American (n=6, 2.6%), American Indian/Alaska

Native (n=1, 0.4%), and Native Hawaiian/Pacific Islander (n=1, 0.4%).

Study 1

Research staff contacted 234 eligible participants to complete study 1's questionnaire, either via REDCap or by mail; 138 (59%) participants completed the questionnaire (Figure 2). Participants in study 1 were primarily non-Hispanic White and married, and their mean age was 57.4 (SD 10) years (Table 1). Median time since end of radiation treatment was 4 years and 26 days (Table 1). Analyses of responders versus nonresponders showed that responders were more likely to be non-Hispanic, have a bachelor's degree, and have higher annual income; differences in race, age, and disease stage were not significantly different (Table 1).

Figure 2. Recruitment CONSORT (Consolidated Standards of Reporting Trials) for study 1 (n=138).



Survivor Preferences for Wearable Throat Sensor

Of the 138 respondents, 115 (83.3%) agreed that they would have been willing to wear the sensor for 9 months during the first year after radiation. However, patients were not willing to wear the sensor during the workweek due to fear of coworkers or strangers asking about the sensor. Instead, they were willing to wear the sensor on weekends, but only for one weekend a month as opposed to every weekend. When presented with several potential reasons explaining their willingness to wear the sensor, nearly all participants cited altruism, whereas 88% (92/105) cited interest in the sensor technology and 77% (75/97) thought that the sensor would help them adhere to their preventive swallowing exercises (Table 3). For example, several patients commented that the personalized feedback from the sensor would provide additional motivation to adhere to their preventive swallowing exercises:

> *It would push me to do my exercises diligently...*
>
> *It would get me on the ball and do my exercises more often...*
>
> *It would give me the information I can use to fight back the scar tissue problem. And see the importance of my neck exercises.*

Table 3. Studies 1-3: Number of patients endorsing reasons for willingness/unwillingness to wear the sensor every weekend for 9 months.

Reasons for willingness/unwillingness to wear the sensor for 9 months[a]	Would wear sensor, n (%)		Would not wear sensor, n (%)	
	True	False	True	False
Study 1 (n=138)[b]				
The technology of the patch sounds interesting.	92 (87.6)	13 (12.4)	—[c]	—
Wearing the patch would have reminded me to do my swallowing exercises.	75 (77.3)	22 (22.7)	—	—
I wanted to help with MD Anderson's research.	108 (99.1)	1 (0.9)	—	—
My skin was still sensitive during that time.	—	—	11 (50)	11 (50)
I wouldn't want to put on and take off the patch every weekend.	—	—	14 (63.6)	8 (36.4)
I wouldn't want to wear the patch for 9 months.	—	—	19 (86.4)	3 (13.6)
I would feel uncomfortable if people noticed the patch and ask me questions or wanted to talk about it.	—	—	12 (57.1)	9 (42.9)
I was being asked to participate in too many studies.	—	—	1 (5.3)	18 (94.7)
It would have added to my daily responsibilities.	—	—	11 (55.0)	9 (45.0)
It would have been a reminder of my cancer treatment.	—	—	6 (30.0)	14 (70)
I would not be able to see my data from the patch.	—	—	6 (28.6)	14 (71.4)
Study 2 (n=14)[d]				
The technology of the patch sounds interesting.	8 (80)	2 (20)	—	—
Wearing the patch would have reminded me to do my swallowing exercises.	10 (100)	0 (0)	—	—
I wanted to help with MD Anderson's research.	10 (100)	0 (0)	—	—
My skin was still sensitive during that time.	—	—	1 (25)	3 (75)
I wouldn't want to put on and take off the patch every weekend.	—	—	2 (50)	2 (50)
I wouldn't want to wear the patch for 9 months.	—	—	4 (100)	0 (0)
I would feel uncomfortable if people noticed the patch and ask me questions or wanted to talk about it.	—	—	2 (50)	2 (50)
I was being asked to participate in too many studies.	—	—	0 (0)	4 (100)
It would have added to my daily responsibilities.	—	—	3 (75)	1 (25)
It would have been a reminder of my cancer treatment.	—	—	1 (25)	3 (75)
I would not be able to see my data from the patch.	—	—	0 (0)	4 (100)
Study 3 (n=14)[e]				
The technology of the patch sounds interesting.	12 (100)	0 (0)	—	—
Wearing the patch would have reminded me to do my swallowing exercises.	12 (100)	0 (0)	—	—
I wanted to help with MD Anderson's research.	12 (100)	0 (0)	—	—
My skin was still sensitive during that time.	—	—	0 (0)	2 (100)
I wouldn't want to put on and take off the patch every weekend.	—	—	0 (0)	2 (100)
I wouldn't want to wear the patch for 9 months.	—	—	1 (50)	1 (50)
I would feel uncomfortable if people noticed the patch and ask me questions or wanted to talk about it.	—	—	1 (50)	1 (50)
I was being asked to participate in too many studies.	—	—	0 (0)	2 (100)
It would have added to my daily responsibilities.	—	—	2 (100)	0 (0)
It would have been a reminder of my cancer treatment.	—	—	0 (0)	2 (100)
I would not be able to see my data from the patch.	—	—	0 (0)	2 (100)

[a] Participants were asked the following question "Which of the following reasons would motivate you to wear the sensor every weekend for 9 months after radiation?"

[b] In study 1, 155 (83.5%) participants indicated that they would wear the sensor, while 23 (16.5%) participants indicated that they would not wear it.

[c] Not applicable.

[d] In study 2, 10 (71.4%) participants indicated that they would wear the sensor, while 4 (28.5%) participants indicated that they would not wear it.

[e] In study 3, 12 (85.7%) participants indicated that they would wear the sensor, while 2 (14.3%) participants indicated that they would not wear it.

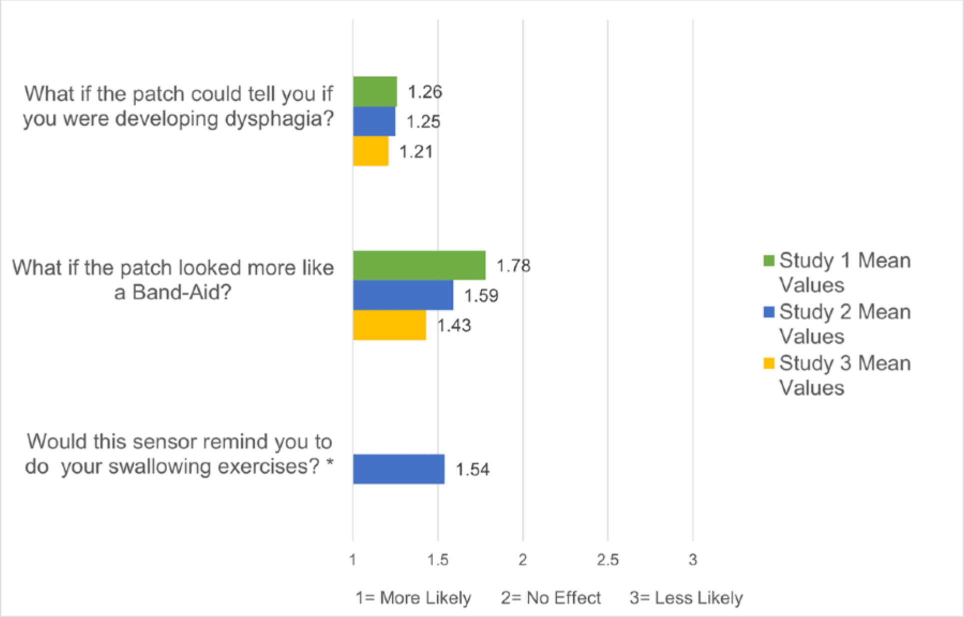
Others valued the additional information that the sensor would provide:

> *I would be curious to know what is going on with my body...*
>
> *I would have liked to have known what was happening to my throat...*
>
> *It's my neck! Why wouldn't I want to know?*

Among the 22 participants who indicated that they would have been unwilling to wear the sensor, nearly 90% (24/28, 85.7%) of all unwilling participants cited the lengthy duration of having to wear the sensor and 57% (16/28) disliked the idea of having to wear the sensor every weekend. The photograph of the proposed sensor had large black letters embedded within the sensor (Figure 1) to contain its wiring; over half of the unwilling participants objected to the sensor being noticeable enough that others would want to ask questions about its purpose. Just under one-third of unwilling participants disliked the idea of being reminded of their cancer treatment during the first year after radiation (Table 3). Participants who were unwilling to wear the sensor for 9 months did not have any significant demographic or clinical differences compared to participants who expressed willingness to wear the sensor. When asked whether changing the sensor's appearance to that of a Band-Aid would impact willingness, 29% (4/14) of all study 1 participants agreed that this would increase their willingness, whereas 71% (10/14) stated that unobtrusive appearance would not affect their willingness (mean 2.45, SD 0.87; Figure 3):

> *Cosmetics is the least of my worries when I am going through treatment and fighting for my life.*

Figure 3. Studies 1 to 3: design feature impact on willingness to use the sensor for 9 months. *Only the participants in study 2 (n=14) were asked this question.



When asked about the sensor's proposed function of delivering individual risk for dysphagia, the majority of the sample (21/28, 75%) agreed that this feature would increase their willingness (mean 1.5, SD 0.88; Figure 3). Notably, half of the free-text comments indicated that had they been able to measure muscle fibrosis earlier, they would have been more diligent about performing their prescribed swallowing exercises. Some simply wrote that they wanted the sensor to be available so that future patients would understand that the risk of dysphagia was high:

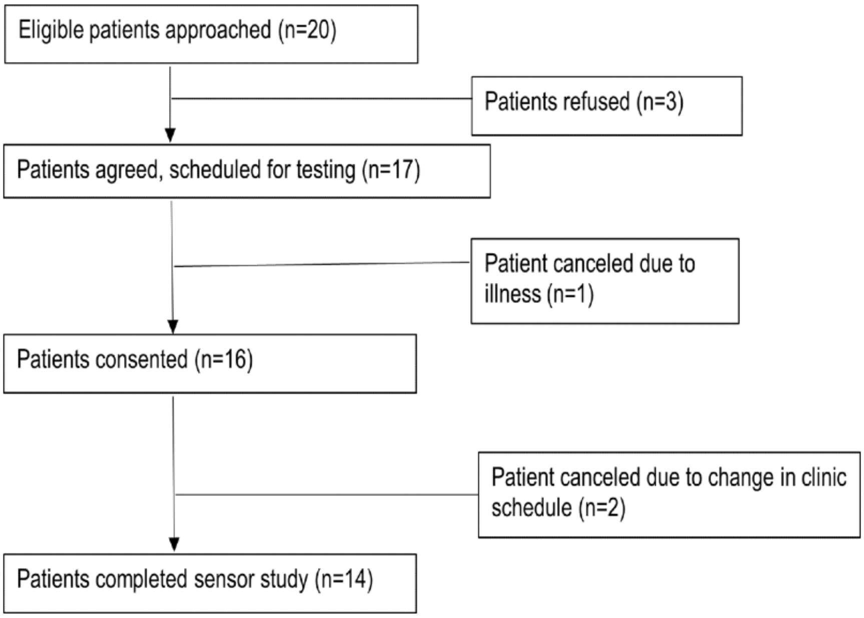
> *I would like to see this in ACTION NOW*

Study 2

Within a 1-week period, a convenience sample of 20 potentially eligible survivors of oropharyngeal cancer who were nonmetastatic and able to speak English were approached at their surveillance visit for enrollment into the study. To test the sensor's performance in distinguishing between normal and dysphagic swallowing patterns, survivors who had developed severe dysphagia as a result of their radiation were oversampled for study 2. Potentially eligible survivors were first identified in the electronic medical record; approached during a surveillance visit; and if consented, scheduled with the engineers for the sensor testing session in a clinic exam room. Three patients refused to participate, citing fatigue or disinterest; all were White, 2 were male, and 1 was female, and their age ranged from 63 to 74 years. Two of the patients were dysphagic and the third was nondysphagic. All three had been diagnosed with late-stage oropharynx cancer (data not shown). A total of 17 (85%) patients agreed, but 1 patient subsequently dropped out due to receiving news of cancer recurrence (Figure 4). Another 2 participants experienced scheduling conflicts; informed consent was obtained from the remaining 14 participants.

Consistent with this cancer type's demographic profile, the average age of the sample was 61 years, with 12 male participants and 2 female participants. Three participants were Hispanic or Latino and 3 were of non-White race (Table 2). Specific cancer diagnoses included cancer of the oropharynx (9/14, 64%), larynx (3/14, 21%), and nasopharynx (1/14, 7%), and unknown primary cancers (1/14, 7%). The average time since completion of radiation treatment was 47.9 months, and half of the sample had received a diagnosis of radiation-associated dysphagia (Table 2).

Figure 4. Recruitment flowchart for study 2 (n=14).



After wearing the sensor, 10 of the 14 (71%) patients indicated that they would have been willing to wear the sensor for 9 months of the first year post radiation. The most prevalent reasons for willingness were wanting to help future patients detect developing dysphagia and wanting to help MD Anderson research (Table 3). Of the 4 (29%) patients who did not think they would have been willing to wear the sensor, the most popular reason for unwillingness was study burden, specifically, that 9 months was too long of a testing period and the increased responsibilities associated with the sensor. Using a 5-point Likert response scale, patient ratings of discomfort (mean 1.21, SD 0.42), embarrassment (mean 1.14, SD 0.36), and difficulty in application and removal (mean 1.5, SD 0.52) were minimal (Table 4). Therefore, these questions were not repeated in the next phase of user testing.

Table 4. Study 2's mean patient ratings for sensor discomfort, embarrassment, and difficulty of application (n=14), and study 3's mean patient ratings of helpfulness for haptic signaling (n=14).

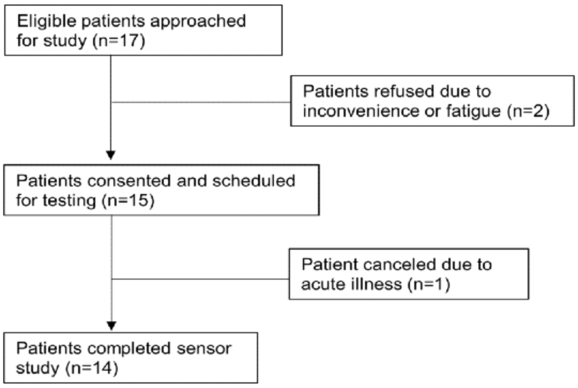
	Patient ratings, mean (SD)	Range[a]
Study 2 (n=14)		
The sensor was uncomfortable to wear.	1.21 (0.426)	1.0-5.0
The sensor would be difficult for me to use at home.	1.5 (0.519)	1.0-5.0
I thought the experiment was fun.	3.79 (0.893)	1.0-5.0
The testing session was embarrassing.	1.14 (0.363)	1.0-5.0
I am good about doing my swallowing exercises every day.	3.27 (1.51)	1.0-5.0
I believe it is important for me to do as many of my swallowing exercises as possible.	4.46 (1.13)	1.0-5.0
Study 3 (n=14)		
Would it help for the sensor itself to vibrate when you put it in the right spot on your throat?	1.85 (0.376)	0-2.0
Do you think it would be helpful to have the sensor vibrate once you did your swallowing exercise correctly?	2.00 (0.000)	0-2.0
Do you think that having the sensor process your swallowing data and give you feedback about the quality of your swallowing would help?	1.46 (0.877)	0-2.0

[a] For study 2, the scale ranged from 1 (strongly disagree) to 5 (strongly agree). For study 3, the scale ranged from 0 (no) to 2 (yes).

Study 3

As with study 2, a convenience sample of 14 participants were recruited within a 1-week period to assess user preferences to the updated sensor prototype. As in the previous two studies, the majority of patients were diagnosed with oropharyngeal cancer (11/14, 79%). Unlike the previous two studies, 11 of the 14 (78.6%) were undergoing radiation at the time of testing; the remaining 2 participants were 1-5 year survivors (data not shown). The long-term dysphagic status was not yet known for patients on active treatment. A total of 17 participants were eligible and approached to participate in the sensor study. Two patients refused, both being White and male: 1 patient was aged 76 years and had been diagnosed with late-stage oropharyngeal cancer 2 years prior and the other was aged 23 years and was in the third week of radiation for late-stage oropharynx cancer (data not shown). A total of 15 (83%) patients agreed to participate and gave informed consent. One participant developed an acute illness episode the following day and was, therefore, unable to complete the sensor test, leaving 14 participants who completed user testing (Figure 5). Study 3's sample was primarily male (12/14, 86%) and non-Hispanic White (12/14, 86%) with an average age of 62 years (Table 2).

Figure 5. Recruitment flowchart for study 3 (n=14).



As with the previous studies, the majority of patients (12/14, 86%) indicated willingness to wear the sensor for 9 months during the first year post radiation. Wanting to help future patients detect developing dysphagia and wanting to help MD Anderson research were the most prevalent reasons for willingness to wear the sensor (Table 3). As in study 2, the most oft-cited reasons for unwillingness were that of study burden (lengthy testing period and increase in daily responsibilities; Table 3). Patients' opinions regarding the helpfulness of haptic feedback were obtained for 13 of the 14 participants. All 13 participants thought it would be helpful for the sensor to vibrate when placed in the correct spot on the neck (mean 1.85, SD 0.38) as well as when swallowing exercises were performed correctly (mean 2.0, SD 0.00; Table 4). A total of 11 (85%) participants felt it would be helpful for the sensor to give haptic feedback of swallow quality during at-home testing (mean 1.5, SD 0.88; Table 4).

Discussion

Principal Findings

To our knowledge, this is the first study to assess evaluations from patients with head and neck cancer of a wearable throat sensor in clinical settings with separate cohorts at varying time points along their treatment trajectory. Across all studies, the overall willingness to wear the sensor for 9 months during the first year after radiation was high and the perceived need was rated highly. However, study 1's results should be interpreted with caution since the participation rate was 59%, with non-Hispanic and higher income/education patients more likely to complete the questionnaire. While study 2 and 3 used convenience samples for user testing, accrual rates were high (88%), even for those undergoing active treatment at the time of approach.

Direct comparison of our results with other works is not possible since the vast majority of published data regarding wearable devices equipped with mechanical, optical, biochemical, electrical, or acoustic sensors are pilot studies conducted with graduate students in a laboratory under highly controlled conditions [60-64]. While it did not test actual user engagement over repeated time points, it did gather patients' opinions about the likelihood that they would wear the sensor for a period of several months. This question was asked in study 1 for patients who were only exposed to a photo of the proposed sensor, whereas patients and survivors in study 2 were asked this question after wearing the actual sensor while swallowing boluses of varying textures in a controlled setting. When searching for comparable studies that address extended user engagement with health technologies, the extant literature is limited to nonsensor research with mobile websites or apps [65] and to real-world studies of fitness tracker abandonment rates in healthy adults; these studies tend to describe a steep decline in user engagement over time. It is possible that our high rates of expressed willingness to wear the sensor for 9 months is due to the perceived usefulness of this device for this highly specialized problem.

Since the majority of participants (137/166, 83%) expressed willingness to wear the sensor for 9 months, data from those participants who were unwilling provided valuable insight into the potential barriers to its long-term use. Across all three studies, nearly 86% (24/28) of the unwilling participants perceived the 9-month testing period as too long. The second-most prevalent reason, that the sensor's appearance would provoke unwanted attention, was endorsed by 56% (15/27) of the unwilling participants. The third-most frequent reason was an unwanted increase in daily responsibilities (16/26, 62%). This was also borne out by spontaneous comments in study 3, when nearly all 14 patients communicated a preference for a more streamlined one-step application process, rather than the separate applications for the strain sensor and surface EMG electrodes. On the other hand, several of the unwilling participants were much more willing to wear the sensor for 9 months if the sensor could provide individual dysphagic risk feedback and were made more unobtrusive in appearance (Figure 3). These findings are consistent with other mHealth reports citing multiple aspects of participant burden [48] and social implications of the technology's appearance [66] as being relevant constructs to user engagement.

Bidirectional Communication

Our data confirmed two other persuasive design principles: the desire for bidirectional communication (dialog support) with a team of clinical experts (system credibility). In all three studies, a large proportion of patients endorsed the rationale for the sensor (study 1: 115/138, 83.5%; study 2: 10/14, 71.4%; study 3: 12/14, 85.7%; ie, that sensor data be processed and sent back with contextual explanations of their risk of dysphagia development). Furthermore, of the three proposed persuasive design features, feedback about dysphagia risk had the greatest impact in increasing willingness among all participants (Table 4). These findings point to the importance of fostering a sense of connectedness and reassurance between the user and the technology so that patients' association between their own health behaviors and subsequent health outcomes can be continually reinforced [42]. Future plans for implementation include data visualization of near-time individualized risk for dysphagia in the form of an app that can be linked with the throat sensor. When asked about direct haptic communication with the sensor itself, patients in study 3 rated haptics as helpful, especially when unsure about correct placement on the throat and whether preventive exercises were being done correctly (Table 4). One patient commented that he was never really sure if he was performing the exercises correctly at home and was "just winging it."

Sensor and Adherence to Exercises

The majority of participants (97/119, 82%) agreed that the sensor would serve as a reminder for them to do their speech pathology swallowing exercises. While the main goal of the sensor is to provide earlier detection of radiation-associated dysphagia, reminding patients to complete their swallowing exercises at home to counteract the development of dysphagia could be an additional benefit to this developing technology. Since personalized risk information is generally not sufficient in itself to increase exercise adherence per se [67], further user-centered testing would be needed to assess preferred modes of sensor feedback (eg, within an app or coupled with virtual coaching) [68].

Limitations

Our study was conducted solely with survivors and patients attending clinical visits at MD Anderson, which generally requires high-quality insurance for access. Generalizability of our results are further limited by examining the demographic patterns among respondents versus nonrespondents in study 1. A total of 38% (21/55) of the eligible survivors did not complete the questionnaire despite repeated contact by the study team; nonresponders were significantly more likely to be Hispanic (P=.003), without a bachelor's degree (P=.02), and of lower annual household income compared to respondents (P=.007). This is consistent with Rising et al's [69] recent analysis of National Cancer Institute's 2018 Health Information National Trends (HINTS) population survey data showing that nonusers of personal mHealth technologies were more likely to be older than 65 years and have lower incomes. Given the challenge of sustaining patient engagement in mHealth technology, future research should target these patients who fit within the above demographic profiles. Finally, the sample sizes for study 2's and 3's on-patient testing were constrained by the need to complete all testing within 1-week periods, as the sensors were applied/tested by visiting engineers and not MD Anderson research staff. It is conceivable that larger sample sizes might have produced a wider variation in response to the sensor's features and perceived usefulness.

Conclusion

Large proportions of non-Hispanic well-educated patients with high-quality insurance and above-average incomes were receptive to the idea of wearing a personalized risk sensor for an extended period during the first year after radiation. User ratings of discomfort and difficulty were minimal; however, a significant minority of patients expressed concern with various aspects of the sensor's burden and its appearance.

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Data Availability

The data that support the findings of this study are available from the corresponding author EHS upon reasonable request.

Conflicts of Interest

None declared.

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Abbreviations

EMG: electromyography
HINTS: Health Information National Trends
IMRT: intensity-modulated radiation therapy
MBS: modified barium swallow
mHealth: mobile health

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Original Paper

Co-Design, Development, and Evaluation of a Mobile Solution to Improve Medication Adherence in Cancer: Design Science Research Approach

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Abstract

Background: Medication nonadherence negatively impacts the health outcomes of people with cancer as well as health care costs. Digital technologies present opportunities to address this health issue. However, there is limited evidence on how to develop digital interventions that meet the needs of people with cancer, are perceived as useful, and are potentially effective in improving medication adherence.

Objective: The objective of this study was to co-design, develop, and preliminarily evaluate an innovative mobile health solution called Safety and Adherence to Medication and Self-Care Advice in Oncology (SAMSON) to improve medication adherence among people with cancer.

Methods: Using the 4 cycles and 6 processes of design science research methodology, we co-designed and developed a medication adherence solution for people with cancer. First, we conducted a literature review on medication adherence in cancer and a systematic review of current interventions to address this issue. Behavioral science research was used to conceptualize the design features of SAMSON. Second, we conducted 2 design phases: prototype design and final feature design. Last, we conducted a mixed methods study on patients with hematological cancer over 6 weeks to evaluate the mobile solution.

Results: The developed mobile solution, consisting of a mobile app, a web portal, and a cloud-based database, includes 5 modules: medication reminder and acknowledgment, symptom assessment and management, reinforcement, patient profile, and reporting. The quantitative study (n=30) showed that SAMSON was easy to use (21/27, 78%). The app was engaging (18/27, 67%), informative, increased user interactions, and well organized (19/27, 70%). Most of the participants (21/27, 78%) commented that SAMSON's activities could help to improve their adherence to cancer treatments, and more than half of them (17/27, 63%) would recommend the app to their peers. The qualitative study (n=25) revealed that SAMSON was perceived as helpful in terms of reminding, supporting, and informing patients. Possible barriers to using SAMSON include the app glitches and users' technical inexperience. Further needs to refine the solution were also identified. Technical improvements and design enhancements will be incorporated into the subsequent iteration.

Conclusions: This study demonstrates the successful application of behavioral science research and design science research methodology to design and develop a mobile solution for patients with cancer to be more adherent. The study also highlights the importance of applying rigorous methodologies in developing effective and patient-centered digital intervention solutions.

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KEYWORDS

cancer; behavioral science; design science research; digital; medication adherence; mobile solution; Safety and Adherence to Medication and Self-Care Advice in Oncology; SAMSON; mobile phone

Introduction

Background

Optimal adherence to medication is increasingly one of the top priorities in oncology care [1-3]. Medication adherence (MA) is "the extent to which patients take their medication as recommended by their health care provider" [4]. Despite this importance, the MA rate is very low: only 14% for some cancer regimens [3,5,6]. Poor MA negatively impacts the health outcomes of the patient [3,7-9] and increases pressure on health services and health care fiscal restraints [9,10].

MA is a complex and multifaceted phenomenon that can be influenced by 5 interacting dimensions: socioeconomic and health system factors as well as condition-, therapy-, and patient-related factors [11]. Patient-related factors are the most important [12] because adherence interventions may potentially make the most impact on these factors without necessarily having systemic solutions [11]. Multicomponent interventions that involve collective adherence strategies and are tailored to patients are likely more effective than single-strategy interventions in addressing these factors and improving adherence to oral anticancer medicines [13]. Technology can help to deliver multicomponent interventions more effectively and efficiently [13-15] without requiring too many extra resources, which are already scarce, from the health system [16].

With the rapidly evolving nature and increased uptake of information and communications technologies in the last 20 years [14,17], mobile phone–based interventions have been widely used to address the problem of medication nonadherence, specifically in cancer [18,19]. Literature reviews showed the potential of using technologies such as mobile solutions in promoting MA by providing patients rapid, continuous, and easy access to educational resources and symptom or side effect self-management strategies as well as facilitating direct patient-provider communication [11,15,17]. However, there is very limited evidence on how to develop mobile solutions that meet the needs of people with cancer, are perceived as useful, and are potentially effective in improving MA [1,13,19,20].

Research Context

In our previous research, we developed REMIND, which is a mobile health system to increase adherence to oral medication in people with chronic myeloid leukemia (CML) [21]. It comprises daily SMS text messages to provide drug reminders and symptom self-care advice, as well as nurse telephone consultations to promote adherence [21]. The development of REMIND was guided by the framework for the development of complex interventions [22]. To understand patients' experiences of CML and identify their possible facilitators and barriers to adherence, a prior qualitative study was conducted [23]. To increase the acceptability of the intervention, stakeholders (eg, consumers and oncology professionals), were involved in reviewing iterative REMIND revisions and resource manuals [21]. The intervention content and delivery mechanisms were based on theories and available evidence [21].

Findings from the REMIND pilot study [21] showed that most patients reported episodes of nonadherence during the study period. Some reasons for their nonadherence were intentional [24], such as to reduce dose-dependent side effects. Some patients reported unintentional nonadherence [25] due to forgetfulness and miscommunication with health care providers [23]. Health care professionals (HCPs) had challenges in accurately assessing patients' adherence status and identifying causes of nonadherence [23]. Users found REMIND generally acceptable to use and appreciated its benefits in establishing medication routines, resolution of symptom uncertainty, increased awareness of self-care, and informed decision-making [21].

REMIND had limitations. First, using a design framework specifically for digital interventions is crucial; yet, this was missing in the REMIND system's development. Second, although stakeholder involvement was reported in the intervention's development process, a genuine co-design process, defined as "meaningful end-user engagement in research design and includes instances of engagement that occur across all stages of the research process and range in intensity from relatively passive to highly active and involved" [26], was not adopted. Third and last, patients reported some functional errors and expressed their need for an advanced iteration with improved functionality and presentation as well as a more user-friendly application [21].

Given the importance of the medication nonadherence problem that has not been well addressed and the gap in literature on how to develop acceptable, useful, and potentially effective digital interventions to solve the problem, as well as the need to resolve the identified limitations of REMIND, we combined design science research methodology (DSRM) and co-design to develop its new version, named Safety and Adherence to Medication and Self-Care Advice in Oncology (SAMSON) mobile health solution.

DSRM Cycles and Stages

Over the last couple of decades, design science research (DSR) [27] has been one of the main paradigms characterizing most information system research that aims to design and implement innovative technologies [28,29] through 3 design cycles: rigor, design, and relevance [30]. In 2007, Peffers et al [31] presented 6 process stages of the DSRM: problem identification and motivation, definition of the objective of the solution, design and development, demonstration, evaluation, and communication. Later, Drechsler and Hevner [32] extended the original DSRM with a fourth cycle (change and impact) to capture the dynamic nature of information system artifact design for volatile environments. Furthermore, the DSRM has been used in different health care contexts [29,33,34], demonstrating its importance in developing patient-centered digital health solutions. We adapted these 4-cycle and 6-process DSRM models to direct the steps required for the design and development of the SAMSON mobile health solution (hereinafter SAMSON) to improve MA in cancer. We present SAMSON and describe in detail the process of applying DSRM to design and develop it to answer the research question "How can DSRM be applied to enhance the initial mobile health system to provide a better user experience to improve MA to oral anticancer agents in adults with cancer?" Our study aimed to co-design, develop, and preliminarily evaluate SAMSON.

Methods

Overview

In this section, we explain how the 4 cycles and 6 processes of DSRM were adapted to design and develop SAMSON. Figure 1 presents the 4 DSRM cycles used to design and develop SAMSON. Table 1 illustrates how the 6-process DSRM models were applied in this study.

Figure 1. The adapted 4-cycle design science research methodology of the Safety and Adherence to Medication and Self-Care Advice in Oncology (SAMSON) mobile health solution. DSR: design science research; KB: knowledge base.

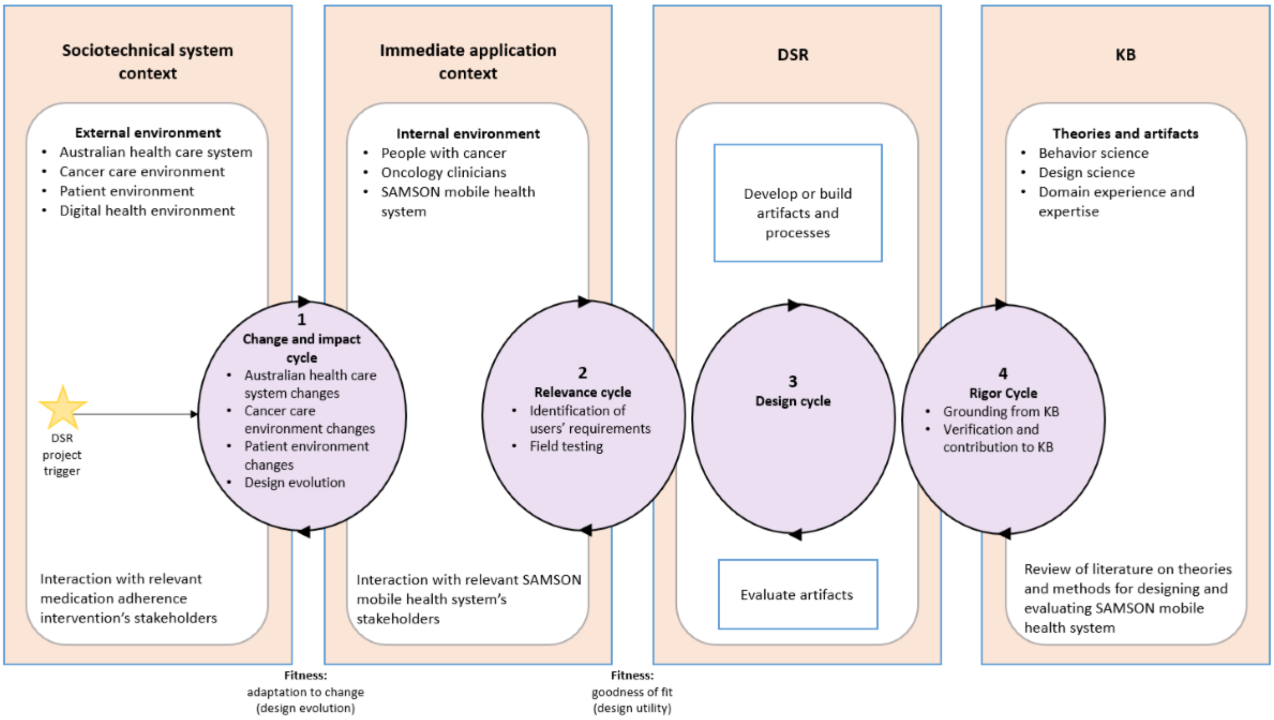


Table 1. Adapted 6-process design science research methodology (DSRM) applied to design and develop the Safety and Adherence to Medication and Self-Care Advice in Oncology (SAMSON) mobile health solution.

DSRM stages	Interaction of DSRM cycles and stages	Approaches
Stage 1: problem identification and motivation	Cycle 1: change and impact impacts on stage 1	• Review literature on MA[a] problems in cancer • Review literature on current MA interventions and their effect • Identify problems in the current design • Define a set of requirements in the new design
Stage 2: definition of the objective of the solution	Cycle 1: change and impact and cycle 2: relevance impact on stage 2	• Review literature on BSR[b] • Adapt BSR principles in design
Stage 3: design and development	Cycle 2: relevance, cycle 3: design, and cycle 4: rigor impact on stage 3	• Conceptualize design requirements and features
Stage 4: demonstration	Cycle 4: rigor impact on stage 4	• Test the design and acquire feedback from the design's users
Stage 5: evaluation	Cycle 4: rigor impact on stage 5 Stage 5 impact on cycle 3: design and cycle 4: rigor	• Evaluate the acceptability, usability, and potential effect of the intervention
Stage 6: communication	Stage 6 impact on cycle 3: design	• Report and publish the evaluation results

[a] MA: medication adherence.

[b] BSR: behavioral science research.

DSRM Cycles

The change and impact cycle [32] ensures that SAMSON (internal environment) would fit for purpose in the context of the Australian health care system, cancer care, digital health, and patient environments (external environment). The internal environment here includes the designed mobile solution and the users (patients and oncology clinicians). This was defined through the process of problem identification and motivation (DSRM stage 1).

The relevance cycle links the key identified requirements of the users, including the users' needs from REMIND's pilot test, and the problems that they are facing in their environments. This was done through a range of discussions with SAMSON's stakeholders and was demonstrated in DSRM stage 2 (definition of the objective of the solution) and impacted to stage 3 (design and development).

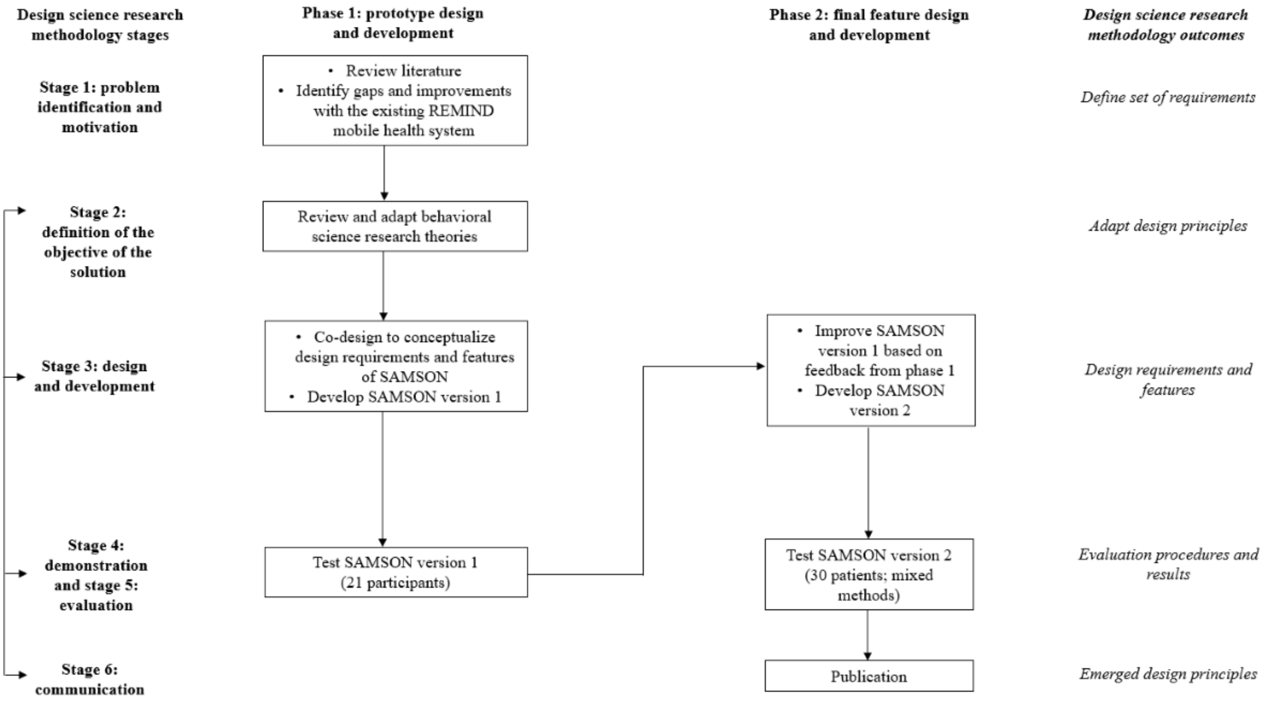
The co-design cycle (phase 1 and 2) consists of smaller cycles or phases (interacting iterative processes), including constructing the artifact, evaluating it, and using evaluation feedback to further refine it until a satisfactory design is achieved [27]. This cycle is the center of the research project because it is directed by the relevance cycle and the rigor cycle [33]. However, this is not a 1-way process because the results of the co-design cycle will then become a part of the relevance cycle. This cycle was performed in DSRM stage 3.

The rigor cycle links design science activities and grounded knowledge bases, such as the scientific theories, experience, and expertise that inform the DSRM project [33]. The scientific theories applied in this study include the health belief model (HBM) [35], self-determination theory (SDT) [36], and behavioral learning perspective (BLP) [11]. The impact of these knowledge bases on the SAMSON was demonstrated in DSRM stages 3 (design and development), 4 (demonstration), and 5 (evaluation). In parallel, the design and use of the SAMSON provide new knowledge (eg, the effect of this solution in terms of promoting adherence among people with cancer) to the external environment (Australian health care and cancer care context) in which the mobile solution is embedded. This process was rigorously validated in stage 5.

DSRM Processes

The SAMSON design comprises two phases: (1) prototype design and development and (2) final feature design and development (Figure 2).

Figure 2. Design and development phases of the Safety and Adherence to Medication and Self-Care Advice in Oncology (SAMSON) mobile solution.



Phase 1: Prototype Design and Development

The first phase (prototype design and development) started by defining a specific research problem (stage 1). The research problem focuses on MA problems in cancer, barriers to MA, and current MA interventions and their effects. To establish problem awareness, a literature review on MA in cancer and a systematic review of current MA interventions in cancer were conducted by THD and the research team (ARMF, NW, PPJ, and PS) to define MA barriers and facilitators as well as the characteristics of effective MA interventions [13]. Besides, feedback from HCPs and patients regarding REMIND was examined thoroughly by THD and PS to define necessary changes in the next iteration (SAMSON). Guided by the problem awareness, behavioral science research (BSR) was used by THD and PS to conceptualize preliminary design requirements (stage 2). Subsequently, the design requirements were translated into design features for the SAMSON prototype (SAMSON version 1), with ARMF leveraging the available features of the REMIND system in consultation with HD and the research team (stage 3). A test was then conducted on a convenient community sample to investigate whether the prototype works, examine its features, and propose more design requirements that may be helpful for patients (stages 4 and 5). Purposive and snowball sampling [37] were used to recruit participants to test SAMSON version 1. The convenient community sample included project team members, HCPs, and people in the community.

Phase 2: Final Feature Design and Development

Feedback from the testing of SAMSON version 1 initiated the second phase (final feature design and development; stage 3). In this phase, the problems detected in phase 1 were fixed. On the basis of feedback from participants in the SAMSON version 1 testing, THD and the research team returned to the literature and consulted the BSR to address the participants' suggestions and develop the final designed features in SAMSON version 2. A preliminary evaluation of SAMSON version 2 was conducted among people with cancer (stages 4 and 5). Details of the preliminary evaluation study (hereinafter SAMSON evaluation) are presented in the following subsections. The results of the design and development of the SAMSON will be presented in publications (stage 6).

SAMSON Evaluation Methods

Study Design and Setting

This is a study with an explanatory sequential mixed methods design: a quantitative survey was conducted first, followed by qualitative interviews [38]. The quantitative study was conducted using a purpose-built questionnaire. The qualitative component consisted of in-depth interviews with a subset of patient participants. The mixed methods study design was applied to use the qualitative interviews to *explore and make sense* of the quantitative findings [38].

Participants

Purposive sampling [39] was used to select outpatient patients from the hematology department at Peter MacCallum Cancer Centre in Melbourne, Victoria, Australia. To be eligible, participants were required to be adults (aged ≥18 years); have an established diagnosis of chronic lymphocytic leukemia, CML, essential thrombocythemia, malignant neoplasm, myelofibrosis, myeloproliferative neoplasms, or polycythemia rubra vera; be taking or commencing an oral anticancer medication; and have smartphone and internet access. Before participating in the study, the study staff helped participants to install the SAMSON app on their mobile phone and briefed them on how to use it. They also received the SAMSON app user manual with detailed information, including app introduction, features, how to install and navigate, and common issues and how to solve them.

Intervention

The SAMSON has two elements: (1) a smartphone-based app to remotely prompt MA, monitor the patient's side effects, and provide self-care advice; and (2) a web-based application to program the patient's daily drug reminders and side effect surveys, and provide relevant drug information. In this evaluation study, patients were asked to trial the SAMSON smartphone app (the first element). The SAMSON web page (the second element) was used to populate daily drug reminders, weekly side effect surveys, and relevant patient information. Data collected on patients' self-reported MA and side effects were uploaded and archived on the SAMSON web page.

Measures

Patients used the SAMSON app for at least 6 weeks. Subsequently, they were asked to complete the questionnaire via a Qualtrics (Qualtrics International Inc) link [40] that they received in an email from a researcher. The purpose-built questionnaire was adapted from the Evaluation Tool for Mobile and Web-Based eHealth Interventions (Enlight) [41]. The items in the questionnaire were language adapted for respondents without a background in IT and health. Next, face validity testing [42] was applied to achieve a consensus on the adapted Enlight questions. Finally, usability testing following the think-aloud protocol [43] was conducted on 2 consumers to finalize the questionnaire for use.

The questionnaire assesses the quality of the SAMSON app on 6 main constructs or dimensions: usability, visual design, user engagement, content, therapeutic persuasiveness, and general evaluation. Each dimension had between 3 and 6 items, for a total of 25 items. The stem of the item was presented as a statement (eg, "Overall, I found the mobile app was easy to use"), and the response scale was a 5-point Likert scale (1=*strongly disagree*, 2=*disagree*, 3=*neither*, 4=*agree*, and 5=*strongly agree*; Multimedia Appendix 1).

Qualitative Interview

All interviews were conducted either face-to-face or via web-based videoconference platform (Zoom; Zoom Video Communications, Inc) by THD, using a semistructured interview guide [39] (Multimedia Appendix 2). Each interview lasted between 45 and 90 minutes and was audio recorded.

Data Analysis

Quantitative Data

Descriptive statistics were used to analyze the quantitative data. SPSS (version 28.0; IBM Corp) [44] was used.

Qualitative Data

Each interview was transcribed verbatim [39]. NVivo 12 qualitative data management software (Lumivero) [45,46] was used. Qualitative data were analyzed thematically using a comparative, iterative, and predominantly inductive process, informed by grounded theory [47,48]. Thematic analysis has been used widely in information system research for different purposes, such as to understand phenomena related to information systems [49] or to evaluate the effectiveness of IT artifacts [50]. A qualitative interrating process was also conducted [51]. First, THD completed coding all interview records. Next, CO reviewed all interviews as well as THD's codes and agreed or disagreed with each code and also suggested additional codes. Subsequently, both researchers discussed the codes until they reached agreement. Codes were then collated into subcategories (labels for comparable code groups), categories (labels for comparable subcategory groups), and themes (labels for comparable category groups). THD led category and thematic development, which was followed by a review of the categories and themes by CO. All disagreements were also discussed, and adjustments were made until consensus was reached. Both authors reviewed the data to ensure that the themes worked in relation to the entire data set and to generate a thematic map of the analysis. The researchers' interrating process helped to strengthen the credibility and trustworthiness of this study [52,53].

Ethical Considerations

The SAMSON evaluation was approved by the human research ethics committees of Peter MacCallum Cancer Centre (HREC/74134/PMCC) and Swinburne University of Technology (20215811-8152). Written consent was obtained from all participants. Throughout the comprehensive consent process, participants were informed that their participation in this research was voluntary and that they were free to withdraw at any stage if they wished to do so. In addition, they were informed that their data would be deidentified for analysis and publication. Participants did not receive any compensation from the research team.

Results

The results are presented in the sequence of DSRM stages as shown in Figure 2: review literature, review and adapt BSR, co-design and test SAMSON version 1 (design cycle 1), develop SAMSON version 2, and SAMSON evaluation (design cycle 2).

Review Literature

The literature review of most recent research on MA in cancer showed that the problem of medication nonadherence in cancer is still persistent [5,15]. The results of the systematic review of intervention solutions to enhance adherence to oral anticancer medicines in adults [13] were in line with those of earlier reviews of the same topic [54,55]: multidimensional interventions that use collective strategies (educational, reminder, cognitive, behavioral, and affective) to promote adherence were potentially more effective than single-strategy interventions. This could be explained because MA is a complex and multifaceted phenomenon determined by 5 dimensions—socioeconomic and health system factors as well as condition-, therapy-, and patient-related factors—that require different strategies to address [11,13]. The review also suggested that a combination of cognitive and behavioral theories may better explain the diverse barriers and facilitators to MA and provide stronger direction to formulate interventions [13].

Review and Adapt BSR

Guided by the problem awareness from the literature review and REMIND studies, we conducted a review of BSR to select cognitive and behavioral theories that can potentially address MA barriers and promote MA facilitators via the SAMSON. The HBM [35], SDT [36], and BLP [11] were chosen to govern the design requirements of the SAMSON mobile solution [56]. According to the HBM, people will take health actions (eg, adherence) if they have 4 basic conditional beliefs or perceptions regarding the disease, the effect of the disease on people's lives, the action to respond to the disease, and the conviction that the benefit of action will outweigh the barriers [57]. According to the SDT, motivation (intrinsic and extrinsic) is crucial to successful behavior change [36]. The behavioral theory emphasizes the role of positive and negative reinforcements in controlling people's behaviors that are immediately relevant to adherence [11].

Co-Design and Test SAMSON Version 1

Using knowledge gained from the literature and core theories, as well as users' feedback on REMIND's limitations, preliminary design requirements were conceptualized. The outcome of such conceptualization is presented in Figure 3.

Figure 3. Conceptualization of Safety and Adherence to Medication and Self-Care Advice in Oncology (SAMSON) design requirements using wireframes.

Action	From	When	Completed
Call M.Londonberry	You	Today	○
Create Survey	Supervisor	This Week	○
Add Patient	Supervisor	Today	○

Who	Type
M.Londonberry	Medicine
D.Periwinkle	Survey

Name	Age	Diagnosis	Medication	Adherence	Symptom Alarms
Eduardo Indianapolis	68	Leukemia AML	Cytarabine Midostuarin Idarubicin Hydrochloride	80% 80% 80%	Pain - lvl 8
Micheal Londonberry	50	Leukemia AML	Daunorubicin Hydrochloride	45%	
Dorothy Periwinkle	73	Leukemia AML	Cytarabine Midostuarin Idarubicin Hydrochloride	78% 75% 78%	Pain - lvl 9 Vomiting
Philomena Bosworth	65	Leukemia AML	Thioguanine	100%	Nausea
Blanche Newcombe	81	Leukemia AML	Thioguanine	95%	
Gertrude Barrybottom	79	Leukemia AML	Thioguanine	100%	Nausea

During the SAMSON design stage, we focused on the following target behaviors: knowledge, reinforcement, intentions, emotion, social influences, beliefs about capabilities, behavioral regulation, memory, and attention. These behaviors were originated from key barriers to MA, considered most feasible to influence, and expected to contribute most to the improvement of adherence. On the basis of behavioral analysis of these behaviors, potential behavior change techniques (BCTs) from the HBM, SDT, and BLP as well as intervention functions were selected for the SAMSON app; for example, the *prompts* or *cues to action* technique from the HBM [58] was applied for the *medication reminder* feature. *Problem-solving* and *self-monitoring* techniques from the HBM and SDT [36] were applied for the *symptoms assessment and management* module of the app. The *feedback on behavior* technique from the BLP [11] was applied for the *reinforcements* module. Textbox 1 shows the conceptual model picturing this process using BSR, including the selection of final BCTs and the app's features.

Textbox 1. Conceptualizing Safety and Adherence to Medication and Self-Care Advice in Oncology (SAMSON) design requirements and features using behavioral science research.

Requirements and features

1. Medication adherence barriers
    - Drugs’ side effects
    - Lack of medication knowledge
    - Lack of motivation
    - Lack of health care professional (HCP) support to manage side effects
    - Poor patient-HCP communication
    - Lack of self-efficacy
    - Forgetfulness
2. What needs to change
    - Knowledge
    - Reinforcement
    - Intentions
    - Emotion
    - Social influences
    - Beliefs about capabilities
    - Behavioral regulation
    - Memory and attention
3. Behavior change techniques from the theories
    - Information about side effects and medicines
    - Feedback on behavior
    - Social support
    - Problem-solving
    - Self-monitoring behavior
    - Prompts
    - Habit formation
4. App features
    - Side effects section
    - Medication information section
    - HCPs’ contacts
    - HCP connections
    - Side effects self-management section
    - Drug reminders
    - Reinforcements

The aforementioned step is followed by a translation into design features for prototype implementation. The features were designed to provide a solution within 1 IT artifact, which is called the SAMSON mobile solution, including a mobile app, a web portal, and a cloud-based database for storing patient-specific information. The mobile app is available for patients to use, while the web portal is available for both patients and their care team. The SAMSON included 5 different modules with some key requirements (Textbox 2).

Textbox 2. The 5 different modules of the Safety and Adherence to Medication and Self-Care Advice in Oncology (SAMSON).

Medication reminder and acknowledgment

- The app should support and display multiple medications and send a reminder per medication. The reminder can address the medication adherence (MA) barrier of forgetfulness. Patients need to tap each reminder for an acknowledgment.

Symptom assessment and self-care management

- A list of available side effects and symptoms and self-care management in the mobile app is displayed for the medication that the patient is taking. Patients should be able to complete a symptom assessment survey through the app that will be distributed to patients using app reminders. They should be able to view information on how to manage their symptoms (if minor) and when they need to contact health care professionals (HCPs). This provides patients with medication knowledge as well as support in side effects self-management, both of which are important enablers of MA.

Reinforcement

- The app sends a positive reinforcement to the patient at a specific time each week based on the MA profile for that week. Positive reinforcement can help motivate patients' adherence.

Patient profile

- Patients can use the app to view their profile information, such as their basic personal and clinical information, emergency contact and care team contact details, and medication information (both general and important). This information can address the MA barriers of lacking or misunderstanding medication information and poor patient-HCP communication.

Reporting

- Analytical reports of patients' adherence status and their symptoms are available on the web portal for HCPs and patients in real-time. HCPs should be able to use these data in monitoring patients and providing them in-time and tailored support to manage side effects as well as to overcome MA barriers.

Test SAMSON Version 1

SAMSON version 1 was tested by 21 participants from a convenient community sample, which included project team members, HCPs, and people in the community. We sought participants' feedback on issues regarding the expected features and functionalities of the prototype and its visual design. Overall, participants reported some functional errors, such as misdelivered medication reminders and data entry failures in some fields both in the smartphone app and on the web page. They also asked for new visual design requirements to meet users' needs (details are presented in Multimedia Appendix 3).

Develop SAMSON Version 2

Overview

In phase 2, consumers' feedback from design cycle 1 was reviewed by the project team. We grouped them based on the artifact's functions and priority in terms of improvement (Multimedia Appendix 3). The main improvements in SAMSON version 2 are described in terms of priority in the following subsections.

Priority 1: Fix Functional Errors

All functional errors were fixed in this stage, including misdelivered medication reminders, app log-in–related issues, slow responsiveness to load app content, editing errors of medication schedules on the website, and functional errors related to data saving and data sorting on the website.

Priority 2: Enhance Existing Features and Functions

Textbox 3 presents feature and function enhancements in SAMSON version 2 in comparison to version 1.

Textbox 3. Enhanced features and functions in Safety and Adherence to Medication and Self-Care Advice in Oncology (SAMSON) version 2 in comparison to version 1.

Version 1

1. The medication reminders had no expiry time
2. Medications did not have color attributes
3. Patients could not view their data on the website
4. Patients could not export side effects surveys from the website to their data folder

Version 2

1. Setting up an expiry time (6 hours) for the reminders
2. Adding color attributes for medications on the website
3. Enabling patients to log in to the website to view their own adherence performance, symptom reports, and completed side effects surveys
4. Enabling patients to export the side effects surveys from the website to Excel (Microsoft Corp) spreadsheets

Priority 3: Create New Functions

The need expressed by consumers for new functions was discussed by the project team and conceptualized to guide the development of new selected design features in the new iteration of SAMSON. The literature, BSR theories, and BCTs were revisited when necessary to address new suggested requirements. Some selected new functions of SAMSON version 2 in comparison to version 1 are described in Multimedia Appendix 4.

SAMSON Evaluation

Overview

In the SAMSON evaluation, 30 (81%) of the 37 patients who were approached agreed to participate in the study and used SAMSON. None of them withdrew from the study. After 6 weeks, of the 30 participants, 27 (90%) completed the questionnaire, and 25 (83%) participated in the interview (Multimedia Appendix 5). Data retrieved from the SAMSON web page showed that 100% (1890/1890) of the drug reminders were sent on time, and all participants responded to the reminders and viewed the reinforcement messages. Most of the participants (23/30, 77%) reported side effects during the study period.

Participant demographics are described in Table 2. The mean age of the patient participants was 57.6 (SD 12.5) years. Most of the participants (20/27, 74%) were male individuals. The average time that participants had received treatments before the start of the study was 7.2 (SD 6.7) years. Approximately two-thirds of the participants (17/27, 63%) lived in the metropolitan areas of Melbourne. The proportions of participants using iPhones and Android mobile phones were equal.

Table 2. Participant demographics and clinical characteristics.

Characteristics	Values
Age (years), mean (SD)	57.6 (12.5)
Sex (n=27), n (%)	
Male	20 (74)
Female	7 (26)
Country of birth (n=27), n (%)	
Australia	14 (52)
Croatia	1 (4)
India	3 (11)
New Zealand	1 (4)
Pakistan	1 (4)
United Kingdom	2 (7)
Not provided or missing	5 (19)
English as first language (n=27), n (%)	
Yes	25 (93)
Not provided or missing	2 (7)
Education (highest level completed; n=27), n (%)	
No formal schooling or incomplete schooling	1 (4)
Primary school	9 (33)
Secondary or high school	3 (11)
Vocational	6 (22)
University	7 (26)
Postgraduate diploma or master’s degree or PhD	1 (4)
Employment status (n=27), n (%)	
Working full-time	8 (30)
Working part-time	5 (19)
Casual	2 (7)
Sick leave (permanent)	2 (7)
Unemployed	1 (4)
Retired	9 (33)
Residence (n=27), n (%)	
Metropolitan	17 (63)
Rural	10 (37)
Time since diagnosis (years), mean (SD)	7.2 (6.7)
Diagnosis (n=30), n (%)	
Chronic lymphocytic leukemia	15 (50)
Chronic myeloid leukemia	12 (40)
Essential thrombocythemia	1 (3)
Myeloproliferative neoplasms	1 (3)
Polycythemia rubra vera	1 (3)
Mobile phone operating system (n=30), n (%)	
Android	15 (50)
iOS	15 (50)

Quantitative Survey

Participants' responses to the Enlight questionnaire are presented in Multimedia Appendix 6. Enlight aims to examine individual quality constructs or dimensions, which means it is a suite of scales rather than 1 quality measure; therefore, we did not present the overall scale of the questionnaire.

Usability assesses the ease of learning how to use an app and the ease of using it properly. Overall, of the 27 participants, 21 (78%) rated the app as *easy to use*; only 1 (4%) participant rated it as *difficult*.

Visual design assesses the look and feel of an app. Participants mentioned that the app is attractive (14/27, 52%); well organized (19/27, 70%); and has appropriate font size, buttons, and menus (23/27, 85%). Some of them expressed a need for the app to be redesigned to increase its appeal (3/27, 11%) and encourage engagement (5/27, 19%).

User engagement assesses the extent to which an app's design attracts people to use it. In general, participants were interested in using the app (18/27, 67%) because it was presented in an interesting way (19/27, 70%), different features were used to increase users' interactions (19/27, 70%), automated features to respond to the survey were easy to use (21/27, 78%), and the app's features were personalized to users (23/27, 85%). However, of the 27 participants, 2 (7%) were not interested in using the app at all.

In terms of the content, more than two-thirds of the participants (19/27, 70%) were satisfied with the amount of information and the way it was presented in the app. Nevertheless, 7% (2/27) of the patients thought that information about the app's purpose was missing. Patients also reported that information about drugs and side effects was presented with gaps, overexplanation, or irrelevance (5/27, 19%).

Therapeutic persuasiveness assesses the extent to which an app is designed to encourage a patient's MA. High proportions of participants agreed that the app provided activities to improve their adherence (21/27, 78%) and appropriate ongoing feedback (19/27, 70%). However, approximately one-fifth of the participants (6/27, 22%) did not think that completing activities on the app would help them to be more adherent to treatments. Patients thought that the app did not fully disclose information on how it can help them to be more adherent (7/27, 26%) and what they need to do for this (8/27, 30%).

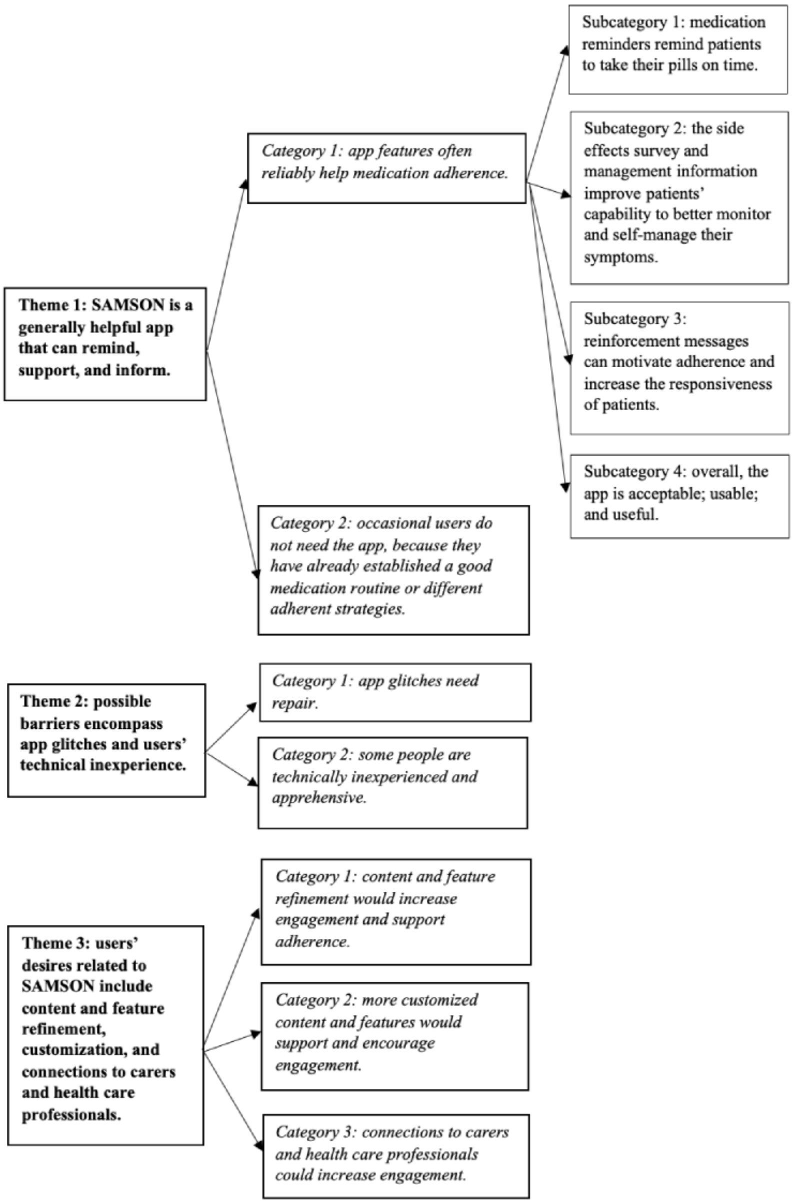
Overall, 18 (67%) of the 27 participants thought that the app was valuable in assisting MA via improving their confidence in complying to treatments (11/27, 41%) and motivating them to do so (15/27, 56%). More than half of the participants (17/27, 63%) would recommend the SAMSON app to other people with cancer.

Qualitative Interview

Overview

Three common themes were generated from the interview data: (1) SAMSON is a generally helpful app that can remind, support, and inform; (2) possible barriers encompass app glitches and users' technical inexperience; and (3) users desire customization, health care connections, and content refinement of SAMSON (Figure 4). A full presentation of themes, categories, and subcategories is presented in Multimedia Appendix 7. Further clarification of the themes is provided in the following subsections.

Figure 4. Qualitative interviews: themes, categories, and subcategories mapping. SAMSON: Safety and Adherence to Medication and Self-Care Advice in Oncology.



SAMSON Is a Generally Helpful App That Can Remind, Support, and Inform

Participants valued the SAMSON app's features (eg, medication reminders and side effects information) because they are reliable, both in terms of content and functioning. As patients had to take >1 drug, different drug schedules and a busy life made it easy to forget taking pills on time. However, with the use of SAMSON, patients were reminded to take their medication on time:

> *[U]sually the reminder comes very close to the time...I do like that.* [P6]
>
> *[T]he medication reminder is very prompt, and I have been, you know, taking my medication regularly, absolutely, I never missed out.* [P11]

Although patients had access to different sources of information about the drug and its side effects, they found it easy to obtain the appropriate information that they needed in SAMSON:

> *[W]hen you go into the individual drugs and you've got the side effects, information is much easier to access from the app than it is if you go online. Or if you go into the drug information sheet, which is just, you know, overwhelming, it's difficult. Particularly for somebody without a medical or paramedical background. But I thought the content was really well done. So you know I could find what I needed to know...it was a very good summary.* [P13]

A participant and their carer trusted the app's information because it was based on reputable research:

> *[O]n the Samson app, you can go through and actually know you can trust what's in there...you guys*

> *and [Swinburne University of Technology] have done the research.* [P1 and carer]

Patients could also benefit from information about drugs and side effects in the app. It supported them in managing unpleasant symptoms as consequences of cancer treatments that can be discouraging:

> *The side effects part of the screen was helpful to me in in a simple fashion...support for people that are trying to manage their side effects. I thought it was good...excellent.* [P14]

SAMSON could also encourage MA maintenance via reinforcement messages:

> *I liked the way it encouraged. You know, I was like, you know, try better this week, you know, do better.* [P1]
>
> *It is encouraging the patient to always use the app and to take the medicine on time.* [P12]

Overall, most of the participants thought that SAMSON is a helpful digital solution to promote MA:

> *It does its job, so it's good...It's a very neat app in this in the sense there's no extra stuff. It's just exactly just what it needs to do. That's all, so yeah, it's pretty good.* [P7]

However, some of the participants mentioned that they did not need the app to comply with the treatment because they either had a well-established drug-taking routine for many years or had another medication reminder strategy:

> *I've got a container with my medications in, as soon as I get them, I write the dates on there, I know exactly, I don't need my phone, I don't need an app, I don't need anything to remind me, I know, it's a routine that I've done for too long...I've been on it over 14 years, so for me it's a daily thing.* [P24]

Nonetheless, these participants still praised the app as helpful for other patients, especially for those who are new to the treatment and like to use technology:

> *I can see when someone's first-time treatment it'd be very very useful.* [P9]
>
> *A newer person coming into their treatment, or a younger person that's a bit more tech savvy, would probably prefer to use technology as a reminder. And you know that would be very handy.* [P10]

Possible Barriers Encompass App Glitches and Users' Technical Inexperience

Despite the benefits that SAMSON can bring to patients, it has some functional errors and drawbacks. These could annoy patients and make the app less effective:

> *I've got an Android [mobile phone] and I had to refresh the page many, many, many times.* [P14]
>
> *The notification does come up, but it sits in the background on your phone, so it comes up separate from the app, as a notification. But it just sort of sits in the background.* [P30]

Besides, as in the case of other advanced technologies, the use of SAMSON could be challenging for some people, especially older adults and people who are not technology savvy. A participant reflected on how others might view the app:

> *I think an app like that for my father who's in his 80s, I couldn't see it being used, he'd see it as a nuisance.* [P9]

Users' Desires Related to SAMSON Include Content and Feature Refinement, Customization, and Connections to Carers and HCPs

Patients expressed their desire for refinements in the new version of SAMSON to make it more appealing and capable of serving diverse needs of different users:

> *Maybe you can increase the size or to magnify for people.* [P31]
>
> *[P]ossibly people might find something that gives them their compliance, or you know a color changes, [signifying] you're on track, no you're not. That may help them.* [P7]

New features were also suggested to improve SAMSON's effectiveness for both patients and their clinicians in disease management:

> *It might be handy on the app somewhere for the person using it to be able to make a note and say, put dates in "I've been in hospital" or "I've had broken, been in a car accident" or "I've got some bruising as a result of a fall" or something.* [P10]
>
> *You probably need to have areas where people can actually add things to it, other than just keep going click click click and then get nothing at the end...it doesn't really help...a section where you can add additions to it, even say a basic of when there's a section on gastro and vomiting...did it affect you for a percentage...and then you may be able to assist from that side.* [P24]

App modifications were also advised to improve patients' proactiveness in treatment management:

> *It makes you feel more like you're in control and that you can I think you're more likely to use an app if you can customize it to meet your own needs. And, whereas you know if I wanted to change it, and then I had to get in touch with someone to do that. Yeah, it's just a bit disempowering.* [P27]

Furthermore, patients emphasized new features to assist carer engagement with the app, which would support their MA, and communication with their HCPs when needing additional support:

> *Some patients, they don't have this ability to manage their own medications, even when they have the app, and they need carer or family member to be also involved in the app.* [P12]
>
> *There were times in the past that I might've had a side effect, or something had happened, and sometimes it was very hard to contact the nurse that's*

> *linked in with my hematologist. So to have something like that [2-way SMS feature] on the app would be good because you could get almost feedback a lot quicker.* [P10]

Discussion

Overview

This research study co-designs, develops, and evaluates an innovative mobile health solution to improve MA in cancer. Preliminary results demonstrate the successful application of BSR and DSRM to enhance the initial mobile health system and provide a better user experience. The study contributes to theory and practice in many ways.

Theoretical Contributions

Our study contributes to DSRM theory in 4 different ways. First, we expanded the scope of DSRM by applying it to the design and development of a mobile health solution for MA. Given the current challenges in public health and clinical fields, the potential of using DSRM to improve the effectiveness and efficiencies of health care innovations is enormous [33]. DSRM has been used to design new artifacts in different health care application areas [29,34] (eg, medical devices), but none of them target MA in cancer [13,33]. Hence, this study sheds new light on how DSRM can be applied in this area.

Second, we addressed the knowledge gap on how BSR and DSRM can be integrated to develop engaging and effective behavior change digital health solutions. There is a strong view that design science and behavioral science are 2 distinct research paradigms [27]. Design science is related to the creation of new artifacts, while behavioral science studies behavior in relation to IT use [59]. While behavioral science could be seen as a reactive and retrospective process to explain what already exists, design science is more proactive in its way in terms of creating technological solutions for the future [59]. Nevertheless, these 2 seemingly divergent research paradigms have some similarities. They both emphasize the importance of understanding the health problem before designing a solution and aim to ensure that the designed solutions can effectively engage users [60]. Engagement with mobile health interventions is a precondition for their effectiveness [61]. Behavior change theory and BCTs can assist macroengagement with the behavior changes the mobile health intervention aims to support (eg, MA) [62], while design science approaches, such as user-centered design, is more likely to facilitate microengagement with the mobile health interface (eg, logging in to the app) [60,63]. Therefore, integrating best practices from BSR and DSRM can bring more mutual benefits to design engaging behavior change interventions [60]. Research also showed that digital interventions developed using behavior change theory and BCTs are more likely to be effective than those without [60,62]. However, little is known about how these 2 approaches can be blended throughout the design process of artifacts to ensure that microengagement and macroengagement needs will be met [60]. Here, our study provided more understanding about how this integration can be done.

Third, an explanatory sequential mixed methods design [38] was applied in the evaluation stage of the SAMSON's DSRM. This type of design is helpful for us to know why the user rated the solution's quality as *low* or *high* for each criterion and gain further understanding on how we can improve the SAMSON in its next version. Because of the assumption that technical knowledge is needed to complete the questionnaire, we adapted Enlight for a lay audience. Unlike some other assessment tools, Enlight includes some quality constructs associated with intervention outcomes, such as persuasive design, behavior change, or therapeutic alliance [41], which is specifically necessary for a mobile solution, such as SAMSON, to change patients' behavior toward medical treatments. This tool has been validated for assessing eHealth interventions regardless of delivery mediums and clinical aims [41]. In our study, it was language adapted but requires further validation for a community sample. Measures for evaluating the quality of a designed artifact are often difficult to define and are controversial [33]. Therefore, applying a mixed methods design with an appropriate, reliable, and valid assessment tool in the evaluation of digital interventions (eg, in the case of SAMSON) could be one of the effective ways to address this challenge.

Fourth, we effectively involved stakeholders, including real users, early and throughout the co-design and evaluation processes. We formed a project steering committee that included experts in allied health, app development, computer sciences, digital health, oncology, and psychology, as well as consumer representatives. They were involved very early in the co-design process to guide the review of behavior change literature and the selection of targeted change in nonadherence behavior. The committee was also involved in reviewing problem identification and design motivation, adapting BSR principles, and conceptualizing design requirements for SAMSON. After development, SAMSON was thoroughly tested by reasonable numbers of users (21 consumers tested version 1, and 30 patients tested version 2). Their feedback in the testing was then used to construct new requirements or refine the next version of SAMSON. By recognizing users as experts of their own experience, the proper co-design process can address pitfalls in the design and development of mobile health solutions that might limit adoption and effective use in practice [64-66] by facilitating necessary collaborations of diverse stakeholders [67,68] and leveraging expert insights and best practices [69,70].

Our study also contributes to the literature of interventions to promote MA in cancer. Systematic reviews of MA interventions in adults with cancer showed that there was limited use or poorly reported use of theory [71] and frameworks [20] in the design and development of digital interventions [13]. A high number of MA digital interventions have been proposed, but many of them have low user acceptance [72], and their effectiveness in clinical oncology practice is poorly supported [17,20]. Perhaps poor design is 1 reason for these issues [33]. To the best of our knowledge, SAMSON is one of the very first mobile health solutions to improve MA in cancer that applied rigorous DSRM in the design and development process. The use of DSRM provided various improvements in identifying and addressing requirements as well as evaluating this digital solution.

SAMSON was perceived as acceptable, usable, and useful by end users.

Implications for Practice and Future Research

Broadly, our study's findings have implications for behavioral science and design science researchers, MA intervention developers, and oncology care providers. These findings provide additional evidence on the use of DSRM in health innovations. They can be used to develop principles for guiding DSRM adaptation and BSR integration in the design and development of mobile health solutions in general as well as those targeting MA. The findings of this work provide insights for oncology care providers to use, while encouraging the use of digital solutions to promote MA and drive health care outcomes. Technologies can enhance measures to improve MA, such as patient education as well as side effect monitoring and reporting, and facilitate effective communication between patients and their care team.

Our respondents indicated their acceptance of the mobile solution and valued its usability and usefulness in supporting their adherence to medication. They also reported some functional errors and the need for some further improvements in the design and features of SAMSON. We will use these findings to refine SAMSON and evaluate its acceptability, usability, and effectiveness in a future randomized controlled trial. On the basis of the feedback of participants, in the trial's protocol, we will include assessments to help identify those who would benefit from the SAMSON.

Limitations

This study has limitations. Participants enrolled in the SAMSON preliminary evaluation are from the Peter MacCallum Cancer Centre hematology department, and most of them used only 1 oral anticancer regimen. As Peter MacCallum Cancer Centre is one of the leading oncology hospitals in Australia, in the interview, patients acknowledged that the care service that they received was of high quality. Many were provided medication education before starting treatments and at ongoing follow-up appointments. As a result, their perceptions of MA solutions may not represent those of patients who use multiple anticancer medicines and receive care from low-resource oncology settings. Future research can extend the evaluation of SAMSON to patients with other types of cancer at different levels of oncology care institutions.

Conclusions

By following the systematic DSRM approach, a patient-centered mobile health solution was developed to meet the needs and preferences of people with cancer and thus highly likely to be used by end users. This extensive report of the intervention development process provides transparent guidance on how to develop patient-centered digital mobile health solutions that will have a high likelihood of uptake.

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Data Availability

The data sets generated and analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

All authors have made substantial contributions and approved the conceptions, drafting, and final version of the manuscript. THD undertook the analysis and interpretation of the data. THD drafted the paper with contribution from NW, ARMF, PPJ, KB, CO, AW, and PS.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Evaluating the Safety and Adherence to Medication and Self-Care Advice in Oncology (SAMSON) mobile app questionnaire.
[DOC File , 76 KB - cancer_v10i1e46979_app1.doc]

Multimedia Appendix 2
Interview guide.
[DOC File , 46 KB - cancer_v10i1e46979_app2.doc]

Multimedia Appendix 3
Feedback from consumers on Safety and Adherence to Medication and Self-Care Advice in Oncology (SAMSON) version 1.
[XLSX File (Microsoft Excel File), 15 KB - cancer_v10i1e46979_app3.xlsx]

Multimedia Appendix 4
New designed features of Safety and Adherence to Medication and Self-Care Advice in Oncology (SAMSON) version 2 in comparison to version 1.
[DOCX File , 264 KB - cancer_v10i1e46979_app4.docx]

Multimedia Appendix 5
CONSORT (Consolidated Standards of Reporting Trials) diagram.
[DOC File , 50 KB - cancer_v10i1e46979_app5.doc]

Multimedia Appendix 6
Safety and Adherence to Medication and Self-Care Advice in Oncology (SAMSON) participant rating.
[XLSX File (Microsoft Excel File), 13 KB - cancer_v10i1e46979_app6.xlsx]

Multimedia Appendix 7
Qualitative analysis codebook.
[DOC File , 34 KB - cancer_v10i1e46979_app7.doc]

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Abbreviations

BCT: behavior change technique
BLP: behavioral learning perspective
BSR: behavioral science research
CML: chronic myeloid leukemia
DSR: design science research
DSRM: design science research methodology
Enlight: Evaluation Tool for Mobile and Web-Based eHealth Interventions
HBM: health belief model
HCP: health care professional
MA: medication adherence
SAMSON: Safety and Adherence to Medication and Self-Care Advice in Oncology
SDT: self-determination theory

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Original Paper

Telehealth With Comprehensive Live-Fed Real-World Data as a Patient Care Platform for Lung Cancer: Implementation and Evaluation Study

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Abstract

Background: Telehealth has emerged as a popular channel for providing outpatient services in many countries. However, the majority of telehealth systems focus on operational functions and offer only a sectional patient journey at most. Experiences with incorporating longitudinal real-world medical record data into telehealth are valuable but have not been widely shared. The feasibility and usability of such a telehealth platform, with comprehensive, real-world data via a live feed, for cancer patient care are yet to be studied.

Objective: The primary purpose of this study is to understand the feasibility and usability of cancer patient care using a telehealth platform with longitudinal, real-world data via a live feed as a supplement to hospital electronic medical record systems specifically from physician's perspective.

Methods: A telehealth platform was constructed and launched for both physicians and patients. Real-world data were collected and curated using a comprehensive data model. Physician activities on the platform were recorded as system logs and analyzed. In February 2023, a survey was conducted among the platform's registered physicians to assess the specific areas of patient care and to quantify their before and after experiences, including the number of patients managed, time spent, dropout rate, visit rate, and follow-up data. Descriptive and inferential statistical analyses were performed on the data sets.

Results: Over a period of 15 months, 16,035 unique users (13,888 patients, 1539 friends and family members, and 174 physician groups with 608 individuals) registered on the platform. More than 382,000 messages including text, reminders, and pictures were generated by physicians when communicating with patients. The survey was completed by 78 group leaders (45% of the 174 physician groups). Of the participants, 84% (65.6/78; SD 8.7) reported a positive experience, with efficient communication, remote supervision, quicker response to questions, adverse event prevention, more complete follow-up data, patient risk reduction, cross-organization collaboration, and a reduction in in-person visits. The majority of the participants (59/78, 76% to 76/78, 97.4%) estimated improvements in time spent, number of patients managed, the drop-off rate, and access to medical history, with the average ranging from 57% to 105%. When compared with prior platforms, responses from physicians indicated better experiences in terms of time spent, the drop-off rate, and medical history, while the number of patients managed did not significantly change.

Conclusions: This study suggests that a telehealth platform, equipped with comprehensive, real-world data via a live feed, is feasible and effective for cancer patient care. It enhances inpatient management by improving time efficiencies, reducing drop-off rates, and providing easy access to medical history. Moreover, it fosters a positive experience in physician-patient interactions.

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KEYWORDS

telehealth; real-world data; patient engagement; lung carcinoma; patient-reported outcomes

Introduction

According to the GLOBOCAN 2020 report, the cancer mortality rate is higher in China than that in developed countries [1]. Lung cancer remains the most common and deadliest type of cancer, with an estimated 0.82 million new cases and 0.72 million deaths in 2020 in China [1]. In contrast to the rapidly declining mortality rate for lung cancer in high-income countries between 2000 and 2012 [2], the trend in the lung cancer mortality rate was stable in China from 2000 to 2016 [3]. Despite favorable survival outcome data for Chinese patients in international randomized clinical trials, these data do not reflect the real-world situation for the general population. The less-than-optimal progress in cancer control, especially in terms of the mortality rate, may be attributed to health care disparities between different regions, particularly urban and rural areas [4,5]. Clinical trial data from inadequately represented cancer patient populations could be complemented with real-world evidence to better inform health care practice and policy decisions [6].

The rapid development and adoption of new treatment regimens have made posttreatment care a critical factor in extending the cancer survival rate and improving patients' quality of life [7]. Concurrently, telehealth has quickly become a major care delivery mechanism in recent years, a trend accelerated by the COVID-19 pandemic. One ongoing effort to sustain and scale digital health involves enabling data sharing and integration across different health systems [8]. Consequently, most telehealth systems today rely on point-in-time medical records that do not contain historical records nor data from other institutes. To overcome this data barrier, the platform implemented in this study has the capability to acquire medical records directly from patients.

Though there are perceivable benefits to having comprehensive medical records for telehealth, enabling comprehensive and longitudinal data for each patient involves tremendous effort. Such data are also critical for deriving conclusive real-world evidence [9]. Data acquisition must be inclusive, especially of vital signs related to the patient's daily health status throughout the entire treatment period, in addition to diagnosis and treatment information [10]. Although this is currently achievable with the adoption of wearables and mobile devices, there are still tremendous challenges in longitudinally compiling patients' journeys as there are no unified nationwide platforms that can consolidate all relevant data from all health care institutions in China [11,12]. The ever-increasing mobility of patients across the country has exacerbated the issue of data segmentation. Presumably, due to the recent improvement in annual income per household and the deployment of interstate health care systems, many patients opt for top-tier hospitals regardless of the travel distance from their home. It is quite common for one patient to receive treatment from different hospitals at various stages, while the hospital systems remain disconnected. The lack of longitudinal data from such fragmented health services may also contribute to subpar care and survival outcomes [13,14].

The distinct feature of telehealth, in which this study is interested, is its use as an adjunct to traditional physical visits and face-to-face consultations, particularly for posttreatment care and continuity of care from a physician's perspective. Much of the research on telehealth usage has been focused on patients as the user population. Williams and Shang [15] examined telehealth use among a low-income, minority population in the United States and found the use of telehealth varies based on race, employment status, identified gender, education level, and age. Acoba et al [16] studied racial disparities in cancer patients during telehealth visits and confirmed that satisfaction with the visit is different between races. Turner et al [17] evaluated the experiences of health care providers and professionals during the COVID-19 pandemic and concluded the need for implementation strategies and necessary policies. Specifically for cancer patients, teledermatology has emerged as a popular mechanism [18]. In a cross-sectional study, Lama et al [19] found that more than one-half of cancer survivors use the internet or telehealth to access providers.

One of the specific aspects being assessed is follow-up, a unique challenge for cancer care in China, primarily due to the substantial patient-to-physician ratio [20]. Follow-ups using patient-reported outcomes (PROs) can improve the overall survival rate due to early relapse detection and better performance status at relapse. A study published in 2017 found that patients who reported their symptoms via an online tool survived 7 months longer than those who received usual care through regular screenings [21]. A previous meta-analysis of 21 studies also demonstrated that the reporting of PROs, including quality of life and disease symptoms, were significantly associated with tumor response to anticancer therapies such as chemotherapy, targeted therapy, and radiotherapy [22].

The platform used in this study, named WeDoc, is cloud-based and currently focuses on lung cancer. It consists of a mobile app for physicians, a WeChat mini-program for patients, and a cloud-based data and analytical component serving as the back end. The platform contains comprehensive, longitudinal medical records sourced from all relevant hospitals and supplemented with third-party test results, PROs, follow-up data, and more. The underlying data model is highly customizable to individual physicians' needs and contains curated fields commonly used for cancer clinical research.

Methods

Overview

A cloud-based telehealth platform was built and launched for licensed oncologists and their patients. Patient medical records were collected and curated into a proprietary lung cancer data model. Physician and patient activities are recorded on the platform. A survey containing qualitative and quantitative questions was conducted 20 months after launch. Descriptive statistics and regression analysis were conducted on the survey data.

Analysis was conducted on 2 sets of data: activities recorded on the platform and results from a usage survey. Both sets of data were gathered from the perspective of physicians, as the goal in the first stage of this platform is to function as an assistant for physicians.

Platform Implementation and Recording of User Activity

The back end of the platform features a data processing pipeline; data and process management interfaces; and cloud repositories for raw, curated, and research data. Original data are deidentified, masking all personal details. These data are then abstracted and reviewed by trained personnel, and the abstracted data are consolidated, checked for quality, and committed to the real-world data repository.

Patients are invited to the platform by their oncologists and can form a user group with family members or friends. Oncologists can invite physicians and caregivers to create a treatment group, facilitating remote collaboration and simplifying hospital transfers. Patient reminders, assessments, and symptom feedback are gathered, and any potential adverse events are escalated to the primary oncologist.

The system's data model incorporates the schema of electronic medical records, patient outcome reports, and periodic progression assessments by physicians, with a primary focus on lung cancer data. Data abstraction and data quality assurance involve both manual processes and regularly executed algorithms.

Survey Design and Questionnaire

The platform records the number of registered users and their activities. In March 2023, about 20 months after launch, an online usage survey was carried out using a WeChat survey mini-program. The program was pushed to all registered users as a study advertisement. The survey consisted of both qualitative and quantitative questions. Instead of individual physicians, each treatment group leader was asked to compile the group's experience and provide responses. This approach was taken because the group leader dictates the use of the platform, and each group member may only utilize a subset of its functions.

The survey questions were designed to evaluate physicians' patient care experiences using the platform. This includes basic functions and follow-up, their estimation of promptness in answering patient questions, patient risk reduction, cross-organization collaboration, and handling out-of-town patients. Quantitative questions asked for the number of both outpatients and inpatients managed, reduction in the number of physical visits, patient drop-off rates, and time spent collecting medical history during each visit. All identifiable information about participants was removed, and each individual was assigned a unique participant ID.

Table 1. Survey question categories, descriptions, and answer options.

Question category and description	Answer options
Patient care functions	
A1: (Efficient communication) The platform serves as a communication channel for physicians to provide online notification of important matters.	Single-choice selection of binary options (agree or disagree) for each statement as a checkbox selection
A2: (Remote supervision) The platform enables physicians to provide continuous supervision and remote interaction.	Single-choice selection of binary options (agree or disagree) for each statement as a checkbox selection
A3: (Medical history retrieval) The platform offers patients' medical history and communication records for physicians to review.	Single-choice selection of binary options (agree or disagree) for each statement as a checkbox selection
A4: (Patient administrative processes) The platform helps hospital appointment scheduling for both outpatient and inpatient procedures.	Single-choice selection of binary options (agree or disagree) for each statement as a checkbox selection
A5: (Response to patient question on time) The platform enables physicians to promptly answer patients' questions without in-person visits.	Single-choice selection of binary options (agree or disagree) for each statement as a checkbox selection
A6: (Adverse event prevention) The platform enables physicians to timely capture potential adverse reactions from patient feedback.	Single-choice selection of binary options (agree or disagree) for each statement as a checkbox selection
Follow-up	
B1: (Treatment status availability) Before: It was hard to acquire patient status. After: Patient status is easy to gather from the platform.	Single-choice selection of binary options (agree or disagree) for each statement as a checkbox selection
B2: (Survival status availability) Before: It was hard to acquire survival status. After: Survival status is provided on the platform.	Single-choice selection of binary options (agree or disagree) for each statement as a checkbox selection
B3: (Data comprehensiveness) Before: Records were incomplete. After: Multidimensional, comprehensive data are available on the platform.	Single-choice selection of binary options (agree or disagree) for each statement as a checkbox selection
B4: No differences between before and after using the platform.	Single-choice selection of binary options (agree or disagree) for each statement as a checkbox selection
Response promptness	
C: With the platform, are you able to respond to patient inquiries quicker than before?	Single-choice selection of 3 options (yes, no, or unknown) for each question as a radio button selection
Patient risk reduction	
D: After using the platform, do you feel that your patients have a lower risk of adverse reactions?	Single-choice selection of 3 options (yes, no, or unknown) for each question as a radio button selection
Cross-organization collaboration	
E: Have you established collaborations across different departments, hospitals, or even regions through the platform?	Single-choice selection of 3 options (yes, no, or unknown) for each question as a radio button selection
Management of remote patients	
F: Is managing out-of-town patients more convenient for you by using the platform?	Single-choice selection of 3 options (yes, no, or unknown) for each question as a radio button selection
More patients managed per unit time	
G: With the platform, how many more patients can you manage within the same amount of time?	Single-choice selection of 5 quantitative ranges: 10%-20%, 20%-50%, 50%-100%, >100%, 0%
In-person visits saved	
H: After using the platform, what is your estimation of the average number of in-person visits reduced per patient per year?	Single-choice selection of 5 quantitative ranges: 1-3, 4-6, 7-10, >11, 0
Prior telehealth experience	
I: Before using WeDoc, did you use any other telehealth platforms for patient management?	Single-choice selection of yes or no
Patient management specifics	
How many minutes per day do you spend managing patients?	
J1: Before	Quantitative values entered by participants
J2: After	Quantitative values entered by participants
What is the total number of patients you manage?	

Question category and description	Answer options
K1: Before	Quantitative values entered by participants
K2: After	Quantitative values entered by participants
Outpatient management	
How many outpatient visits in total do your lung cancer patients have per month?	
L1: Before	Quantitative values entered by participants
L2: After	Quantitative values entered by participants
What percentage of your lung cancer patients are likely to miss their outpatient visits each month?	
M1: Before	Quantitative values entered by participants
M2: After	Quantitative values entered by participants
Inpatient management	
How many lung cancer patients do you see for inpatient treatment per month?	
N1: Before	Quantitative values entered by participants
N2: After	Quantitative values entered by participants
What percentage of your inpatients discontinue their treatment each month?	
O1: Before	Quantitative values entered by participants
O2 – After	Quantitative values entered by participants
Medical history collection	
How many minutes do you spend collecting the medical history in each patient visit?	
P1: Before	Quantitative values entered by participants
P2: After	Quantitative values entered by participants

Statistical Analysis

Descriptive statistics and regression analysis were conducted using the Python program. For descriptive analysis, we calculated the means, medians, standard deviations, and ranges. For quantitative questions regarding usage before and after, we used the Shapiro-Wilk test to assess the normal distribution of the data. Subsequently, we used the Wilcoxon rank sum test to evaluate the significance of the data sets. We used G*Power [23] to analyze the difference between 2 dependent means (matched pairs), setting the alpha at .05, beta at .2, and dz at 0.5. Assuming a medium-level difference between the before and after groups, a sample size of 27 was considered sufficient for the tests.

Ethical Considerations

This study was reviewed and approved by Yinchuan Ningfei Internet Hospital (approval number HLWYJ-2022-016). Participants were not compensated for their participation.

Results

Activities Recorded on the Platform

Over a period of 15 months, 608 physicians from 153 hospitals registered on the platform. The hospitals were from 21 of the 34 total provinces in China. Of the physicians, 92.8% (142/153) were from hospitals rated as Grade III, Level A, which is the highest rating according to the latest statistics [24] (Table 2). From a departmental perspective, 46.3% (125/270) of the physicians were from the oncology department, 41.9% (113/270) were from the department of respiratory and critical care medicine, and 11.9% (32/270) were from other departments.

Table 2. Physician and patient profiles registered in the system, including the numbers of hospitals, departments, physicians, treatment groups, and patients.

Characteristics	Results
Hospitals (n=153), n (%)	
Grade III, Level A	142 (92.8)
Others	11 (7.2)
Departments (n=270), n (%)	
Oncology	125 (46.3)
Respiratory and critical care medicine	113 (41.9)
Others	32 (11.9)
Physicians (n=608), n (%)	
Treatment group leader	174 (28.6)
Treatment groups, n	211
Patients and family members, n	15,427
Patients (n=13,888), n (%)	
Nonresident patients	7826 (56.3)

One of the platform's features for physicians is creating treatment groups by including other physicians. Among the 608 physicians, 174 have one or more groups. There are a total of 211 groups, with most physicians managing between 1 and 3 groups. A patient may be part of multiple groups, depending on the group's purpose and treatment stage. For instance, a patient undergoing inpatient chemotherapy might initially be in a group with a radiologist in the hospital but later transferred to a follow-up group consisting only of the lead oncologist and the follow-up assistant. Table 2 describes the profiles of physicians and treatment groups.

In addition to physicians and caregivers, there are 15,427 patients and family members on the platform. Within that user group, 9.98% (1539/15,427) are family members or friends.

Table 3 demonstrates the message types and quantities of physician-patient communication from the system activity logs. More than 382,000 messages including text messages, reminders, and pictures were recorded during the study period. Text was the most commonly used message type. Pictures and voice messages were used significantly less often than text messages. Reminders, patient education materials, team messages, and scaled assessments were usually initiated by physicians for different purposes.

Table 3. Activity log of the message types and quantities between physician-patient communication.

Message type	Typical usage	Message count, n
Text	Chats between patients and physicians	222,012
Reminder	Appointments and preparation items for appointments	66,985
Picture	Pictures in chat with patients	32,548
Patient education	General patient education through formats such as articles, videos, and URLs	27,538
Team message	Messages between physicians within the same group	19,779
Scaled assessment	Patient self-assessment of various aspects	8005
Voice	Voice messages for patients	5884

Survey Questionnaire Responses

Participant Characteristics

A total of 78 group leaders participated in the survey, representing 44.8% (78/174) of the treatment groups. All the groups were associated with Group III, Level A hospitals. Participant characteristics including city locations, gender distribution, departments, age groups, and prior experience with telehealth platforms are summarized in Table 4.

Table 4. Profiles of participants in the survey questionnaire (N=78).

Characteristics	Results, n (%)
City location	
Beijing, Shanghai, or Guangzhou	33 (42)
Others	45 (58)
Gender	
Female	36 (46)
Male	42 (54)
Departments	
Oncology	46 (59)
Respiratory	26 (33)
Others	6 (8)
Age group (years)	
20-30	4 (5)
30-40	15 (19)
40-50	33 (42)
50-60	24 (31)
>60	2 (3)
Prior telehealth usage	
No	25 (32)
Yes	53 (68)

Qualitative Question Results

For questions A1 to F, which included the topics of communication efficiency, remote supervision, question response times, adverse event prevention, follow-up data completeness, patient risk reduction, cross-organization collaboration, and remote patient management, participants provided qualitative answers to each question. The results are shown in Table 5. A positive answer indicates agreement with the statement or yes to the question. A negative answer indicates disagreement with the statement or no to the question. Most of the questions received positive answers except for the topic of cross-organization collaboration, which had nearly neutral feedback: 54% positive versus 46% negative. The questions of treatment status availability (B1), survival status availability (B2), and data comprehensiveness (B3) contain both before and after statements. A negative answer may indicate that the participant only disagrees with part of the statement. Therefore, the final results of these questions indicated less favorable evaluations of the WeDoc tool.

Table 5. Results of the qualitative survey questions (N=78).

Question description	Survey results, n (%)
A1: Efficient communication	
Positive	76 (97)
Negative	2 (3)
A2: Remote supervision	
Positive	73 (94)
Negative	5 (6)
A3: Medical history retrieval	
Positive	69 (89)
Negative	9 (12)
A4: Patient administrative processes	
Positive	58 (74)
Negative	20 (26)
A5: Respond to patient questions on time	
Positive	69 (89)
Negative	9 (12)
A6: Adverse event prevention	
Positive	67 (86)
Negative	11 (14)
B1: Treatment status availability	
Positive	68 (87)
Negative	10 (13)
B2: Survival status availability	
Positive	58 (74)
Negative	20 (26)
B3: Data comprehensiveness	
Positive	68 (87)
Negative	10 (13)
B4: No difference	
Positive	8 (10)
Negative	70 (90)
C: Response promptness	
Positive	70 (90)
Negative	8 (10)
D: Patient risk reduction	
Positive	70 (90)
Negative	8 (10)
E: Cross-organization collaboration	
Positive	42 (54)
Negative	36 (46)
F: Management of remote patients	
Positive	78 (100)
Negative	0

Question description	Survey results, n (%)
I: Prior telehealth experience	
Positive	53 (68)
Negative	25 (32)
G: Additional patients managed per unit time	
0%	6 (8)
10%-20%	20 (26)
20%-50%	28 (36)
50%-100%	7 (9)
>100%	17 (22)
H: In-person visits saved per year	
0	6 (8)
1-3	12 (15)
4-6	30 (39)
7-10	21 (27)
>11	9 (12)

On the question of the number of patients managed using the tool, 36% (28/78) of the participants estimated that they were able to see 20%-50% more patients with the same amount of time spent. However, 6 of the participants estimated a 0% increase. Similarly, on the question regarding the number of in-person patient visits reduced, 39% (30/78) estimated 4 to 6 visits saved per year, and 6 respondents did not see a reduction.

Among the 78 participants, 53 (68%) had prior telehealth usage experience, while it was the first time using a telehealth tool for the rest of the group. We divided the participants into 2 groups, with and without telehealth usage experience, for some of the additional analyses.

Quantitative Question Results

For questions J to P, participants were asked to provide quantitative values for their experiences both before and after using the tool. Table 6 summarizes the values for each question. The “Unknown” category indicates null values in the survey, and these responses were omitted in the analysis. The highest number of unknown answers we received was for the question about the number of patients managed before using the tool. We used G*Power analysis for the remaining nonnull before-and-after pairs to ensure that there was a sufficient sample for analysis. With an assumption of medium differences between the before and after groups, at least 27 samples had to be present in the group.

Table 6. Results for the quantitative survey questions (N=78).

Question description	Unknown responses, n (%)	Valid responses				
		Minimum-maximum	Median	Mean (SD)	Mean improvement, %	*P* value for the before-after comparison[a]
Time spent managing patients (minutes)						<.001
J1: Before	18 (23)	10-180	30	50.5 (45.1)	N/A[b]	
J2: After	10 (13)	3-120	20	25.5 (22.7)	88	
Number of patients managed						.01
K1: Before	20 (26)	0-800	40	105.7 (177.4)	N/A	
K2: After	13 (17)	1-1606	100	324.3 (428.8)	63	
Monthly number of outpatient lung cancer patients						.66
L1: Before	8 (10)	0-2000	85	221.8 (352.2)	N/A	
L2: After	8 (10)	0-2000	80	237.1 (369.6)	—[c]	
Outpatient drop-off rate (%)						<.001
M1: Before	11 (14)	0-80	25	26.8 (21.1)	N/A	
M2: After	11 (14)	0-50	10	13.1 (11.4)	105	
Monthly number of lung cancer inpatients						.59
N1: Before	2 (3)	0-350	60	110.1 (93.5)	N/A	
N2: After	2 (3)	0-350	70	116.2 (94.8)	—	
Inpatient drop-off rate (%)						<.001
O1: Before	5 (6)	0-50	10	14.9 (12.1)	N/A	
O2: After	5 (6)	0-100	5	9.2 (16.2)	62	
Time collecting medical history (minutes)						<.001
P1: Before	5 (6)	2-180	10	14.0 (28.8)	N/A	
P2: After	3 (4)	1-120	3	8.8 (19.2)	57	

[a] Assessed using Wilcoxon tests.

[b] N/A: not applicable.

[c] No improvement.

To better understand the differences between the before and after results, we used the Shapiro algorithm to test whether the values fell within a normal distribution. For normally distributed data series, a *t* test can be used to compare the pairs. Otherwise, the Wilcoxon test is a more suitable method. Since the *P* values of the Shapiro test were all <.001, which is much lower than the common hypothesis threshold of .05, we concluded that none of the pairs were normally distributed. Therefore, Wilcoxon tests were performed on the before-and-after pair data (Table 6). The Wilcoxon results suggest that there were 2 questions that were not significantly different between before and after the platform: the monthly number of outpatients admitted and the monthly number of inpatients admitted. This result is quite explainable, as the telehealth tool itself is not aimed at recruiting new patients; therefore, the monthly numbers of patients remained nearly the same. For the topics that had significant changes, we calculated the improvements based on the mean values collected in the survey, which are also shown in Table 6.

Although the survey was not specifically designed to compare the group with prior telehealth platform experience with the group without prior experience, we discovered that 68% (53/78) of the participants had used telehealth tools before. In order to understand the experience by group, we carried out a Wilcoxon test to compare the responses before and after (Table 7). The numbers of monthly admitted outpatient and inpatient lung cancer patients still did not change significantly. However, there was also no significant change in the number of patients managed, suggesting that physicians may not manage more patients using WeDoc than with other telehealth platforms.

Table 7. Results for the quantitative survey questions for those who had prior telehealth platform experience (n=53).

Question description	Unknown responses, n (%)	Valid responses				
		Minimum-maximum	Median	Mean (SD)	Mean improvement, %	*P* value for the before-after comparison[a]
Time spent managing patients (minutes)						<.001
J1: Before	5 (9)	10-180	30	50.7 (46.8)	N/A[b]	
J2: After	5 (9)	3-120	20	28.6 (25.2)	77	
Number of patients managed						.06
K1: Before	11 (21)	1-800	40	125.8 (199.5)	N/A	
K2: After	6 (11)	1-1200	100	322.3 (403.4)	—[c]	
Monthly number of outpatient lung cancer patients						.75
L1: Before	4 (8)	0-2000	60	214.7 (388.9)	N/A	
L2: After	4 (8)	0-2000	60	225.6 (407.9)	—	
Outpatient drop-off rate (%)						<.001
M1: Before	7 (13)	0-80	30	28.2 (22.7)	N/A	
M2: After	7 (13)	0-50	10	13.9 (12.1)	102	
Monthly number of lung cancer inpatients						.65
N1: Before	0	0-350	60	109.6 (100.0)	N/A	
N2: After	0	0-350	60	113.8 (98.4)	—	
Inpatient drop-off rate (%)						<.001
O1: Before	3 (6)	0-50	10	14.7 (13.3)	N/A	
O2: After	3 (6)	0-12	5	5.7 (4.1)	159	
Time collecting medical history (minutes)						<.001
P1: Before	3 (6)	2-180	8	15.3 (34.1)	N/A	
P2: After	3 (6)	1-120	3	9.3 (22.8)	63	

[a] Assessed using Wilcoxon tests.

[b] N/A: not applicable.

[c] No improvement.

Discussion

Principal Findings

Specific Feedback About the Platform

Results from activity logs and survey responses demonstrate the feasibility of cancer patient care using telehealth with a live-transmitted real-world database. Specifically, 84% (65.6/78, SD 8.7) of participants responded positively to questions A1 through F. The lowest scores were for patient administrative processes and survival status. Patient administrative processes in China are complex and not the primary focus of this platform, while obtaining updated survival status during follow-up is clearly an area for improvement. Another area that did not stand out was cross-organization collaboration, presumably due to the deployment of other specialized platforms such as Multidisciplinary Team, which is popular in China. Of the participants, 92% believed that they could manage more patients with the same amount of time, and an equal number of physicians agreed that the platform saves at least one or more instances of in-person visits.

Our analysis of the before and after experiences of the same population showed that 5 of the 7 categories were significantly different after use of the platform, as determined using the Wilcoxon signed rank test. The 2 categories that were not significantly different were the monthly numbers of outpatient and inpatient admissions. These 2 factors are unaffected by the use of any patient management tool; thus, they are indeed irrelevant to our telehealth platform.

Perceptions of Those With Prior Telehealth Usage

Given that 68% of the participants had prior experience with telehealth platforms, analyzing this population alone yielded similar results, except that the number of patients managed did not meet our significance value assumption of .05. This implies that, although managing more patients is a benefit of telehealth platforms, it may not be unique to ours. The strengths of a telehealth platform with real-world data are manifested in the categories of time efficiency, drop-off rates, and access to patients' medical histories.

Remote Patient Management

The adoption of remote patient management was evident in the patient profiles, which showed that more than one-half of patients, about 56.3%, were nonresidents; 941 patients had transferred from one hospital to another, and almost 1500 patients had prior diagnoses or treatments from hospitals other than their current hospital. Taking hospitals in Shanghai as an example, the platform showed that about 35% of patients were from cities other than Shanghai. Although more than one-half of the patients were from adjacent provinces such as Jiangsu and Zhejiang, some travel thousands of miles from places like Heilongjiang, Sichuan, and Liaoning. Because of the unbalanced health care situation in China, it is quite common for patients to be diagnosed in one hospital and receive treatments at another. Despite significant improvements over the past few decades, the best oncologists and medical facilities are still heavily concentrated in top cities.

Text as the Dominant Message Type

The activity log indicated that text was the most commonly used message type to communicate with patients. The use of pictures and voices messages was significantly lower than that of text. Reminders were also quite popular, followed by educational materials. The preliminary analysis did not reveal significant differences in usage patterns among physicians, so we did not present usage data by physician profile.

Security and Privacy

With the adoption of the Personal Information Protection Law (PIPL) [25] in China on November 01, 2021, all systems handling data from Chinese citizens must be compliant with the law. This law is widely seen as China's equivalent of the EU General Data Protection Regulation (GDPR) [26]. The system in question acts as both a data handler and data processor. It controls the scope of data usage based on the level of consent obtained from users, making user consent a mandatory prerequisite for successful user registration. By separating raw data and identifiers from curated, deidentified data, the system ensures the proper implementation of data protection policies.

From an operational perspective, privacy protection remains one of the most significant challenges in building such a platform. The challenge is less technical, as there are rich sets of mechanisms available, such as data anonymization, encryption, access control, and audit. The main challenge comes from the perceptions and cooperation of patients. Ideally, patients and their relatives should also have access to real-world data, enabling them to participate in treatment decisions. Apart from patient perceptions, potential malpractice concerns also hinder data sharing, preventing people from gaining strategic insights. Health care policymakers and scientific researchers need to collaborate with data analysts to promote a proper data sharing process.

Limitations

Although this study is based on a live system with real-world data and experiences, the findings remain preliminary. At present, the platform only provides services to the lung cancer population, and the results of this study are derived from physicians from a subset of the treatment paradigm. Although the user base of the platform encompasses both physicians and patients, future research involving a broader population, including more physicians and direct patient experiences, may yield new, insightful findings. It would also be interesting to expand to other diseases. Given the large quantity of chat messages accumulated on the platform, a detailed examination of these messages paired with language processing models would be a fascinating next step.

Conclusion

This study demonstrates the feasibility of using telehealth for patient management. As the focus of cancer treatment shifts toward patient care, telehealth in the form of mobile apps, web-based interfaces, or other formats will play an increasingly critical role in enabling physicians to maintain close contact with patients, regardless of physical location. We advocate for the integration of telehealth with comprehensive real-world medical record data, so that such a platform can provide patient management capabilities. This could eventually lead to improved quality of life and survival rates of cancer patients.

Data Availability

The data sets analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

DZ, YS, YR, and LJ contributed to the conception and design of the study. JN, LP, XT, ZD, YZ, AG, JW, XL, and JZ refined the research questions and provided feedback on the study design. WH, CZ, CL, HL, YD, JX, DW, XC, RM, and XD assisted with platform function review, usability testing, and participant recruitment. YS and SL designed the survey questions and analyzed the data. DZ, LP, XT, YD, XD, YR, and LJ drafted the manuscript.

Conflicts of Interest

YR and SL are co-founders of Metafame Technologies Inc, which developed the system. However, the system is not marketed as a paid service.

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Abbreviations

GDPR: General Data Protection Regulation
PIPL: Personal Information Protection Law
PRO: patient-reported outcome

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Original Paper

Applying the Unified Theory of Acceptance and Use of Technology to Identify Factors Associated With Intention to Use Teledelivered Supportive Care Among Recently Diagnosed Breast Cancer Survivors During COVID-19 in Hong Kong: Cross-Sectional Survey

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Abstract

Background: Many supportive cancer care (SCC) services were teledelivered during COVID-19, but what facilitates patients' intentions to use teledelivered SCC is unknown.

Objective: The study aimed to use the unified theory of acceptance and use of technology to investigate the factors associated with the intentions of breast cancer survivors (BCS) in Hong Kong to use various types of teledelivered SCC (including psychosocial care, medical consultation, complementary care, peer support groups). Favorable telehealth-related perceptions (higher performance expectancy, lower effort expectancy, more facilitating conditions, positive social influences), less technological anxiety, and greater fear of COVID-19 were hypothesized to be associated with higher intentions to use teledelivered SCC. Moreover, the associations between telehealth-related perceptions and intentions to use teledelivered SCC were hypothesized to be moderated by education level, such that associations between telehealth-related perceptions and intentions to use teledelivered SCC would be stronger among those with a higher education level.

Methods: A sample of 209 (209/287, 72.8% completion rate) women diagnosed with breast cancer since the start of the COVID-19 outbreak in Hong Kong (ie, January 2020) were recruited from the Hong Kong Breast Cancer Registry to complete a cross-sectional survey between June 2022 and December 2022. Participants' intentions to use various types of teledelivered SCC (dependent variables), telehealth-related perceptions (independent variables), and sociodemographic variables (eg, education, as a moderator variable) were measured using self-reported, validated measures.

Results: Hierarchical regression analysis results showed that greater confidence using telehealth, performance expectancy (believing telehealth helps with daily tasks), social influence (important others encouraging telehealth use), and facilitating conditions (having resources for telehealth use) were associated with higher intentions to use teledelivered SCC (range: $\beta=0.16$, $P=.03$ to $\beta=0.34$, $P<.001$). Moreover, 2-way interactions emerged between education level and 2 of the telehealth perception variables. Education level moderated the associations between (1) performance expectancy and intention to use teledelivered complementary care ($\beta=0.34$, $P=.04$) and (2) facilitating conditions and intention to use teledelivered peer support groups ($\beta=0.36$,

P=.03). The positive associations between those telehealth perceptions and intentions were only significant among those with a higher education level.

Conclusions: The findings of this study implied that enhancing BCS' skills at using telehealth, BCS' and their important others' perceived benefits of telehealth, and providing assistance for telehealth use could increase BCS' intentions to use teledelivered SCC. For intentions to use specific types of SCC, addressing relevant factors (performance expectancy, facilitating conditions) might be particularly beneficial for those with a higher education level.

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KEYWORDS

telehealth; tele-delivered supportive cancer care; breast cancer; COVID-19; technology acceptance; UTAUT

Introduction

Potential Impacts of COVID-19 on Breast Cancer Care

The COVID-19 pandemic has been an international public health emergency, posing severe threats to lives and health care systems worldwide. In Hong Kong, the implementation of different preventive measures (eg, regulations for social distancing, reprioritization of hospital services) affected the lives of not only the general population but also individuals with chronic diseases. Being one of the most commonly diagnosed cancers in Hong Kong, breast cancer diagnosis and treatment delays occurred during the COVID-19 pandemic [1]. For example, the number of pathologic specimens for the 4 most common cancer regions in Hong Kong (including breast cancer) received by public laboratories and public hospitals for cancer diagnostic services reduced by 15.5% overall in 2020, compared with the prior 3-year average [2]. Another study suggested that breast cancer patients in Hong Kong needed to wait 3 weeks longer for their first specialist consultation during the COVID-19 crisis than before the pandemic [3].

After completion of active treatments, many breast cancer survivors (BCS) still need supportive cancer care (SCC) and rehabilitation services to help with different cancer-related life aspects [4]. In the Netherlands, one-third of 1051 surveyed BCS reported difficulties contacting their general practitioner due to COVID-19 [5]. The COVID-19–related lockdowns in the United States and Germany also disrupted patients' referrals to cancer survivorship programs [6,7]. To reduce the impact of COVID-19 on cancer care, alternative modes of SCC delivery are therefore important.

Acceptability of Telehealth for Cancer Patients

Research suggests that COVID-19 might have catalyzed new models of health care (eg, telehealth) [4]. Telehealth is the use of technology to deliver health care, health information, or health education at a distance [8]. Telehealth technologies (including telephone, videoconferencing, and internet-based intervention) can bring services into the patient's home and help them cope with their illness without the need to be physically present at a hospital or clinic [8]. A recent qualitative study in Australia reported that patients with hematological cancer considered telehealth an acceptable alternative during the pandemic [9]. However, some patients encountered difficulties using teledelivered cancer care services due to a lack of knowledge and skills, plus some preferred to see the doctor visually through a video call over other teledelivered options [9]. Another survey explored the prospect of using telemedicine for follow-up among Australian BCS and found that 70% of respondents had suitable devices to access telehealth but only 15% accepted the postoperation teleconsultation with their surgeon [10]. Given that relevant research is limited in the Hong Kong context, this study examined the level of acceptability of telehealth for BCS to access SCC and its associated factors amid the COVID-19 pandemic.

Telehealth-Related Perceptions as Determinants of Patients' Intentions to Use Telehealth for SCC

Different theoretical models have been applied to explore intentions to use telehealth among general healthy populations and patient populations outside the COVID-19 context [11]. Among the models, the unified theory of acceptance and use of technology (UTAUT) is one of the most influential theories to understand people's acceptance of different types of information technologies including telehealth [11]. According to the UTAUT, performance expectancy (whether the individuals believe using the system would provide benefits), effort expectancy (whether the system is easy to use), social influence (perception of important others' opinions about using the system), facilitating conditions (organizational and technical infrastructure supporting the use of the system), and technology anxiety (users' negative emotional states related to learning to use technology [eg, nervousness, fear]) are the important determinants of people's intentions to use technology [12]. Compared with other traditional behavioral theories (eg, Theory of Planned Behavior, Health Belief Model), the UTAUT seems to have stronger explanatory power for understanding people's intentions to use telehealth [11].

The model has been applied to people's use of telehealth in different disease contexts. For example, higher performance expectancy, lower effort expectancy, more favorable social influences, less technology anxiety, and more facilitating factors have been associated with intention to use telehealth among Chinese populations (eg, older individuals in the community, individuals with chronic diseases) [13,14]. Performance expectancy and social influence were associated with higher intention to use telehealth service and treatment among patients with diabetes in Korea [15]. Similarly, among patients with type 2 diabetes in South Africa [16], lower performance expectancy, lower effort expectancy, less social influence, and fewer facilitating conditions explained the generally lower intention to use telehealth services. To the best of our knowledge, research on examining cancer survivors' intentions to use teledelivered

SCC during the COVID-19 pandemic was limited. Therefore, this study aimed to examine how telehealth-related perceptions were associated with intentions to use telehealth for SCC among BCS in Hong Kong during the COVID-19 pandemic.

Individual Characteristics and Fear of COVID-19 as Potential Determinants of Intentions to Use Telehealth for Supportive Cancer Services Among BCS

In addition to telehealth-related perceptions, patients' sociodemographic characteristics might also contribute to the acceptability of telehealth [11]. Factors like age, education, possession of smart device(s), the nature of the consultation (routine follow-up versus urgent need for physical examination), and experience with using technology could contribute to the acceptability of telehealth for cancer survivors [17]. Specific to the pandemic situation, recent studies found that fear of COVID-19 transmission was associated with higher intentions to use contact tracing apps among the general population in Germany [18] and telehealth services among cancer patients in the United States [19]. Expecting the same phenomenon to apply to BCS in Hong Kong, we aimed to examine the roles of patients' individual characteristics (eg, sociodemographic and clinical factors, fear of COVID-19) and prior experience with using technology in intentions to use telehealth for SCC.

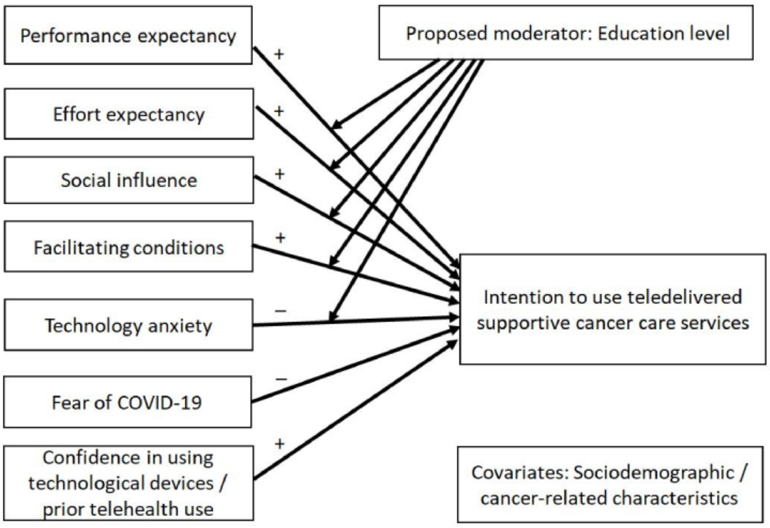
Moderating Role of Education Level

Despite the wide use of the UTAUT to explain people's intentions to use technology, whether the contribution of the variables in the theory differs based on people's sociodemographic and individual characteristics has not been extensively examined. Prior studies have generally regarded sociodemographic variables as covariates for intentions or behavior, which fails to unpack the complex ways in which such characteristics might interact with beliefs to determine behavioral intention and actual behaviors (eg, [20-22]). Education level has been suggested as a potential moderator between perceptions about behaviors and intentions to engage in online behaviors. For example, studies measured the intention of individuals to use e-banking based on the UTAUT model in the United Kingdom and Jordon and found that education level had a positive moderating effect on performance expectancy, facilitating conditions [23], and effort expectancy [24]. Another study in Indonesia also found that education level moderated the relationship between effort expectancy and intention to use e-money services [25]. Similar research on the intentions of BCS to use telehealth amid the COVID-19 pandemic was limited. Specifically, the role of education as a moderator between telehealth perceptions and BCS' intentions to use teledelivered SCC were investigated in this study.

Purpose of the Study

This study aimed to examine how telehealth-related perceptions contribute to the intention to use telehealth for cancer care among BCS in Hong Kong during the COVID-19 pandemic (Figure 1). We hypothesized that favorable telehealth-related perceptions (higher performance expectancy, lower effort expectancy, more facilitating conditions, positive social influences), less technological anxiety, and greater fear of COVID-19 would be associated with higher intention to use telehealth for SCC. We also hypothesized that the associations between telehealth-related perceptions and intentions to use teledelivered SCC would be moderated by education level, such that associations between telehealth-related perceptions (higher performance expectancy, lower effort expectancy, more facilitating conditions, positive social influences, less technological anxiety) and intention to use teledelivered SCC would be stronger among those with a higher education level.

Figure 1. Conceptual model of the study.



Methods

Participants and Procedure

A cross-sectional study was conducted. BCS were eligible to participate if they (1) were older than 18 years, (2) had a confirmed diagnosis of Stage 0-III breast cancer since the outbreak of COVID-19 in Hong Kong (January 2020), (3) were receiving active treatment (eg, radiotherapy, chemotherapy), (4) could read Chinese to answer questionnaires and communicate in Cantonese, and (5) were able to provide meaningful informed consent. BCS were excluded if they had (1) a history of any psychiatric disorder, (2) metastatic brain disease, (3) any other type of cancer, or (4) recurrent breast cancer.

Prospective participants were recruited from the Hong Kong Breast Cancer Registry (HKBCR). The HKBCR has been the most comprehensive, representative local data collection and monitoring system for BCS in Hong Kong [26]. Upon approval, BCS who fulfilled the inclusion criteria based on the data in the HKBCR were invited to participate in the study through telephone calls. Of the 943 BCS contacted, 409 were not reachable, 23 were not eligible, and 227 were not interested in the study. With initial verbal consent via phone, those who were eligible and interested in the study (N=287) were asked to complete the cross-sectional survey. Participants received a cover letter explaining the study details, consent form, packet of questionnaires, stamped return envelope, thank you/reminder letter, and replacement packet via mail. After consent, participants completed the survey in the home setting. Telephone calls were used to remind individuals who had not returned the questionnaires. The study was conducted between June 2022 and December 2022 (amid the fifth wave of the COVID-19 pandemic in Hong Kong) [27]. A total of 209 completed surveys were returned (out of 287 sent), yielding a completion rate of 72.8%.

Ethical Considerations

Ethics approvals were sought from the Joint Chinese University of Hong Kong - New Territories East Cluster Clinical Research Ethics Committee (CREC Ref. 2021.286) and Hong Kong Breast Cancer Foundation. We obtained informed consent before participation in the survey. Upon completion of the survey, participants received supermarket vouchers (worth HK$100; approximately US $12.80) to compensate them for their time. We guaranteed that the identity of the participants would not be revealed.

Sample Size Planning

The dependent variable was the intention to use teledelivered SCC services. Based on prior studies on the acceptability of telehealth among Chinese populations [28,29], we expected a small to medium overall effect size (f^2=0.10) in the association between telehealth-related perceptions and intentions to use telehealth services in the hierarchical regression analysis. To achieve a statistical power of .80 at α=.05, a minimum of 201 participants were needed (G*Power 3.1.2). The sample size (N=209) achieved via the recruitment strategy was expected to allow the detection of the expected effect size with sufficient statistical power.

Measures

A written, closed-ended, anonymous, self-administered questionnaire was used in the study. To ensure that the questionnaire was readily comprehensible, a pilot test was conducted among 10 BCS who were eligible for the study. The study questionnaire was finalized based on feedback from the pilot test participants.

Intention to Use Telehealth for Future Supportive Cancer Services

Participants’ intentions to use telehealth for future supportive cancer services was measured using a SCC service utilization scale [30] that was modified according to the local health care context. The checklist covered different categories of services, including psychological support (6 items; α=.91), medical consultation (5 items; α=.86), integrated or complementary care (6 items; α=.87), and peer support (2 items; α=.83). On a 4-point scale (1, no intention or not applicable; 2, low intention; 3, moderate intention; 4, high intention), participants were asked to indicate their intention to use telehealth for each SCC service (eg, “I intend to use telehealth for ‘psycho-oncology counseling.’”). The scale has been shown to be reliable and valid among Western cancer survivors [30].

Perceptions About Telehealth for SCC Services

We used 4 subscales (performance expectancy [3 items], effort expectancy [4 items], social influence [3 items], and facilitating conditions [3 items]) to measure participants’ perceived usefulness, perceived ease, social influence, and facilitating conditions, respectively, for using telehealth in cancer care [31]. Sample items include “Using telehealth for cancer care is beneficial to my health.” (α=.83; performance expectancy), “It is easy for me to become skillful at using telehealth for cancer care service.” (α=.87; effort expectancy), ”People whose opinions that I value (eg, my doctors) think I should use telehealth for cancer care services.” (α=.86; social influence), and ”I have the resources necessary to use telehealth for cancer care services.”(α=.90; facilitating conditions). On a 5-point scale (1, strongly disagree; 5, strongly agree), higher mean item scores from the scales indicate higher levels of the corresponding constructs. The Chinese versions of these scales were shown to be reliable and valid among Chinese adults [32].

Technology Anxiety

A 3-item scale was adapted to measure participants’ technology anxiety while using telehealth services [14]. On a 5-point scale (1, strongly disagree; 5, strongly agree), a higher mean item score indicates a higher level of technology anxiety (eg, “I feel nervous about using telehealth.” α=.91). The Chinese version of the scale was shown to be reliable and valid among Chinese adults [14].

Fear of COVID-19

The Chinese version of the 7-item Fear of COVID-19 scale was adapted to measure participants’ fear of COVID-19 [33]. On a 5-point scale (1, strongly disagree; 5, strongly agree), a higher mean item score indicates a higher level of COVID-19 fear (eg, “It makes me uncomfortable to think about COVID-19.” α=.88). The scale has been shown to be reliable and valid in the Chinese population [34].

Clinical and Sociodemographic Characteristics

Participants self-reported their (1) sociodemographic characteristics (eg, age, education level, employment status, marital status), (2) treatment-related variables (eg, surgeries undergone, treatments receiving or undergone, time since last treatment), (3) daily living variables (eg, access to the internet, use of electronic or mobile devices), and (4) breast cancer-related variables (eg, stage at diagnosis, time since diagnosis).

Cancer Care Experiences During COVID-19

Participants were asked if they had participated in any telehealth online consultation sessions for SCC (including psychological support services, medical support services, integrated and complementary support services, spiritual support services, other support services; no=0, yes=1).

Statistical Analysis

Descriptive and bivariate Pearson correlation analyses were conducted. Hierarchical regression analyses were also conducted to examine factors associated with intentions to use telehealth for supportive cancer services. The sequence of entering independent variables followed suggestions from prior studies that examined factors associated with people's health or health behavior outcomes and the interaction effects among those factors (eg, [35,36]). The process usually involves entering important sociodemographic and individual experience variables in the first block (as a statistical control for confounding variables), variables representing major theoretical constructs in the next block(s), and the interaction terms between the proposed moderating variable and the independent variables of interest in the last block. In our study, fear of COVID-19 and the sociodemographic and clinical variables that had significant bivariate correlations with the dependent variables were entered in block 1 of the regression model. Telehealth-related perceptions (ie, performance expectancy, effort expectancy, social influence, facilitating conditions, technology anxiety) were entered into block 2 of the regression model. In the last block, 5 interaction terms between telehealth-related perceptions and education level were entered into the model. To compute the interaction terms, the mean-centered scores of telehealth perceptions and education level (binary: college level versus below college level) were multiplied. All continuous independent variables were centered prior to the analyses. For statistically significant interactions, simple slopes analyses [37] were conducted to examine how the main effects of telehealth perceptions on intentions to use teledelivered SCC varied at different education levels. Those with $P \leq .05$ in the final regression model were considered statistically significant. These analyses were performed using SPSS version 26.0.

Results

Participant Characteristics

Among the 209 participants, 82 (39.2%) were 50 years or younger, 63 (30.1%) were 51 years to 60 years old, and 62 (29.7%) were at least 61 years old. In addition, of the 209 participants, 91 (43.5%) had a tertiary education, 72 (34.4%) worked full-time, 99 (47.4%) reported a religious affiliation, and 53 (25.4%) had a comorbid chronic illness. Regarding cancer-related characteristics, 10 (4.8%), 60 (28.7%), 86 (41.1%), and 53 (25.4%) of the 209 participants reported being diagnosed with Stage 0, Stage I, Stage II, and Stage III breast cancer, respectively, and 194 (94.3%) had undergone breast cancer surgery. The average time since diagnosis was 16.6 (SD 8.00) months. Regarding internet access, 204 of the 209 participants (97.6%) had a mobile phone with internet access (Table 1).

Table 1. Demographic characteristics of the participants (N=209).

Characteristics	Results
Age (years), n (%)	
≤50	82 (39.2)
51-60	63 (30.1)
≥61	62 (29.7)
Refused to answer	2 (1)
Gender (female), n (%)	209 (100)
Cancer stage, n (%)	
Stage 0	10 (4.8)
Stage 1	60 (28.7)
Stage 2	86 (41.1)
Stage 3	53 (25.4)
Time since diagnosis (months), mean (SD)	16.6 (8.0)
Breast cancer surgery, n (%)	197 (94.3)
Type of breast cancer surgery, n (%)	
Lumpectomy	103 (49.3)
Axillary dissection	126 (60.3)
Mastectomy	97 (46.4)
Breast reconstruction	25 (12)
Treatment, n (%)	
Chemotherapy	152 (72.7)
Radiotherapy	159 (76.1)
Targeted therapy	60 (28.7)
Immunotherapy	8 (3.8)
Comorbid chronic illness (yes), n (%)	53 (25.4)
Educational level, n (%)	
Primary education	15 (7.2)
Secondary education	102 (48.8)
Tertiary and higher	91 (43.5)
Refused to answer	1 (0.5)
Marital status, n (%)	
Single	33 (15.9)
Married	153 (73.6)
Divorced or widowed	22 (10.6)
Monthly household income (HK$), n (%)	
≥10,000	46 (22)
10,001-30,000	42 (20.5)
30,001-50,000	43 (20.6)
>50,000	35 (16.7)
Refused to answer	42 (20.1)
Had a religious affiliation, n (%)	99 (47.4)
Employment status, n (%)	
Full-time	72 (34.4)

Characteristics	Results
Part-time	20 (9.6)
Retired, housewife, unemployed, or other	114 (54.5)
Refused to answer	3 (1.4)
Had a mobile phone with internet access, n (%)	204 (97.6)
Had an electronic device with internet access, n (%)	170 (81.8)

Intentions to Use Teledelivered SCC Services

Participants' intentions to use different types of teledelivered SCC services are presented in Table 2. Almost all the teledelivered SCC services listed were accepted by most of the participants. The most accepted teledelivered SCC services in different categories were psychooncology counseling (140/209, 67%), nutrition consultation (165/209, 78.9%), movement and exercise activities (146/209, 69.9%), and patient support groups (131/209, 62.6%).

Table 2. Acceptability of teledelivered supportive cancer care services among breast cancer patients (N=209).

Teledelivered supportive cancer care services	Reporting moderate or high intention to use, n (%)
Psychosocial care	
Psychotherapy	117 (56)
Psychological counseling and support	119 (56.9)
Psychooncology counseling	140 (67)
Therapist-led group	133 (63.6)
Cancer prevention and adaption offers for patients and healthy family members	113 (54)
Family counseling	71 (34)
Medical consultation	
Cancer helpline	130 (62.2)
Special medical consultation	132 (63.1)
To get a second opinion about treatment options	128 (61.2)
Palliative care consultation	129 (61.7)
Expert consultation	126 (60.3)
Nutrition consultation	165 (78.9)
Complementary and alternative medicine (including traditional Chinese medicine) consultation	139 (66.5)
Complementary care	
Movement and exercise activities (eg, yoga, qigong, exercises for pain relief)	146 (69.9)
Creative therapeutic offers (music and art therapy)	105 (50.2)
Relaxation, breathing, meditation exercise group sessions	121(57.9)
Mindfulness exercises	103 (49.2)
Massage exercises	108 (51.7)
Peer support groups	
Internet forum with peers	95 (45.5)
Patient support group	131 (62.6)

Correlations Between Major Variables and Intention to Use Telehealth

The correlation analysis results showed that the participants with a higher education level, prior telehealth experience, and more confidence using technology devices were more likely to report a higher intention to use telehealth (Table 3). Older age was associated with lower intentions to use 3 different types of teledelivered oncology services. Higher levels of performance expectancy, effort expectancy, facilitating conditions, and social influence were associated with higher intentions to use teledelivered oncology services. A higher level of technology anxiety was negatively correlated with intentions to use teledelivered oncology services. Contrary to the hypotheses, fear of COVID-19 was not associated with intentions to use teledelivered oncology services (Table 3). Other demographic characteristics (eg, marital status, *P*=.82; cancer stage, *P*=.83; time since diagnosis, *P*=.18; income, *P*=.10) were not correlated with the intention to use telehealth (data not tabulated).

Table 3. Correlations among major independent variables and intentions to use teledelivered supportive cancer care services (N=209).

Independent variables		Intention to use psychosocial teledelivered supportive care	Intention to use teledelivered medical consultations	Intention to use teledelivered complementary cancer care	Intention to use teledelivered peer support groups
1. Age[a]					
	r	–0.20	–0.17	–0.10	–0.28
	P value	.005	.02	.16	<.001
2. Education[b]					
	r	0.22	0.16	0.24	0.32
	P value	.001	.02	<.001	<.001
3. Prior telehealth use[c]					
	r	0.29	0.24	0.22	0.32
	P value	<.001	.001	.001	<.001
4. Confidence using technological devices					
	r	0.34	0.34	0.31	0.30
	P value	<.001	<.001	<.001	<.001
5. Fear of COVID-19					
	r	0.05	0.01	–0.05	0.03
	P value	.47	.92	.47	.65
6. Performance expectancy					
	r	0.45	0.39	0.36	0.40
	P value	<.001	<.001	<.001	<.001
7. Effort expectancy					
	r	0.37	0.32	0.29	0.32
	P value	<.001	<.001	<.001	<.001
8. Facilitating conditions					
	r	0.41	0.34	0.30	0.43
	P value	<.001	<.001	<.001	<.001
9. Social influence					
	r	0.30	0.32	0.26	0.22
	P value	<.001	<.001	<.001	.001
10. Technology anxiety					
	r	–0.18	–0.18	–0.14	–0.22
	P value	.009	.01	.04	<.001

[a] ≤55 years (0); >55 years (1).

[b] High school or less (0); at least college (1).

[c] No (0); Yes (1).

Hierarchical Regression Analysis

Given that the independent variables were moderately correlated, the independent variables were checked for multicollinearity in the regression analysis. None of the variables had a variance inflation factor ≥5, which indicated the absence of multicollinearity problems.

In block 1, the background variables explained 16.4%, 14.9%, 13.4%, and 20.2% of the variance in the intentions to use teledelivered psychosocial care, medical consultation, complementary care, and peer support groups, respectively. Specifically, a higher education level was associated with higher intentions to use teledelivered complementary care and peer support groups, and greater confidence with using technological devices was associated with higher intentions to use all 4 types of teledelivered SCC services. Prior telehealth use was associated with greater intentions to use teledelivered medical consultation and peer support groups (Tables 4 and 5).

Table 4. Hierarchical regression analyses to explain intentions to use telehealth services (N=209).

Steps	Intentions to use teledelivered supportive cancer care							
	Psychosocial care[a]				Medical consultation[b]			
	β	*P* value	ΔR^2	*P* value	β	*P* value	ΔR^2	*P* value
Step 1: Background variables			0.164	<.001			0.149	<.001
Age[c]	–0.06	.67			–0.03	.83		
Education[d]	0.27	.06			0.11	.46		
Prior telehealth use[e]	0.27	.08			0.38	.01		
Confidence using technological devices	0.28	<.001			0.29	<.001		
Fear of COVID-19	0.12	.08			0.05	.46		
Step 2: Telehealth-related perceptions			0.159	<.001			0.126	<.001
Age[c]	–0.02	.89			–0.02	.92		
Education[d]	0.12	.39			0.02	.91		
Prior telehealth use[e]	0.19	.19			0.34	.02		
Confidence using technological devices	0.20	.01			0.23	<.001		
Fear of COVID-19	0.06	.35			–0.01	.86		
Performance expectancy	0.34	<.001			0.26	<.001		
Effort expectancy	–0.07	.47			–0.08	.44		
Facilitating conditions	0.20	.02			0.12	.19		
Social influence	0.08	.30			0.16	.03		
Technology anxiety	0.08	.28			0.06	.41		
Step 3: Interaction terms			0.013	.58			0.006	.90
Age[c]	–0.03	.81			–0.01	.96		
Education[d]	0.13	.36			0.04	.77		
Prior telehealth use[e]	0.17	.25			0.32	.03		
Confidence using technological devices	0.20	.01			0.22	.01		
Fear of COVID-19	0.07	.30			0.00	.99		
Performance expectancy	0.30	.01			0.24	.03		
Effort expectancy	–0.07	.56			–0.05	.68		
Facilitating conditions	0.19	.09			0.17	.14		
Social influence	0.09	.35			0.17	.09		
Technology anxiety	–0.03	.73			0.05	.64		
Performance expectancy × education	0.07	.67			0.08	.62		
Effort expectancy × education	0.02	.90			–0.05	.79		
Facilitating conditions × education	0.03	.85			–0.14	.44		
Social influence × education	–0.03	.82			–0.03	.83		
Technology anxiety × education	0.26	.07			0.02	.89		

[a] Total R^2: 0.336.

[b] Total R^2: 0.281.

[c] ≤55 years (0); >55 years (1).

[d] High school or less (0); at least college (1).

[e] No (0); Yes (1).

Table 5. Hierarchical regression analyses to explain intentions to use telehealth services (N=209).

Step	Intentions to use tele-delivered supportive cancer care							
	Complementary care[a]				Peer support groups[b]			
	β	*P* value	ΔR^2	*P* value	β	*P* value	ΔR^2	*P* value
Step 1: Background variables			0.134	<.001			0.202	<.001
Age[c]	0.17	.26			–0.26	.08		
Education[d]	0.36	.01			0.45	.002		
Prior telehealth use[e]	0.21	.19			0.38	.01		
Confidence using technological devices	0.27	<.001			0.16	.03		
Fear of COVID-19	0.01	.87			0.10	.12		
Step 2: Telehealth-related perceptions			0.096	<.001			0.122	<.001
Age[c]	0.18	.23			–0.19	.17		
Education[d]	0.28	.05			0.32	.02		
Prior telehealth use[e]	0.17	.26			0.30	.04		
Confidence using technological devices	0.23	.01			0.08	.28		
Fear of COVID-19	–0.05	.50			0.08	.22		
Performance expectancy	0.25	.002			0.30	<.001		
Effort expectancy	–0.05	.64			–0.17	.08		
Facilitating conditions	0.07	.44			0.26	.002		
Social influence	0.13	.09			0.03	.70		
Technology anxiety	0.06	.41			–0.02	.77		
Step 3: Interaction terms			0.031	.16			0.029	.13
Age[c]	0.20	.17			–0.21	.13		
Education[d]	0.34	.02			0.32	.02		
Prior telehealth use[e]	0.13	.40			0.31	.03		
Confidence using technological devices	0.22	.01			0.07	.38		
Fear of COVID-19	–0.02	.79			0.08	.24		
Performance expectancy	0.12	.30			0.25	.02		
Effort expectancy	–0.00	.10			–0.05	.67		
Facilitating conditions	0.17	.17			0.11	.32		
Social influence	0.15	.14			0.05	.62		
Technology anxiety	0.01	.94			–0.11	.23		
Performance expectancy × education	0.34	.04			0.05	.77		
Effort expectancy × education	–0.10	.63			–0.29	.13		
Facilitating conditions × education	–0.27	.13			0.36	.03		
Social influence × education	–0.09	.56			0.01	.92		
Technology anxiety × education	0.09	56			0s.22	.12		

[a] Total R^2: 0.261.

[b] Total R^2: 0.353.

[c] ≤55 years (0); >55 years (1).

[d] High school or less (0); at least college (1).

[e] No (0); Yes (1).

In block 2, telehealth-related perceptions explained an additional 15.9%, 12.6%, 9.6%, and 12.2% of the variance in intentions to use teledelivered psychosocial care, medical consultation, complementary care, and peer support groups, respectively. Specifically, performance expectancy was associated with intentions to use all 4 types of teledelivered SCC services (Tables 4 and 5). More facilitating conditions were associated with higher intentions to use teledelivered psychosocial care and peer support groups. Greater social influence was associated with higher intentions to use teledelivered medical consultation (β=0.16, *P*=.03; Tables 4 and 5).

In block 3, 5 interaction terms between education level and telehealth-related perceptions were entered; 2 significant interactions emerged. Specifically, there was an interaction between education level and performance expectancy when explaining the intention to use teledelivered complementary care (β=0.34, *P*=.04). In addition, there was an interaction between education level and facilitating conditions when explaining the intention to use teledelivered peer support groups (β=0.36, *P*=.03). Simple slopes analysis results indicated that the association between performance expectancy and intention to use teledelivered complementary care was only significant among those with a higher education level (β=0.46, *P*<.001) but not among those with a lower education level (β=0.12, *P*=.30; Figure 2). Similarly, the association between social influence and intention to use teledelivered peer support groups was only significant among those with a higher education level (β=0.48, *P*<.001) but not among those with a lower education level (β=0.11, *P*=.32; Figure 3). Overall, the models explained 26.1% to 35.3% of the variance in the intentions to use different types of teledelivered SCC services (Tables 4 and 5).

Figure 2. Relationship between performance expectancy and intention to use teledelivered complementary care by education level.

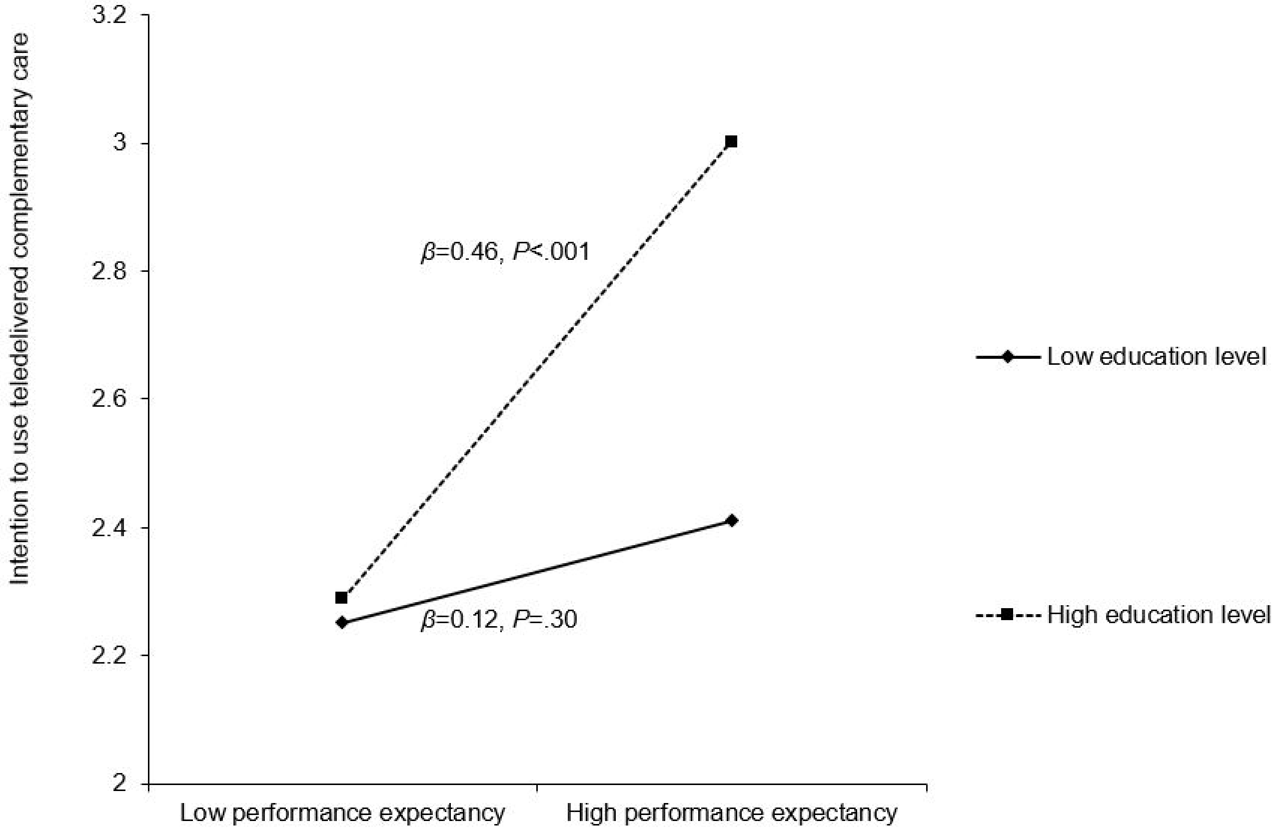
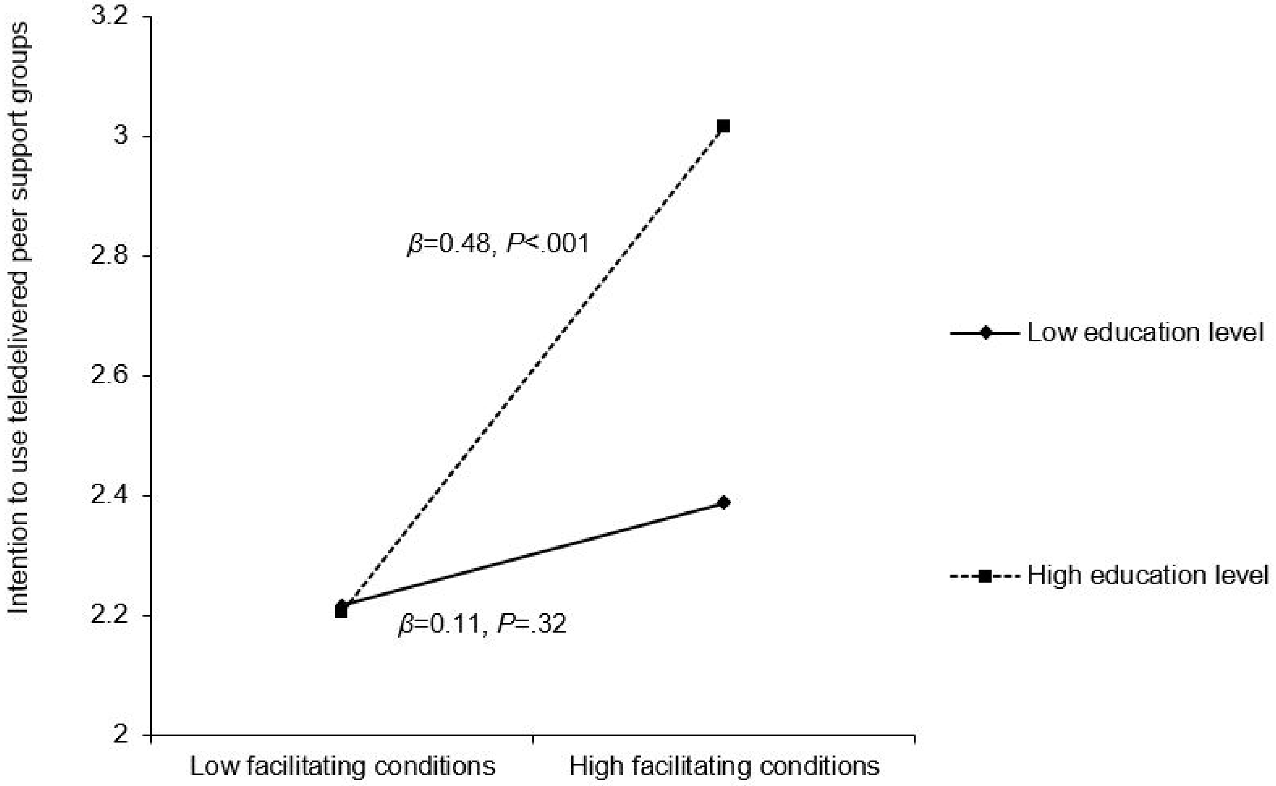


Figure 3. Relationship between facilitating conditions and intention to use teledelivered peer support groups.



Discussion

Principal Findings

This study examined how sociodemographic and clinical factors and telehealth-related perceptions contributed to the intentions to use telehealth for SCC among BCS in Hong Kong during the COVID-19 pandemic. It is noteworthy that most of the participants reported moderate-to-high intentions to use different types of teledelivered SCC services. The most accepted teledelivered SCC services in different categories were psychooncology counseling (67%), nutrition consultation (78.9%), movement and exercise activities (69.9%), and patient support groups (62.6%). We found that greater confidence in telehealth use, performance expectancy (believing telehealth helps with daily tasks), social influence (important others encouraging telehealth use), and facilitating conditions (having resources for telehealth use) were associated with higher intentions to use teledelivered SCC. Our findings were comparable to those of a study in Singapore amid the COVID-19 pandemic [38] that showed that general acceptance of telemedicine by patients with cancer was around 60%. Perceptions that telemedicine could improve health care access and the availability of necessary resources for telemedicine were associated with higher acceptance among those patients [38].

Sociodemographic Factors, Fear of COVID-19, and Intention to Use Teledelivered SCC

In our regression analyses, education level, prior telehealth use, and confidence using technological devices were associated with the use of telehealth services. Our findings were consistent with findings from patient populations in Western countries supporting that people with mobile device access, who were confident using technological devices, and with prior telehealth experience were more likely to use teledelivered SCC [38-40]. The facilitating roles of those variables seem to be culturally and geographically universal. To increase patients' intentions to use teledelivered SCC, it might be important to provide education and training on how to use technology and telehealth services, which could help increase confidence with using these tools and make it easier for patients to access care.

Consistent with a population-based study in the United States during the COVID-19 pandemic [41], household income was not a significant contributor to intentions to use teledelivered SCC in our study. However, the findings should be interpreted with caution, as a high proportion of participants (20.1%) refused to report their household income. Household income has been associated with other important sociodemographic factors (eg, education, ownership of mobile devices, internet access) that were associated with cancer survivors' intentions to adopt telehealth before and during the COVID-19 pandemic [42,43]. Given that 97.6% of our participants possessed a mobile phone with internet access, the unique contribution of household income on intention to use telehealth might become less apparent.

Despite a significant bivariate correlation between age and intention to use teledelivered SCC, age did not emerge as a significant contributor in the regression analyses beyond the influence of other potential contributors. These findings imply that other individual characteristics (eg, confidence using technological devices) played a stronger role in the intentions of BCS to use teledelivered SCC. Moreover, it is important to note that Hong Kong has a very high internet coverage rate at the household level (96.1%) and a very high smartphone ownership rate (99.8% and 90.7% among individuals aged 45-64 years or ≥65 years, respectively) [44], which could influence the acceptability of and perceptions toward telehealth services. The generalizability of our findings to other countries with different internet use patterns should also be interpreted with caution [45].

Fear of COVID-19 did not emerge as a significant contributor to the intention to use teledelivered SCC services in our sample, which was contrary to the findings of prior studies in the United States [19] and Germany [46]. However, our findings seem to be in line with those of An and colleagues [47] who showed that anxiety about COVID-19 was not associated with telehealth acceptance among individuals with chronic disease in South Korea. A potential reason for the discrepancies in the findings could be related to the focus of the measurements. The Fear of COVID-19 scale used in this study primarily measures participants' affective responses and anxiety symptoms toward cues related to COVID-19, but it might not capture individuals' perceptions of the threat of contracting COVID-19 at different occasions (eg, hospital and clinic settings, crowded places). Such concerns have been reflected in studies among BCS [48]. Future studies might elucidate how patients' specific COVID-19 worries and concerns contribute to their intentions to use telehealth services.

Telehealth-Related Perceptions and Intentions to Use Teledelivered SCC

In the correlation analyses, all the measured telehealth-related perceptions were significantly correlated with the intentions to use SCC. However, in the regression analyses, the relative importance of the perception variables on intentions to use SCC was apparent. Specifically, only performance expectancy was associated with the intention of using all types of the measured teledelivered SCC. Similar findings have also been reported regarding the prediction of the acceptance of cancer patients in the Netherlands to use a virtual assistant in health care settings [49] and the acceptance of using a digital cardiac rehabilitation tool among patients with ischemic heart disease in Germany [50]. The findings imply that highlighting the benefits of teledelivered SCC on daily life for BCS tends to increase their intentions to use such services.

On the other hand, social influence was associated with the intention to use teledelivered medical consultation. In the Chinese culture, coping with cancer is largely a family issue, such that opinions of family members are important in patients' treatment decision-making [51]. Given that it might also be easier for family members who do not live together to participate in medical consultations, family members might tend to welcome the option to have such consultations teledelivered. That might be the reason why social influence had a relatively strong contribution to the intention of BCS to use teledelivered medical consultations (but not other SCC services).

Furthermore, facilitating conditions were associated with the intention to use psychosocial care services and peer support groups (but not other types of SCC). It is noteworthy that psychological care and peer support group services are not commonly utilized among local BCS [25]. The dynamics in psychological counseling and peer support groups involve more disclosure of personal challenges and distress, which might be incongruent with the cultural preference of not bringing up negative emotions to maintain social harmony [33]. It might be possible for local BCS to believe that they need a certain level of knowledge and informational resources (facilitating conditions) to understand what to expect in teledelivered psychosocial care and peer support groups before enrolling in those services.

Although our findings suggested that effort expectancy and technology anxiety contributed less significantly to intentions to use teledelivered SCC, it is still noteworthy that facilitators and barriers are likely to differ across different cultural contexts and by types of telemedicine service [52]. Future research should investigate how those factors jointly contribute to the acceptability of teledelivered SCC services for BCS.

Telehealth Perceptions and Intentions to Use Teledelivered SCC: Education Level as a Moderator

We found that education level moderated the interaction between (1) between performance expectancy and intention to use teledelivered complementary care and (2) facilitating conditions and intention to use teledelivered peer support groups. From the perspective of the UTAUT model, performance expectancy (ie, degree to which the individual believes that using the technology will help them better cope with daily life or be more effective) was found to be associated with higher intentions to use teledelivered complementary care (including creative therapies, relaxation, and mindfulness exercises) only among those with a higher education level. It is also noteworthy that similar patterns of findings were also apparent in other aspects of technology use. Education level moderated the positive associations between technology use perceptions (performance expectancy, facilitating conditions) and people's intentions to use mobile banking services in Jordan [23].

Our findings suggested that just highlighting performance expectancy might not be sufficient to significantly increase intentions to use teledelivered complementary care among those with a lower education level. A basic understanding of those complementary care options might be important. Given that those with higher levels of education may be more likely to have better awareness of the potential benefits of those complementary therapies for oncology care [53], the facilitating role of performance expectancy in the intention of BCS to use teledelivered complementary care could be strengthened by a higher education level.

Similarly, we found that facilitating conditions were associated with higher intentions to use teledelivered peer support groups only among those with a higher education level. Facilitating conditions refer to people's perceptions about whether the necessary resources and support are available to use the technology effectively. It is important to note that peer support groups generally involve mutual interactions and sharing with other cancer survivors, which could also be subject to challenges such as confrontation involving others' suffering, divergent information needs, conflicts in group dynamics, and challenges with sustainability [54]. Individuals with higher levels of education may be more comfortable using teledelivered services to interact with other patients with similar (stressful) experiences plus have more resources to deal with the potentially negative experiences in the support group context (eg, worsened health of peers in the group, appraising information about their illness, and therapy options shared in the support groups). These reasons might explain why the facilitating role of facilitating conditions in the intention of BCS to use teledelivered peer support group was only apparent among those with a higher education level.

Limitations

This study was subject to several limitations. First, this study used a cross-sectional design, which might not highlight the causal relationship among the variables. Cancer survivors' expectations and motivations for teledelivered cancer care may also change over time. Future studies could use longitudinal designs to better understand the temporal relationships among the variables and their future use of teledelivered care services. Second, to allow more systematic recruitment of recently diagnosed BCS (since the COVID-19 outbreak in Hong Kong), we recruited BCS through local cancer registries. Even though the HKBCR is the most comprehensive registry for BCS in Hong Kong, it is noteworthy that not everyone in the total BCS population was covered due to the HKBCR's voluntary enrollment system. Based on the Hong Kong Cancer Registry data [55] and HKBCR [56] for individuals with BCS aged 18 years to 70 years, the age group distributions were as follows: 40% (<50 years), 33% (50-59 years), 27% (60-70 years). Similarly, in our sample, the age group distributions were as follows: 39.2% (<50 years), 30.1% (51-60 years), and 29.7% (≥61 years). Our sample was highly comparable in terms of the age distribution of the local BCS. However, the generalizability of the findings to BCS in other regions or countries with different health care systems and to survivors of other cancer types might be limited. Third, the studied variables only explained a moderate proportion of variance in the intentions of BCS to use teledelivered SCC. Other factors might be at play. Research has found that other telehealth-related perceptions (eg, privacy concerns), the specific characteristics of different teledelivered services (eg, expected durations and schedules of the services, the necessity to use cameras for the services, group- and individual-based delivery), and contextual factors (eg, severity of the pandemic situation, availability of specific types of teledelivered care services) could be important determinants for those intentions [18,57]. Consideration of those variables might further improve the explanatory power of the regression model.

Implications

The COVID-19 pandemic impacted cancer service utilization among cancer patients worldwide. Telehealth can be a new service model for SCC services, especially after the experience of the COVID-19 pandemic. The use of telehealth for SCC not only provides flexibility for services in hospitals and cancer clinics but also potentially improves cancer survivors' well-being. Recent reviews and trials have found that teledelivered interventions facilitate positive physical and psychological health impacts on cancer survivors [58-60]. Therefore, identifying the potential determinants for people's intentions to use telehealth for SCC could facilitate the proposal of novel service models.

This was one of the first attempts to examine how telehealth-related perceptions, sociodemographic and clinical characteristics, and cancer care service utilization experiences during COVID-19 contributed to the intention of BCS to use telehealth for SCC during the COVID-19 pandemic in Hong Kong. It is essential for health care providers to be knowledgeable about specific factors facilitating the intention to use telehealth, so that patients' needs and cancer care preferences can be met, especially for the response to a potential pandemic of an emerging infectious disease in the future.

Researchers have started to advocate for a patient-centered approach to address patients' facilitators and barriers to using telehealth. By fitting telehealth into the overall patient journey and treatment plan and applying inclusive design principles, the needs of the most vulnerable populations who may not be engaging with telehealth owing to their age, education level, socioeconomic status, technology skills, and experiences could be better addressed [40]. Our findings imply that enhancing BCS' skills for using telehealth, improving BCS' and their important others' perceived benefits of telehealth, and providing assistance for telehealth use could increase BCS' intentions to use teledelivered SCC. For intentions to use specific types of SCC (eg, complementary care and peer support groups), addressing relevant factors (performance expectancy, facilitating conditions) might be particularly beneficial for those with a higher education level.

Acknowledgments

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Data Availability

Research data will be shared upon request.

Authors' Contributions

NCYY contributed to the supervision and conceptualization of the study and acquired funding. NCYY and STYL were involved in the data curation, conducted the data analysis, and wrote the original manuscript draft. PSYC provided advice on the implementation of the study using the Hong Kong Breast Cancer Registry. NCYY, STYL, EYYC, CC, WWSM, JYMS, and PSYC contributed to the methodology, survey design, and review and editing of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

BCS: breast cancer survivors
HKBCR: Hong Kong Breast Cancer Registry
SCC: supportive cancer care
UTAUT: unified theory of acceptance and use of technology

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Original Paper

Usability and Preliminary Efficacy of an Adaptive Supportive Care System for Patients With Cancer: Pilot Randomized Controlled Trial

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Abstract

Background: Using an iterative user-centered design process, our team developed a patient-centered adaptive supportive care system, PatientCareAnywhere, that provides comprehensive biopsychosocial screening and supportive cancer care to patients across the continuum of care adaptively. The overarching goal of PatientCareAnywhere is to improve health-related quality of life (HRQOL) and self-efficacy of patients with cancer by empowering them with self-management skills and bringing cancer care support directly to them at home. Such support is adaptive to the patient’s needs and health status and coordinated across multiple sources in the forms of referrals, education, engagement of community resources, and secure social communication.

Objective: This study aims to assess the usability of the new web-based PatientCareAnywhere system and examine the preliminary efficacy of PatientCareAnywhere to improve patient-reported outcomes compared with usual care.

Methods: For phase 1, usability testing participants included patients with cancer (n=4) and caregivers (n=7) who evaluated the software prototype and provided qualitative (eg, interviews) and quantitative (eg, System Usability Scale) feedback. For phase 2, participants in the 3-month pilot randomized controlled trial were randomized to receive the PatientCareAnywhere intervention (n=36) or usual care control condition (n=36). HRQOL and cancer-relevant self-efficacy were assessed at baseline (preintervention assessment) and 12 weeks from baseline (postintervention assessment); mean differences between pre- and postintervention scores were compared between the 2 groups.

Results: Participants were highly satisfied with the prototype and reported above-average acceptable usability, with a mean System Usability Scale score of 84.09 (SD 10.02). Qualitative data supported the overall usability and perceived usefulness of the intervention, with a few design features (eg, “help request” function) added based on participant feedback. With regard to the randomized controlled trial, patients in the intervention group reported significant improvements in HRQOL from pre- to postintervention scores (mean difference 6.08, SD 15.26) compared with the control group (mean difference −2.95, SD 10.63; P=.01). In contrast, there was no significant between-group difference in self-efficacy (P=.09).

Conclusions: Overall, PatientCareAnywhere represents a user-friendly, functional, and acceptable supportive care intervention with preliminary efficacy to improve HRQOL among patients diagnosed with cancer. Future studies are needed to further establish the efficacy of PatientCareAnywhere as well as explore strategies to enhance user engagement and investigate the optimal intensity, frequency, and use of the intervention to improve patient outcomes.

Trial Registration: ClinicalTrials.gov NCT02408406; https://clinicaltrials.gov/study/NCT02408406

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KEYWORDS

cancer; distress screening; eHealth; supportive care; mobile phone

Introduction

Background

One-third [1,2] to half [3-5] of patients with cancer report psychological distress. Common causes of distress include fatigue, pain, worry about the future, finances, and the side effects of treatment [6-8]. Supportive care is a complex specialty that encompasses an array of multidisciplinary services addressing a variety of biopsychosocial concerns and needs. The 2008 Institute of Medicine report, *Cancer Care for the Whole Patient* [6], lists the main supportive care services as "information about illness, treatments, health, and services; help in coping with emotions accompanying illness and treatment; help in managing illness; assistance in changing behaviors to minimize impact of disease; material and logistical resources, such as transportation; help in managing disruptions in work, school, and family life; and financial advice and/or assistance." In addition to these formal sources of supportive care, the report stressed that informal sources, such as family and friends, are also key providers of supportive care. At the heart of a successful supportive care practice is comprehensive biopsychosocial screening, covering multiple domains including physical symptoms, psychosocial issues, and practical concerns. Effective biopsychosocial screening integrated with triage, referrals, patient and caregiver education, and follow-up services promotes successful whole patient-centered care across the cancer treatment trajectory. Studies have demonstrated that adequate integration of biopsychosocial screening with supportive care results in better patient outcomes [9-18], better patient-provider communication [9,12,15,19-25], higher patient satisfaction [12,20,22-24], detection of unrecognized problems [10,12,15,21,23-25], improved referrals [11,25-29], and better health service use and lower costs [30-35].

Recognizing the importance of distress management, the National Comprehensive Cancer Network (NCCN) recommends distress screening for all patients with cancer to address problems before a crisis develops and necessitates higher levels of intervention, with guidelines in place since 1999 [36]. Unfortunately, a serious gap remains between the screening services that are needed and those provided today [6,37,38]. In a 2018 survey to NCCN member institutions, 87% (20/23) of institutions reported conducting routine screening for distress as per the guidelines, but only 26% (6/23) strived to screen all patients and 57% (13/23) screened outpatients only [39]. Compared with the 2012 survey [37], the percentage of institutions conducting screening of all patients decreased from 30% to 26% and the percentage of institutions screening outpatients only increased from 50% to 57% over a 6-year span. Most institutions administered screening via paper and pencil (12/23, 52%) or electronically (12/23, 52%), while 30% conducted interviews (6 in person and 1 via telephone). In addition, only 7 institutions reported automatic triage based on computer-generated results, whereas 14 institutions required clinical staff to manually review the screening results to generate referrals.

Furthermore, there is often a large gap between the onset of patients' distress and the communication about it to their health care team, especially when these problems and symptoms occur outside of the clinical environment. This disconnect is exacerbated by the lack of uniform systems to document problems and communications between the health care professionals themselves. In addition, the absence of systematic criteria-based identifiers for referring patients to suitable consultation services and resources results in important clinical information not being communicated promptly to the appropriate professionals. Electronic methods for distress screening, including automated touch screen technologies and web-based assessments, have been recommended as they can be helpful with systematically identifying, tracking, and managing sources of distress [40]. Over the past decade, technology and eHealth interventions have increasingly been used in the delivery of patient-centered cancer care [41-43]. A recent systematic review of technology-based supportive care interventions for patients with cancer demonstrated significant effects on health-related quality of life (HRQOL), cancer-related symptoms, levels of fatigue and pain, depression, and functional capacity [44]. A meta-analysis was precluded due to heterogeneity in intervention design and features (eg, duration, frequency, and use of technology) and outcome measures.

To address this pressing gap in supportive cancer care, City of Hope in partnership with BrightOutcome, a health care technology company, developed a technology-based, patient-centered adaptive supportive care system for patients newly diagnosed with cancer (named PatientCareAnywhere) using an iterative user-centered design process. PatientCareAnywhere was derived from two existing systems: (1) SupportScreen from City of Hope [45], a clinic-based biopsychosocial screening tool that connects new patients with individualized educational and professional symptom triage support based on self-reported distress; and (2) MyCaringCircle from BrightOutcome, a home- and community-based patient portal solution that offers self-reported symptom assessment, individualized education content delivery, facilitation of remote medical care, and coordination of support from the patient's friends and family and from community resources. While SupportScreen excels in the provision of a broad range of biopsychosocial screenings, facilitation of referrals, and integration of electronic health records (EHRs), MyCaringCircle's strengths are its focus on symptom assessment via its access to a large library of validated measures and its facilitation of social support outside the clinical environment involving community resources.

Objective

This study includes 2 phases. In phase 1, with the software prototype, we conducted usability tests, which are an integral part of the user-centered design process and help ensure the intervention meets users' expectations and functions as intended. In phase 2, to evaluate the preliminary efficacy of PatientCareAnywhere compared with usual care (control condition), we conducted a pilot randomized controlled trial

(RCT) evaluating changes in self-reported patient outcomes, including HRQOL and self-efficacy, from baseline to postintervention assessment. We hypothesized that PatientCareAnywhere would result in significant improvements in HRQOL and patient self-efficacy compared with usual care among patients newly diagnosed with cancer.

Methods

PatientCareAnywhere

Overview

City of Hope, in partnership with BrightOutcome, a health care technology company, developed a patient-centered adaptive supportive care system (PatientCareAnywhere) to improve patient outcomes for patients with cancer while reducing health care costs. This project was funded by the National Cancer Institute via a Small Business Innovation Research Fast-Track grant (R44CA192588). PatientCareAnywhere is a patient empowerment solution that promotes internal resilience, self-efficacy, and independence. The key features of PatientCareAnywhere include (1) multilevel and adaptive biopsychosocial screening covering a comprehensive set of supportive cancer care domains (eg, emotional, physical, practical, and social) without overburdening patients with long static questionnaires; (2) automatic alert messages for abnormal screening results to clinical team; (3) specialist referrals and community support resources based on screening results; (4) individualized patient education contents based on screening results; (5) social media support for engagement of caregivers, family, friends, and community resources; (6) optimized display for different devices (eg, smartphones and tablets); and (7) EHR integration. The PatientCareAnywhere experience begins with an initial comprehensive biopsychosocial assessment covering physical symptoms (eg, pain), psychosocial issues (eg, anxiety), and practical concerns (eg, finances). Table 1 provides a list of biopsychosocial screening topics and designated care professionals for follow-up. The assessments start with first-level questions, which, when a patient's response exceeds a pre-established threshold, will trigger additional follow-up questions to gain further insights into the patient's needs and concerns. Additionally, alert messages are generated for the clinical and support care teams.

These self-reported needs and the individual's disease and treatment stages form the basis for PatientCareAnywhere to offer responsive supportive care in terms of individualized patient education content, triage to specialists, and referrals to community resources. Cancer-specific content (eg, information about breast, lung, or prostate cancer and its treatment) and generic content (eg, emotional distress) was adapted from public domain sources, such as the National Cancer Institute, American Cancer Society, and NCCN, and from materials developed by the Division of Patient and Family Community Education at City of Hope. We also collected contact information for supportive care services provided by City of Hope and local community resources, which were recommended to patients based on their self-reported symptoms and needs. The system was designed to be used by patients, friends and families, health care professionals, and community resources. With PatientCareAnywhere, patients are at the center of the "circle of care," receiving support from multiple clinical, social, and community sources and across the continuum of care, from diagnosis to treatment to survivorship and end-of-life care. In addition, PatientCareAnywhere provides a communication platform to allow caregivers, family members, and friends to interact directly with the patient through the system. As a security feature, patients have complete control over who is included in their care circles and how much communication or information is shared with each person invited. In particular, caregivers are granted full access to patient medical records and can obtain information about the patient's current medications, laboratories and tests, vitals, biopsychosocial screenings, and symptom histories as well as keep track of medical appointments on PatientCareAnywhere, while noncaregivers have limited access. The main components of PatientCareAnywhere are listed in Multimedia Appendix 1, and screenshots of PatientCareAnywhere are included in Multimedia Appendix 2.

Table 1. Biopsychosocial screening items and associated referrals.

Biopsychosocial screening items	Primary follow-up
Social and practical needs	
Ability to have children	Physician
Communication about medical care	Pharmacy clinical manager, physician, social worker
Finding local support resources	Social worker
Finding reliable medical information	Cancer information resource nurse, nurse
Health insurance	Financial counselor
Help with home or medical care	Patient navigator, resource coordinator, social worker
Hospice service	Physician, nurse practitioner or physician extender
Personal finances	Social worker
Physical appearance	Positive image center, social worker
Social support	Social worker
Spiritual or religious concerns	Chaplin
Worries about the future	Social worker
Physical and emotional well-being	
Anxiety	Social worker
Appetite loss	Nurse
Bladder control	Nurse
Breathing difficulties	Nurse
Bowel control	Nurse
Cognitive issues	Physician
Constipation	Nurse
Depression	Social worker
Diarrhea	Nurse
Eating, chewing, or swallowing difficulties	Clinical nutritionist, nurse
Fatigue	Nurse practitioner or physician extender
Fever	Nurse
Mobility or physical issues	Nurse
Mouth sores	Nurse
Nausea or vomiting	Nurse
Numbness	Nurse
Pain	Physician
Sexual issues	Nurse
Skin rash	Nurse
Sleep issues	Nurse practitioner or physician extender
Swelling	Nurse
Weight change	Clinical nutritionist, nurse

Prototype Design and Development

User-Centered Design

The PatientCareAnywhere prototype was developed using an iterative user-centered design approach, in which targeted end users (patients with cancer) and other key stakeholders (eg, caregivers and health care professionals) were involved in the design and development process to ensure the intervention aligns with the needs and preferences of patients newly diagnosed with cancer (target population). Research has shown that involving stakeholders throughout intervention development and evaluation is essential to increasing user acceptance and intervention effectiveness [46,47]. In addition, an expert panel with expertise in the fields of supportive care, oncology, nursing, mental health, outcome research, palliative care, and patient education was assembled to provide continuous guidance and consultation on our prototype design and evaluation efforts.

Stakeholder Input

Feedback from patients with cancer and caregivers was largely unanimous in agreement with the idea of a system such as PatientCareAnywhere and the functions that they would like to see implemented. Notably, they all expressed strong support for social networking functions, the ability to keep track of appointments and medical records, access to tailored recommendations for educational support materials and local events and support groups, and the ability to report symptoms at any time that would send alerts to their care team. Patients expressed a strong interest in being able to connect with other patients with cancer who are going through or have been through the same experiences. Caregivers expressed support for the ability to connect with other caregivers to build a support network of others who are also going through the same caregiver experiences. Finally, patients and caregivers felt that the ability to create "help requests" that they could share with their network would make the logistics involved with having cancer and caring for someone with cancer a lot easier. All participants felt that they would like to use PatientCareAnywhere when it was available and that it would be a great resource for others in the same position. The only barriers that these focus groups identified involved possibly leaving out those who are not as technology savvy. However, each group concluded that most people have someone around who is able to help them with the technology.

Feedback from the expert panel highlighted a number of features that they wanted to see implemented in PatientCareAnywhere and the barriers that they foresaw in using PatientCareAnywhere. Overall, the expert panel liked the idea of a system such as PatientCareAnywhere for clinic use and clinic-based research. All members of the expert panel immediately recognized the benefits of having features such as social networking, tailored educational materials, event recommendations, and symptom reporting and management for patients with cancer and felt that PatientCareAnywhere would enable them to provide better care to their patients. The expert panel members also wanted to have the information from PatientCareAnywhere to be integrated into the EHR or have the 2 systems "speak" to each other so that they only had to enter information into 1 system, and it would automatically populate into both systems. The members also wanted to have additional clinical research features available as part of the initial biopsychosocial screening tool to deliver specialized questionnaires to the patients who are part of different research studies at City of Hope.

Ethical Considerations

All study procedures and assessments were reviewed and approved by the City of Hope Institutional Review Board before participant enrollment (institutional review board #15025). Written informed consent was provided by all study participants recruited for the usability testing (phase 1) and pilot RCT (phase 2), and all participants were provided the ability to opt out of the study at any time. To ensure participant privacy and confidentiality, study data were deidentified using participant ID numbers. The mapping between participant IDs and actual participant identities was maintained by the City of Hope research team in a password-protected electronic file. Each study participant was given a unique participant login ID to access the prototype system, which also enabled researchers to retrieve information related to a specific participant. Usability testing participants (phase 1) were compensated US $50 for their time. Pilot RCT participants (phase 2) received a US $100 stipend as compensation for the time spent in the study.

Phase 1: Usability Testing

Overview

We conducted 2 types of usability testing to evaluate the usability, usefulness, and acceptability of the prototype system. The first usability test was "design oriented" and conducted after wireframes (schematics showing information elements and page flows) were produced. This allowed us to resolve initial design issues before significant development efforts took place. Once most of the development work was completed, we then conducted "metric-oriented" usability tests to formally evaluate the usability of the PatientCareAnywhere using quantitative assessments.

Study Participants and Design

To be eligible to participate in usability testing, patients were required to be (1) aged ≥21 years, (2) diagnosed with any cancer, (3) currently receiving any type of cancer treatment, (4) treated on an outpatient status (participation was suspended during hospitalization), (5) fluent in English, and (6) able to access the internet at home. Caregivers, friends, and family members of patients with cancer were also eligible to participate in the study. Those with evidence of cognitive or psychological impairment as well as prisoners and pregnant women were ineligible. Participants were also excluded if they were currently participating in another psychosocial study.

All patients with cancer and caregivers were recruited from City of Hope, a National Cancer Institute–designated comprehensive cancer center in Duarte, California, via physician referrals, subject recruitment flyers, and a touch screen biopsychosocial screening system (SupportScreen [45]), which included a question about participating in this study. Trained research assistants approached potentially eligible patients and discussed study participation either in person during an already scheduled clinic visit or via telephone. Interested patients were then screened for eligibility criteria, and those eligible wishing to enroll provided written informed consent. All participants consented before study participation and were enrolled between March and April 2016.

Each participant completed a 60-minute one-on-one usability testing session, in which they completed specific tasks using the prototype, and an observer recorded how the tasks were completed (or failed). Participants were asked to talk aloud as they performed the tasks. After completing all assigned tasks, participants for the second usability test also completed self-report measures to evaluate perceived usability, usefulness, and acceptability of the PatientCareAnywhere prototype.

Usability testing sessions were audio recorded using encrypted audio recorders and professionally transcribed. The audio files were transmitted via secure protocols to an encrypted project folder on a secure file server at City of Hope. The original audio files were permanently deleted from the audio recorders once uploaded to the file server.

Measures

Usability

The System Usability Scale (SUS) is a validated and widely used 10-item usability measure [48]. Participants' scores for each item are added together and then multiplied by 2.5 to convert the original scores of 0 to 40 to 0 to 100, with higher scores indicating higher usability [48]. Overall SUS scores ≥70.0 are considered above average in terms of acceptable usability [49,50].

Usefulness

Participants also completed a 35-item Usefulness Questionnaire, which was developed specifically for PatientCareAnywhere and includes statements assessing the usefulness and design features of the system. Participants rated their level of agreement with each statement using a 5-point Likert scale ranging from 1="strongly disagree" to 5="strongly agree."

Data Analytic Plan

Data were collected and analyzed using SPSS (IBM Corp). Descriptive statistics (eg, means, frequencies, percentages) were used to characterize the sociodemographic and clinical characteristics of the study sample. Summary statistics were used to describe the usability outcomes, including overall SUS scores and perceived acceptability and usefulness ratings.

Phase 2: Pilot RCT

Study Participants and Design

Textbox 1 shows the inclusion and exclusion criteria for the pilot RCT.

Textbox 1. Inclusion and exclusion criteria.

Inclusion criteria

- At least 21 years of age
- Diagnosis of breast, lung, or prostate cancer at any stage
- Currently being treated on an outpatient basis
- Life expectancy of at least 6 months
- Fluent in English
- Have home internet access

Exclusion criteria

- Clinical evidence of cognitive or psychological impairment
- Prisoners and pregnant women
- Currently participating in other psychosocial studies

Study recruitment included physician referrals, advertisements and flyers, and a patient health care portal (SupportScreen [45]) from City of Hope. Participants were enrolled between October 2017 and September 2019. All study participants were screened for complete eligibility criteria and provided written informed consent before study participation. Consented participants were randomized to either the PatientCareAnywhere intervention or usual care control condition using a computer-based random assignment program using a 1 to 1 ratio. Due to the nature of the study, it was not possible to blind participants' study conditions. Participants in both the intervention and control groups participated in their respective study arm for a 3-month period and completed a baseline assessment at the time of enrollment (T1), which included a sociodemographic questionnaire and 2 biopsychosocial questionnaires assessing HRQOL, as measured by the Functional Assessment of Cancer Therapy-General (FACT-G) [51], and cancer-related self-efficacy, as measured by the Self-Efficacy for Managing Chronic Disease (SEMCD) [52]. Follow-up assessments (FACT-G and SEMCD) were completed monthly until the end of participation, resulting in 3 additional time points: 4 weeks from baseline (T2), 8 weeks from baseline (T3), and 12 weeks from baseline (T4). Table 2 outlines the procedures conducted at different time points of the RCT.

Table 2. Procedures conducted at different phases of the pilot randomized controlled trial.

Time	Patient tasks	Clinical team tasks
Enrollment	• All: complete sociodemographic questionnaire at clinic • All: complete baseline FACT-G[a] and SEMCD[b] (T1[c]) • All: set up an account for and receive an orientation to the PatientCareAnywhere system	• All: enter clinic data into trial management system
Once a week	• Intervention: use the PatientCareAnywhere system, including the symptom reporting feature	• None
Every month	• All: complete FACT-G and SEMCD after 1 month (T2[d]) and 2 months (T3[e]) of participation	• All: enter survey data collected on paper into the system
Before every visit	• None	• Intervention: ensure symptom assessment report from PatientCareAnywhere is either printed or available on computer
During every visit	• Intervention: review symptom assessment report with the provider	• Intervention: review symptom assessment report with the patient
Conclusion of participation	• All: complete FACT-G and SEMCD after 3 months of participation (end of the study; T4[f])	• All: enter all paper-based data into trial management system • Intervention: compile metrics of PatientCareAnywhere system use (eg, frequency of use and time spent)

[a] FACT-G: Functional Assessment of Cancer Therapy-General.

[b] SEMCD: Self-Efficacy for Managing Chronic Disease.

[c] At the time of enrollment (baseline).

[d] 4 weeks after baseline (first midpoint of the study).

[e] 8 weeks after baseline (second midpoint of the study).

[f] 12 weeks after baseline (end of participation).

Study Conditions

Intervention Condition

Patients in the intervention group were encouraged to use PatientCareAnywhere at least weekly to not only report symptoms when necessary but also use other features of the site, such as the education content. Reminder emails were sent to patients to encourage the use of the system after 1 week of inactivity. Patient-reported symptoms of moderate or worse severities triggered email alerts to the study coordinators for triage, who then contacted appropriate providers or supportive care staff to address the patient’s concerns.

Control Condition

Patients in the control group received usual care, including a 1-time use of SupportScreen for symptom checking at the clinic during initial treatment consultation after a cancer diagnosis. The use of SupportScreen could also trigger the delivery of consultation, print patient education materials, and specialist referrals.

Measures

Sociodemographic and Cancer-Specific Characteristics

At baseline, before the intervention, patients self-reported sociodemographic information (eg, age, race, ethnicity, education, and income) and clinical information (eg, cancer diagnosis and stage of cancer), which were confirmed via medical record review.

Health-Related Quality of Life

The FACT-G is a 27-item self-report questionnaire designed to measure 4 domains of HRQOL in patients with cancer, including emotional, functional, physical, and social well-being [51]. Patients rate the degree to which the items applied to them over the past 7 days using a 5-point response scale ranging from 1=“not at all” to 5=“very much.” Total FACT-G scores range from 0 to 108, with a higher score indicating better quality of life.

Patient Self-Efficacy

Patient self-efficacy is an essential component of the treatment and management of illnesses, including cancer. The 6-item SEMCD scale measures patients’ confidence in their ability to manage fatigue, physical discomfort or pain, emotional distress, and other symptoms or health problems; to carry out different tasks or activities to reduce the need to see a physician; and to do things other than taking medication to reduce illness effects [52,53]. Items are rated on a 10-point scale ranging from 1=“not at all confident” to 10=“totally confident,” and scores are averaged across items. The final score (mean of the 6 items) ranges from 0 to 10, with higher scores indicating greater self-efficacy.

Intervention Use

PatientCareAnywhere tracked the frequency with which participants accessed the intervention over the 3-month study period. The system also recorded participants' responses to multiple symptom assessments and the time (minutes) it took to complete each assessment.

Sample Size

The primary goal of the pilot RCT was to compare the FACT-G change across time in the intervention group with the FACT-G change across time in the control group. The sample size calculation was based on prior research that established the minimally important difference for the total FACT-G ranges from 4 to 7 points [54-56]. Specifically, a sample size of 72 participants (36 participants per group) would achieve >80% power to detect a difference in mean changes of 7 (with SD of 12 at both time points and a correlation between measurement pairs of 0.65). The significance level is .05 using a 2-sided, 2-sample *t* test.

Data Analytic Plan

Descriptive statistics (eg, means, frequencies, and percentages) were used to characterize the sociodemographic and disease characteristics of the RCT participants. Demographic differences between intervention and control groups were evaluated using *t* test for continuous variables and Fisher exact test for categorical variables. Regarding FACT-G and SEMCD scores, independent sample *t* test was used to compare mean differences (ie, mean difference between pre- and postintervention scores) between the 2 groups at T4. All statistical analyses were conducted using SPSS.

Hypotheses

We hypothesized that at postintervention, patients randomized to the PatientCareAnywhere intervention would report better HRQOL outcomes, as measured by the FACT-G (primary hypothesis), and self-efficacy, as measured by the SEMCD (secondary hypothesis), compared with patients randomized to the usual care control condition.

Results

Phase 1: Usability Testing

Participant Characteristics

A total of 11 participants (patients: n=4 and caregivers: n=7) participated in usability testing with a prototype of the PatientCareAnywhere system. This sample size was justified based on previous usability research demonstrating that 5 to 7 participants is sufficient to reveal about 80% of the usability issues [57]. Table 3 presents the sociodemographic characteristics of the usability testing sample. Patients were mostly non-Hispanic (7/11, 64%) and White (10/11, 91%), with an average age of 50 (SD 6.8) years. The average age of caregivers was 44 (SD 20) years.

Table 3. Sample characteristics of usability testing participants (N=11).

	Patients (n=4)	Caregivers (n=7)
Age (y), mean (SD; range)	50.3 (6.8; 44-59)	43.7 (20.4; 23-73)
Gender, n (%)		
Man	0 (0)	4 (57.14)
Woman	4 (100)	3 (42.86)
Race, n (%)		
Asian	1 (25)	0 (0)
White	3 (75)	7 (100)
Ethnicity, n (%)		
Hispanic or Latino	2 (50)	1 (14.29)
Non-Hispanic	2 (50)	5 (71.43)
Unknown	0 (0)	1 (14.29)

Usability Outcomes

Qualitative Results

Individual interviews with patients with cancer and caregivers were conducted to evaluate the usability and usefulness of the PatientCareAnywhere system. The interviews consisted of asking the participants to complete a list of tasks that addressed each of the features of the PatientCareAnywhere system (eg, where to find certain information on the page or how to complete a symptom report) and recording the time it took for each task to be completed as well as identifying any tasks that were difficult to complete. Multimedia Appendix 3 provides the list of tasks that were asked of participants. In addition to the task-completion activity, we solicited feedback from the participants on the site functions, features, and design as well as their ideas for improvement. All participants were able to complete the tasks within 5 seconds of being asked, and no participant experienced confusion about navigating the site and completing specific activities.

Participants also had high levels of satisfaction with the PatientCareAnywhere design, features, and functionality of the system. Specifically, patients enjoyed the ability to connect with friends, family, community organizations, other patients with cancer and survivors of cancer, and their care team. They felt that the PatientCareAnywhere layout made sense to them as users, and they did not find any parts of the pages to be confusing. The patients uniformly liked the layout of the biopsychosocial screening tool and preferred the idea that they only had to give responses to the topics that they were concerned about on the tool. They also felt that the personalized recommendations would be a great asset to them during their cancer journey and were especially happy about being able to report their symptoms at any time. In addition, patients really liked the "one-stop-shop" idea of PatientCareAnywhere—the ability to keep track of their appointments and medical information in the same place as connecting with friends and family and finding local events and support groups. All patients felt that the wireframes were well thought out, and each one asked when the system would be available for use at City of Hope.

The caregivers also highly praised the PatientCareAnywhere wireframes. All caregiver participants felt that the wireframes were laid out in a logical manner. They particularly liked having access to their loved one's medical records and appointments (given only with the caregiver permission level), and they felt that this system would make caregiving a much easier experience. Other features that the caregivers highlighted would make a difference for them were the ability to complete a symptom report for their loved one (patient) and the "help request" feature that would allow caregivers (and patients) to send requests for help (eg, assistance with transportation) to their PatientCareAnywhere friends. The PatientCareAnywhere friends can respond to the email request if they can help and this affirmation is noted by the PatientCareAnywhere system. Overall, patients and caregivers did not have any trouble identifying how to complete the biopsychosocial screening tool and where to find recommendations, medical information, educational materials, and local events on the PatientCareAnywhere wireframes.

Quantitative Results

The average SUS total score was 84.09 (SD 10.02; range 75.00-100.00), which was well above the predetermined 70-point threshold reflecting "excellent" usability (Table 4). Regarding the Usefulness Questionnaire, participants agreed or strongly agreed with all 35 statements (refer to Tables 5 and 6, which include average ratings for each statement). Specifically, patients and caregivers rated the usefulness of PatientCareAnywhere site features from 4.00 to 5.00 (Table 5) or 3.86 to 4.86 (Table 6) and, respectively (4="agree" and 5="strongly agree").

Table 4. Results from the System Usability Scale questionnaire (N=11)[a].

Item	Score, mean (SD)
1. I think that I would like to use this system frequently.	4.18 (0.60)
2. I found the system unnecessarily complex.	1.64 (0.82)
3. I thought the system was easy to use.	4.36 (0.48)
4. I think that I would need the support of a technical person to be able to use this system.	1.36 (0.70)
5. I found the various functions in this system were well integrated.	4.36 (0.48)
6. I thought there was too much inconsistency in this system.	1.55 (0.70)
7. I would imagine that most people would learn to use this system very quickly.	4.27 (0.42)
8. I found the system very cumbersome to use.	1.73 (1.03)
9. I felt very confident using the system.	4.36 (0.67)
10. I needed to learn a lot of things before I could get going with this system.	1.64 (0.67)

[a] Total usability score is a sum of individual items multiplied by 2.5 to convert original scores of 0 to 40 to 0 to 100. Possible item responses range from 1 (strongly disagree) to 5 (strongly agree).

Table 5. Results from the Patient’s Usefulness Questionnaire (N=4)[a].

Item number and item	Score, mean (SD)
In managing my cancer care, it is useful to...	
1. Connect with friends, family, and doctors/nurses through private messaging and wall posting features.	4.75 (0.50)
2. Receive education recommendations that are tailored to my medical situation and/or personal needs.	5.00 (0.00)
3. View support group recommendations that are tailored to my needs.	4.25 (0.50)
4. View recommendations for local classes and events that are tailored to my needs.	4.25 (0.50)
5. Be able to create help requests that are sent out to caregivers and/or friends.	4.75 (0.50)
6. Report symptoms via the symptom reporting tool.	5.00 (0.00)
7. Be able to track my symptoms over time via the symptom reporting tool.	4.25 (0.50)
8. View the educational articles that were recommended to me based off the reported symptoms.	5.00 (0.00)
9. Have access to my medication and supplement list.	4.75 (0.50)
10. Have access to my laboratories and tests results.	5.00 (0.00)
11. Have access to my other medical records.	5.00 (0.00)
12. Be able to add additional medical information or upload other medical documents.	4.75 (0.50)
13. View the care team members that have received referrals regarding my personal or medical needs.	4.75 (0.50)
14. See the events that are scheduled at the City of Hope.	4.00 (0.82)
15. See the events for which I am registered.	4.50 (0.58)
16. Add my own events to my calendar.	4.50 (0.58)
17. View the medical appointments that are scheduled for me.	5.00 (0.00)
18. View the help requests that have been sent out.	5.00 (0.00)
19. See which classes, events and support groups are available at the City of Hope.	4.25 (0.50)
20. See which classes, events and support groups are available in my local area.	4.25 (0.50)
21. Be able to register for a class, event or support group.	4.50 (0.58)
22. Read a description of the class/event/support group and the event leader’s contact info.	4.50 (0.58)
23. Be able to read the educational content/articles that have been recommended to me.	4.75 (0.50)
24. Be able to save articles that I want to reference later into a “Favorites” area.	4.75 (0.50)
25. Be able to browse educational materials by category.	4.50 (0.58)
26. Be able to request additional information about a topic.	5.00 (0.00)
27. Be able to share an educational article with the PCA[b] administrators so that they could add it to PCA.	4.75 (0.50)
In general, I feel...	
1. Comfortable using PCA on my own.	4.50 (0.58)
2. That PCA is an easy site to navigate.	4.50 (0.58)
3. That the overall look-and-feel of PCA is appealing.	4.50 (0.58)
4. That the overall organization of PCA is logical.	5.00 (0.00)
5. That for noncritical medical situations, I would rather get information and nurse help via PCA instead of having an in-person doctor’s appointment.	4.50 (0.58)
6. That I would recommend PCA to other caregivers.	4.75 (0.50)
7. That I would recommend PCA to other patients.	4.75 (0.50)
8. That cancer centers should use PCA as part of their standard care practices.	4.75 (0.50)
Total score	4.66 (0.28)

[a] The highest score is 5.00 (strongly agree) and the lowest score is 1.00 (strongly disagree).

[b] PCA: PatientCareAnywhere.

Table 6. Results from the Caregiver’s Usefulness Questionnaire (N=7)[a].

	Score, mean (SD)
In caring for my family member/friend who has cancer, it is useful to...	
1. Connect with her/him and others through private messaging and wall posting features.	3.86 (0.90)
2. Receive education recommendations that are tailored to my friend/family member’s medical situation.	4.86 (0.38)
3. View support group recommendations that are tailored to my friend/family member’s needs.	4.71 (0.49)
4. View recommendations for local classes and events that are tailored to my friend/family member’s needs.	4.71 (0.49)
5. Be able to create help requests that are sent out to other caregivers and/or friends.	4.71 (0.49)
6. Report symptoms via the symptom reporting tool on behalf of my family member/friend.	4.71 (0.49)
7. Be able to track her/his symptoms over time via the symptom reporting tool.	4.71 (0.49)
8. View the educational articles that were recommended for her/him based off the reported symptoms.	4.86 (0.38)
9. Have access to her/his medication and supplement list.	4.86 (0.38)
10. Have access to her/his laboratories and tests results.	4.86 (0.38)
11. Have access to her/his other medical records.	4.86 (0.38)
12. Be able to add additional medical information or upload other medical documents.	4.86 (0.38)
13. View the care team members that have received referrals for my family member/friend.	4.71 (0.49)
14. See the events that are scheduled at the city of hope.	4.43 (0.79)
15. See the events for which he/she is registered.	4.43 (0.53)
16. Add my own events to my calendar.	4.29 (0.95)
17. Add events for my family member/friend.	4.29 (0.95)
18. View the medical appointments that are scheduled for my family member/friend.	4.86 (0.38)
19. View the help requests that have been sent out.	4.71 (0.49)
20. See which classes, events and support groups are available at the city of hope.	4.43 (0.98)
21. See which classes, events and support groups are available in my local area.	4.43 (0.79)
22. View the classes, events and support groups that are recommended for my family member/friend.	4.43 (0.79)
23. Be able to register my family member/friend for a class, event or support group on their behalf.	4.29 (0.76)
24. Read a description of the class/event/support group and the event leader’s contact info.	4.43 (0.79)
25. Be be able to read the educational content/articles that have been recommended to my family member/friend.	4.86 (0.38)
26. Be able to save articles that i want to reference later into a “favorites” area.	4.86 (0.38)
27. Be able to browse educational materials by category.	4.71 (0.49)
28. Be able to request additional information about a topic.	4.71 (0.49)
29. Be able to share an educational article with the PCA[b] administrators so that they could add it to PCA.	4.43 (0.53)
For me personally as a caregiver, it is useful to...	
1. Have education recommendations that are tailored to my role as caregiver	4.86 (0.38)
2. Have support group recommendations that are tailored to my role as caregiver.	4.29 (0.76)
3. Have recommendations for local classes and events that are tailored to my role as caregiver.	4.43 (0.53)
In general, I feel...	
1. Comfortable using PCA on my own.	4.57 (0.79)
2. That PCA is an easy site to navigate.	4.43 (0.79)
3. That the overall look-and-feel of PCA is appealing.	4.43 (0.79)
4. That the overall organization of PCA is logical.	4.57 (0.53)
5. That for noncritical medical situations, I would rather get information and nurse help via PCA instead of having an in-person doctor’s appointment.	4.29 (0.76)
6. That I would recommend PCA to other caregivers.	4.71 (0.76)

	Score, mean (SD)
7. That I would recommend PCA to other patients.	4.71 (0.76)
8. That cancer centers should use PCA as part of their standard care practices.	4.57 (0.79)
Total scores	4.59 (0.23)

[a] The highest score is 5.00 (strongly agree) and the lowest score is 1.00 (strongly disagree).

[b] PCA: PatientCareAnywhere.

Phase 2: Pilot RCT

Participant Characteristics

A total of 72 patients with cancer were enrolled and individually randomized (1:1) to the PatientCareAnywhere intervention (n=36, 50%) or usual care control condition (n=36, 50%) for 3 months. The following analysis was limited to 59 participants who completed at least 2 of the questionnaires (FACT-G and SEMCD): 28 (47%) patients in the intervention group and 31 (53%) patients in the control group. Of note, there were no significant differences in demographic characteristics between the included (59/72, 82%) and excluded (13/72, 18%) participants (Multimedia Appendix 4). Table 7 summarizes the pilot RCT participants' sociodemographic and cancer-related characteristics, with no significant between-group differences. Overall, the RCT participants had a mean age of 53.85 (SD 12.37) years and were predominantly women (49/59, 83%), White (41/59, 69%), and non-Hispanic or Latino (41/59, 69%). Most participants were married (43/59, 73%), had at least a college degree (33/59, 56%), and earned >US $100,000 (29/59, 49%). The most common diagnosis was breast cancer (43/59, 73%) and nonmetastatic (stages 0-III; 33/59, 56%).

Table 7. Sample characteristics of the pilot randomized controlled trial participants (N=59).

	Intervention (n=28)	Control (n=31)	*P* value
Age (y), mean (SD; range)	54.82 (12.32; 34-77)	52.97 (12.37; 30-79)	.57
Gender, n (%)			.73
Man	4 (14.29)	6 (19.35)	
Woman	24 (85.71)	25 (80.65)	
Race, n (%)			.55
Asian American	6 (21.43)	4 (12.90)	
Black or African American	2 (7.14)	5 (16.13)	
White	20 (71.43)	21 (67.74)	
Unknown	0	1 (3.23)	
Ethnicity, n (%)			.24
Hispanic or Latino	9 (32.14)	6 (19.35)	
Non-Hispanic	17 (60.71)	24 (77.42)	
Unknown or not reported	2 (7.14)	1 (3.23)	
Marital status, n (%)			.07
Single	2 (7.14)	6 (19.35)	
Married	19 (67.86)	24 (77.42)	
Separated or divorced	5 (17.86)	1 (3.23)	
Widowed	2 (7.14)	0 (0)	
Education, n (%)			.23
Less than high school	2 (7.14)	1 (3.23)	
High school	5 (17.86)	7 (22.58)	
College	13 (46.43)	20 (64.52)	
Graduate school	8 (28.57)	3 (9.68)	
Household income (US $), n (%)			.93
<20,000	4 (14.29)	4 (12.90)	
20,000-29,999	2 (7.14)	1 (3.23)	
30,000-49,999	2 (7.14)	4 (12.90)	
50,000-69,999	3 (10.71)	5 (16.13)	
70,000-99,999	3 (10.71)	2 (6.45)	
>100,000	14 (50)	15 (48.39)	
Cancer, n (%)			.57
Breast	20 (71.43)	23 (74.19)	
Lung	5 (17.86)	2 (6.45)	
Prostate	2 (7.14)	3 (9.68)	
Unknown	1 (3.57)	3 (9.68)	
Disease stage, n (%)			.86
Stage 0	2 (7.14)	3 (9.68)	
Stage 1	6 (21.43)	5 (16.13)	
Stage 2	4 (14.29)	7 (22.58)	
Stage 3	2 (7.14)	4 (12.90)	
Stage 4	8 (28.57)	7 (22.58)	
Unknown	6 (21.43)	5 (16.13)	

Study Outcomes

Health-Related Quality of Life

The mean difference in FACT-G scores between the preintervention (T1; baseline) and postintervention (T4; 12-week postbaseline) assessments of each patient (Table 8) for the intervention group was 6.08 (SD 15.26), indicating an improvement in HRQOL among patients who received PatientCareAnywhere. For the control group, the mean difference in FACT-G scores between the preintervention (T1) and postintervention (T4) assessments was –2.95 (SD 10.63), indicating a worsening of HRQOL among patients who received usual care. The between-group difference was statistically significant (*P*=.01), with a medium effect size (Cohen *d*=0.70).

Table 8. Results from the pilot randomized controlled trial.

Group	Mean difference[a] (SD)	*P* value[b]
HRQOL[c] (FACT-G[d])		
Control (n=31)	−2.95 (10.63)	*.01*
Intervention (n=26)	6.08 (15.26)	*.01*
Self-efficacy (SEMCD[e])		
Control (n=31)	−0.84 (11.20)	.09
Intervention (n=27)	4.22 (10.91)	.09

[a] Mean difference between preintervention (T1; baseline) and postintervention (T4; 12 weeks from baseline) scores.

[b] Significant *P* values (*P*<.05) are italicized.

[c] HRQOL: health-related quality of life.

[d] FACT-G: Functional Assessment of Cancer Therapy-General.

[e] SEMCD: Self-Efficacy for Managing Chronic Disease.

Patient Self-Efficacy

Similarly, the mean difference in SEMCD scores between the preintervention (T1; baseline) and postintervention (T4; 12-week postbaseline) assessments (Table 8) for the intervention group was 4.22 (SD 10.91) and for the control group was –0.84 (SD 11.20). However, the between-group difference was not statistically significant (*P*=.09), with a small-to-medium effect size (Cohen *d*=0.46).

Intervention Use

Overall, 61% (17/28) of the patients in the intervention group were classified as "Frequent Users," defined as having accessed the PatientCareAnywhere site at least 5 times during the study. Among the frequent users, the mean difference between the first and last FACT-G scores was 7.12 (SD 15.4), which was statistically significantly higher than that of the control group (*P*=.007), with a large effect size (Cohen *d*=0.80). The mean difference between the first and last SEMCD scores (mean 5.47, SD 6.43) was also statistically significantly better than that of the control group (*P*=.03), with a medium effect size (Cohen *d*=0.71). In comparison, among the infrequent users (n=11), the mean difference between the first and last scores on the FACT-G (mean 4.02, SD 17.39; *P*=.10) and SEMCD (mean 0.73, SD 15.37; *P*=.68) did not significantly differ from the control group.

Symptom Reporting

Finally, a total of 140 symptom reports were recorded. On average, each symptom reporting session included 4.4 symptoms and lasted for 3.4 minutes.

Discussion

The primary aim of this study was to evaluate the usability and preliminary efficacy of PatientCareAnywhere, a patient-centered adaptive supportive care system, to improve patient-reported outcomes for patients newly diagnosed with cancer.

Principal Findings

Both qualitative and quantitative usability testing results were notably positive and support the usability of PatientCareAnywhere. Overall, patients with cancer and caregivers were highly satisfied with the purpose and functions of the intervention, found the content relevant and useful, and expressed strong support for the biopsychosocial screening tool and personalized recommendations. On the basis of participant feedback, several changes were made to the design features: a "help request" function was added, caregivers were given greater access to the patient's medical information, and symptom reporting was added to the caregiver portal, allowing caregivers to report symptoms on the patient's behalf. In addition, the quantitative feedback demonstrated a high usability level for PatientCareAnywhere, with an average SUS score of 84.09 (SD 10.02), indicating above-average acceptable usability [49,50]. The scores on the Usefulness Questionnaire also reflected the positive experience that users had with the system and underlined the beliefs of participants that the features of PatientCareAnywhere were acceptable and useful during the cancer care journey.

Results from the pilot RCT demonstrate the preliminary efficacy of the PatientCareAnywhere intervention. Compared with usual care, patients with cancer who received PatientCareAnywhere showed statistically significant improvements in HRQOL from pre- to postintervention scores. While self-efficacy scores also increased in the intervention group, the difference was not statistically significant compared with the control group. When evaluating intervention use, "frequent users" (ie, patients who accessed the intervention at least 5 times during the study) reported greater improvements in both HRQOL and self-efficacy outcomes (medium to large effect sizes) compared with the control group. These results confirmed our hypotheses that routine use of PatientCareAnywhere could result in improved HRQOL outcomes and greater patient self-efficacy among patients newly diagnosed with cancer, and that these effects were more prominent with greater intervention use. Furthermore, patients on average reported about 4 symptoms and completed the symptom assessment in <4 minutes. Notably, this is drastically shorter than SupportScreen, which takes approximately 15 to 20 minutes to complete [45]. This observation indicates that PatientCareAnywhere is also an efficient symptom reporting tool.

There is growing evidence of technology-assisted assessments and interventions enhancing the delivery of patient-centered care through improved symptom monitoring, communication between patients and providers, tailored resources, and patient empowerment and engagement across the continuum of care [42]. Our findings are in line with previous studies that have demonstrated the effectiveness of technology-based interventions in cancer care [42]. Recently, a comprehensive scoping review was conducted on 134 literature reviews of digital health and telehealth interventions across the cancer continuum, in which a majority focused on patients with cancer (n=128) in the active treatment (n=48) and survivorship (n=29) phases using eHealth programs, synchronous telehealth, mobile apps, asynchronous messaging (eg, email), and SMS text messaging [58]. A total of 29 reviews included a meta-analysis, with results signifying positive effects of digital health and telehealth in cancer care on quality of life, psychological outcomes (eg, anxiety and depression), and cancer screenings [58]. Of note, the benefits of digital supportive cancer care interventions have been demonstrated independent of demographic and disease factors [44,59]. The lack of a positive effect on self-efficacy warrants further evaluation. Similar to our findings, an RCT evaluating an internet-based interactive health communication application that allows patients with cancer to monitor their symptoms and provides tailored self-management support reported no significant between-group differences in depression, HRQOL, self-efficacy, and social support, although self-efficacy and HRQOL outcomes significantly worsened over time in the control group [60]. Conversely, an earlier review and meta-analysis of eHealth-based self‐management interventions demonstrated a statistically significant effect on self-efficacy but noted that the effect size was small (<0.4) [61]. A larger sample size may be needed to observe meaningful changes in self-efficacy.

Strengths and Limitations of PatientCareAnywhere

PatientCareAnywhere was developed using a user-centered design approach to ensure the needs and preferences of patients newly diagnosed with cancer were addressed. Applying user-centered design principles to the overall development of PatientCareAnywhere resulted in a user-friendly, functional, useful, and acceptable supportive care intervention. In addition, the web-based delivery and responsive-design technologies allow patients to access the intervention at anytime and anywhere, including outside of clinic and at home, and use PatientCareAnywhere on multiple devices (eg, desktops, smartphones, and tablets), thereby providing more flexible intervention delivery and reducing common practical barriers to care (eg, transportation issues and scheduling conflicts). Furthermore, by remotely and routinely monitoring patients' biopsychosocial symptoms and distress, PatientCareAnywhere provides supportive cancer care tailored to their needs. Compared with other distress management systems, additional advantages of PatientCareAnywhere include (1) PatientCareAnywhere has access to numerous validated questionnaires, allowing an institution to pick and choose the ones that are most suitable for their patients and providers; (2) PatientCareAnywhere allows the invocation of another questionnaire for follow-up questions based on the results from a top-level screening tool; (3) PatientCareAnywhere provides a communication platform to allow caregivers, family members, and friends to interact directly with the patient via the system; (4) PatientCareAnywhere allows community organizations to post events and respond to patient requests for help; (5) PatientCareAnywhere delivers tailored and responsive patient education contents that evolve with the patient based on their current needs and concerns; and (6) PatientCareAnywhere is backed by City of Hope's comprehensive supportive care training program.

This study has some limitations. First, the objectives of this study were to establish the usability and preliminary effects of PatientCareAnywhere rather than investigate intervention efficacy. However, results from this pilot study will inform the next phase of research to conduct a full-scale RCT evaluating the efficacy of PatientCareAnywhere to improve HRQOL and reduce symptom burden compared with usual care. Second, the study was limited to patients diagnosed with breast, lung, or prostate cancer. We initially focused on these 3 common cancers to develop cancer-specific educational materials, with plans to expand to all cancer types (eg, gastrointestinal, gynecologic, head and neck, and hematologic) and treatment options following successful initial pilot testing results. Further study is warranted to adapt PatientCareAnywhere to other types of cancer and examine the extent to which our initial findings are generalizable to patients with different cancer diagnoses. Third, while sufficient for the purposes of our study, sample sizes for usability testing (N=11) and pilot RCT (N=78) were relatively small, limiting power and study results. It is possible that with a larger sample, stronger intervention effects may emerge. Fourth, study participants were limited to patients receiving care at City of Hope and may not be representative of the general cancer population in the United States. Furthermore, the intervention was only available in English and required patients to have internet access to participate in the study, which also may limit the generalizability of our findings. Future studies should investigate the efficacy of PatientCareAnywhere with a more diverse and larger sample of patients with cancer over a longer study period and explore the optimal intervention use to improve patient outcomes.

Conclusions

Engaging key stakeholders throughout the design and development process helped ensure PatientCareAnywhere was a patient-centered, user-friendly, efficient, and effective supportive care system. Overall, the results from initial pilot testing demonstrate the usability and preliminary efficacy of PatientCareAnywhere to improve HRQOL outcomes among patients newly diagnosed with cancer.

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Data Availability

The data sets generated during and analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization of this paper was done by SHB, KC, ML, DY, WD, and NH. SHB contributed to data analysis and interpretation, writing, and original draft preparation. KC, ML, DY, and NH participated in obtaining funding, methodology, project administration, and supervision of the study. AC was involved in project implementation, including participant recruitment, study coordination, and collection and assembly of data. MR conducted the formal analysis. KC, MS, ML, MR, WD, and NH contributed to the interpretation of data and writing, reviewing, and editing of the original manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Main components of PatientCareAnywhere.
[DOCX File , 18 KB - cancer_v10i1e49703_app1.docx]

Multimedia Appendix 2
Screenshots of PatientCareAnywhere.
[DOCX File , 2954 KB - cancer_v10i1e49703_app2.docx]

Multimedia Appendix 3
PatientCareAnywhere usability tasks (phase 1).
[DOCX File , 18 KB - cancer_v10i1e49703_app3.docx]

Multimedia Appendix 4
Sample characteristics of the included versus excluded pilot randomized controlled trial participants (phase 2).
[DOCX File , 20 KB - cancer_v10i1e49703_app4.docx]

Multimedia Appendix 5
CONSORT eHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 2119 KB - cancer_v10i1e49703_app5.pdf]

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Abbreviations

EHR: electronic health record
FACT-G: Functional Assessment of Cancer Therapy-General
HRQOL: health-related quality of life
NCCN: National Comprehensive Cancer Network
RCT: randomized controlled trial
SEMCD: Self-Efficacy for Managing Chronic Disease
SUS: System Usability Scale

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Original Paper

Artificial Intelligence–Based Co-Facilitator (AICF) for Detecting and Monitoring Group Cohesion Outcomes in Web-Based Cancer Support Groups: Single-Arm Trial Study

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Abstract

Background: Commonly offered as supportive care, therapist-led online support groups (OSGs) are a cost-effective way to provide support to individuals affected by cancer. One important indicator of a successful OSG session is group cohesion; however, monitoring group cohesion can be challenging due to the lack of nonverbal cues and in-person interactions in text-based OSGs. The Artificial Intelligence–based Co-Facilitator (AICF) was designed to contextually identify therapeutic outcomes from conversations and produce real-time analytics.

Objective: The aim of this study was to develop a method to train and evaluate AICF's capacity to monitor group cohesion.

Methods: AICF used a text classification approach to extract the mentions of group cohesion within conversations. A sample of data was annotated by human scorers, which was used as the training data to build the classification model. The annotations were further supported by finding contextually similar group cohesion expressions using word embedding models as well. AICF performance was also compared against the natural language processing software Linguistic Inquiry Word Count (LIWC).

Results: AICF was trained on 80,000 messages obtained from Cancer Chat Canada. We tested AICF on 34,048 messages. Human experts scored 6797 (20%) of the messages to evaluate the ability of AICF to classify group cohesion. Results showed that machine learning algorithms combined with human input could detect group cohesion, a clinically meaningful indicator of effective OSGs. After retraining with human input, AICF reached an F_1-score of 0.82. AICF performed slightly better at identifying group cohesion compared to LIWC.

Conclusions: AICF has the potential to assist therapists by detecting discord in the group amenable to real-time intervention. Overall, AICF presents a unique opportunity to strengthen patient-centered care in web-based settings by attending to individual needs.

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KEYWORDS

group cohesion; LIWC; online support group; natural language processing; NLP; emotion analysis; machine learning; sentiment analysis; emotion detection; integrating human knowledge; emotion lining; cancer; oncology; support group; artificial intelligence; AI; therapy; online therapist; emotion; affect; speech tagging; speech tag; topic modeling; named entity recognition; spoken language processing; focus group; corpus; language; linguistic

Introduction

Overview

Web-based care has become increasingly important in health care delivery as a means to accessibly reduce emotional distress. Online support groups (OSG) offer a convenient solution to those who cannot attend in-person support groups [1-3]. Professionally led OSGs occur in real time with participants engaging with a therapist and other participants in the group. Therapists facilitate the sharing of personal experiences to foster a mutually supportive environment. OSG participants report an increased sense of empowerment and control, as well as improved knowledge about their conditions [4].

Cancer Chat Canada (CCC) offers web-based professionally led, synchronous, text-based support groups to patients with cancer or caregivers across 6 Canadian provinces with a text-based nature allowing for anonymity while reaching people in rural areas. All groups provided via CCC are manual-based, consisting of 8-12 sessions. Each session focuses on a specific theme, homework readings, and web-based activities. Participants exchanged their experiences and ideas through a chatbox on the CCC platform. During sessions, therapists facilitate discussions based on the weekly readings, address issues or concerns, attend to emergent emotional needs of the members, and employ therapeutic techniques that promote a continuous sense of mutual support among the 6-10 members [5].

For group interventions to be effective, therapists encourage authentic emotional expression while effectively monitoring and addressing signals of distress [6]. However, the absence of visual cues, along with the simultaneous entries by multiple participants, can impose challenges for therapists to attend to all participants' needs during the session [4]. Therapists' failure to recognize and respond to participants' expressions of distress can reduce the participants' perceived level of support, safety, and trust in the group, leading to disengagement and attrition [7].

One way to reduce attrition and improve OSG services is through tracking and monitoring group cohesion [8,9]. A cohesive group experiences a sense of warmth, comfort, acceptance, affiliation, and support from other members they value [5]. Group cohesion is associated with positive participant outcomes, including reductions in distress and improvements in interpersonal functioning [5].

Traditionally, group cohesion is measured by participant self-report instruments, such as the Harvard Community Health Plan Group Cohesiveness Scale[10] and the Group Cohesion Scale Revised [10]. Alternatively, it can be measured by content analysis, where analysts assign ratings to the participants' statements [11]. While useful, these approaches have limitations of participant recall bias, measurement fatigue in self-reports, and time and cost of labor in post hoc qualitative analyses.

Previous studies demonstrate that a higher frequency of first-person singular pronouns use (ie, I, my), also referred to as "iTalk" or self-referential language, is a linguistic marker of general distress and is associated with negative psychological outcomes such as depression and suicidal behaviors [12-14]. In contrast, collective identity language use (ie, our group, us) was instrumental to group attachment [15]; with greater uses of references to the group as a whole and to other members predicting reduced symptoms of grief [11]. Aside from content analysis, such as Psychodynamic Work, Object Rating System [16], many studies adopted computerized textual analysis systems such as dtSearch [17], Linguistic Inquiry, and Word Count (LIWC) to track levels of cohesion through text [18-21]. In particular, Lieberman et al [20] detected group cohesion by combining LIWC to count the proportion of group referential language use and dtSearch to count words indicative of positive connotations (ie, hope, altruistic, accept, affection) within 10 words of such group referential language in an OSG for patients with Parkinson. However, Alpers et al [19] questioned the software's ability to process complex communications, suggesting that future studies should develop systems that analyze the context of discourse for real-time analysis.

Given the evidence, group cohesion can be systematically measured by a well-designed computer analytical system. We designed the Artificial Intelligence–based Co-Facilitator (AICF) to contextually identify therapeutic outcomes, including group cohesion from conversations, and produce real-time analytics [22-25]. AICF can track basic emotions, including joy, sadness, anger, trust, fear, anticipation, disgust, surprise, and psychological outcomes such as distress, group cohesion, and hopelessness for each participant in the OSGs [22,23]. AICF extracted emotions from the text by parsing through over 120,000 lines of chat messages from a training data set to multiple levels of granularity: word, phrase, sentence, post, and posts by each user [26]. AICF employed several natural language processing (NLP) techniques, such as Word2Vec [27] and text classification models. Classification models were trained to classify posts containing group cohesion mentions to determine the level of group cohesion in this web-based conversation setting. Each level of extraction served as an input for calibration for the subsequent extraction to increase accuracy [26,28,29]. AICF could, therefore, track and inform facilitators of each participant's level of cohesive statement use in their posts.

We hypothesized that AICF could detect first-person plural pronoun use (eg, we, our) in OSGs and group-references language use ("we-talk") as group cohesion, machine learning–based NLP could also identify a broader definition of group cohesion, including expressing gratitude, mutual support, and sense of belonging.

Objective

This study is focused on the development of a method to train and evaluate AICF's ability to detect group cohesion among cancer OSG members.

Methods

AICF Training and Development

The steps involved in the training and development of AICF's cohesion detection is outlined below.

Collecting Design Specifications

Experienced CCC therapists participated in phase 1 and phase 3 focus groups to obtain design specifications for which clinically meaningful outcomes AICF should capture and provide real-time analytics for, as well as the pros and cons after experiencing AICF clinically. All therapists who responded to our request to participate were involved in the study and are experienced in their field. In addition to the individual emotion tracking feature, the therapists expressed interest in tracking group processes with a particular emphasis on group cohesion. Therapists described group cohesion as a high frequency of posting by members with a sense of interconnectedness through replying to others. A successful group session results in members feeling supported and acknowledged by other group members. The results herein this manuscript excluded the results of these focus groups as they were published elsewhere.

Scoring Guide Development

A literature-based guide was developed to ensure that group cohesion statements were consistently identified and annotated by the human team.

Group cohesion is the sense of warmth, acceptance, support, and belongingness to the members [5], a sense of closeness, and participation [30]. It is measured by statements that reflect a sense of belonging and support in the group.

This belonging and support could be expressed with the statement themes below [31]. The following examples were from the CCC chat training data.

1. Reassurance or encouragement between peers
2. Expressing support or feeling supported
3. Deepening emotional disclosure and trust
4. A sense of belonging
5. Gratitude for the group
6. Finding shared experiences and commonalities
7. Looking forward to future sessions or connecting outside of the group
8. Reflecting on the positive aspects of the group

Creating Training Data

To train AICF to identify group cohesion, 1000 examples of cohesive statements from 10 OSG sessions were annotated by 2 human group therapists (EW and JH). These annotated examples were used for training the algorithm.

Algorithm Development

Feature Selection of Group Cohesion Expressions

First, a corpus of CCC chat sessions (~80,000 messages) was used to train a word embedding model using Word2Vec using the Gensim library in Python (gensim.models.Word2Vec [documents, size=100, window=10, min_count=2, workers=10]). This enabled the creation of a vector representation for each word in the corpus. This positioned semantically similar expressions in closer proximity to generate contexts of cancer OSG discussion. Second, to expand the group cohesion mentions, the annotated samples were fed into the trained Word2Vec model as inputs to query for neighboring words. This resulted in a set of semantically similar, contextually relevant group cohesion expressions. This enabled AICF to identify statements representing group cohesion, including keywords such as "us," "we," and "our group," as well as themes such as expressing gratitude, eagerness to attend upcoming group sessions, chatting outside of group time, mutual support, and a sense of belonging.

Training the Classifiers of Group Cohesion

To produce the probability of each post containing group cohesion, 3 models, multinomial naive Bayes, logistic regression, and multilayer perceptron (MLP) classifier with the group cohesion features selected were trained using the training data set.

Before training the classifier, a series of feature engineering steps were followed. Feature engineering is the process of creating features by extracting information from the data. For this purpose, the term frequency–inverse document frequency (TF-IDF) approach was used. TF-IDF is a statistical measure that evaluates how relevant a word is to a document in a collection of documents. It is performed by multiplying the term frequency and inverse document frequency of the word across a set of documents. In this classification task, the TF-IDF vectorizer was used with a limit of 5000 words capturing both unigrams (single words) and bi-grams (2 words that occur together). Next, the vectorizer was applied to the preprocessed training data set.

Once the data set was transformed, it was used to train multiple classifiers; naïve Bayes, random forest, support vector machine (SVM), multilayer perceptron (MLP), and logistic regression models. The objective of training multiple classifiers was to increase the performance of the final classification by incorporating multiple high-performing classifiers. This technique is called "soft voting," which is an ensemble machine learning technique that combines predictions from multiple models. Table 1 shows the F_1-scores of the trained classifiers.

Table 1. The F1-scores of trained classifiers.

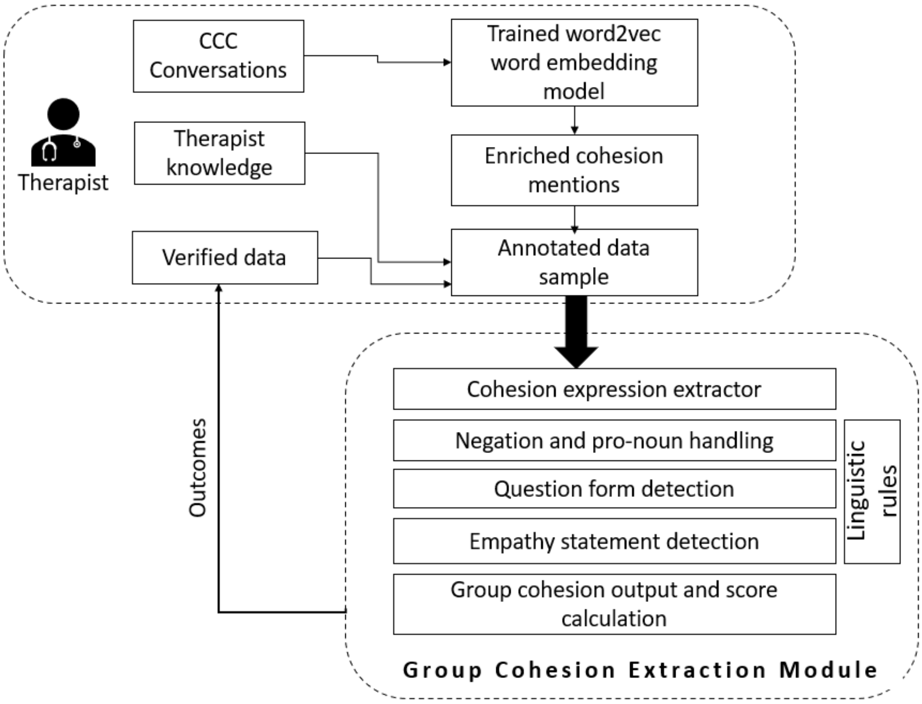
Classifier	F_1-score
Support vector machine	0.63
Naïve Bayes	0.79
Multilayer perceptron	0.77
Random forest	0.72
Logistic regression	0.82

Group Cohesion Score Calculation

Based on this, the top 3 classifiers were selected: naïve Bayes, MLP, and logistic regression. The outcomes of all 3 classifiers were used to make the final prediction. If a post is classified into the same label by 2 of the 3 classifiers, then the output label is used as the final outcome. A confidence value was generated for each classification based on the weighted F_1-scores of each classifier. The average F_1-score using 3 classifiers was 0.8.

In order to improve the performance of the model, an active learning approach [32] was used where human input is used as feedback to fine-tune the models. Therapists examined 20% (6797/34048) of the outputs using a confusion matrix (see Active Learning via Human Scoring section). The scoring results were then used as a feedback loop to improve the list of keywords of queried expressions. Lastly, to fine-tune group cohesion extraction, linguistic rules were hand-coded to handle exceptions such as past tense and empathetic questions by participants (Figure 1).

Figure 1. Process of group cohesion extraction. CCC: Cancer Chat Canada.



Linguistic Rules for Group Cohesion Score Adjustment

The following rules were added after the first round of scoring based on therapists' feedback:

1. Intensifiers: We have used the intensifiers from a pretrained library, Valence Aware Dictionary and Sentiment Reasoner (VADER; [33], which considers intensity boosters such as "very" and "so much" to enhance the valence.
2. Past tense (in the part-of-speech tagging via the NLTK Python library): The score would be multiplied by 0.5 if past tense was present, as the event had happened in the past, we assume that the effect of the event on the person would subside.
3. Negation: The calculated cohesion score would be set to zero in case of a negation expression.
4. First-person tagging: This was set to be "False" if second or third person pronouns were found.
5. Empathy: If an empathy statement were found, then the calculated group cohesion score would be doubled to denote the intensity.

Finally, an aggregated score of group cohesion (β) was calculated for specific time intervals using the following formula:

where β is the group cohesion score; T is the specified time interval (30 minutes); $A(t,t+T)$ is the set of all posts the occurred during the time t to $t+T$; and $C(t,t+T)$ is the set of cohesion mentioned posts that occurred during the time t to $t+T$.

A group cohesion score was displayed and updated at 30-minute intervals on the 90-minute timeline in a real-time dashboard for therapists.

Active Learning via Human Scoring

Outputs were scored by undergraduate students (responsible for basic emotions), graduate students, and clinical experts (responsible for clinical and process outcomes). The team scored 20% of the output to inform AICF development, which was improved in light of the human scoring results. The updated AICF was run on the data of a new OSG (test data). Each AICF version was saved before training with new data. The team scored the output using definitions or examples from well-established psychometric measures such as the Group Cohesiveness Scale and Group Openness and Cohesion Questionnaire. A confusion matrix was used to score AICF outputs. The scoring process was based on recall, precision, and F_1 measures. Scorers' feedback using their domain expertise was used to improve AICF's performance until it achieved an F_1-score of 80% before deploying in real-time OSG for beta-testing [34].

LIWC Evaluation

The Linguistic Inquiry Word Count (LIWC) software [35], considered the gold standard of psychology-based NLP, was used as a validation tool. LIWC reads a given text and calculates the percentage of total words in the text that match each of the LIWC dictionary categories. We tried to capture the concept of group cohesion using multiple LIWC dictionary categories: "we," "positive emotion," "family," "friend," and "affiliation" as the measurement criteria. We classified the text as an instance of group cohesion when at least 3 out of 5 criteria were met.

Ethical Considerations

The study protocol including the human participant recruitment method was approved by the University Health Network Research Ethics Board (confirmation number: UHN REB#18-5354). All identifiable information was removed from the quotes in this report. Participants were compensated with a CAD (73.34 USD) gift card upon the completion of the focus group.

Results

The results herein only focus on the human evaluation of the AICF system and its ability to detect group cohesion. We compared AICF to LIWC using human judgment using the confusion matrix and F_1-score to measure accuracy and precision. AICF was run on 34,048 messages of CCC chat history to generate outputs for human scoring. Every fifth message was scored, totaling 6797 messages (20%). The precision, recall, and F_1-scores are reported in Table 1 and show that logistic regression, followed by naive Bayes and MLP classifiers performed the best.

In this first round, AICF missed a high number of group cohesive statements (Table 2).

All scored statements were incorporated into AICF for improvement. In the second round, the team checked another 296 of 1208 messages (20%) from a separate set of CCC group conversations. AICF was able to improve the false-negative rate (recall) from 0.52 to 0.70.

We also ran LIWC on new OSG data (12,034 messages) from the CCC platform. Precision, recall, and F_1-scores are listed in Table 3.

Within the "true positive" instances identified by AICF in agreement with the human scorers, several thematic categories and keywords emerged. They closely align with established measures of group cohesion [31], including expressions of support or a sense of belonging (Table 2). Moreover, some keywords consistently emerged within the true-positive statement classifications (eg, "we," "us," "our," "group," "support"). Among the false-positive identifications, it was typically due to a missed subtle negation within the sentence or when a participant wrote about a supportive person or activity from outside the group (Table 2).

Where AICF missed a classification of group cohesion (ie, a false negative), it was typically also due to nuanced conversational features on which it had not yet been trained, such as local expressions or idioms, supportive responses to others or statements missing identified group cohesion keywords (such as "we," "us," and "our"; Table 2). These correct and incorrect classifications were used to refine AICF detection of group cohesion as the algorithm progresses in development.

Table 2. Themes, keywords, and examples of AICF[a] outputs.

Themes	Examples
True-positive themes	
Reassurance among peers	“Good for you, that must have been really difficult to do”
Expressing support/feeling supported	“sending hugs”; “thanks everyone for your support <3”
Deeping emotional disclosure and trust	“At my last treatment, I felt really scared, I didn’t want to tell my family this. But I can tell this group”
Sense of belonging	“I am glad to be part of this group”
Gratitude for the group and peers	“Thank you everyone, this is such a great group.”
Shared experiences	“It is amazing how much we all have in common”
Reflecting on the positive aspects of the group	“This group has been a great resource venue for meeting and I will continue down the road with fond memories of the time spent here”
Anticipating future groups/chats	“I can’t wait to chat with you all next week”
Keywords: we, us, our, you all/all of you, thanks / thank you, time, chat, group, support, miss	“we are friends”; “thinking of you all!”; “time went by fast!”;“A very good chat session”; “I’m so glad I found this group”; “thank you for your support and input”; “I am going to miss this group”
False-positive themes	
False detection of “we” or “us” when it is not indicative of group cohesion	“When I mentioned that last week, when we all said what our situations were, no one even acknowledged it. I was very hurt by that”
Talking about support from nongroup members	“When I put my things in order I involved my children and as challenging and emotional as it was it made it easier for me and for them - we laughed and cried but it really made me feel supported”
False-negative themes	
Idioms/expressions	“been there, am there... got the t-shirt”; “I hope you don't think you've been placed in a hot seat. It's just that I missed you and worried about you.”; “we are joining our circle“
Missed detection of providing empathy, encouragement, appreciation, and support to other members	“I am with you, be strong please”; “Are you going to be alright? I want you to know how much I appreciate your presence.”
Missed detection of agreeing with or relating to others’ stories	“I can relate”; “I feel the same way”;
Missed statements because of lack of “we” language	“I am sure there will be a sense of connection, so much sharing already”; “I am sure I will think of you often”

[a]AICF: Artificial Intelligence–based Co-Facilitator.

Table 3. Artificial Intelligence–based Co-Facilitator performance evaluation for identification of group cohesion.

Scoring round/method	Precision	Recall	F_1-score
First	0.99	0.52	0.68
Second	0.98	0.70	0.82
Linguistic Inquiry and Word Count	0.36	0.23	0.28

Discussion

Principal Results

AICF, an ensemble of NLP and machine learning algorithms combined with annotation and human scoring, offers a novel way of measuring the group cohesion changes for each group member and alerting the therapist of these changes in real time. This affords therapists the opportunity to allocate their attention and resources for effective facilitation. The objective was to determine whether AICF can detect group cohesion beyond the first-person plural pronunciation use. The findings indicate that it is feasible to measure group cohesion in text-based complex human interactions using AICF. The level of congruency with human scoring suggests that it can be a helpful tool to therapists in improving the group cohesion outcome.

This study has opened an avenue to person-centered and process-outcome research using AI combined with human inputs to improve the quality of care, which otherwise is a labor-intensive research process. Initially, after being trained with 1000 annotated group cohesion statements processed by word embeddings and the domain expertise from therapists, AICF was able to achieve reasonable F_1, precision, and recall scores. Furthermore, training the algorithm using only word embeddings allows AICF to identify the various cohesion themes that emerged, which are consistent with previous research 34]. These themes include expressing support, reassurance, a sense of belonging, trust, deepening emotional disclosure, gratitude, remarking on shared experiences, reflecting on positive aspects of the group, and anticipating future chats. The findings suggest that training AICF to monitor therapeutic responses in web-based care is promising.

When combined with the human scoring examples in the algorithm, as little as 20% of the outputs, AICF obtained a high F_1-score. The human rater detected both false-positive examples (eg, "Just have to find what works for you, I listen to a lot of audible books while I do chores, it's a mental distraction and really helps me") and false-negative examples (eg, "Thanks so much to all of you, for being in this moment. You've helped me get ready for yet another week."). These examples contributed to the rule-based algorithms as a second layer of analysis. While precision values remained relatively low in both rounds (0.99 vs 0.98), the recall value improved from 0.52 to 0.70 due to a reduction in false-negative classifications. These increases strongly suggest that a continuous effort to train AICF using human input can lead to a higher level of accuracy in detecting group cohesion.

After running LIWC on a test data set, its performance was evaluated by a human scorer. The precision, recall, and F_1-scores were lower compared to the performance of AICF. Unlike AICF, which is capable of identifying group cohesion expressions and idioms, LIWC is programmed to identify certain keywords. For a false-negative example, LIWC was unable to detect the following quote as an instance of group cohesion due to the lack of the keyword "we": "I feel like I've suddenly inherited a whole group of sisters." Another instance of an LIWC false positive was that LIWC dictionary categories "family," "positive emotion," and "affiliation" falsely detected group cohesion from this quote: "My husband has helped me see that it isn't something I did, or who I am."

Comparison With Prior Work

This study successfully trained a machine learning system to detect cohesive statements in contrast to qualitative content analysis, which tends to be onerous and prone to human errors when dealing with large amounts of data [11]. Emerging computer programs such as Discourse Attributes Analysis Program (DAAP) [36] and LIWC [35,37] offer an iterative psycholinguistic approach to coding transcripts of psychotherapy for therapeutic moments [18,21]. For example, DAAP is based on a weighted dictionary that assigns weights to different words instead of solely detecting them as belonging to various categories where all matching words contribute equally to the generated scores. This method allows for greater accuracy in measuring different concepts compared to human coding while processing large amounts of data. However, these weighted dictionary approaches can be limited by a fixed number of instances that can be detected, and only one keyword can be considered in each matching rather than taking contexts into account. Additionally, they do not consider emerging words, phrases, idioms of expressions, word order, negation, and context-dependent factors, as well as their post hoc nature [19]. In this study, the word embedding approach was used to create contextual variables from the keywords to successfully detect a reasonably broad definition of cohesiveness. Thus, work will continue toward improving the accuracy of AICF in upcoming OSG sessions.

Limitations

AICF is based on a previously trained ensemble called Patient-Reported Information Multidimensional Exploration (PRIME) that was primarily trained on Australian web-based forum data [29]. Thus, Canadians may have used expressions or idioms that were unfamiliar to the original PRIME system and, therefore, not detected (eg, "My head is swirling" to describe feeling overwhelmed or "the clock is ticking" to describe an impending end of life). The local idioms and expressions were handled by the rule-based approach; ideally, AICF would be (re)trained with a large amount of local data in order to capture such idioms and expressions.

Currently, the interactional nature of the statement is not incorporated into AICF, including responses to other members' or therapists' statements. Furthermore, AICF cannot consistently distinguish whether participants are speaking about the group or about people outside of the group. When data accumulate, this distinction will become more obvious and refine AICF's detection ability within the context of an OSG.

The performance of AICF's group cohesion classification was evaluated in comparison to scores by 2 human experts, whose scoring was guided by the same criteria. However, given the nuanced nature of a group process like cohesion, there was still an element of personal judgment and openness to interpretation in the statements. Finally, emojis were not considered in the algorithm; future studies need to incorporate them as expressions of group cohesion.

Future Directions

ICF has been running in the background on 3 CCC groups and will soon be deployed for beta-testing on 10-12 groups. Participants will be filling out a survey package that includes the psychometrically validated questionnaire that tabs group cohesion for further validation. For algorithm development, sequencing the emotions expressed by each participant will be explored to capture more accurate emotional profiles.

The use of large language models (LLMs), such as ChatGPT, has revolutionized natural language understanding in the field of affective computing. Research suggests that an LLM called ROBERTa [38] has been equipped with emotion knowledge that contains 14 human conceptual attributes of emotions, including 2 affective, 6 appraisals, and 6 basic emotions. Future work will incorporate LLMs into our system to enhance AICF's ability to detect group cohesion and other significant clinical outcomes. For example, the LLM has already understood the syntactic difference between first-person and third-person pronunciation uses and their contexts. Combining both of these emotional attributes and syntax, we are able to better formulate an equation to calculate the tendency of a writer to be self-focused or other-focused. This will truly improve the accuracy and precision of group cohesion detection.

Lastly, In this study, 5 LIWC dictionary categories were used to capture the concept of group cohesion. Future studies may test whether there is a way that will improve the performance of group cohesion prediction using LIWC by (1) adding more categories, (2) reducing some categories, and (3) adding weighting to each criterion.

AICF will explore ways to measure multiple processes comprising group climate, including the level of participation, expression of emotion, signs of cohesion, avoidance, and therapeutic factors such as conflict, altruism, universality, interpersonal learning input and output, catharsis, identification, self-understanding, and instillation of hope [5,9,31]. If successful, AICF will be applied alongside the mobile health chatbot technology to provide a scalable, automated monitoring and referral system that screens users for specific symptoms, recommends individualized web-based and community resources, tracks each user's psychological outcomes through, and refers them to local therapists when necessary.

Conclusions

Optimal OSG delivery requires rapid alerts for therapists to effectively monitor markers of positive and negative responses within the group. This study has demonstrated that advanced machine learning algorithms combined with human inputs can reasonably detect the clinically meaningful indicator of group cohesion in OSGs. Future research in utilizing LLMs in AICF could enhance the capabilities in understanding the context, given the capability of creating a highly customized model in a short time. Therefore, AICF has the potential to assist therapists by highlighting issues that are amenable to intervention in real time, which allows therapists to provide greater levels of individualized support.

Acknowledgments

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Data Availability

The data sets generated during or analyzed during this study are not publicly available due to the presence of private health information but are available from the corresponding author on reasonable request.

Authors' Contributions

YWL contributed to conceptualization, data curation, formal analysis, funding acquisition, investigation, methodology, project administration, resources, supervision, validation, writing the original draft, and reviewing and editing the manuscript. EW was involved in formal analysis and methodology. AA handled visualization, writing the original draft, reviewing and editing, formal analysis, and software. JH participated in formal analysis and methodology. VA contributed to writing the original draft and reviewing and editing. LD and CL were involved in the formal analysis. CK and KPC were involved in software validation. DDS provided supervision and funding acquisition. LT and HR contributed to validation and conceptualization. JW and MJE were responsible for writing, reviewing and editing, supervision, data curation, and funding acquisition.

Conflicts of Interest

None declared.

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Abbreviations

AICF: Artificial Intelligence–based Co-Facilitator
CCC: Cancer Chat Canada
DAAP: Discourse Attributes Analysis Program
LIWC: Linguistic Inquiry and Word Count
NLP: natural language processing
OSG: online support group
PRIME: Patient-Reported Information Multidimensional Exploration
TF-IDF: term frequency–inverse document frequency
VADER: Valence Aware Dictionary and Sentiment Reasoner

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Original Paper

A Smart Water Bottle and Companion App (HidrateSpark 3) to Improve Bladder-Filling Compliance in Patients With Prostate Cancer Receiving Radiotherapy: Nonrandomized Trial of Feasibility and Acceptability

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Abstract

Background: Patients with prostate cancer undergoing radiation therapy (RT) need comfortably full bladders to reduce toxicities during treatment. Poor compliance is common with standard of care written or verbal instructions, leading to wasted patient value (PV) and clinic resources via poor throughput efficiency (TE).

Objective: Herein, we assessed the feasibility and acceptability of a smartphone-based behavioral intervention (SBI) to improve bladder-filling compliance and methods for quantifying PV and TE.

Methods: In total, 36 patients with prostate cancer were enrolled in a single-institution, closed-access, nonrandomized feasibility trial. The SBI consists of a fully automated smart water bottle and smartphone app. Both pieces alert the patient to empty his bladder and drink a personalized volume goal, based on simulation bladder volume, 1.25 hours before his scheduled RT. Patients were trained to adjust their volume goal and notification times to achieve comfortably full bladders. The primary end point was met if qualitative (QLC) and quantitative compliance (QNC) were >80%. For QLC, patients were asked if they prepared their bladders before daily RT. QNC was met if bladder volumes on daily cone-beam tomography were >75% of the simulation's volume. The Service User Technology Acceptability Questionnaire (SUTAQ) was given in person pre- and post-SBI. Additional acceptability and engagement end points were met if >3 out of 5 across 4 domains on the SUTAQ and >80% (15/18) of patients used the device >50% of the time, respectively. Finally, the impact of SBI on PV and TE was measured by time spent in a clinic and on the linear accelerator (linac), respectively, and contrasted with matched controls.

Results: QLC was 100% in 375 out of 398 (94.2%) total treatments, while QNC was 88.9% in 341 out of 398 (85.7%) total treatments. Of a total score of 5, patients scored 4.33 on privacy concerns, 4 on belief in benefits, 4.56 on satisfaction, and 4.24 on usability via SUTAQ. Further, 83% (15/18) of patients used the SBI on >50% of treatments. Patients in the intervention arm spent less time in a clinic (53.24, SEM 1.71 minutes) compared to the control (75.01, SEM 2.26 minutes) group (*P*<.001). Similarly, the intervention arm spent less time on the linac (10.67, SEM 0.40 minutes) compared to the control (14.19, SEM 0.32 minutes) group (*P*<.001).

Conclusions: This digital intervention trial showed high rates of bladder-filling compliance and engagement. High patient value and TE were feasibly quantified by shortened clinic times and linac usage, respectively. Future studies are needed to evaluate clinical outcomes, patient experience, and cost-benefit.

Trial Registration: ClinicalTrials.gov NCT04946214; https://www.clinicaltrials.gov/study/NCT04946214

(JMIR Cancer 2024;10:e51061) doi:10.2196/51061

KEYWORDS

digital therapeutics; behavioral intervention; digital health; prostate cancer; radiation; smart water bottle; companion app; oncology; prostate; privacy; radiation therapy; bladder; compliance; smartphone-based behavioral intervention; mobile phone

Introduction

Background

Patients with prostate cancer (PCa) undergoing radiation therapy (RT) are asked to self-manage bladder volumes throughout their daily radiation treatments. A consistent and comfortably full bladder is important to (1) minimize treatment-related toxicity by decreasing radiation dose to adjacent normal organs, and (2) to potentially maximize treatment precision by decreasing prostate motion and improving target stabilization. However, dosimetric analyses have shown considerable intrapatient variation in bladder volumes during treatment [1-3]. This multifactorial issue limits the effectiveness of a radiation treatment plan by reducing the plan's overall reproducibility.

Currently, there is no industry-standardized practice built into the management of an unfilled bladder. Some clinical practices have rigorous protocols in place, with standardized drinking and voiding intervals combined with pretreatment volume checks using bladder ultrasounds [4]. Yet bladder scan volumes vary by as much as 20% from daily cone-beam computerized tomography (CT) volumes, leaving much to be desired [5,6]. For practices that check bladder volumes with cone-beam CTs, patients with suboptimal bladder filling may need their treatment postponed until they fill their bladders appropriately, causing a preventable treatment delay. This translates to a loss of value for the patient and the clinician, and an identifiable inefficiency in the health care system.

Prior Work

Prior attempts at maintaining consistent, comfortably filled bladders, as defined by the treatment planning CTs, have found little success. For example, in a previous clinical trial aimed at determining the best technique for maintaining consistent bladder volumes, a set of explicit instructions was given to patients where they were told to drink 300 ml of water 1 hour before radiation treatment or told to arrive with a full bladder [7]. They discovered that despite having bladder-filling protocols, about half the patients in both arms forgot to do *anything* and arrived with an empty bladder. Attempts at identifying a minimum volume required for consistent filling are highly variable [8], and shift away from the expectation of a personalized treatment experience. Noncompliance with bladder filling remains a common occurrence in the daily treatment of PCa [9,10]. Treating with empty bladders may increase the risk of toxicity, as a full bladder pushes away the parenchymal bladder dome and bowel superiorly, away from the high-dose radiation field. Additionally, the dose delivered to the rectum increased in patients with empty bladders [11], and other studies have found that at least 150 ml was needed in the bladder to meet dosimetric constraints for adjacent normal tissue [12-14].

Additionally, Grün et al [15] demonstrated that using biofeedback mechanisms for maintaining constant bladder volumes led to lower rates of significant (grade 2 or higher) acute genitourinary toxicities. In this current age, digital behavioral interventions found utility by improving health outcomes through promoting habitual change. The earliest successful trials that leveraged smartphone technology, or rather personal digital assistants, were directed at patients who were obese and at high risk for developing metabolic syndrome [16]. By assisting patients with the resources to effectively self-monitor their progress or regress and provide feedback, digital behavioral interventions empowered patients to take ownership of their health care. Subsequent studies found success even in socioeconomically disadvantaged populations, suggesting that the ubiquity of technology can disrupt socioeconomic health disparities [17]. The Pew Research Center's 2019 survey revealed 81% of Americans own a smartphone, a significant increase from the 35% identified in 2011 [18]. Between the age 50 and 64 years brackets, this ~80% (4644/5733) smartphone ownership rate does not break down across gender, ethnicity, or income. However, smartphone ownership drops to 53% (1014/1914) in people aged older than 65 years. The primary demographic of men with PCa who receive RT is aged ≥50 years.

Rationale for Study

Patients with PCa are generally a highly motivated population, compliant with dietary or lifestyle recommendations and actively engaged in their cancer care; yet the high rate of nonadherence to bladder-filling protocols leaves room for improvement. Sensory awareness of a bladder is usually limited to 2 states, full and not full. Patients with PCa may find it difficult to hold their bladder once they are aware it is full, which may be exacerbated by the high rate of comorbid prostatomegaly and lower urinary tract symptoms. Otherwise, patients normally do not have an awareness of a fractionally filled bladder (ie, 25% filled and 50% filled). Yet 50%-75% full is likely where the optimal filling of a bladder lies for radiation treatments. Therefore, we hypothesize that a smartphone-based behavioral intervention can motivate patients with PCa to optimally fill their bladders, reducing the need for reimaging while on the radiation treatment table and decreasing their overall time in a clinic.

Methods

Patient Selection

In total, 18 patients were prospectively enrolled in the intervention arm of a closed-access trial. They were eligible for enrollment if they were aged between 18 and 80 years, had American Joint Committee on Cancer 8th Edition Stage IA to IVA adenocarcinoma of the prostate requiring radiation treatment to the prostate, self-identified as “smartphone owners,” owned either an iPhone (iOS 13.0 or higher) or Android (version 5.0.1 or higher), and were English or Spanish speaking. Patients were excluded if they had any history of pre-existing chronic or acute urinary retention; had any history of kidney, urothelial tract, or bladder cancer; underwent prior pelvic radiation, prostatectomy, pelvic surgery, or penile augmentation; did not have a functional bladder; or did not have functional vision.

In addition, 18 patients who met eligibility criteria but declined to enroll in the trial were retrospectively selected as controls. Patients were age, stage, risk, and fractionation scheme matched to the interventional cohort. Additionally, only patients who received treatment within the same enrollment period as the interventional cohort were included in the control group. Outcomes data for the control group was only collected for quantifying patient and health system-centered value. Patients in this cohort received standard written or verbal instructions for bladder and bowel preparation.

Ethical Considerations

Institutional review board approval was obtained (20200017) for this trial without any concerns. Informed consent was obtained from all patients at the first study visit. Patients were allowed to opt out at any time without penalty or fear of retaliation. All consumption volumes and times were synchronized to a cloud-based, remote patient monitoring platform based on anonymized research identification numbers (RIN). Generic user accounts were created for patients, with anonymized personal information (names were their RIN, emails were randomized emails generated by the institution). No institutional affiliations were displayed in the app or on the smart water bottle. Only patients’ RIN and smartphone make or model were collected in the cloud. No other personal health or self-identifying information was collected. While the remote patient monitoring platform was available for viewing to staff, they were instructed not to intervene if activity or usage decreased. Patients were not compensated for their participation in the trial, except for the smart water bottle intervention.

Patients were recruited at a single radiation oncology clinic at a National Cancer Institute–designated comprehensive cancer center. No selective patient sampling for study selection was performed. After being prescreened by our study coordinators, they were contacted either in person or via telephone to be introduced to this study. Informed consent was performed in person only at a subsequently determined study visit by our coordinators. No study advertisements or flyers were used.

Intervention

The intervention is a combination of a smart water bottle, a black HidrateSpark 3, and its companion smartphone app (versions 2.4.1-3.0.3 used during the trial). Its volumetric quantification abilities were previously validated [19] and used in a large, multicenter, prospective trial to reduce the formation of kidney stones in patients with a history of recurrent nephrolithiasis [20]. The app synchronizes with the bottle when placed within Bluetooth range. Within the app, the timing of notifications and volume goals (VGs) for consumption can be programmed. At the appropriate time, the smartphone will send a notification reminding patients to void their bladders and begin drinking the VG (Figure 1). Simultaneously, the bottle glows a bright, fluorescent green to provide another visual reminder (Figure 2). Notifications will be sent every 15 minutes until the VG is met that day. Patients were encouraged to use the intervention daily.

Figure 1. App will remind patients to drink water at preset times related to radiation treatment.

Don’t forget to drink your water!

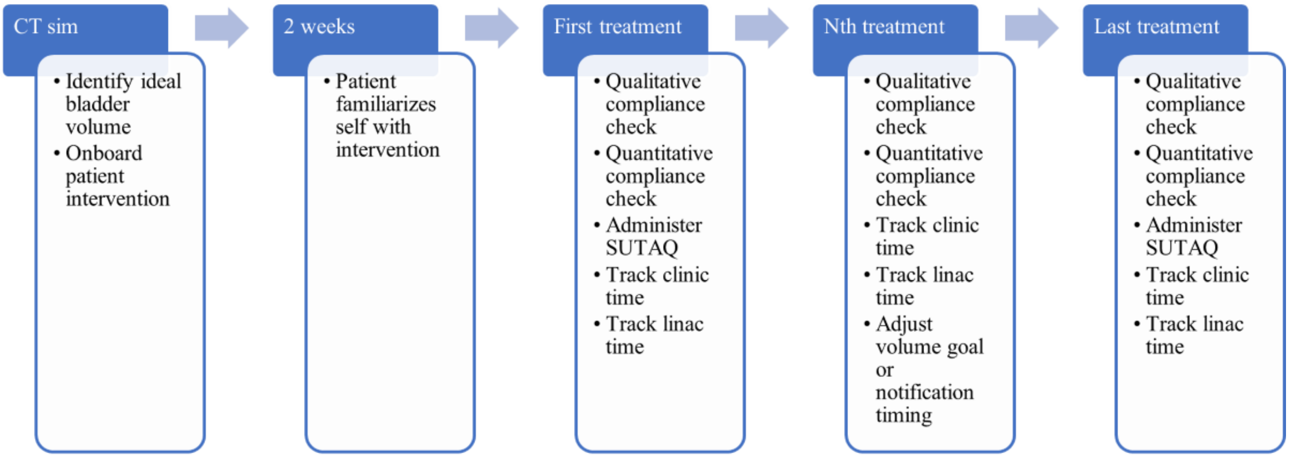
Figure 2. Smart water bottle will glow a bright fluorescent green color simultaneously with notifications.

Study Scheme

Patients were provided in-person information about this study between the initial clinic visit and CT simulation; they could be enrolled at any point up until CT simulation, the first step in the standard of care RT pathway. During this session, the patient’s anatomy is captured in a CT scan and then exported to a treatment planning system. A radiation oncologist then delineates targets for treatment and organs at risk for dose minimization. Informed consent was obtained in person from research coordinators. On the day of the CT simulation, patients were onboarded and trained to use the intervention (Figure 3). Smart water bottles were also given at no cost to patients. Trained staff reviewed the functions of the app, particularly on how to adjust notification timings and daily VGs. The initial VG was set to the volume of the bladder contour delineated on CT simulation. The initial notification times were set at 1 hour and 15 minutes before their treatment time.

On the first day of treatment, patients were administered an in-person questionnaire aimed at addressing the acceptability of digital technologies. During daily radiation treatments, patients were asked (in person) if they felt their bladders were adequately prepared. Staff were available during clinic hours to assist with any technical issues, such as adjustment of VGs, adjustment of notification times, bugs, malfunctions, and software issues. On the last day of treatment, patients were given the same in-person questionnaire.

Figure 3. Study scheme. CT: computerized tomography; SUTAQ: Service User Technology Acceptability Questionnaire.



Primary End Point: Qualitative and Quantitative Bladder-Filling Compliance

Before every fraction of radiation, patients were asked if "[they] adequately prepared the bladder for treatment?" Qualitative compliance was measured by recording patients' daily responses. Individual compliance status for this measure was met if ≥80% of responses were "yes." Additionally, daily compliance was quantitatively assessed via 2 criteria. First, the patient must not be taken off the treatment table by the treating radiation oncologist after a review of initial CBCTs. Second, the bladder volume on the CBCT must be ≥75% of the bladder volume on the initial simulation CT. Individual compliance status for this measure was met if ≥80% (15/18) of patients met both criteria. The overall compliance rate for both measures was defined as the number of patients whose compliance status equals "yes" divided by the total number of patients in this study.

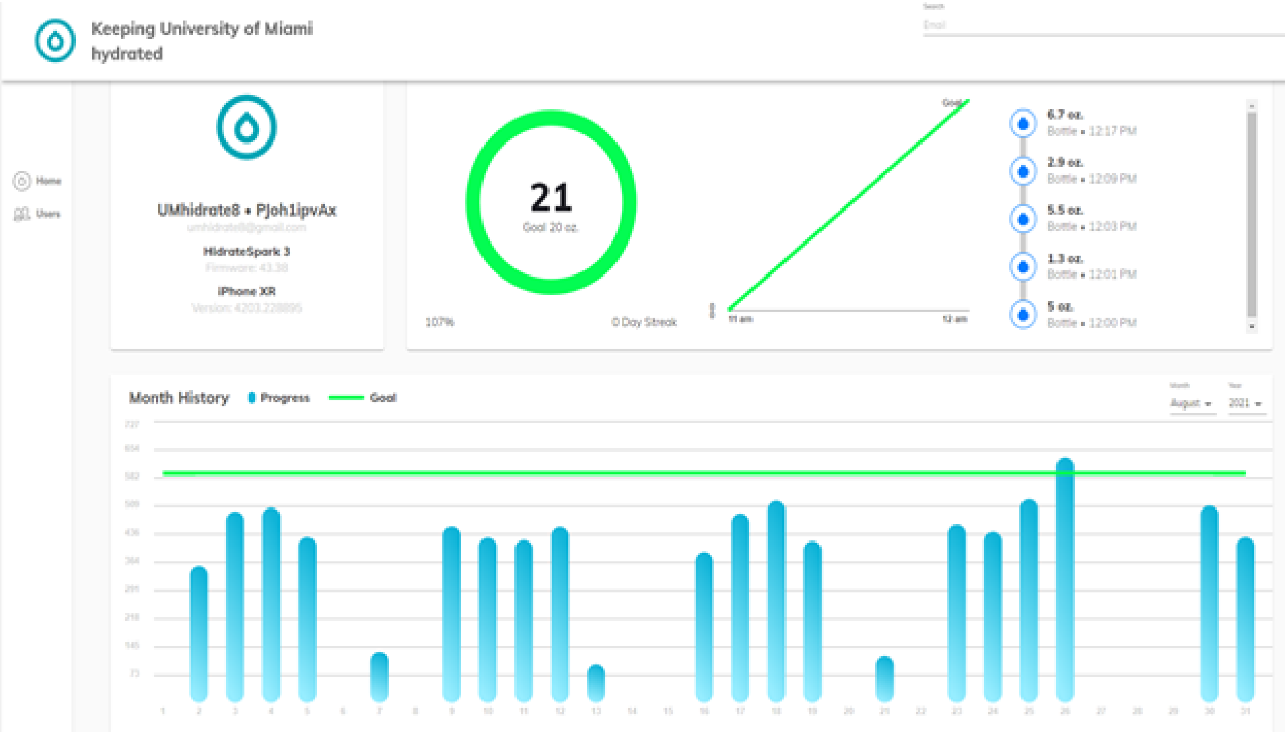
Acceptability

Acceptability was evaluated using a modified version of the Service User Technology Acceptability Questionnaire [21]. This end point was met if mean scores in all domains of the Service User Technology Acceptability Questionnaire were ≥3 (SD 1.4142). Pre- and postintervention analyses were assessed via paired *t* tests (2-tailed). In addition, an in-person qualitative review of the patients' responses was performed after the second questionnaire to improve acceptability in future trials and clinic integration.

Engagement

The engagement end point was met if >80% (15/18) of patients used their bottles on >50% of daily treatments. Engagement was tracked using the remote monitoring platform (Figure 4). Age at diagnosis, race, phone manufacturing year, median home price of patient's zip code, distance from the cancer center, preferred language, and radiation fractionation scheme were evaluated for associations with poor engagement via binomial logistic regression.

Figure 4. Remote patient monitoring platform showing example water bottle usage data. oz: ounce.



Quantifying Value—Patient Centered and Health System Centered

Patient value was quantified by the amount of time patients spent in the clinic, captured from the time that the patient signed into the check-in desk until the patient gets off the linear accelerator (linac). Health system value was quantified by the amount of time the patient spent on the linac, captured from when the patient was initially taken into the linac room to the time the patient gets off the linac table. To meet this end point, the prospective interventional cohort was contrasted with a retrospectively generated control group matched by age, stage, risk stratification, and radiation fractionation scheme. This end point was met if there was a statistically significant difference in mean times between the 2 groups.

Statistical Analysis

All patients were prescreened from the radiation oncologic clinic for the prospective intervention arm and, if they met eligibility criteria, were invited to participate. To calculate the appropriate sample size, we used a historical bladder-filling compliance rate of 50%, based on data presented by Braide et al [7]. We anticipate the intervention will provide a 30% improvement over historical controls, thus requiring a sample size of 16 men. However, we aimed to recruit 18 men, which would allow for a 10% dropout or noncompliance rate, this would leave at least 16 evaluable patients, which would achieve 80% statistical power to detect a difference of 30% using a 1-sided binomial exact test with a 5% significance level.

Our primary end point, consisting of both qualitative and quantitative components, was assessed via descriptive statistics. To meet the end point, both components required ≥80% compliance. For acceptability, pre- and postintervention analyses were assessed via paired *t* tests. The engagement was similarly evaluated via descriptive statistics, where the end point was met if >80% (15/18) of patients used their bottles on >50% of daily treatments. Secondary analyses of engagement were evaluated by converting engagement (>50% daily use) into a binary categorical variable. This was set as the dependent variable, and age at diagnosis, race, phone manufacturing year, median home price of patient’s zip code, distance from the cancer center, preferred language, and radiation fractionation scheme were set as independent variables. Subsequently, univariate logistic regression was performed and statistically significant independent variables would be included in a multivariate model. Patient-centered and system-centered values were evaluated by 2-sample *t* tests, using time spent as the continuous variable.

For all statistics, *P*<.05 was considered significant. Data were analyzed using IBM SPSS (version 23.0.0.2; IBM Corp).

Results

Patient Demographics

Between June 6, 2021, and June 15, 2022, 18 men were enrolled in a single-arm, phase zero pilot study to evaluate a digital therapeutic for improving bladder-filling compliance during PCa radiotherapy. Most patients were English-speaking Hispanic-White men with unfavorable intermediate to high-risk PCa (Table 1). The most common fractionation scheme received was split evenly between 36.25 Gy in 5 fractions and 80 Gy in 40 fractions. The interventional cohort did not significantly differ from the retrospective control group in terms of race or ethnicity, preferred language, stage, risk stratification, or fractionation scheme.

Table 1. Patient demographics.

	Intervention	Control	*P* value
Age at diagnosis (years), mean (SD)	64.94 (9.67)	68.00 (8.12)	.31
Race or ethnicity, n (%)			.34
Black	3 (16.7)	1 (5.6)	
Hispanic White	10 (55.6)	14 (77.8)	
Non-Hispanic White	5 (27.8)	3 (16.7)	
Preferred language, n (%)			.08
English	14 (77.8)	9 (50)	
Spanish	4 (22.2)	9 (50)	
American Joint Committee on Cancer 8th Edition Staging, n (%)			.21
II-A	2 (11.1)	2 (11.1)	
II-B	6 (33.3)	2 (11.1)	
II-C	4 (22.2)	7 (38.9)	
III-A	4 (22.2)	2 (11.1)	
III-C	1 (5.6)	5 (27.89)	
IV-A	1 (5.6)	0 (0)	
Risk stratification, n (%)			.84
Low	2 (11.1)	1 (5.6)	
Favorable intermediate	4 (22.2)	3 (16.7)	
Unfavorable intermediate	5 (27.8)	7 (38.9)	
High	7 (38.9)	7 (38.9)	
Radiation fractionation scheme, n (%)			≥.99
36.25 Gy in 5 fractions	7 (38.9)	7 (38.9)	
70.2 Gy in 26 fractions	4 (22.2)	4 (22.2)	
80 Gy in 40 fractions	7 (38.9)	7 (38.9)	

Primary End Point: Feasibility in Assessing Qualitative and Quantitative Bladder-Filling Compliance

Both qualitative and quantitative end points for bladder-filling compliance were met. Qualitatively, 18 out of 18 (100%) patients stated they prepared their bladders on 375 out of 398 (94.2%) daily radiation treatments. In addition, 16 out of 18 (89%) patients attained quantitative compliance on aggregate 341 out of 398 (85.7%) fractions.

Acceptability

Overall, patients were accepting of the intervention (Table 2). There were minimal concerns for privacy issues (mean score 4.33, SD 0.97). Patients believed there were perceived benefits from the intervention (mean score 4.00, SD 0.918), were satisfied with the intervention (mean score 4.56, SD 0.56), and noted high usability (mean score 4.24, SD 0.62). In addition, there was a statistically significant association between feeling less concerned about their health between pre- and postintervention scores (*P*=.02).

Table 2. Service user technology acceptability questionnaire results.

Domain and question text	Preintervention score, mean (SD)	Postintervention score, mean (SD)	*P* value
Privacy			
The kit I received has not invaded my privacy.	4.056 (0.99)	4.556 (0.62)	.06
I am not concerned about the level of expertise of the individuals who monitor my health status via the kit.	4.000 (1.14)	4.056 (1.39)	.86
The kit does not make me worried about the confidentiality of the private information being exchanged through it.	4.333 (0.69)	4.389 (0.70)	.79
Perceived benefits			
This kit has made it easier to get in touch with my health care professionals.	3.667 (0.97)	4.056 (0.80)	.25
The kit I received has increased my access to care.	4.000 (0.77)	4.111 (0.67)	.54
The kit I received has helped me improve my health.	3.778 (0.81)	4.056 (0.73)	.33
This kit has helped me to improve my health.	4.056 (0.80)	4.278 (0.67)	.33
I do not feel anxious or nervous about the required bladder and rectal preparation for radiation treatment.	3.667 (1.28)	3.833 (1.15)	.64
The kit has allowed me to be less concerned about my health and social care.	3.111 (1.08)	3.889 (1.08)	.02
The kit has made me more actively involved in my health.	4.167 (0.92)	4.222 (0.73)	.83
This kit can certainly be a good addition to my regular health or social care.	4.444 (0.51)	4.389 (0.70)	.77
This kit has allowed me to be less concerned about my health status.	2.611 (1.46)	2.944 (1.11)	.38
The kit allows the people looking after me, to better monitor me and my condition.	4.500 (0.62)	4.278 (0.70)	.16
Satisfaction			
I am satisfied with the kit I received.	4.389 (0.61)	4.556 (0.51)	.33
This kit can be and should be recommended to people in a similar condition to mine.	4.500 (0.62)	4.556 (0.62)	.67
Usability			
The kit I received has been explained to me sufficiently.	4.500 (0.62)	4.611 (0.61)	.43
The kit can be trusted to work appropriately.	4.278 (0.83)	4.333 (0.84)	.77
The kit has not made me feel uncomfortable, either physically or emotionally.	4.278 (1.13)	4.667 (0.49)	.17
This kit interferes with the continuity of care I receive.	2.000 (1.08)	2.000 (1.19)	.99
The kit I received has not interfered with my everyday routine.	4.167 (1.29)	4.611 (0.50)	.18

Engagement

The minimum engagement end point was met, as 15 out of 18 (83%) patients used the intervention on >50% of treatments throughout the trial. Additionally, 9 out of 18 (50%) patients used the bottle on 100% of treatments while 12 out of 18 (67%) patients used it on >85% of treatments. None of the a priori variables were significantly associated with poor engagement in univariate analysis, so a multivariate model was not generated. Specifically, the independent variables were age at diagnosis (*P*=.18), self-identified race (*P*=.82), median home price of zip code (*P*=.13), distance from cancer center (*P*=.10), preferred language (*P*=.87), and radiation fractionation (*P*=.34). Of the 3 patients who did not meet the minimum engagement criteria, 2 stated they needed a reminder to keep the physical water bottle nearby, and one encountered too many technical issues with water bottle refilling.

Feasibility in Quantifying Value—Patient Centered and Health System Centered

Patients in the intervention arm spent less time in the clinic (53.24, SEM 1.71 minutes) compared to the control (75.01, SEM 2.26 minutes) group (*P*<.001, Figure 5). Similarly, the intervention arm spent less time on the linac (10.67, SEM 0.41 minutes) compared to the control (14.19, SEM 0.32 minutes) group (*P*<.001, Figure 6).

When looking at the data more granularly, patients with empty bladders (n=43) spent significantly more time (75.14 vs 50.59 minutes, *P*=.007) in the clinic than patients who came with full bladders (n=355, Table S1 in Multimedia Appendix 1). Similarly, these same patients spent nearly twice as long on the linac (21.63 vs 12.50 minutes, *P*<.001, Figure S1 in Multimedia Appendix 1). However, the presence of stool in the rectum had more impact on clinic time. Expectedly, the presence of both an unprepared bladder and rectum led to the longest time spent in the clinic at 93.13 minutes (Figure S2 in Multimedia Appendix 1).

Figure 5. Mean time spent in minutes (SEM) in clinic between intervention and control cohorts.

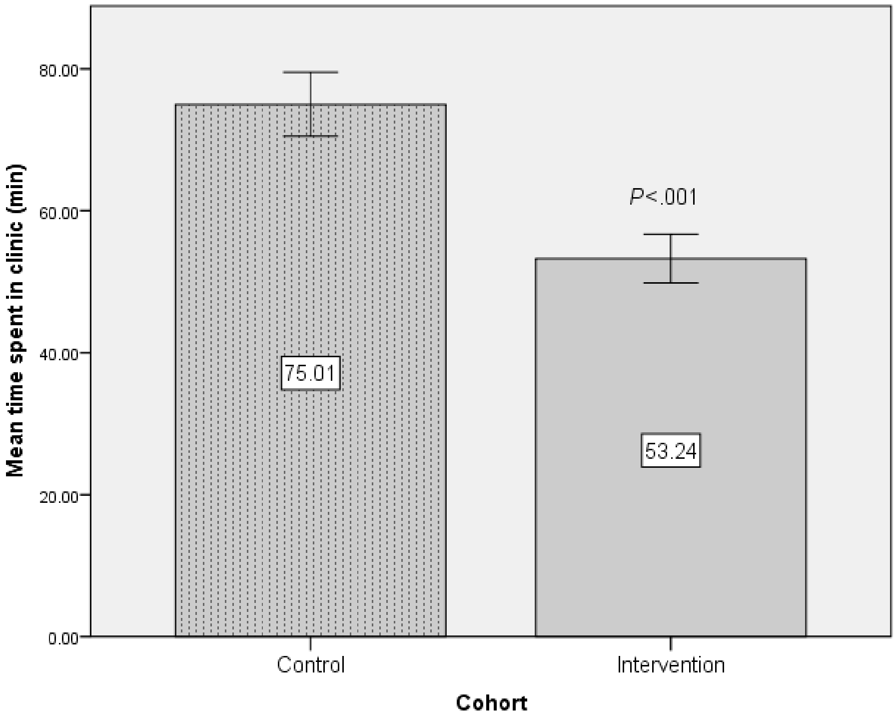
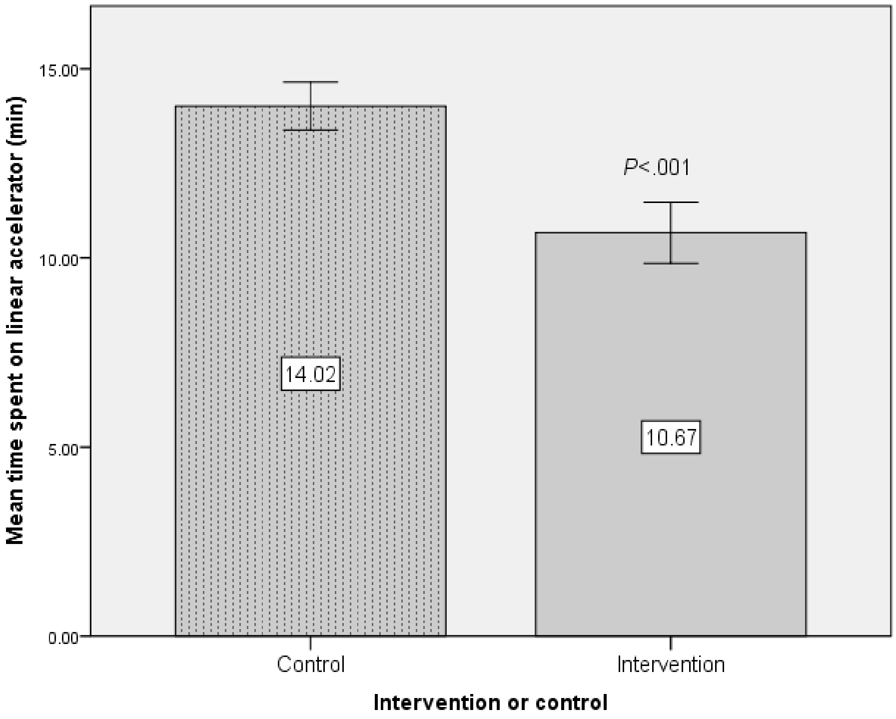


Figure 6. Mean time spent in minutes (SEM) on the linear accelerator between intervention and control cohorts.



Discussion

Principal Results

This prospective study aimed to assess the feasibility and acceptability of a smart water bottle and companion app as an intervention to improve bladder-filling compliance in patients with PCa receiving RT. We showed that the intervention can be feasibly integrated into the clinic, retains high engagement, and was perceived by patients with high acceptability. In addition, the intervention was effective at reducing wasted value for the patient and the clinic, compared to matched controls.

Results in Context of Prior Work

To our knowledge, this is the only prospective study that evaluated a digital intervention for bladder filling in patients with PCa undergoing radiotherapy. However, multiple institutions have identified the benefits of delivering scalable care using mobile apps and started preliminary, pilot, and feasibility studies. For example, the Karolinska Institute reported on their study of the Interaktor app for their patients with PCa undergoing RT [22]. This app collected and triaged patient symptoms during RT, sent alerts to managing health care providers, and provided self-care advice. It was well received by patients (n=75), and daily symptom reporting was high, with 83%-87% adherence or engagement reported [22,23]. In addition, Thomas Jefferson University evaluated the feasibility and acceptability of its Strength Through Insight app, a tool that assessed electronic patient-reported outcomes during RT using a validated symptom questionnaire [24]. Similarly, we found that our patients were not only accepting and enthusiastic about using the intervention, but many believed that smartphone integration into their clinical care was long overdue. Digital consumer experiences in other industries may be shifting expectations for similar services in health care [25-27].

However, many barriers remain that prevent seamless digital therapeutic integration in the clinic. Key stakeholder buy-in is missing. Identifying the concerns of all stakeholders is necessary to create and mimic the infrastructure supporting the pharmaceutical industry. Our trial quantified the value of poor prostate radiotherapy preparation for both the clinic *and* the patient. Whereas prior studies only sought to identify waste that impacts health care spending, we also quantified patient value to prevent 0-sum game situations. For example, 4 separate institutions used bladder scanners to increase the probability of an adequately filled bladder on daily cone-beam CT [4,7,28,29], thereby potentially reducing the time wasted on the linac for checking unprepared bladders. However, it is often at the cost of the patient's experience. If a patient arrives for his PCa treatment with an unprepared bladder, he still needs to spend time at the clinic fixing the issue, regardless of how much time was saved in the treatment room. Often, patients may feel that they failed their responsibility for adequate preparation, creating a sense of anxiety and a devalued overall experience [30].

Our study suggests that network effects may have a large role in engagement, a critical component of a successful digital intervention [31]. The goal is to smoothly embed itself into the daily lives of patients, continually analyze recorded data, and interject behavioral interventions when needed. Failures arise when subclinical usage occurs [32]. This study did not isolate patient experiences; those with the intervention were waiting for their treatments in the same waiting room as nontrial patients. Anecdotally, 2 of the patients with nearly 100% engagement felt empowered that they could use the intervention to improve their bladder-filling compliance, especially when they saw another patient struggling. The 2 patients who did not meet the engagement end point also had interesting similarities. Both were actively working and delegated the task of keeping the water bottle nearby to their spouses.

Finally, while the purpose of this trial was to evaluate an intervention on bladder-filling compliance, our data suggests there were nearly twice as many patients with poor rectal preparation than poor bladder preparation (Figures S1 and S2 in Multimedia Appendix 1). This suggests that to maximize time-based value metrics, better strategies for rectal preparation are also required.

Limitations

This study was limited by its design as a pilot study, specifically in extrapolating conclusions for the value-based end points using retrospectively matched controls. Specifically, quantitative and qualitative compliance data were only collected in the intervention arm. Additionally, interpreting the end points regarding acceptability may be confounded by patients who self-select as participants in a digital interventional trial. Designing apps agnostic to digital literacy is critical for ubiquitous adoption. The patient population may be limited in its diversity, as patients were enrolled at a private, National Cancer Institute-designated cancer hospital in South Florida. Quantification of digital literacy was not performed, as the intent of this study was to assess the technical, multi-stakeholder value, and subjective acceptance of the intervention, and this study would otherwise be underpowered.

Conclusions

A smart water bottle and companion app can be feasibly integrated into a radiation oncology clinic for patients with PCa. Patients are accepting of this digital intervention, with minimal concerns for privacy issues. It is crucial to quantify value for all stakeholders (patients, clinical team, economics) and identify 0-sum situations. This digital intervention has the potential to enhance value for all stakeholders concerned.

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Data Availability

The data sets generated or analyzed during this study are not publicly available due to secondary analyses currently being run on them for another paper but are available from the corresponding author upon reasonable request.

Authors' Contributions

WJ was responsible for study conceptualization, design of the methodology, formal analysis, data visualization, and writing of the original draft of this paper. ADP was responsible for project administration, provisioning of resources, funding acquisition, overall supervision of this study, and review or editing of this paper. DK was responsible for data curation, formal analysis, statistical methodology, and review or editing of this paper. CM, BJR, and CST were responsible for formal analysis, data curation, and review or editing of this paper. All other authors were responsible for the review or editing of this paper. WJ, BJR, CST, and ADP were responsible for the study's design. WJ and ADP wrote the protocol and enrolled all patients for the trial. WJ and DK were responsible for statistical analysis. WJ generated figures and tables for publication. WJ, BJR, and CST wrote the initial draft of this paper. All authors contributed to this paper's editing.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Quantifying value for the patient and for the health system, time spent on linear accelerator, and time spent in clinic.

[DOCX File , 30 KB - cancer_v10i1e51061_app1.docx]

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Abbreviations

CT: computerized tomography
linac: linear accelerator
PCa: prostate cancer
PV: patient value
QLC: qualitative compliance
QNC: quantitative compliance
RIN: research identification number
RT: radiation therapy
SBI: smartphone-based behavioral intervention
SUTAQ: Service User Technology Acceptability Questionnaire
TE: throughput efficiency
VG: volume goal

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Original Paper

Uncovering the Daily Experiences of People Living With Advanced Cancer Using an Experience Sampling Method Questionnaire: Development, Content Validation, and Optimization Study

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Abstract

Background: The experience sampling method (ESM), a self-report method that typically uses multiple assessments per day, can provide detailed knowledge of the daily experiences of people with cancer, potentially informing oncological care. The use of the ESM among people with advanced cancer is limited, and no validated ESM questionnaires have been developed specifically for oncology.

Objective: This study aims to develop, content validate, and optimize the digital Experience Sampling Method for People Living With Advanced Cancer (ESM-AC) questionnaire, covering multidimensional domains and contextual factors.

Methods: A 3-round mixed methods study was designed in accordance with the Consensus-Based Standards for the Selection of Health Measurement Instruments (COSMIN) and the European Organization for Research and Treatment of Cancer guidelines. The study included semistructured interviews with 43 people with stage IV breast cancer or stage III to IV lung cancer and 8 health care professionals. Round 1 assessed the appropriateness, relative importance, relevance, and comprehensiveness of an initial set of ESM items that were developed based on the existing questionnaires. Round 2 tested the comprehensibility of ESM items. Round 3 tested the usability of the digital ESM-AC questionnaire using the m-Path app. Analyses included descriptive statistics and qualitative content analysis.

Results: Following the first round, we developed an initial core set of 68 items (to be used with all patients) and a supplementary set (optional; patients select items), both covering physical, psychological, social, spiritual-existential, and global well-being domains and concurrent contexts in which experiences occur. We categorized items to be assessed multiple times per day as momentary items (eg, “At this moment, I feel tired”), once a day in the morning as morning items (eg, “Last night, I slept well”), or once a day in the evening as evening items (eg, “Today, I felt hopeful”). We used participants’ evaluations to optimize the questionnaire items, the digital app, and its onboarding manual. This resulted in the ESM-AC questionnaire, which comprised a digital core questionnaire containing 31 momentary items, 2 morning items, and 7 evening items and a supplementary set containing 39 items. Participants largely rated the digital questionnaire as “easy to use,” with an average score of 4.5 (SD 0.5) on a scale from 1 (“completely disagree”) to 5 (“completely agree”).

Conclusions: We developed the ESM-AC questionnaire, a content-validated digital questionnaire for people with advanced breast or lung cancer. It showed good usability when administered on smartphone devices. Future research should evaluate the potential of this ESM tool to uncover daily experiences of people with advanced breast or lung cancer, explore its clinical utility, and extend its validation to other populations with advanced diseases.

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KEYWORDS

cancer; quality of life; ecological momentary assessment; experience sampling method; telemedicine; mHealth; eHealth; patient outcome assessment; validated instruments

Introduction

Background

Quality of life assessment among people with cancer often relies on retrospective patient-reported outcome measures (PROMs), which typically require patients to aggregate their experience over several days or weeks into 1 score (eg, "During the past week, were you tired?") [1-3]. This precludes temporally fine-grained knowledge on how cancer-related experiences such as physical or psychological symptoms and concerns change within and across days and the mechanisms underlying these changes. Moreover, studies found that retrospective PROMs often over- or underestimate in-the-moment somatic and psychological experiences across various populations, indicating a need for more fine-grained measures [4,5]. From a research and clinical perspective, this detailed knowledge on in-the-moment experiences is critical for improving patient symptom management and psychosocial support, such as by identifying novel intervention targets.

To bridge this gap, the experience sampling method (ESM) [6], also called ecological momentary assessments [7], may be suitable. The ESM or ecologic momentary assessments involve repeatedly gathering self-reported data from participants in the context of their daily lives, often multiple times per day for several consecutive days through mobile devices such as smartphones [7-9]. Contrary to traditional PROMs, the ESM mitigates retrospective biases and improves ecological validity of findings by asking questions about momentary experiences in their natural environment (eg, "At this moment, I feel...") [7]. Moreover, the ESM provides the opportunity to study affect over time (ie, experiences of feelings or emotions) as an important indicator of emotional functioning and psychological well-being [9-11] and to investigate patients' experiences together with concurrent contexts, such as the social environment [12]. Including contextual items can facilitate the identification of situations that alleviate or exacerbate certain experiences, thereby informing future psychosocial interventions.

Despite the ESM's potential to provide novel insights into the daily experiences of people with cancer, its use in oncology research remains limited, especially among people with advanced (ie, metastatic) cancer [9,12,13]. Nevertheless, compared to people in the earlier stages of cancer, people with advanced cancer have a higher likelihood of experiencing symptoms and concerns that negatively impact their quality of life [14,15]. A possible explanation for the limited use of these methods among people with advanced cancer is that researchers may avoid them to prevent placing additional burden on patients through repeated assessments. However, to develop and improve interventions to alleviate these high levels of symptoms and distress, gaining a more detailed understanding of the well-being of people with advanced cancer in the context of their daily life (ie, its fluctuations, mechanisms, determinants, and consequences) is imperative; for this purpose, the use of the ESM is recommended [16,17]. The limited number of ESM studies among people with advanced cancer have investigated a range of symptoms, concerns, and measures of well-being across quality of life domains and provided evidence for the dynamic nature and associations thereof [18-30]. For example, Badr et al [21] found that greater pain in the morning was associated with feeling less aroused mood (eg, more tiredness and less peppy) during the rest of the day for women with metastatic breast cancer, with pain and low arousal mood being associated with romantic relationship interference.

There is currently no validated ESM questionnaire designed specifically for people with advanced cancer [9,13]. Validity, especially content validity, is a crucial indicator of whether the content of an instrument is an adequate reflection of the construct being measured [31,32]. However, it is often overlooked in ESM research as a whole, leading to recent calls for more content validation of ESM questionnaires [9,13,32,33].

By reporting the development, content validation, and optimization of an ESM questionnaire, this study is the first step of a larger project in which we aim to test the feasibility of the ESM and use it to obtain novel insights into the daily experiences of people with advanced cancer. Because symptoms can vary across different advanced cancer diagnoses and our aim was to develop a questionnaire that is highly relevant to the specific experiences of intended users, our project's scope is narrowed to people living with advanced breast or lung cancer. We selected these diagnoses as they are among the most prevalent cancer diagnoses with high mortality rates [34-36] and are associated with considerable risk for experiencing serious symptom burden [37-41].

Objectives

In this study, we aimed to develop, validate, and optimize the Experience Sampling Method for People Living With Advanced Cancer (ESM-AC) questionnaire. The digital ESM questionnaire aims to comprehensively assess relevant daily experiences (ie, symptoms, concerns, and well-being) of people with advanced breast or lung cancer and the context in which these experiences occur; it collects these data multiple times per day for several consecutive days.

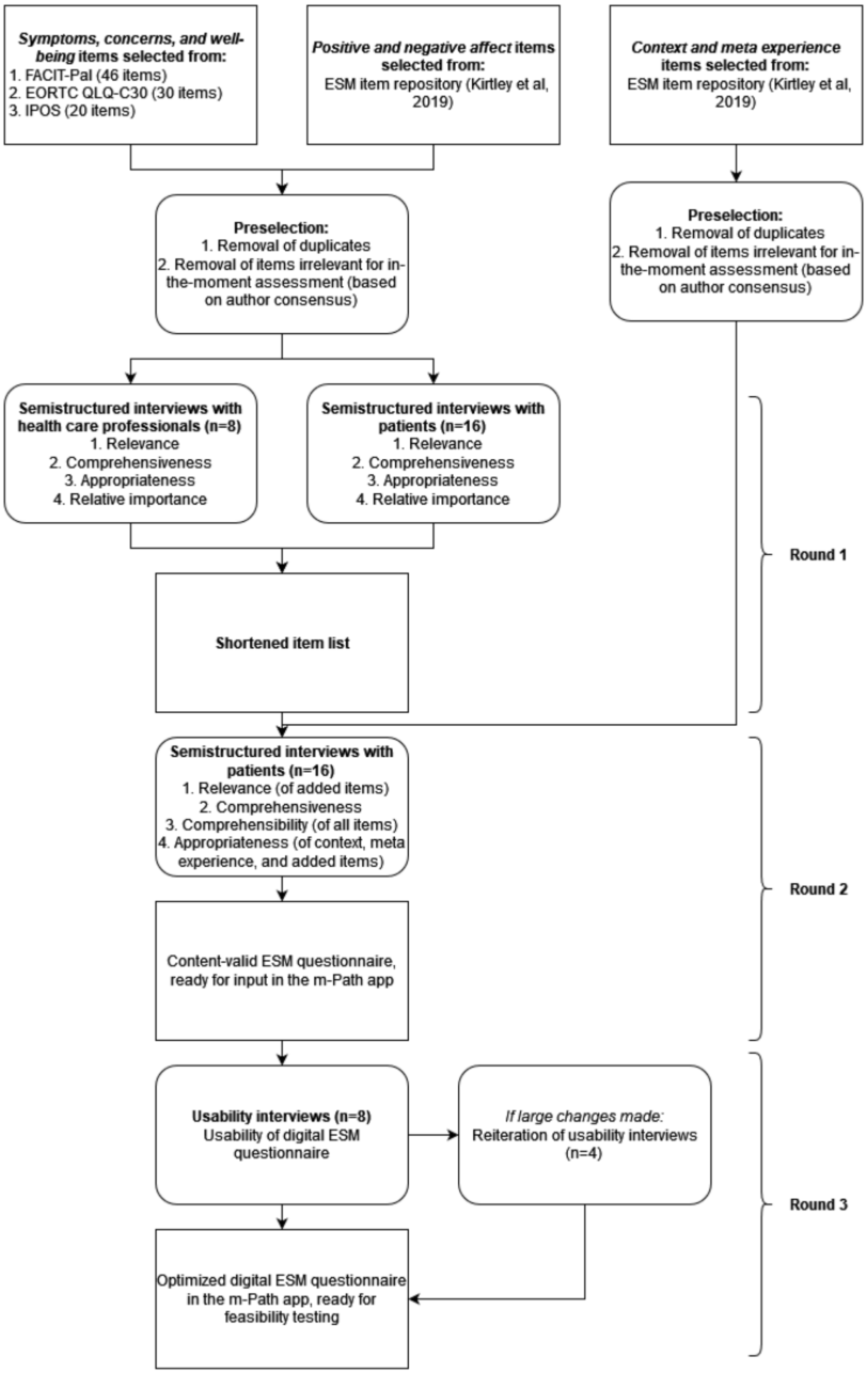
Methods

Study Design

We conducted a 3-round interview study with patients and health care professionals using a mixed methods research design (summarized in Figure 1 [42]). To develop and validate the ESM questionnaire in the first 2 interview rounds, we based our design on the guidelines of PROMs [31,43] because no specific guidelines for ESM questionnaires were available [32].

Specifically, the Consensus-Based Standards for the Selection of Health Measurement Instruments (COSMIN) methodology [31] guided the assessment of the content validity of our initial set of items in the first 2 rounds (ie, covering relevance, comprehensibility, and comprehensiveness; refer to Textbox 1 for an overview of key psychometric concepts used in this study). In the first round, the item set was shortened and categorized into a core and supplementary item set based on content validity, appropriateness, and relative importance, following the European Organization for Research and Treatment of Cancer (EORTC) guidelines for module development [43-45]. The second round focused on the comprehensibility of all items and on the relevance and appropriateness of the items added after round 1. In the third round, we optimized the digital (core) ESM questionnaire by assessing barriers related to its usability for patients using the dedicated ESM smartphone app (ie, m-Path; KU Leuven [46]).

Figure 1. Flowchart of the development and validation procedure [42]. EORTC QLQ-C30: European Organization for Research and Treatment of Cancer Core Quality of Life Questionnaire; ESM: experience sampling method; FACIT-Pal: Functional Assessment of Chronic Illness Therapy—Palliative Care; IPOS: Integrated Palliative Care Outcome Scale.



Textbox 1. Key concepts with their respective definitions.

- Content validity: the extent to which the content of an instrument is an adequate reflection of the construct to be measured. This includes relevance, comprehensiveness, and comprehensibility [31].
- Relevance: the extent to which a questionnaire item is relevant for the construct of interest within a specific population and context of use [31].
- Comprehensiveness: the extent to which all key aspects of the construct are included in the questionnaire [31].
- Comprehensibility: the extent to which a questionnaire item is understood by patients as intended [31].
- Appropriateness: the extent to which a questionnaire item is perceived as appropriate and not upsetting [43].
- Relative importance: the extent to which a questionnaire item is deemed more important for the questionnaire's context of use than other items in the same content domain.
- Usability: the extent to which a system, product, or service can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use [47].

Ethical Considerations

This study was approved by the central ethics committee of university hospital Brussels (Belgian Unique Numbers: 1432021000533 and 1432023000043) and by the local committee of general hospital Aalst, Belgium. All participants provided written informed consent before study participation. Patients did not receive any compensation. Health care professionals received a €25 (US $27.06) gift card. Data were treated confidentially and were strictly analyzed in a deidentified form.

Participants and Setting

For the first 2 rounds, we planned to interview 32 patients and 8 health care professionals from 1 university hospital and 1 regional hospital in Belgium. These sample sizes adhere to the COSMIN and EORTC guidelines [31,43]. In the third round, we aimed to include 8 patients from the former university hospital [48] and 4 additional patients if, after the previous usability interviews, large changes would be made that would require further testing. JG and the hospital staff identified eligible patients through clinic appointment lists, and JG invited patients to participate via telephone or in-person communication during hospital visits. Health care professionals were identified through the research team's professional networks and contacted via email.

Inclusion criteria included the following: (1) a diagnosis of stage III or IV lung cancer or stage IV breast cancer; (2) patient aged ≥18 years; (3) patient spoke and understood the Dutch language; and (4) patient assigned an Eastern Cooperative Oncology Group performance status of 0, 1, or 2, based on the assessment by their treating physician.

Exclusion criteria included the following: (1) patient having major communication difficulties or insufficient cognitive abilities to take part in a semistructured interview (as judged by their treating physician); (2) patient having any psychiatric disorder that, in the opinion of their treating physician, might hinder participation due to expected burden or unreliable responses; (3) patient having uncorrectable hearing or poor vision; or (4) patient had participated in a previous part of this study.

We aimed to include 4 equally sized subgroups based on the primary tumor site (breast or lung cancer) and age (<70 years or ≥70 years) [49,50].

As for health care professionals, we aimed to include a specialist in respiratory oncology, an oncologist specialized in breast cancer, a radiotherapy specialist, an oncology nurse, an onco-psychologist, a health sciences researcher, and 2 specialist palliative care providers (ie, a physician and a nurse affiliated with a palliative home care team).

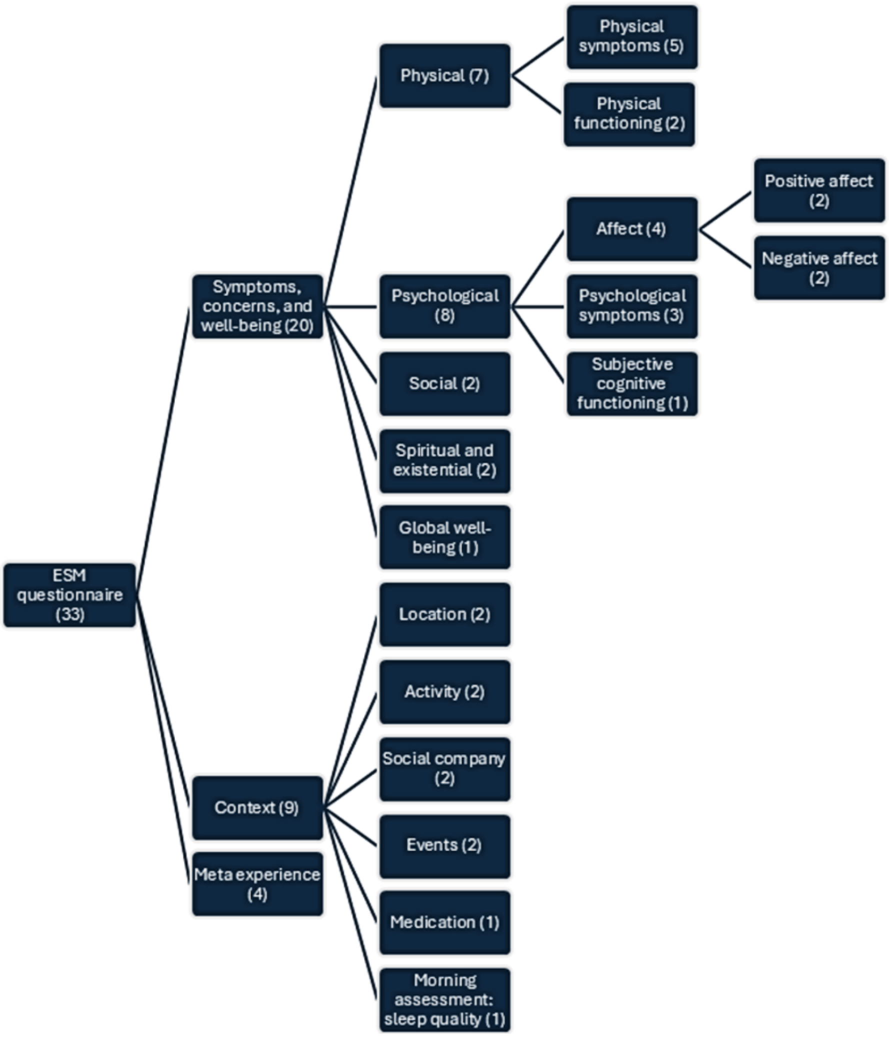
Measurement Instruments and Procedures

Initial Item Set

The questionnaire aimed to comprehensively measure and evaluate daily experiences of people with advanced cancer and the context in which they occur. More specifically, we conceptualized daily experiences as symptoms, concerns, and well-being across physical (including physical symptoms and functioning), psychological (including positive and negative affect, psychological symptoms, and cognitive concerns), social, spiritual-existential, and global well-being domains (Figure 2). Context was conceptualized as the person's current location, activity, social company, substantial events, medication use, and sleep quality.

We created an initial item set capturing in-the-moment experiences based on (1) the items of questionnaires identified in the 2018 review of PROMs in patients with advanced cancer by van Roij et al [1] and (2) an existing ESM item repository from the field of mental health sciences [42]. From the review by van Roij et al [1], we selected 3 questionnaires: the European Organization for Research and Treatment of Cancer Core Quality of Life Questionnaire (EORTC QLQ-C30), Functional Assessment of Chronic Illness Therapy—Palliative Care (FACIT-Pal), and the Integrated Palliative Care Outcome Scale [51-53], as they relate to our target population, have sufficient content validity, and have a comprehensive symptom coverage (ie, did not focus on one specific symptom or experience). On the basis of the consensus achieved through discussion among the authors, we excluded overlapping items and items with low expected intraday variability (eg, "I have family members who will take on my responsibilities") and retained 43 items suitable for the measurement of symptoms, concerns, and well-being across various subdomains (Figure 2). When consensus was required for adding, changing, or removing items, the content was first discussed primarily among JG, LP, and LVdB, who are all trained psychologists. LP and LVdB have >10 and 20 years of experience as end-of-life researchers, respectively. JG had 1 year of prior expertise in ESM mental health research. If further discussion or advice was needed, other authors were consulted, including a research assistant (LR; no prior expertise), a medical oncologist (EN; 7 years of experience), a health psychology researcher with experience in ESM research (GC; ≥30 years of experience), and a radiation oncologist (MDR; ≥20 years of experience).

Figure 2. Subdomains that the Experience Sampling Method for People Living With Advanced Cancer (ESM-AC) questionnaire intended to cover. Note that the between-bracket numbers after each domain name indicate the approximate number of items that we aimed to retain per domain and the number of most important items that participants had to choose for each right-most subdomain.



From the ESM item repository, we purposively selected 12 items measuring affect, spanning across the valence and arousal dimensions [54] (ie, levels of pleasantness and physiological activation, respectively), and 13 items measuring context. We additionally selected items to measure the patient's experience while completing the ESM questionnaire (ie, meta-experience items). We obtained official Dutch translations for all items and rephrased them to reflect in-the-moment experiences (eg, changing "During the past 7 days, I felt..." to "In this moment, I feel..." or "Since the last beep, I felt..." with "beep" referring to the assessment prompt). For less frequent experiences or events, such as, for the item "I have had diarrhea," we used the phrase "Since the last beep" instead of "In this moment." One item measuring sleep quality was adapted from the FACIT-Pal questionnaire [52] and used for the first assessment of the day (ie, "Last night, I slept well"). All English translations of items presented in this paper are phrased analogous to their existing PROM counterparts, or if no such counterparts were available, we provided translations of the Dutch versions used in this study.

Content Validity and Usability Assessments

In all study rounds, we conducted individual semistructured interviews with patients with advanced breast or lung cancer. One round also included interviews with health care professionals, as outlined in Figure 1. These interviews served to assess content validity, to shorten the initial item list and divide it into a core and supplementary set, and to optimize the digital ESM questionnaire based on its usability. At the start of all interviews, the patients completed a baseline questionnaire on sociodemographic and clinical characteristics (age, gender, living situation, marital status, education level, employment status, religious denomination, and received treatments). In round 3, the baseline questionnaire additionally assessed cognitive concerns [55] and smartphone use [56,57]. We conducted all interviews in person, either at patients' homes or in quiet hospital rooms. Patients' friends and relatives were allowed to be present during the interviews. Across rounds, we introduced the ESM to participants as a digital diary on a smartphone device that uses 10 assessments per day for several consecutive days to study people's symptoms, concerns, well-being, and daily situations as well as their fluctuations within and across days.

During round 1, JG interviewed patients and health care professionals to evaluate the relevance and comprehensiveness of symptoms, concerns, and well-being items. We aimed to create a core item set of 33 items, which was the foreseen number of items needed to cover all subdomains, and a supplementary set with no item limit and aimed to improve its comprehensiveness by adding items deemed relevant but missing by the participants. Participants were asked to verbally rate each item's relevance ("not at all," "a little," "quite a bit," and "very much"), select the most important items for each subdomain (Figure 2 displays the number of items to select per subdomain, as instructed by the interviewer), suggest missing concepts, and mark inappropriate items. Participants were prompted for reasons for categorizing items as inappropriate or "not at all" or "a little" relevant.

In round 2, JG interviewed patients on the comprehensibility of items resulting from the first round (as the last part of content validation), the relevance and appropriateness of newly added items, and the appropriateness and comprehensiveness of context and meta-experience items and their response options (assessed analogous to round 1). To assess comprehensibility, patients completed a pen-and-paper questionnaire while thinking out loud [58].

In round 3, JG and LR conducted interviews to assess and optimize the ESM questionnaire's usability by letting patients respond to it in the m-Path app [46]. m-Path is a web-based platform that provides "an intuitive and flexible framework to conduct smartphone-based ecological momentary assessment and intervention studies..." [46]. Patients were each provided with a Motorola E20 smartphone device (Motorola Mobility LLC) with the digital ESM questionnaire available in the m-Path app. They were instructed on how to use the app and asked to complete the digital questionnaire on the provided device while thinking out loud. The researcher prompted patients when difficulties were observed (eg, difficulties answering certain ESM questions). Afterward, a brief semistructured interview assessed the usability of the questionnaire through an adapted version of the System Usability Scale (5-point Likert scale; 1=totally do not agree and 5=totally agree) [59,60]. Usability outcomes included readability, comprehensibility, ease of use, reasons for encountered difficulties, and expected burden of receiving 10 assessments per day for 6 days. Finally, patients completed the digital ESM questionnaire a second time without thinking out loud to estimate completion times. All interviews were recorded and transcribed verbatim. More details on procedure and instruments for this round have been reported in the study protocol [61].

Data Analyses and Continuous Adaptations of the Questionnaire

Following the EORTC guidelines for module development, as applied by Sprangers et al [43] and Groenvold et al [45], we transformed item relevance ratings into a 0 to 100 scale, with "not at all" corresponding to 0 and "very much" to 100. We calculated mean relevance scores and SDs per item. In addition, we calculated the percentages of respondents who rated an item as inappropriate or upsetting, who listed an item among the top *n* most important items per subdomain (*n* was the approximated number of items to retain in the final questionnaire for each subdomain; Figure 2), and who found an item incomprehensible. We calculated descriptive statistics for usability.

Using conventional content analysis [62] on the interview transcriptions, we inductively developed content categories for participants' reasons of lack of item relevance (provided by participants who judged an item as "not at all" or "a little" relevant), inappropriateness, problems with comprehensibility, and themes of novel items to add [62]. We added items to the list if at least 2 participants suggested adding it to the questionnaire. Furthermore, we developed content categories for difficulties or conveniences in the user experience or comprehension of the digital questionnaire.

The questionnaire was adapted after each of the 3 rounds. After round 1, we used descriptive statistics of relevance, importance, and appropriateness ratings from the patients and health care professionals to guide item exclusion and categorization into core and supplementary sets (refer to Multimedia Appendix 1 for an overview of the categorizations). We assigned items to the core item set if they ranked among the top *n* most important per subdomain (refer to Figure 2 for n values), were judged "quite a bit" or "very much" relevant by half of the participants (50%), and were deemed appropriate (or amenable to rewording). For the removal of items, the authors discussed the participants' reasons for low relevance of items that were rated as "not at all" or "a little" relevant by at least half of the participants, or of items for which the participants provided recurring reasons for lack of relevance or the inappropriateness of items and the item could not be appropriately reworded or changed to resolve those reasons. Items that were not removed or categorized into the core set were assigned to the supplementary set. Note that the decision to use the core and supplementary sets was made after analysis of round 1.

After round 2, we made necessary and feasible item revisions based on the descriptive statistics of comprehensibility and inappropriateness and on the content categories for reasons of items' low comprehensibility and inappropriateness.

After round 3, we used descriptive statistics of usability outcomes and content categories of difficulties when using the digital questionnaire to improve the usability of the questionnaire in m-Path. Following general recommendations in ESM research [16,63], we used a mean questionnaire completion time threshold of 3 minutes to determine whether the questionnaire was considered too long.

Results

Participant Characteristics

In round 1, a total of 15 patients and 8 health care professionals participated; in round 2, a total of 18 new patients participated; and in round 3, a total of 10 new patients participated (Table 1). The overall mean age was 67.3 (SD 10.3) years. Overall, 23 (53%) of the 43 patients had a stage III or IV lung cancer diagnosis, and the remaining 20 patients (47%) had a stage IV breast cancer diagnosis. Close others were present during 4 interviews in round 1, seven in round 2, and seven in round 3.

Table 1. Sociodemographic and clinical characteristics of patients per interview round (N=43).

Characteristics	Round 1 (n=15)[a]	Round 2 (n=18)[b]	Round 3 (n=10)
Age (years)			
Mean (SD)	68.0 (8.5)	68.7 (11.3)	63.8 (11.1)
Range	56-78	44-86	45-78
Gender (female), n %	11 (73)	14 (78)	6 (60)
Living situation, n			
Living alone at home	2	4	2
Living with a partner/children/others at home	13	14	8
Marital status, n			
Married	13	8	—[c]
Living together but not married	0	6	—
Widowed	1	1	—
Divorced	1	3	—
Educational level, n			
Primary	2	0	1
Secondary	8	10	4
Tertiary	5	8	5
Employment status, n			
Professionally active	2	1	1
Not professionally active	13	17	9
Religious denomination, n			
Catholic Christian	6	8	6
Not religious	5	9	4
Not specified	4	1	0
Cancer diagnosis, n			
Stage III or IV lung cancer	7	10	6
Stage IV breast cancer	8	8	4
Treatment or treatments received, as reported by the patient, n			
Chemotherapy	14	13	9
Radiotherapy	13	10	5
Surgery	12	3	7
Hormonal therapy	4	5	2
Immunotherapy	6	9	4
EORTC QLQ-C30[d] concentration problems, n			
Not at all	—	—	7
A little	—	—	2
Quite a bit	—	—	1
Very much	—	—	0
EORTC QLQ-C30 memory problems, n			
Not at all	—	—	5
A little	—	—	3
Quite a bit	—	—	2

Characteristics	Round 1 (n=15)[a]	Round 2 (n=18)[b]	Round 3 (n=10)
Very much	—	—	0
Smartphone ownership in years, mean (SD)	—	—	10.2 (4.4)
Daily time spent on smartphone in hours, mean (SD)	—	—	3.2 (2.8)
Confidence using smartphone (1="not at all confident," 5="very confident"), mean (SD)	—	—	4.1 (0.7)

[a] Due to an oversight, we did not collect participation rates and reasons for nonparticipation in this round.

[b] Out of 25 invited patients. Reasons for nonparticipation included no interest, as indicated by patient or partner (n=5), inability to find an appropriate interview location (n=1), experiencing distress (n=1), or no reasons provided (n=1).

[c] Not measured.

[d] EORTC QLQ-C30: European Organization for Research and Treatment of Cancer Core Quality of Life Questionnaire.

The following sections present the results per interview round and relevant adaptations made to the ESM questionnaire based on these findings.

Interview Round 1

Relevance

Most items received positive relevance ratings, with no unanimous low relevance ratings across all participants (Multimedia Appendix 2). The most frequent reasons for considering an item lacking in relevance were overlapping content with other items, not experiencing the measured construct, not perceiving the measured construct as bothersome, and thinking the item could be phrased better. After discussion among the research team, we removed 12 items that at least half of the participants rated as having "a little" relevance or less or that participants noted had considerable overlapping content with other items. For instance, we removed the item "At this moment, I feel sick" due to overlap with specific symptoms such as nausea and removed the item "At this moment, I feel capable of making decisions" due to low reported relevance because patients reported not having to make decisions.

Some items were considered irrelevant by the participants because they measured stable constructs within a day. To address this, we deviated from the planned approach to develop in-the-moment items only and instead developed several items for designated morning and evening assessments. We dedicated 1 item of the initial item list to morning assessments and 11 to evening assessments. For instance, the in-the-moment item "At this moment, I feel moral support by my close ones" was revised to the evening item "Today I felt supported by others." Items excluded before round 1 based on little expected within-day variability were reconsidered for inclusion in the once-daily questionnaires. Hence, we added 8 initially removed items to the evening list for further testing in round 2 (eg, "Today, I was able to openly discuss my concerns with my close ones").

Appropriateness

Out of 55 items, 22 (40%) were deemed inappropriate by between 1 and 5 participants (Multimedia Appendix 2), with 12 (22%) items deemed inappropriate by at least 2 participants. Reasons included privacy concerns, content overlap, confronting questions, infrequent experiences, question formulation, clinical utility, and bad subdomain fit (Multimedia Appendix 3). We removed the most inappropriate item "At this moment, I feel enthusiastic" as 4 patients and 1 health care professional marked it as inappropriate due to content overlap and patients not experiencing this feeling.

Comprehensiveness

Participants suggested adding several constructs to improve comprehensiveness, leading to the addition of 13 items to the item list (Multimedia Appendix 4). Among these, 2 were conditional items administered only if certain responses are given during the same assessment, such as reporting moderate pain levels or poor sleep. These questions included "The pain is located in these parts of the body: ..." and "I think I didn't sleep so well, because: ... ." Examples of other added items included "At this moment, I feel capable of working" and "At this moment, I have negative thoughts or feelings." In addition, we included 3 items in the questionnaire as the research team thought them to be necessary for comprehensive measurement of the psychological domain ("At this moment, I feel restless" and "At this moment, I feel depressed") and an open question concerning other contextual factors ("If there is anything else you want to mention about the period since last beep, you can do that here:").

Relative Importance

We assigned 46 items with the highest relative importance of their subdomain to the core questionnaire and 38 items to the supplementary list (refer to Multimedia Appendix 2 for the proportions of how many times items were chosen as among the top most important).

Interview Round 2

Comprehensibility

Between 1 and 5 participants provided remarks for 31 (39%) out of 79 items (Multimedia Appendix 5). Reasons for marking items as incomprehensible included unclear word meanings, different interpretations from the intended meaning, situational content, response options misalignment, and other issues. In response to this feedback, we changed the wording of some items and response options and removed some items (Multimedia Appendix 6). For instance, we replaced the response option "On the move" under the item "What am I doing?" to "En route (eg, on the bus)" for clarity. Another example is the core questionnaire item "Today I felt supported by others," which we changed to "Today I received the support

I needed from my loved one(s)" because some patients indicated not needing or seeking support all the time.

Relevance of Added Items

On average, most added items were rated as at least "a little" relevant, with mean ratings typically exceeding "quite a bit" relevant (Multimedia Appendix 2).

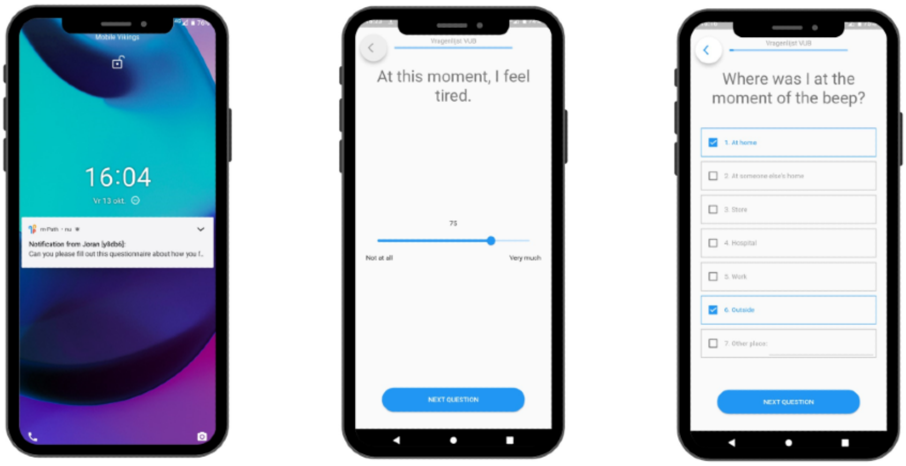
Appropriateness of Added Items

No items were considered as inappropriate by the participants.

Additional Findings and Changes Made

Three patients reported frequently experiencing muscle cramps, leading to the addition of the item "Since the last beep, I had muscle cramps" to the supplementary list. On the basis of research team consensus, we improved the comprehensiveness of the "Where am I?" item by adding an "outside" response option. Figure 3 displays the resulting questionnaire in the m-Path app.

Figure 3. Screenshots of the Experience Sampling Method for People Living With Advanced Cancer questionnaire in the m-Path app. Left: receiving a notification, middle: example of the slider response scale; right: example of the multiple-choice response scale.



Notification from Joran [y8db6]:
Can you please fill out this questionnaire about how you f...

At this moment, I feel tired.

Where was I at the moment of the beep?

☑ 1. At home
☐ 2. At someone else's home
☐ 3. Store
☐ 4. Hospital
☐ 5. Work
☑ 6. Outside
☐ 7. Other place:

Interviews Round 3

Usability

On a scale ranging from 0="completely disagree" to 5="completely agree," participants generally expressed positive sentiments about using the ESM-AC questionnaire in their daily lives (mean 3.6, SD 0.8), finding it easy to use (mean 4.5, SD 0.5), and expecting no need for support with the questionnaire or the smartphone device in their daily lives (mean 1.6, SD 0.7 and mean 1.5, SD 0.7, respectively). They also indicated that there was no inconsistency in the questionnaire (mean 1.6, SD 0.7). They expected that most people would quickly learn to use the questionnaire (mean 4.0, SD 1.1), felt confident using it (mean 4.2, SD 1), did not require a lot of knowledge to complete it (mean 1.3, SD 0.5), items and response options were clear (mean 4.3, SD 0.5 and mean 4.0, SD 0.9; respectively), the response options were comprehensive (mean 4.1, SD 1), and the lay-out was satisfying (mean 4.2, SD 0.6). Moreover, participants did not experience it as burdensome to complete the questionnaire (mean 1.5, SD 0.7) and did not think it was too long (mean 1.9, SD 0.9). However, as reflected by neutral mean scores with higher variance, participants were more divided regarding the simplicity of item phrasings (mean 2.2, SD 1.2) and the readability of items (mean 3.9, SD 1.4). Moreover, most participants anticipated that completing the questionnaire 10 times per day on 6 consecutive days would be burdensome (mean 3.7, SD 1.1).

Perceived Difficulties

Participants reported various barriers with using the digital ESM-AC questionnaire and device, and we observed some difficulties when participants used the questionnaire. For some patients, response formats and the option to skip open-ended items were initially not clear, the momentariness of items (ie, "At this moment, I feel...") required further instructions (eg, participants would give higher pain scores due to previous pain episodes, when currently not experiencing pain), interpretations of some complex items were unintended (eg, concentration problems were interpreted as wider cognitive problems), the purpose of the intensive assessment schedule of the ESM study and of specific questionnaire content domains were unclear (eg, context items), and the device went into standby mode during the interview. All the changes made to the ESM-AC questionnaire, smartphone device settings, and onboarding instructions are reported in Table 2. Refer to Multimedia Appendix 7 for the resulting core ESM questionnaire. We also created a manual for researchers to provide patients with instructions where needed (Multimedia Appendix 8).

Table 2. Changes made to different ESM-AC[a] questionnaire properties after the usability interviews of round 3.

Property and observed or reported barriers	Changes made
ESM[b] questionnaire	
Momentariness of item unclear	The phrasing “at the moment the beep went off” was added to the multiple-choice context items. For example: “Who am I with?” was replaced with “Who was with me at the moment of the beep?”
Momentariness of item unclear	In-the-moment phrasings were added to items that did not previously include it. For example: “I’m in bed or on the couch” was replaced with “I was in bed or sofa when the beep went off.”
Meaning of “place I was at” wrongly associated with bed or sofa	“I was happy with the place I was at” was reordered to be between “Where was I at the moment of the beep?” and “I was in bed or sofa when the beep went off.”
Unclear what was measured with substance item	“Since last beep, I have used the following” was replaced with “Since last beep, I have used the following substance(s)”; the response option “Other” was changed to “Other substance(s).”
Need for additional open-ended items when participants used the “Other” response option	An m-Path app feature was selected for the multiple-choice items that allows participants to directly type new categories when the “Other” option is selected.
Smartphone device settings	
Device screen darkened while completing the questionnaire	The time-to-standby settings on the devices was changed from 30 seconds to 60 seconds.
Onboarding instructions	
Response formats and option to skip open-ended items were not initially clear, momentariness of items required instructions, unintended interpretations of some complex items, purpose of the intensive assessment schedule of the ESM study and of some study domains (eg, context items) was unclear, reported expectations of missing assessments, and difficulty unlocking the smartphone	A formal interview guide was developed for the training at the onboarding session, which included instructions on how to explain the different response option formats and how to use them, skipping open-ended items, temporality of questions (ie, in-the-moment or since the last beep), content of more complex items (eg, concentration as separate from memory problems), the purpose of the intensive assessment schedule of the ESM study and of some question domains, acceptability of missing assessments, and unlocking the smartphone.

[a] ESM-AC: Experience Sampling Method for People Living With Advanced Cancer.

[b] ESM: experience sampling method.

Completion Times

During the second time of filling in the digital ESM-AC questionnaire (ie, without thinking out loud), it took participants on average 3.8 (SD 1.1) minutes to complete the questionnaire of 25 to 31 items (depending on the number of triggered conditional items).

Discussion

Principal Findings

We developed, content validated, and optimized the ESM-AC questionnaire, a digital ESM questionnaire covering multidimensional domains to capture the experiences of people with advanced breast or lung cancer. Overall, the patients found the questionnaire items comprehensible and appropriate and had positive views toward using the questionnaire in the m-Path app. As all items in the initial set were relevant to at least some patients, we primarily used the perceived importance of the items to categorize them into a core questionnaire for use with all patients and a supplementary item set from which patients can select items to tailor the ESM questionnaire to their needs and experiences.

As a novel and promising tool to assess patients’ symptoms, concerns, and overall well-being, the ESM-AC questionnaire supplements the existing measurement methods in oncology, a field that has traditionally relied on retrospective PROMs [1-3]. The ESM uniquely allows for the measurement of experiences in real time within the patient’s everyday life [16]. By using multiple assessments per day, it enables the investigation of how these experiences change and unfold over time, including their correlations and temporal relationships [16]. The repeated within-day assessments of the ESM can also supplement more traditional daily diary measures in oncology that assess patients once per day to uncover fine-grained fluctuations of symptoms. This can be important to better understand the complexity and dynamics of patient experiences from a research perspective. Moreover, from a clinical perspective, the ESM can be used to improve understanding of symptoms or concerns of individual patients identified using traditional once-daily or weekly administered PROMs.

To the best of our knowledge, the ESM-AC questionnaire is the first of its kind in oncology in several respects. First, the limited number of ESM studies in populations with cancer have never determined the content validity of their questionnaire items to be assessed in a repeated in-the-moment context [9,13]. Second, in cancer ESM research, the ESM-AC questionnaire is among the first to incorporate items on context and context appraisal [9,12]. By including items on concurrent location, activity, and social company, it will be possible to better understand fluctuating symptoms and their interactions with contextual factors. ESM research in other fields has shown how different contexts such as social company, concurrent activities, and location can influence patients' mental and physical experiences [64-66]. Third, by dividing items into a core and supplementary list, item selection can be adapted or tailored to a particular patient or a population of patients, that is, by adding relevant supplementary items such as "At this moment, I feel capable of working." This makes our ESM measurement highly relevant for people with advanced breast or lung cancer.

Using the m-Path app [46], results showed that the ESM-AC questionnaire was easy to use for all patients, and the patients had positive views toward the questionnaire presented on the device. This is crucial because it is important to minimize the potential burden of frequent daily assessments. This is especially true when working with populations that may be more likely to experience increased symptoms and reduced physical functioning related to cancer and related treatments. In addition, although the questionnaire took, on average, longer than the generally recommended 3 minutes' completion time in ESM research [16,63], participants indicated that it was not too long. Therefore, we deviated from our initial 3-minute threshold and did not further shorten the questionnaire [61]. As we purposively sampled people aged >70 years and <70 years (mean 63.8, SD 11.1; range 45-78 years), we were able to conclude that the system questionnaire was usable for older age groups (ie, those aged ≤78 years) that are typically thought to have less smartphone experience, as indicated by their positive views on usability of the system.

Implications for Future Research

The next step in the development of the ESM-AC questionnaire is to evaluate it in a detailed pilot ESM study. Such a study needs to evaluate the optimal number of daily assessments among people with advanced lung cancer or advanced breast cancer. As most participants indicated that they expected 10 assessments per day for 6 consecutive days, as is often used in ESM research [16], to be potentially burdensome, the burden of completing such an intensive assessment schedule should be carefully investigated in real life. This burden needs to be weighed against the necessary resolution to measure change in the construct of interest. In addition, further research is needed regarding the acceptability of the questionnaire length and clarity of the instructions, items, and response options if researcher help is not immediately available. If further research confirms the feasibility and optimal features for a larger-scale ESM study, this will pave the way toward a substantial improvement of our knowledge of how symptoms, concerns, and well-being across multiple domains fluctuate in the everyday life of people with advanced breast or lung cancer.

Researchers aspiring to apply similar methods to other populations with cancer or serious illness are encouraged to further adapt the methods to their target population. We recommend the ESM-AC questionnaire as a starting point for adaptations toward the target population and context. The core ESM questionnaire can be used in its entirety or researchers can select the domains of interest, possibly supplemented by items selected from the supplementary item set. Determining the questionnaire's content validity through semistructured interviews will help to optimize and ensure its relevance, comprehensiveness, and comprehensibility for intended research.

Furthermore, ESM data can be compared to retrospective patient-reported outcome data to confirm and obtain more evidence on the added value of the ESM and the different experiences it captures and to investigate the ecological validity of such data. Another important area of future ESM research in oncology can be to explore its clinical value and utility, for instance, by providing clinicians with time-series visualizations of their patients and comparing these with information gathered through traditional consultations.

Strengths and Limitations

This study is among the first studies to test the content validity of an ESM questionnaire in any scientific field and has resulted in the first content-valid ESM questionnaire in the field of oncology, thereby answering to recent calls for more questionnaire validation in ESM research [9,12,13]. This study has several strengths. First, it involved close collaboration with people with cancer and health care professionals in multiple phases of questionnaire development, ensuring its relevance for the target population. Second, relevance was further ensured by adapting items from existing validated PROMs [51-53]. Moreover, unlike many quantitatively focused questionnaires in ESM research, the use of a free-text response item "If there is anything else you want to mention about the period since last beep, you can do that here:" allows us to study any relevant experiences that are currently missing in the core questionnaire. Third, we included an equal number of patients aged <70 years and >70 years, ensuring the inclusion of the latter as an often underrepresented group in cancer studies. Finally, this study's relatively good participation rate reduces the risk of selection bias.

Several limitations should be noted. First, the study was limited to Dutch-speaking patients from 2 study sites, possibly limiting the extent to which the ESM-AC questionnaire's content validity can be generalized to patients with sociodemographic characteristics different from our sample. However, the ESM questionnaire will be further tested among new patients recruited from different hospitals. Second, the relatively high functional status of patients in our sample (ie, Eastern Cooperative Oncology Group scores between 0 and 2) may lead to limited generalizability of the results to patients with advanced cancer who have more functional limitations. Third, as no people aged >78 years participated, the usability of our ESM is unknown for older populations. Fourth, we did not record whether patients were actively receiving treatment, thereby preventing more detailed insight into the sample's current perspectives and experiences. Finally, due to the study design, we were not able to test how health care professionals viewed the relevance and how patients and health care professionals viewed the relative importance of evening assessment items that that were initially removed by the authors based on their low expected within-day variability.

Conclusions

We successfully developed the ESM-AC questionnaire, the first content-valid digital ESM questionnaire in oncology to study the daily experiences of people with advanced breast or lung cancer in their everyday environments. If the method proves feasible in future research on advanced cancer and in other patient groups, it paves the way toward gaining novel insights into the daily lives of patients with cancer, possibly informing and facilitating patient-centered care.

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Authors' Contributions

The study was conceptualized by LVdB, MDR, LP, and JG. Data were curated by JG and LR. Formal analysis, software, and visualization were performed by JG. LVdB, MDR, and LP were involved in funding acquisition. Investigation was conducted by JG and LR. Methodology was conducted by JG, LP, EN, GC, MDR, and LVdB. LP, MDR, and LVdB provided supervision and validation. The original draft was written by JG, LP, and LVdB, and reviewing and editing were done by LR, EN, GC, and MDR.

Conflicts of Interest

None declared.

Multimedia Appendix 1
A figure about the criteria for categorization into the core questionnaire, supplementary set, or items to be removed.
[DOCX File , 22 KB - cancer_v10i1e57510_app1.docx]

Multimedia Appendix 2
Inappropriateness frequencies, relevance means, and proportions of relative importance ratings of experience sampling method items.
[DOCX File , 33 KB - cancer_v10i1e57510_app2.docx]

Multimedia Appendix 3
Frequency table of the categorized reasons for deeming an item inappropriate.
[DOCX File , 22 KB - cancer_v10i1e57510_app3.docx]

Multimedia Appendix 4
Content categories of patient and health care professional responses to the open-ended question on what content was missing from the item sets.
[DOCX File , 23 KB - cancer_v10i1e57510_app4.docx]

Multimedia Appendix 5
Proportions of participants who had no difficulties with comprehensibility of item per item, ordered by subdomain.
[DOCX File , 21 KB - cancer_v10i1e57510_app5.docx]

Multimedia Appendix 6
Resulting Dutch item versions before and after the first 2 interview rounds.
[DOCX File , 34 KB - cancer_v10i1e57510_app6.docx]

Multimedia Appendix 7
Final core the ESM-AC (Experience Sampling Method for People Living With Advanced Cancer) questionnaire.
[DOCX File , 25 KB - cancer_v10i1e57510_app7.docx]

Multimedia Appendix 8
Dutch onboarding session manual created after interview round 3.

[DOCX File , 19 KB - cancer_v10i1e57510_app8.docx]

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Abbreviations

COSMIN: Consensus-Based Standards for the Selection of Health Measurement Instruments
EORTC: European Organization for Research and Treatment of Cancer
EORTC QLQ-C30: European Organization for Research and Treatment of Cancer Core Quality of Life Questionnaire
ESM: experience sampling method
ESM-AC: Experience Sampling Method for People Living With Advanced Cancer
FACIT-Pal: Functional Assessment of Chronic Illness Therapy–Palliative Care
PROM: patient-reported outcome measure

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Original Paper

Prototype of an App Designed to Support Self-Management for Health Behaviors and Weight in Women Living With Breast Cancer: Qualitative User Experience Study

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Abstract

Background: Accessible self-management interventions are required to support people living with breast cancer.

Objective: This was an industry-academic partnership study that aimed to collect qualitative user experience data of a prototype app with built-in peer and coach support designed to support the management of health behaviors and weight in women living with breast cancer.

Methods: Participants were aged ≥18 years, were diagnosed with breast cancer of any stage within the last 5 years, had completed active treatment, and were prescribed oral hormone therapy. Participants completed demographic surveys and were asked to use the app for 4 weeks. Following this, they took part in in-depth qualitative interviews about their experiences. These were analyzed using thematic analysis.

Results: Eight participants (mean age, 45 years; mean time since diagnosis, 32 months) were included. Of the 8 participants, 7 (88%) were white, 6 (75%) had a graduate degree or above, and 6 (75%) had stage I-III breast cancer. Four overarching themes were identified: (1) Support for providing an app earlier in the care pathway; (2) Desire for more weight-focused content tailored to the breast cancer experience; (3) Tracking of health behaviors that are generally popular; and (4) High value of in-app social support.

Conclusions: This early user experience work showed that women with breast cancer found an app with integrated social and psychological support appealing to receive support for behavior change and weight management or self-management. However, many features were recommended for further development. This work is the first step in an academic-industry collaboration that would ultimately aim to develop and empirically test a supportive app that could be integrated into the cancer care pathway.

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KEYWORDS

breast cancer; self-management; app; health behaviors; weight; prototype; user experience; development; application; coaching; peer support; oncology

Introduction

An estimated 55,200 people in the United Kingdom and 281,550 in the United States are diagnosed with breast cancer each year, and in 2021, breast cancer became the most common cancer globally [1-3]. The overall 5- and 10-year survival rates are estimated at 85% and 75%, respectively [3], indicating that very large numbers of people are living with and beyond their diagnosis. However, breast cancer and its associated treatments can lead to multiple immediate and long-term side effects [4,5]. Physical activity, diet, and maintenance of healthy weight play important roles in the management of breast cancer [5], and many women desire to receive support for these as part of their cancer care [6,7]. However, given the pressure on health care systems and the other barriers that health care professionals face in delivering behavioral interventions in practice [8,9], accessible self-management interventions are required.

Smartphones have the potential for the delivery of scalable supportive interventions, and ownership is continually increasing. For example, between 2011 and 2021, the proportion of US adults who own smartphones increased from 35% to 85% [10]. There are also examples of how, following substantial user development and empirical testing, a smartphone-delivered intervention can become part of the recommended clinical referral pathway (eg "Sleepio" for insomnia in the United Kingdom in 2022 [11]). Many women with breast cancer want to play an active role in the management of their health, and when surveyed, 68% were interested in information delivered via an app or website [12]. However, alongside this is the desire for peer support from others who have experienced cancer [13], with evidence that this can facilitate positive behavioral change [14]. Systematic reviews have highlighted a number of existing apps designed for cancer self-management [15-18]. A meta-analysis of 30 randomized controlled trials of apps found that they improved quality of life and psychological symptoms among people living with cancer [19]. However, few apps incorporate combined support for physical activity, diet, and weight management or integrated social support [15-18]. A review of app-based interventions for supporting lifestyle or healthy behavioral change in people living with cancer, which was published in 2021, included studies of 17 apps designed to promote diet, physical activity, or mental health in people living with cancer. The majority of these apps were explored in pilot studies, qualitative interviews (one from our group described below), or descriptive studies [20], highlighting that there is insufficient evidence to recommend any particular app. In addition, few apps for breast cancer management have been developed or user-tested by collaborative academic and industry partners, a highlighted limitation of the current field [16,18]. An app-store scoping review found 151 apps aimed at people living with cancer (broadly covering the areas of information provision, organizing cancer care, interacting with others, and cancer management). Most were developed commercially, and only 13 of these apps were developed in partnership with organizations [21]. Such a collaboration is important for quality, optimization, empirical testing, and sustainability.

A key early step in the research and development of a supportive care app is appropriate testing with target users. In a focus group study gathering the views of 35 people living with cancer on app features (using screenshots for discussion), participants highlighted a preference for a positive casual tone, tools to support goal attainment, a "prescription" for physical activity, and individual tailoring [22]. A study of 11 people living with cancer, which was designed to explore their experiences of using a physical activity app for 6 weeks, identified a number of valued app features, including tailoring and social support [23]. We also asked people with breast (n=8), prostate (n=16), or colorectal cancer (n=8) to download and use physical activity apps over a 2- to 3-week period and then conducted in-depth qualitative interviews on their experiences [13]. This provided not only invaluable details of how users felt about the apps they tested but also a far richer understanding of the factors that are important to people living with and beyond cancer than would have been gained from interviews on hypothetical app use. This work subsequently informed the design and funding of a pilot randomized controlled trial of a physical activity app for people with breast, prostate, or colorectal cancer [24].

The aim of this study was to use a similar methodology to gather user experience data of a prototype app with built-in peer and coach support designed to support the management of health behaviors and weight in women living with breast cancer. The information provided in this study will highlight which app components are most valued by potential users, feed into further development of the app, and provide valuable information on what women with breast cancer want from digital support in general.

In this manuscript, we will describe the study design, including the app content, and will then present details of the participant demographics, their app usage during the study, and the themes derived from a qualitative analysis based on their interviews. We will then discuss these findings and what they add to the literature.

Methods

Design

This was a qualitative user experience study where participants were asked to complete a brief online survey, use the app (Healthy Habits after Cancer: HHC) for 4 weeks, and then participate in qualitative interviews. The study was conducted between June and August 2021. Our previous work suggested that 8-10 participants with 1 cancer type trying a single app would provide meaningful qualitative user experience data [13].

Participants

Recruitment was conducted in the United States through the Living Beyond Breast Cancer nonprofit organization via email and social media advertising. Members of the organization who were interested were invited to complete an online screening questionnaire to assess eligibility. Participants were eligible if they were female, were aged ≥18 years, were diagnosed with breast cancer of any stage within the last 5 years, had completed active cancer treatment (eg, chemotherapy, surgery, or radiotherapy) at least 1 month previously, were currently prescribed oral hormone therapy (eg, tamoxifen; medication tracking was a feature of the app we were looking for feedback on), were not pregnant or planning to become pregnant in the next 5 months, were not diagnosed with an eating disorder, had a BMI of >18.5, and owned a smartphone with the iOS operating system as the prototype was built for iOS only. The exclusion criteria were any surgery planned within 6 weeks of study enrolment, current treatment for a second primary cancer (ie, cancer of another organ, not due to breast cancer metastasis, with the exception of nonmelanoma skin cancers), inability to understand spoken or written English, and presence of a diagnosed physical or mental health condition that would impact the ability to participate. If there was any doubt over whether individuals met these criteria, it was recommended that they discuss participation with their clinical care team before enrolling; however, this was not required for any of the participants. Those deemed eligible were invited to complete the online informed consent form and baseline survey before they were given access to the HHC app.

Participants received free access to the HHC app for the duration of the study and were provided with a US $20 gift card at the end of the study.

Ethical Considerations

Ethical approval was provided by the Advarra Institutional Review Board (approval number: Pro00055029), and all participants provided informed consent for the study. The Advarra Institutional Review Board is a centralized ethics review board that operates in compliance with US federal regulations and the ethical principles underlying the involvement of human subjects in research [25].

HHC App

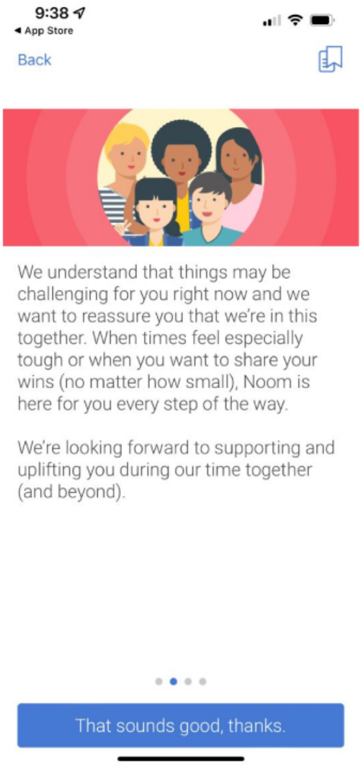
Following preliminary discussions about the content between researchers at Noom and University College London, the HHC prototype was created by Noom, who developed a popular weight loss program for the general population and planned to explore the development of a supportive app for women living with breast cancer. The HHC app was based on psychological behavior change principles from cognitive behavioral therapy (CBT) [26,27], acceptance and commitment therapy (ACT) [28], and dialectical behavior therapy (DBT) [29], as well as the guidelines of the American Cancer Society and World Cancer Research Fund. The key components of the app are summarized in Table 1. Screenshots of example app pages are shown in Figures 1-4.

Table 1. Key content of the Healthy Habits after Cancer app.

Intervention component	Details
Curriculum (articles)	Participants are encouraged to read short daily articles in the app. These address topics, including the 4 pillars of health: nourishment (focusing on mental and behavioral habits), self-care (prioritizing your own well-being), positive experiences (eg, focusing on enjoyment and gratitude), and support (eg, reframing negative thoughts).
Calorie targets	Calorie targets are set based on basal metabolic rate and logged exercise.
Meal logging	Participants are asked to log all the food they eat via the app, which calculates their calorie intake and displays this against their target.
Weight logging	Participants set their own weight target and are asked to log their weight weekly in the app.
Physical activity	Participants can set their own target or choose automatic adjustable step targets (initially set at 2000 steps a day and increased or decreased over time based on tracked steps). Participants can link an activity tracker to the app or manually enter their steps.
Recording of water intake	Participants set their own water intake target and are asked to log their water intake in the app.
Medication logging and reminders	Participants are asked to log their medication use in the app daily and are sent medication reminders.[a]
Individual one-to-one coaching	A one-to-one coach communicates with participants via in-app messaging. Participants have access to their coach chat at all times. The coach responds to participant messages within 24 hours or less.
Group support	An in-app closed group of other women with breast cancer and a group coach are available for discussions via an in-app chat area.

[a] In the prototype, reminders are sent via text messages outside the app rather than as pop-ups within the app.

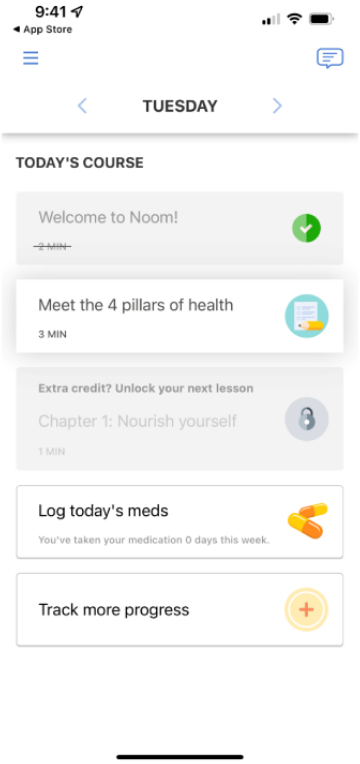
Figure 1. Screenshot of the Noom Health Habits after Cancer app: introductory page.



We understand that things may be challenging for you right now and we want to reassure you that we're in this together. When times feel especially tough or when you want to share your wins (no matter how small), Noom is here for you every step of the way.

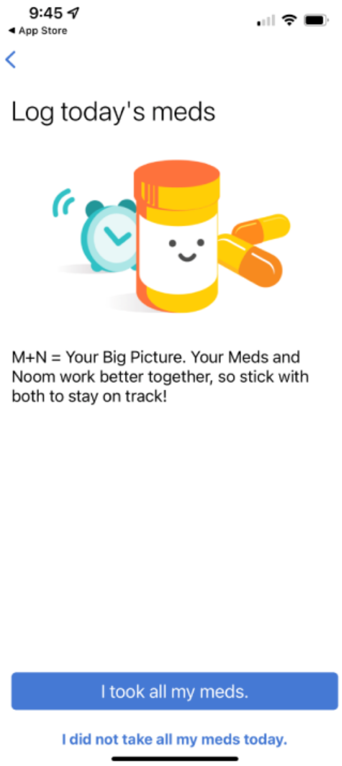
We're looking forward to supporting and uplifting you during our time together (and beyond).

Figure 2. Screenshot of the Noom Healthy Habits after Cancer app.



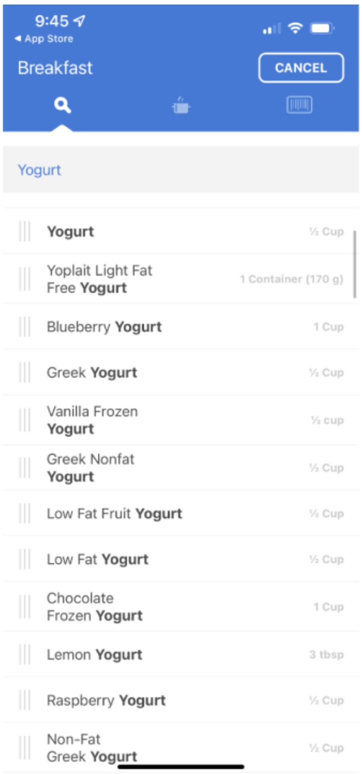
You've taken your medication 0 days this week.

Figure 3. Screenshot of the Noom Health Habits after Cancer app: medication tracker.



M+N = Your Big Picture. Your Meds and Noom work better together, so stick with both to stay on track!

Figure 4. Screenshot of Noom Health Habits after Cancer app: diet tracker.



Yogurt	½ Cup
Yoplait Light Fat Free **Yogurt**	1 Container (170 g)
Blueberry **Yogurt**	1 Cup
Greek **Yogurt**	½ Cup
Vanilla Frozen **Yogurt**	½ cup
Greek Nonfat **Yogurt**	½ Cup
Low Fat Fruit **Yogurt**	½ Cup
Low Fat **Yogurt**	½ Cup
Chocolate Frozen **Yogurt**	1 Cup
Lemon **Yogurt**	3 tbsp
Raspberry **Yogurt**	½ Cup
Non-Fat Greek **Yogurt**	½ Cup

During the first week of the study, participants were introduced to the HCC app, their one-to-one coach, and their support group via the app and were given unlimited free access to the program. They were not instructed to use the app a certain amount but were told that there were daily tasks and articles provided. The coaches had been through Noom's intensive training program. The training is approximately 2 weeks in length, and the philosophy of the coach training is centered on motivational interviewing and active listening. Noom health coaches come from a variety of backgrounds (ie, nutrition, exercise physiology, and mental health professionals). The Noom health coach who worked on this study specifically was a licensed marriage and family counselor who worked within the scope of the Noom health coach role, and had experience working with cancer patients. Coaches used a secure dashboard to monitor participant app use, physical activity, meal logging patterns, dietary intake, and weight, which is used to increase engagement and motivation, and communicated with participants via in-app asynchronous messaging.

A group coach moderated the in-app social support groups by posting content to promote discussion and responding to user posts or comments. During this study, given the small sample size, the group involving this sample was merged with another breast cancer survivor group mid-study to encourage more group engagement and keep conversations more continuous. The other group was from a study Noom was running concurrently with the Dempsey Cancer Center, Maine, which was looking at a group of women diagnosed with breast cancer (stage I, II, or III) within the last 5 years and who had completed active treatment (eg, surgery, chemotherapy, or radiation) at least 6 months ago. They had access to the app for 6 months.

Sociodemographic Variables

At baseline, participants completed an online survey providing date of birth (to calculate age in years at the date of survey completion), race, marital status, employment, education level, date of diagnosis (used to calculate months since diagnosis), cancer stage at diagnosis, height and weight (used to calculate BMI), and details of cancer treatments.

Qualitative Interviews

Interviews were guided by a semistructured schedule designed to explore general experiences of cancer and weight management as well as to probe about specific elements of the HHC app. The interview schedule is provided in Multimedia Appendix 1. One-to-one telephone or video-call interviews were conducted by a member of the Noom research team with training in qualitative interviewing (author MM). MM had no prior relationship with the participants interviewed. Interviews were audio recorded and transcribed verbatim, and the information was deidentified (removing any reference to names or locations).

App Usage

App usage was recorded as the total number of in-app engagements each week. An in-app engagement is defined as reading an article; messaging a coach; interacting with the support group; or logging a meal, water intake, weight, medication, or exercise.

Analyses

Survey analyses were conducted using descriptive statistics. App engagement was assessed through the number of participants using the app at all each week, as well as the average number of engagements each week across those participants who engaged at all.

Qualitative analyses were conducted in NVivo software (QSR International) using reflexive thematic analysis following the 6 phases outlined by Braun and Clarke [30,31]. First, 2 researchers (AF and PL) familiarized themselves with the data by reading and rereading all transcripts and taking notes, and then independently coded the same randomly selected transcript, met to discuss similarities and differences, and generated an initial set of codes that was used to code the rest of the transcripts, with scope to add new codes as required and conduct regular meetings to discuss ongoing findings. Potential themes and subthemes were generated by reviewing all codes. These were then presented back to the wider research team, reviewed, named, and finalized for presentation in this paper (along with illustrative quotes). A deductive and inductive approach to analysis was taken with the aims of understanding the experience of using the HHC content and gathering data on the wider experience of breast cancer and the desired content from a digital intervention.

Results

Participants

It was not possible to know how many potential participants viewed the recruitment advertisements, but 42 expressed interest, 15 signed the consent form, 13 enrolled in the HHC program, and 8 used the app for 4 weeks and took part in interviews. Participant characteristics are presented in Table 2. Of the 8 participants, 7 (88%) were white and 1 (22%) was mixed race. All were married, and the majority (6/8, 75%) had a graduate degree or above.

Table 2. Participant characteristics.

Characteristic	Value (N=8)
Age (years), mean (SD)	45 (8)
Race, n (%)	
White	7 (88)
Mixed race	1 (22)
Education, n (%)	
High school diploma or GED[a]	2 (25)
Graduate degree or above	6 (75)
Marital status, n (%)	
Married	8 (100)
Employment, n (%)	
Employed full time	5 (62.5)
Employed part-time	3 (37.5)
Cancer stage at interview, n (%)	
Localized	6 (75)
Metastatic	2 (25)
Months since diagnosis, mean (SD)	32 (14)
Chemotherapy, n (%)	
Yes	6 (75)
No	2 (25)
Radiotherapy, n (%)	
Yes	6 (75)
No	2 (25)
BMI (kg/m^2), mean (SD)[b]	29 (5)

[a] GED: general educational diploma.

[b] Two participants did not report BMI.

All 8 participants were engaged for the first 3 weeks, and 7 of the 8 participants were engaged for all 4 weeks. The number of engagements each week is shown in Table 3.

Table 3. App engagement over the 4-week study (N=8).

Variable	Week			
	1	2	3	4
Number of engaged participants	8	8	8	7
Average number of total weekly in-app engagements	77.0	54.6	64.9	44.1

Themes and subthemes are presented in Textbox 1. Four overarching themes were identified: (1) Support for providing an app earlier in the care pathway; (2) Desire for weight-focused content tailored to the breast cancer experience; (3) Tracking of health behaviors that are generally popular; and (4) High value of in-app social support.

Textbox 1. Themes and subthemes.

1. Support for providing an app earlier in the care pathway

- More time during active treatment
- Thirst for knowledge about health in early stages
- Later in the pathway already found a community
- Recommendations from oncologists (most powerful)

2. Desire for weight-focused content tailored to the breast cancer experience ("It wasn't what I was expecting")

- Style of articles was enjoyed
- Too much focus on emotional content, not enough on weight (loss)
- Desire for increased tailoring to the breast cancer experience

3. Tracking of health behaviors that are generally popular

- Meal logging and color coding of diet were popular
- Water or fluid tracking was useful for the cancer community
- Physical activity tracking was very useful, but the step target was too low
- Increased prominence of physical activity preferred
- Medication adherence feature not used

4. High value of in-app social support

- Coaches provided accountability and increased engagement
- Groups were popular
- Mixed views on including early stage and metastatic disease together

Support for Providing an App Earlier in the Care Pathway

Participants expressed a strong desire for support (especially around weight loss). They had completed active curative treatment when they participated in the study and strongly felt that this app would be more appropriate for those still on active treatments such as chemotherapy and radiotherapy.

> *I feel like it would have been really helpful for me during chemo and my active treatment.* [age 40-49 years; localized disease]

While some suggested they would like to have had access to the app at diagnosis, most discussed that they would still have been too shocked at this point to use it.

> *...right at diagnosis my brain was completely scrambled with the whirlwind of everything that was going on, I'm not sure at diagnosis I would have had the focus to give it any kind of attention.* [age 30-39 years; localized disease]

More Time During Active Treatment

A key reason women felt that early in the pathway would be a good time was the additional time they had while on active treatment due to, for example, stopping work and social activities. Although they often felt fatigued on treatment, they felt that they would have had the mental capacity to engage with many of the app components and to start to think about health and behaviors.

> *I may have been able to use it more, like, when I was more active in treatment because my life was a little bit less busy, if you will…And I think I might have engaged more in the 1:1, in the group setting, because I think that would have helped fill areas that, because I was not working quite as much -- you know...* [age 40-49 years; localized disease]

> *I mean radiation therapy is exhausting -- if you start on Monday, by Friday you can barely walk upstairs -- but you have enough bandwidth to start thinking about your health.* [age 40-49 years; localized disease]

> *...chemo definitely (be)cause you sit in a chair for hours with nothing to do, that would be a good like positivity booster and things like that while you're sitting there.* [age 40-49 years; localized disease]

Thirst for Knowledge About Health in Early Stages

Some participants described a "sweet spot" once treatment had started where they were keen to gather as much information as possible and take ownership of their health.

> *I think earlier in my cancer journey, when I was so focused on losing weight, I probably would have perhaps asked my coach, like "hey, I'm looking for more nutrition content, or this, or that' and just really explored what could have been available or what resources she could have provided for me, but I didn't push on that because I am much further along in my journey, so I think for earlier-diagnosed people, you're so thirsty for information.* [age 50-59 years; metastatic disease]

Others described a desire to learn more about interactions between health behaviors and active treatment side effects (like which dietary factors might alleviate or enhance diarrhea or nausea) as these were happening.

> *I want to know like the changes my body's going through and how I can change certain aspect of my life whether it is my diet or exercise or anything to that effect that would improve my quality of life or at least be aware of potential side effects and things of that nature.* [age 30-39 years; localized disease]

Later in the Pathway Already Found a Community

Some participants discussed that by the time they had completed active treatment, they had found a community of other breast cancer patients and that if the app had come earlier in the pathway when they were still seeking peer support, they would have engaged with group elements much more.

> *I think earlier on...perhaps I would have found the group to be more enticing to me. I have found my community because I am a little bit further in on my cancer journey, so I have my community, so I didn't need to engage much there.* [age 50-59 years; metastatic disease]

Recommendations From Oncologists (Most Powerful)

Participants felt that if their oncologist had recommended the app to them, they would have been likely to try it, and they linked this to having this recommendation earlier in their care pathway.

> *I ballooned during chemo, so if a doc had been like, "hey, do what you've gotta do to survive, but if you're interested, this is an app that's trying to help women maintain their underlying health while they're doing cancer treatment, and including your mental health. That would have been powerful.* [age 40-49 years; localized disease]

Desire for Weight-Focused Content Tailored to the Breast Cancer Experience

Too Much Focus on Emotional Content, Not Enough on Weight (Loss)

All participants had background knowledge of Noom (some had tried the Noom Weight app) and saw it as a weight loss program. They described that this had therefore been a key motivator for participation, and they expressed a strong desire to lose weight, which was often perceived as gained as a result of their cancer treatments. This led to an element of disappointment when the content of the HHC app was focused on psychological or emotional aspects of having breast cancer and weight maintenance.

> *I think of Noom as a weight loss tool, I was like oh great here's this thing I've been meaning to try and hadn't (be) cause of cost that I can try, tailored to me for weight loss.* [age 40-49 years; metastatic disease]

> *I feel like it spent a lot on emotional stuff -- maybe it should -- but I don't know. I got a little grumpy about it.* [age 40-49 years; localized disease]

> *...my biggest thing going into it was I wanted to lose the weight, and at the very beginning it seemed to be more, more of that like self-acceptance, self-grace, that sort of thing, without ever getting into the – okay this is what we're gonna do to make a change.* [age 30-39 years; localized disease]

This was true for participants with metastatic disease and those with localized disease. One participant described already having developed good coping skills after being diagnosed with an incurable disease, and what they really wanted from this app was weight loss support.

> *I live with this stage 4 diagnosis, my emotional, my coping skills are pretty strong– I didn't get much out of them that helped me with my actual goal which was weight loss.* [age 40-49 years; metastatic disease]

However, participants did like the general idea of showing gratitude to and being kind to themselves (although most would like these aspects linked directly to weight loss). One participant with depression who had recently experienced a breakdown engaged more with the emotional support content (this participant did not engage with the behavior change elements and actually reported gaining weight during the study). However, the participant did perceive benefit from the emotional support.

Although most participants expressed that they were hoping for more focus on weight loss and that there was too much focus on the emotions associated with living with cancer, some did express that they found the psychological advice useful.

> *...feel like I'm able to more identify what the stressors are and kind of bring myself back a little bit.* [age 30-39 years; localized disease]

> *...there was one particular exercise where they talked about when these types of thoughts get in your head, to just use the terminology of, "stop it." And that really hit home for me in a lot of different ways, because when I'm dieting, or really in any other aspect of my life, I tend to be an all-or-nothing-type person.* [age 50-59 years; metastatic disease]

Tailoring to the Breast Cancer Experience

While participants acknowledged a strong desire for an app to support weight loss, there was extensive discussion about the need to tailor the app content more to people with breast cancer. Many participants described how they felt the content was quite general, with very little mention of cancer in the content.

> *I know this was like for breast cancer participants, but I'm not sure if um there's people who don't have breast cancer that were doing it or using it as well but I thought that there would be more information on like, breast cancer and like medications, stuff like that.* [age 30-39 years; localized disease]

> *I guess because throughout the whole thing there was really not a lot of mention of cancer - it was more of everything else, so I really don't feel like, I guess I feel like I was going into there thinking that this would be more a cancer-based thing, um the psychological*

> *effects of the cancer while losing weight, I don't think it mentioned it hardly at all when I think about it.* [age 50-59 years; localized disease]

In particular, participants described how they would have liked more information on specific treatment side effects and guidance on appropriate health behaviors to deal with these (particularly, common active treatment side effects like nausea and diarrhea), in line with a desire for an app during active treatment.

> *If you could have talked about nutrition through chemo - like recipes, how to eat through nausea. For me, like I had some major surgeries, so like, "what would be good nutrition to focus on to rebuild after surgery" would have been helpful. I know that they talk a lot about how you have to focus on protein to help your body rebuild. And also -- maybe you say this somewhere in the app and I missed it.* [age 50-59 years; localized disease]

Some women also discussed the effect of hormone treatment on their weight and that they were seeking information on this, whether it is possible for them to lose weight while on this treatment, and how they can achieve this.

> *...the hormone therapy changes so many things, like your – how your metabolism runs, how you and your body will feel at different times of day and different things like that.* [age 30-39 years; localized disease]
>
> *I don't actually know if its possible for women on hormone therapies to lose weight.* [age 40-49 years; metastatic disease]

Tracking of Health Behaviors That are Generally Popular

Meal Logging and Color Coding of Diet Were Popular

Meal logging and color coding of diet were popular app features.

> *I really liked how like when you started typing things in it came up so I didn't have to like put in the dietary information – like I literally just typed in like coffee or whatever and it came up, already had the calories and stuff in there. Um yeah they pretty much had everything I think there was just one thing that I had to like put in myself. Um that was, that was a good aspect of it I really liked that part.* [age 30-39 years; localized disease]
>
> *I did like having the breakdown of different colors of food because, you know, although I do eat healthy, I do eat -- I try to limit meat to one serving per day and then more plant-based, and it's not like you can't have plant-based proteins, but some things like nuts or seeds, you know, they're red foods, so I think just being cognizant of, you know, if I have nuts, being like 'am I eating one serving of nuts or am I taking a handful, which could be more than one?' Like just those types of things; just trying to make sure the quality of my food remains high, despite if there's foods in the red."* [age 40-40 years; localized disease]

However, there was a perception that these could have been tailored more to the cancer community so that women could include information on the treatment they had or the side effects they were experiencing to understand how that was influencing their diet.

> *It might also be nice to be able to have like a note section, where you could be like -- for me, if I was having a certain digestive issue, I could put like, 'this is what I ate, is my digestion good/bad, or a comment, or something' in there.* [age 40-40 years; localized disease]
>
> *...you don't have an option for, "did you have your infusion today? Are you nauseous today?" You don't, like, talk about that treatment at all and how that's impacting my ability to take in nutrition or what's coming out of me.* [age 50-59 years; localized disease]

Participants engaged with the idea of having calorie targets, but one felt that they needed to be more individualized.

> *...even with this it was telling me I wasn't eating enough calories when I was like stuffed full and gaining weight.* [age 40-49 years; metastatic disease]

Water or Fluid Tracking was Useful for the Cancer Community

A number of participants highlighted the tracking of water as useful and especially relevant to the breast cancer community as treatments can often lead to constipation or diarrhea, so sufficient fluid intake is particularly important.

> *I loved the water tracking and that's also, again, for early-stage and metastatic, also by cancer trait, people tend to get a lot of diarrhea. They get heart disease, but everyone on hormone therapy, we all get constipated. I have to drink gallons of water a day to not have an impacted bowel, and so I loved the water reminders.* [age 40-49 years; localized disease]

Physical Activity Tracking was Very Useful, but the Step Target was Too Low

Tracking of activity was popular and consistently perceived as useful. This was seen as especially useful when participants experienced a change in their daily routines that resulted in a reduction in steps taken in their daily lives, either due to their initial diagnosis and treatment or due to the COVID-19 pandemic.

> *I just think tracking is really useful. You know, I used to be more active than I am now. I used to walk my kids to school and it was a half mile from my house and bike to the grocery store, and I sometimes forget that I'm not getting all of this activity just from being alive anymore like I used to, so tracking it has me out walking my neighborhood while we're on the phone. I mean I've gotten like 2,000 steps since we've been on the phone, and tracking it has me doing this.* [age 40-49 years; localized disease]

However, there was a general perception that the step count was pitched too low. A number of participants talked about being surprised by their "2000 steps" target, feeling that this was not challenging enough, which was then not motivating, and they disengaged from this aspect of the app. Some discussed how this might have been more reasonable during active treatment but that the targets set in the app should be based on the individual's initial step count. Some also referenced information that they were aware of in the public domain, like step count targets, which influenced their perceptions.

> *...it started I believe at 2000 steps a day which is like super low so I wasn't sure, um, you know why that starts so low um but I think it raised to like 4000 or whatever but I think like the standard like what how many steps you're supposed to take in a day is 10,000 which is like the universal.* [age 30-39 years; localized disease]

Increased Prominence of Physical Activity Preferred

Participants in this sample had a high awareness of the importance of physical activity after a cancer diagnosis and felt that this should have had more prominence, with a view that evidence-based information about physical activity after cancer should be provided.

> *...since I had a double mastectomy...now I can barely do a push up so maybe something information on, what exercises I could be doing to like help get my muscle back.* [age 30-39 years; localized disease]

Some participants discussed highlighting cancer-specific guidelines.

> *I don't know how cancer-specific you want to get in this app, but it would have been interesting: "the latest research shows:..." you know? And, actually, for people with metastatic disease, people who exercise can have better overall survival, you know.* [age 40-49 years; localized disease]

Medication Adherence Feature Not Used

No participant used the medication adherence or logging feature. They described how they came to the app with strategies already in place (like pill boxes) and did not perceive a need or desire for this feature.

> *I never like notified it but it was always there, but "did you take your medicine today", I think when I saw it I hid it, but I've got a pretty good routine set up, cause I take my medicine a couple times a day, so that – that I didn't feel like I really needed.* [age 30-39 years; localized disease]

High Value of In-App Social Support

Coaches Provided Accountability and Increased Engagement

Participants were very positive about their one-to-one coach. They felt supported without being judged, and making plans with their coach gave them a sense of accountability and kept them engaged with the app.

> *I liked the amount of checking in she did with me, it wasn't overbearing, it wasn't too much, and she just encouraged me to keep up with the articles and things like that.* [age 50-59 years; metastatic disease]
>
> *She just kept me focused and digging deeper.* [age 50-59 years; localized disease]
>
> *I would say ok my goal this week is like, I'm gonna walk every day and um she would be like ok well 'I'll check in with you on Friday, so like the fact that like there was some kind of accountability mechanism, um I really like that.* [age 40-49 years; metastatic disease]

However, 2 participants chose not to engage with their coach as they felt they did not need this form of support.

Groups Were Popular

In general, groups were viewed as a positive feature, and the ability to engage or not as desired was appreciated. Some participants acknowledged that they just were not "group" people but still felt it was a useful feature to have available.

> *...basically people telling stories about their lives and what works and what doesn't work for them, so that's like my favorite model of gaining wisdom about the human condition. I think it's because I've been doing it for so long, and people have interesting ways that they try to get more steps in and connecting and stuff like that.* [age 40-49 years; localized disease]

One participant commented on group size, suggesting that they had really enjoyed an initial small group that was then merged with a larger one, including people who were much more established, and the participant felt less comfortable in this larger group.

> *I really like the idea of the group and I felt like the group was very weight loss focused which I liked, I had a small group then got combined with another group …and it was also like fifty people which made me feel pretty exposed about being vulnerable, like I would feel more comfortable in a group of 10 to 15 but that may be hard when people aren't actually posting.* [age 40-49 years; metastatic disease]

There were some interesting discussions around the presentation of only positive outcomes (especially around weight loss), and how this could be disheartening if someone was not losing weight. For example, 1 participant mentioned that they had gained a little weight, and after announcing this in the group, the participant received a private message from another participant saying they had too but felt uncomfortable sharing. The participant suggested that this could be mitigated by encouraging people to share when things had not gone so well and for others to empathize and share solutions.

> *I had a couple people contacted me, one on app and two off app, (be)cause the breast cancer community is small so folks knew who I was to say that they had – they didn't feel comfortable posting publicly that they had also gained weight and were pretty upset about it.* [age 40-49 years; metastatic disease]

Mixed Views on Including Early Stage and Metastatic Disease Together

There was an interesting juxtaposition between those with early and metastatic disease on the benefits of mixing people with different cancer stages in groups. Participants with earlier-stage disease felt anxious and self-conscious about discussing certain things like “getting back to normal” as they were concerned about upsetting those with metastatic disease.

> *I got a little anxious in the group. I think most of us had early stage disease, but there was a woman with metastatic disease, and I feel, I become very anxious about being insensitive with someone who has metastatic.* [age 40-49 years; localized disease]

In contrast, 1 woman with metastatic disease really appreciated being included in groups with those with earlier-stage cancers and felt this was a much needed opportunity to break down barriers.

> *I really really appreciated that this app put people together that were both metastatic and early disease, but I’m involved in a cancer advocate program, and I chose the young advocate program because I really believe we need to break down barriers between early stage and late-stage people.* [age 40-49 years; metastatic disease]

This participant expressed that she was really pleased that women with metastatic cancer were being included in this research and that the app was designed for them as well as those with early stage disease.

> *I know there are women who have better response to their therapy who will probably – there are more and more women who are living 10-15 years with metastatic breast cancer and yet there’s a very little for us because the discourse is still meant assuming we’re all gonna be dead in two years, which of course many many women still are, but not all of us.* [age 40-49 years; metastatic disease]

Discussion

Summary of the Findings

This early phase user experience study found that an app-based intervention with peer and coach support was an acceptable and appealing method of self-management for women after breast cancer diagnosis. However, participants expressed that they would have found this most helpful early in their cancer journey because they had already instilled lifestyle habits after active cancer treatment, and their use of the app declined over the 4 weeks, implying that it became less useful to them over time. The areas in which they particularly wanted support were managing the side effects of their treatment and behaviors that would lead to weight loss. They mostly valued the “emotional” content when this was linked to their weight management behaviors and highlighted that they were looking for content that was more tailored to women with breast cancer and dealt with challenges specific to this group.

Comparison With Other Studies

Participants expressed a strong desire for weight management support. This may have been particularly prominent in this study because of their prior knowledge of Noom as a weight loss program. However, it is in line with previous work that has shown that weight gain after diagnosis is a source of concern in many women with breast cancer and that those living with and beyond cancer want to focus on their behaviors in order to play an active role in their health management [6,7,17,32]. In addition, weight gain, overweight, and obesity are associated with worse treatment side-effects and higher mortality after breast cancer diagnosis [33], so it is encouraging that the women we interviewed viewed an app-based intervention as an appealing method of accessing support with weight management. While the previous literature focuses mainly on early stage breast cancer, in our study, patients with metastatic disease also felt strongly that they desired weight or self-management programs and behavioral support. This reflects the changing landscape of treatment since patients with metastatic disease can live for many years; thus, future research should consider how to support those with metastatic disease to live as well as possible [34,35].

In this study, participants reported that they would have preferred the app content to be more tailored to the specific needs of those living with and beyond breast cancer, and the desire for tailoring in apps is consistent with other qualitative studies exploring app preferences [13,22,23]. This presents a challenge in terms of design and cost, and highlights the need to involve relevant cancer specialists in the design of apps intended for this population [16]. The strength of an app-based intervention is that it can successfully tailor a program to the end user, and further development of the program will consider how this could be incorporated. It is exceptionally challenging to develop dietary recommendations that not only encompass general healthy eating guidelines but also account for treatment side effects. However, app content could be continually updated to incorporate the newest evidence, and eventually, back-end data of dietary tracking from the cancer app could help inform tailoring algorithms.

In line with previous research, a recommendation to use the app from oncologists was considered to be most valued, and although health care professionals have reported a lack of confidence and time to provide health behavior support [13], they may feel able to recommend an app to participants that can provide what their patients are looking for. This would fit with reported views that the delivery of behavioral advice should be framed as part of treatment and must be cost-effective [9].

The overall style of the app was popular with participants. They particularly liked the tracking features and the one-to-one coaches. Self-monitoring is known to be an important tool in weight management [36], and there are many apps that can be used for this, but they vary in their usability [37]. Interacting with the one-to-one coaches gave participants a sense of accountability as they felt someone was monitoring whether they acted on their plans and goals. Previous work has also highlighted the importance of this component of interventions in this group [38].

Our previous work suggested that social support was a desired or important feature [13,23], and this was supported by most participants in this study. Discussion groups with other women living with and beyond breast cancer also provide accountability as well as social support, encouragement, and ideas for ways to manage thoughts and behaviors [36]. These were used more by some participants than others, but it was generally agreed to be a useful app feature. Some challenges of these groups were raised. These included a feeling of not being able to discuss perceived failures in weight management. This could be a feature of the particular group that these participants were in, but it does highlight that apps that use a group coach could include coaching that encourages the sharing of setbacks. Some of the participants with localized disease were concerned about sharing their feelings with women with metastatic disease because they felt it might be insensitive, but the women with metastatic disease really valued being included and felt that this was important. As some women with localized disease will go on to have metastatic disease, building relationships in this group would potentially be helpful; however, more work is needed to find ways to meet the needs of both groups of women.

Participants in this study felt that physical activity needed to be more prominent in the app as they were aware of the benefits that this can have. Increasing physical activity is something that women can do to improve their mental and physical health and is something that they can control at a time when things can feel out of control [39]. Participants seemed to be using the automatic adjustable step targets rather than setting their own targets and found these to be too low. This suggests that the option to overwrite this with your own targets needs to be highlighted in the app and that the starting point for automatic targets needs to be better individualized. Participants were happy to track their calories, and only one participant expressed concerns about the calorie target (the participant felt it was too high). It could be further explored whether app users should be able to adjust the calorie target or if coaches could do this for participants. The medication adherence feature was not used, but this might have been because these women already had systems in place to take their medications. As medication adherence can be suboptimal [40], more work is needed to see if this would be a helpful feature for those closer to their diagnosis when they were first taking their medications.

This study adds to previous work suggesting that there is interest in apps that support women with breast cancer [15-17] and highlights that what these women wanted most was help with weight management that is specifically tailored to the breast cancer experience. The themes identified could be used to develop this intervention to better fit these needs and to inform other interventions for this population, as user feedback is an essential component in intervention development [16].

There are however some limitations of this study. In particular, this was a small sample of predominantly white, married, and employed women who were interested in trying out this app, and therefore, the findings may not be transferrable to women from other sociodemographic groups. Findings related to the views of patients with metastatic cancer are potentially important. However, only 2 participants in our sample had metastatic disease; thus, more work investigating the views of this group is crucial. The interviews were conducted by a member of Noom, which could have introduced some bias. However, participants were made aware that this was a very early prototype and that we wanted to understand positive and negative views in order to make changes before further development (and many suggestions for changes were indeed made in interviews). This work was conducted as an industry-academic partnership. This benefitted both sides of the partnership. The industry team benefitted from the expertise of the academics in conducting rigorous high-quality research. The academics benefitted from the opportunity to understand user experiences of a high-quality app, with a higher likelihood of this research being taken forward than when working independently of the industry.

Conclusion

This early user experience work showed that women with breast cancer found an app with integrated social and psychological support appealing to receive support for behavior change and weight management or self-management. However, many features were recommended for further development. This work is the first step in an academic-industry collaboration that would ultimately aim to develop and empirically test a supportive app that could be integrated into the cancer care pathway. Although further work is required, the results suggest that this approach has the potential to make an important contribution to cancer care for this group.

Authors' Contributions

Conceptualization – All authors
Formal analysis – PL, AF
Investigation – MM
Methodology – PL, AF
Project administration – CNM, ESM, AM, MM
Resources – AF
Writing – original draft – PL, AF
Writing – review & editing – All authors

Conflicts of Interest

PL and AF had consultancy time paid by Noom Inc. for working on this project. CM, ESM, MM and AM are, or were previously, employees of NOOM Inc.

Multimedia Appendix 1

Interview schedule.
[PDF File (Adobe PDF File), 53 KB - cancer_v10i1e48170_app1.pdf]

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Abbreviations

HHC: Healthy Habits after Cancer

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Original Paper

Engagement With Daily Symptom Reporting, Passive Smartphone Sensing, and Wearable Device Data Collection During Chemotherapy: Longitudinal Observational Study

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Abstract

Background: Chemotherapy can cause symptoms that impair quality of life and functioning. Remote monitoring of daily symptoms and activity during outpatient treatment may enable earlier detection and management of emerging toxicities but requires patients, including older and acutely ill patients, to engage with technology to report symptoms through smartphones and to charge and wear mobile devices.

Objective: This study aimed to identify factors associated with participant engagement with collecting 3 data streams (ie, daily patient-reported symptom surveys, passive smartphone sensing, and a wearable Fitbit device [Google]) during chemotherapy.

Methods: We enrolled 162 patients receiving outpatient chemotherapy into a 90-day prospective study. Patients were asked to install apps on their smartphones to rate daily symptoms and to collect passive sensor data and to wear a Fitbit device for the duration of the study. Participants completed baseline demographic and quality of life questionnaires, and clinical information was extracted from the electronic medical record. We fit a series of logistic generalized estimating equations to evaluate the association between demographic and clinical factors and daily engagement with each data stream.

Results: Participants completed daily surveys on 61% (SD 27%) of days and collected sufficient smartphone data and wearable sensor data on 73% (SD 35%) and 70% (SD 33%) of enrolled days, respectively, on average. Relative to White participants, non-White patients demonstrated lower odds of engagement with both symptom surveys (odds ratio [OR] 0.49, 95% CI 0.29-0.81; *P*=.006) and wearable data collection (OR 0.35, 95% CI 0.17-0.73; *P*=.005). Patients with stage 4 cancer also exhibited lower odds of engagement with symptom reporting than those with earlier stage disease (OR 0.69, 95% CI 0.48-1.00; *P*=.048), and patients were less likely to complete symptom ratings on the weekend (OR 0.90, 95% CI 0.83-0.97; *P*=.008). Older patients (OR 1.03, 95% CI 1.01-1.06; *P*=.01) and those who reported better cognitive functioning at study entry (OR 1.18, 95% CI 1.03-1.34; *P*=.02) were more likely to engage with Fitbit data collection, and patients who reported higher levels of depressive symptoms were less likely to engage with smartphone data collection (OR 1.18, 95% CI 1.03-1.36; *P*=.02).

Conclusions: Remote patient monitoring during chemotherapy has the potential to improve clinical management, but only if patients engage with these systems. Our results suggest significant associations between demographic and clinical factors and long-term engagement with smartphone and wearable device assessments during chemotherapy. Non-White participants, those with metastatic cancer, or those with existing cognitive impairment may benefit from additional resources to optimize engagement. Contrary to hypotheses, older adults were more likely than younger adults to engage consistently with wearable device assessments.

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KEYWORDS

cancer; chemotherapy; remote monitoring; mobile health; wearable device; mobile phone; oncology; metastases; chemo; mHealth; mobile application; digital health; digital intervention

Introduction

Patients with cancer undergoing chemotherapy often experience numerous adverse effects, including fatigue, nausea and vomiting, peripheral neuropathies, and more [1]. These symptoms can have a significant negative impact on the patient's quality of life and can lead to early discontinuation or reduction of treatment.

Growing evidence suggests that patients who used symptom-reporting software during chemotherapy continued their treatment for longer, required fewer hospital admissions, and survived longer than those who were not randomized to report symptoms [2-4]. Symptom monitoring systems associated with improved clinical outcomes use patient-generated data to trigger alerts to clinicians and to enable the treating oncology team to manage symptoms earlier. To achieve these potential benefits, patients, including those who are older, acutely ill, or with low digital or health literacy, must engage with technological systems to report symptoms and provide other patient-generated health data for remote monitoring purposes. This paper's goal is to characterize patient engagement with a system aimed at capturing daily patient-reported symptoms and continuous wearable and smartphone sensor data during chemotherapy.

Smartphones and other technologies provide a unique opportunity for remote patient monitoring as they allow patients to record their symptoms and other patient-reported outcomes quickly and easily. Clinicians can benefit from patients electronically recording and sharing their symptoms, as they can use this information to track their patient's symptom progression and identify concerning symptoms in real time. Several studies have investigated patient adherence to daily or weekly symptom surveys on the patient's smartphone or by email [5-9]. Typical adherence rates in the literature have varied depending on the technology used, the frequency and duration of assessments, how adherence is defined, and whether participants were given reminders to answer symptom surveys. A systematic review of 33 different electronic symptom self-reporting systems reported response rates ranging from 45% to 92% [5].

Wearable devices such as Fitbits (Google) and other activity monitors as well as passive data from smartphones may also be useful for patient monitoring, as they allow for the continuous collection of physiological and behavioral data related to sleep, activity, geographic mobility, and more. These data may also be helpful to clinicians, as studies have shown a correlation between lower step counts and negative patient outcomes including greater symptom burden, lower quality of life and performance status, and worse clinical outcomes among oncology patients [10-12]. The growing literature in this area suggests that patient adherence to wearable data collection during cancer treatment has been relatively robust [13,14]. A systematic review of 38 studies that investigated adherence of patients with cancer to wearable devices reported adherence rates ranging from 60%-100% [14]. Collecting data from a wearable device may require less active involvement from participants but requires the participant to keep the device charged, wear it consistently and correctly, and sync the wearable to an internet-connected device. Indeed, there is evidence that patient adherence to wearable devices may be limited when the patient is not given reminders to wear and sync the device [15]. Other barriers to wearable device data collection reported in the literature include limited technical literacy and limited access to a reliable internet connection [16]. Passive smartphone sensor data collection is less common, and to our knowledge, no studies to date have examined patient adherence to passive smartphone sensing during chemotherapy. In addition, there has been little research done on the sociodemographic and medical factors that affect a participant's engagement with these technology-based monitoring systems during cancer treatment.

The objective of this study was to identify factors that impacted participant engagement with collecting 3 data streams over 90 days during chemotherapy, that is, daily patient-reported symptom surveys, passive smartphone sensing, and a wearable Fitbit device.

Methods

Participants

Potential study participants were identified for the study by their medical oncology care team. Men and women aged 18 years or older who were undergoing chemotherapy for any solid tumor at a large academic cancer center, who owned a smartphone, who could read and write in English, and who had at least 2 chemotherapy cycles remaining were eligible to participate. In addition, 7 participants were recruited from a community research registry, and these participants were asked to self-report on if they met the above eligibility criteria.

Ethical Considerations

The institutional review board of the University of Pittsburgh reviewed and approved all study activities (study 19070011). The study team conducted informed consent by explaining each study app, what specific data passive sensors would collect, how the data from the Fitbit and mobile apps would be used for the purpose of the study, how information was deidentified, potential risks, and asking participants for permission to install each study app on their phone. All data were stored in secure locations and identified only by anonymized study ID numbers. Participants were compensated US $100 and given the option to keep the Fitbit (approximate value US $100) upon completion of the study.

Study Procedure

First, participants had the MoSHI Surveys app (Carissa Low) installed on their smartphones; this free commercially available app was developed by our research team and is used to configure notifications to remind study participants to complete web-based surveys. This app delivered a daily and weekly (weekly data not reported) symptom survey. We focused on daily symptom surveys given that daily symptom assessments are more burdensome to participants but also potentially beneficial for capturing rapidly developing symptoms sooner [17]. The daily survey asked about symptoms experienced in the past 24 hours, was based on the National Cancer Institute's Patient Reported

Outcome-Common Terminology Criteria for Adverse Events [18], and included the following symptoms, selected to represent common side effects of cytotoxic chemotherapy: nausea, vomiting, decreased appetite, abdominal pain, constipation, diarrhea, shortness of breath, insomnia, fatigue, rash, dizziness, numbness or tingling in hands or feet, anxiety, sad or unhappy feelings, and "other symptoms." Participants were able to set times for daily notifications to remind them to complete the surveys. These notifications would occur once a day at the set time, and alert sounds and other settings were determined by the participant's notification settings for their phone.

The AWARE app (developed by Denzil Ferreira and Yuuki Nishiyama) [19], another free and commercially available app developed by our research collaborators, was also installed on participants' Android (Google) or iOS (Apple Inc) smartphones. AWARE runs in the background to record information about movement and location of the phone, screen on and off events, nearby Bluetooth devices and Wi-Fi networks, and metadata about calls and SMS text messages exchanged using the smartphone. Participants were asked to keep the app open and running in the background of their phones for the duration of the study. Finally, participants were provided with a Fitbit Inspire device that recorded the patient's activity, heart rate, and sleep patterns, and the Fitbit app was installed on their smartphone to enable frequent syncing with the wearable device and upload of data to our research server. Participants were asked to wear the Fitbit at all times except when charging (approximately every 10 days). After installation and setup, a study team member taught each participant how to use all study apps and Fitbit (ie, how to change notification settings, sync their Fitbit device with their phone, view data, and so on).

Data were collected from each participant for 3 months. Incoming data quality was monitored with a secure web-based study dashboard throughout the study. The study dashboard had a column for each of the data sources, and a flag would appear after 3 consecutive days without data from a participant. This dashboard was reviewed at least 3 times a week by study team members. Generally, the participant would be contacted through phone, text, email, or in person according to their preferred method of communication and treatment schedule. If the flag remained for over a week, the participant would be called or visited in person at their next treatment. If the participant did not respond after 3 contacts, we would continue to attempt to reach out every 1 to 2 weeks if the flag remained. All communication with the participants was logged in a record of communication containing pertinent notes that all study team members had access to and updated. There was some subjective judgment around when or if a participant was contacted based on notes from previous contacts (eg, if participants were very sick, if they were receiving surgery, and if they were hospitalized).

At baseline, participants completed a demographic questionnaire as well as the Patient-Reported Outcomes Measurement Information System Profile (PROMIS-29+2 v2.1). Information about participants' cancer and its treatment was extracted from the electronic medical record (EMR).

Measures

Demographics

Demographic variables were self-reported by participants in a baseline questionnaire and included age (in years), gender or sex (male, female, and non-binary), race (White or Caucasian, Black or African American, Asian, other, more than 1 race), highest level of education (less than a high-school diploma, high-school diploma or equivalent, some college but no degree, Associates of arts or other 2-year degree, Bachelor's degree, and Graduate degree). Residential zip code was used to classify participants as rural (yes or no) based on eligible zip code data from the Federal Office of Rural Health Policy [20]. Smartphone model information was recorded by the study team and verified against data collected by AWARE. Phone type was categorized as iOS if the device brand was "iPhone" (Apple Inc) and as Android otherwise.

Clinical

Insurance plan type was extracted from the EMR in June 2023 and categorized by the study team as public; private; mixed public, private, or other; or none, if no insurance was listed. Because we were unable to determine if a lack of available insurance information was due to the participant not having insurance coverage, removal of insurance information from the system upon death, or another reason, we subsequently chose to treat no insurance listed as missing. Cancer type (biliary, bone, breast, gastrointestinal tract, gynecologic, liver, lung, multiple myeloma, pancreas, salivary gland, and urogenital), stage (0, 1, 2, 3, and 4), and diagnosis date were extracted from the EMR at enrollment. For consistency, the cancer diagnosis date was defined as the date listed beside the cancer type in the participant's outpatient progress notes. Time in days since cancer diagnosis at enrollment was calculated by subtracting the cancer diagnosis date from the study enrollment date and was rescaled to time in months for interpretability of analyses.

Quality of Life

To assess quality of life, participants completed the PROMIS Profile 29+2 v2.1 [21] as part of the baseline questionnaire. From each participant's item-level responses, we obtained domain-level theta values from the HealthMeasures Scoring Service [22] and used these values to generate PROMIS preference-based scores [23]. Theta values from the pain interference, cognitive function, depression or sadness, ability to participate in social roles or activities, anxiety or fear, fatigue, physical function, and sleep disturbance domains were used to compute one overall ("PROPr [PROMIS-Preference scoring system]") and 7 domain-specific preference-based scores. Possible scores range from 0 (reflecting death) to 1 (reflecting full health).

Time-Related

Time-varying, day-level variables included an index for study day (with 0 corresponding to the date of enrollment), an indicator for weekday or weekend days, and the time in days since the participant's last known chemotherapy treatment. Dates on which the participant received chemotherapy treatment were extracted from the EMR where available. For each day for each participant, we computed the number of days that had elapsed since the participant's last known chemotherapy treatment as the difference in days between the study day date and the most recent previous treatment date; the value of this variable was 0 on treatment days and was missing on days before the participant's first known treatment day.

Daily Symptom Survey Completion

To evaluate associations between demographic, clinical, quality of life, and time-related factors, and adherence to daily surveys, we created a day-level, binary outcome variable reflecting daily symptom survey completion. For each day for each participant, adherence to daily symptom survey completion was defined as the presence of a recorded survey response that was started at any time on the given day and was at least 50% complete. This threshold was selected based on the literature [24,25].

Smartphone and Fitbit Data Collection

To evaluate associations between demographic, clinical, quality of life, and time-related factors and adherence to smartphone and Fitbit data collection, we created separate day-level, binary outcome variables reflecting the presence of at least 8 valid hours of phone or Fitbit data, respectively. This threshold was also based on the literature as well as our previous work [26-28]. We first used our Reproducible Analysis Pipeline for Data Streams (RAPIDS) [29] to extract day-level (24 hours from midnight to midnight) phone and Fitbit data yield features for each participant. Data yield features approximate the proportion of each day during which the device was sensing data from any of the specified sensors. For each day for each participant, adherence to phone data collection was defined as at least 8 valid hours of data from any AWARE sensor (activity recognition, app crashes, apps foreground, apps notifications, battery, Bluetooth, calls, keyboard, light, locations, SMS text messages, screen, Wi-Fi–connected, and Wi-Fi–visible), and adherence to Fitbit data collection was defined as at least 8 valid hours of Fitbit intraday heart rate data. Valid hours were defined as 60-minute windows in which at least 1 row of raw data from any of the specified sensors was recorded in at least 30 of those minutes.

Statistical Analysis

We first computed descriptive statistics of demographic, clinical, quality of life, and time-related measures to characterize our sample. For continuous variables, Wilcoxon rank sum tests, and for categorical variables, chi-square or Fisher exact tests were used to determine if these measures significantly differed between participants who completed the full study protocol and those who withdrew early. In addition, to characterize overall adherence in our sample, for each participant, we calculated the proportions of days with adherence to daily symptom survey completion, smartphone data collection, and Fitbit data collection as the ratio between the respective number of adherent days and the number of days the participant was enrolled in the study and computed descriptive statistics. For statistical models, we evaluated the day-level, binary outcomes.

For interpretability of analyses, age was centered at the mean age of the sample. Due to low frequencies of some categories, nonbinary gender was treated as missing, and race and highest level of education were collapsed into binary variables (respectively, White or Caucasian, not White or Caucasian; less than a college degree, college degree or higher). In addition, cancer types with frequency <10 were collapsed into a single other category, and the cancer stage was collapsed into a binary variable representing stage 4 cancer (yes or no). Baseline PROMIS preference-based scores were rescaled for interpretability by multiplying each score by 10.

To evaluate the associations between demographic, quality of life, clinical, and time-related factors and daily adherence to daily survey completion and smartphone and Fitbit data collection, we first fit a series of univariable logistic generalized estimating equations (GEE) [30] using the geepack package for R (v1.3.9; R Core Team) [31], with each binary, day-level outcome as the dependent variable and, separately, each factor as the independent variable. Due to a small proportion of missing values for some predictors, we analyzed model-wise complete cases. Because phone data yield was systematically lower among participants using Android devices compared with those using iOS devices due to differences in sensor data sampling frequencies across platforms, all models for the phone data yield outcome were additionally adjusted for phone type. GEE is a method for modeling clustered data, such as those from a longitudinal study, where observations within a cluster (ie, participants) are correlated. Either an exchangeable or first-order autoregressive (ar1) working correlation structure was selected by minimizing the quasi-information criterion (QIC). Robust SEs for parameter estimates were obtained using the sandwich estimator. Estimates were exponentiated to obtain odds ratios (OR) and 95% CIs. Because likelihood-based methods are not available for GEE, we used a series of Wald tests to conduct single- and multi-parameter inference. We accounted for multiple comparisons for each outcome by controlling for the false discovery rate [32] when evaluating global predictor effects across univariable models (Q values). An α level of .05 was used as a strict cutoff for determining statistical significance.

Finally, for each outcome, we fit a single multivariable GEE containing a purposefully selected subset of predictors which were determined a priori. For the sufficient Fitbit data yield outcome, we defaulted to an independent working correlation structure because unstable and extreme parameter estimates were obtained under both exchangeable and ar1 correlation structures; an ar1 correlation structure was selected for all other outcomes based on QIC, with the exception of an exchangeable working correlation structure for the sufficient phone data yield outcome.

All analyses were performed using R (v4.2.3) [33]. All code for data management and analysis is available on GitHub [34].

Results

Participant Characteristics

Of the 320 potential participants approached about the study through March 8, 2023, a total of 167 (52.2%) participants enrolled. Reasons for not participating in the study included concerns about technology, feeling overwhelmed, being too busy, not feeling well, and not being interested. Data collection for this prospective cohort study is ongoing; this analysis focuses on 162 patients who had completed (146/162, 90.1%) or withdrawn from (16/162, 9.9%) the 90-day study protocol between March 2020 and June 2023. Participant characteristics are summarized in Table 1. Participants were aged 59.47 (SD 11.84, range 28-92) years on average, and were mostly female (101/162, 62.3%), White or Caucasian (135/162, 83.3%), had obtained a bachelor's degree (42/162, 25.9%), did not live in a rural zip code (145/162, 89.5%), and used an iOS smartphone (98/162, 60.5%). Most participants had a private insurance plan (79/162, 48.8%), gastrointestinal tract cancer (57/162, 35.2%), stage 4 cancer (103/162, 63.6%), and enrolled in the study 10.88 (SD 22.01, range 0-124) months after their cancer diagnosis, on average. Furthermore, 1 participant enrolled through the community research registry was diagnosed with multiple myeloma rather than a solid tumor. With the exception of insurance plan type (*P*=.02), participant characteristics did not significantly differ between participants who completed the study and those who withdrew early (all *P*>.08). Participants were enrolled in the study for a grand total of 13,954 days, with an average of 86 (SD 17, range 8-92) days per participant. Day-level characteristics are summarized in Table 2.

Table 1. Participant characteristics.

Characteristic	Study completion status			
	Overall, N=162	Completed, n=146	Withdrawn, n=16	*P* value[a]
Age (years), mean (SD)	59.47 (11.84)	59.97 (11.90)	54.94 (10.54)	.11
Sex, n (%)				.09
Female	101 (62.3)	87 (59.6)	14 (88)	
Male	60 (37.0)	58 (39.7)	2 (13)	
Nonbinary	1 (0.6)	1 (0.7)	0 (0)	
Race, n (%)				.71
White or Caucasian	135 (83.3)	122 (83.6)	13 (81)	
Black or African American	21 (13)	18 (12.3)	3 (19)	
Asian	1 (0.6)	1 (0.7)	0 (0)	
Other	2 (1.2)	2 (1.4)	0 (0)	
More than 1 race	3 (1.9)	3 (2.1)	0 (0%)	
Ethnicity, n (%)				.34
Non-Hispanic	158 (97.5)	143 (97.9)	15 (94)	
Hispanic	1 (0.6)	1 (0.7)	0 (0.0)	
Unknown	3 (1.9)	2 (1.4)	1 (6)	
Education, n (%)				.09
Less than a high-school diploma	2 (1.2)	1 (0.7)	1 (6)	
High-school diploma or equivalent	32 (19.8)	30 (20.5)	2 (13)	
Some college but no degree	32 (19.8)	28 (19.2)	4 (25)	
Associate of arts or other 2-year degree	15 (9.3)	13 (8.9)	2 (13)	
Bachelor’s degree	42 (25.9)	37 (25.3)	5 (31)	
Graduate degree	37 (22.8)	36 (24.7)	1 (6)	
Unknown	2 (1.2)	1 (0.7)	1 (6)	
Rural zip code, n (%)				.38
No	145 (89.5)	132 (90.4)	13 (81)	
Yes	17 (10.5)	14 (9.6)	3 (19)	
Phone type, n (%)				.71
iPhone	98 (60.5)	89 (61)	9 (56)	
Android	64 (39.5)	57 (39)	7 (44)	
Baseline PROMIS[b] preference score, mean (SD)[c]				
PROPr[d]	0.43 (0.23)	0.43 (0.23)	0.38 (0.19)	.51
Cognition	0.83 (0.20)	0.83 (0.20)	0.85 (0.13)	>.99
Depression	0.88 (0.15)	0.89 (0.13)	0.80 (0.28)	.26
Fatigue	0.77 (0.15)	0.76 (0.15)	0.79 (0.12)	.57
Pain	0.85 (0.21)	0.85 (0.21)	0.82 (0.16)	.23
Physical	0.76 (0.18)	0.76 (0.18)	0.77 (0.18)	.63
Sleep	0.77 (0.16)	0.77 (0.16)	0.76 (0.13)	.56
Social	0.79 (0.18)	0.79 (0.18)	0.78 (0.17)	.55
Insurance plan type, n (%)				.02
Private	79 (48.8)	68 (46.6)	11 (69)	

Characteristic	Study completion status			P value[a]
	Overall, N=162	Completed, n=146	Withdrawn, n=16	
Public	51 (31.5)	49 (33.6)	2 (13)	
Mixed	21 (13)	21 (14.4)	0 (0)	
Unknown	11 (6.8)	8 (5.5)	3 (19)	
Cancer type, n (%)				.67
Biliary	7 (4.3)	7 (4.8)	0 (0)	
Bone	1 (0.6)	1 (0.7)	0 (0)	
Breast	24 (14.8)	23 (15.8)	1 (6)	
Gastrointestinal tract	57 (35.2)	49 (33.6)	8 (50)	
Gynecologic	9 (5.6)	7 (4.8)	2 (13)	
Liver	2 (1.2)	2 (1.4)	0 (0)	
Lung	6 (3.7)	6 (4.1)	0 (0)	
Multiple myeloma	1 (0.6)	1 (0.7)	0 (0)	
Pancreas	40 (24.7)	35 (24)	5 (31)	
Salivary gland	1 (0.6)	1 (0.7)	0 (0)	
Urogenital	14 (8.6)	14 (9.6)	0 (0)	
Cancer stage, n (%)				.81
0	1 (0.6)	1 (0.7)	0 (0)	
1	10 (6.2)	10 (6.8)	0 (0)	
2	25 (15.4)	23 (15.8)	2 (13)	
3	20 (12.3)	19 (13)	1 (6)	
4	103 (63.6)	90 (61.6)	13 (81)	
Unknown	3 (1.9)	3 (2.1)	0 (0)	
Time since diagnosis (months), mean (SD)	10.88 (22.01)	11.69 (23.00)	3.50 (4.62)	.15

[a] Wilcoxon rank sum test; Fisher exact test; Pearson chi-square test.

[b] PROMIS: Patient-Reported Outcomes Measurement Information System.

[c] Data missing for 3/162 participants (1.8%).

[d] PROPr: PROMIS-Preference scoring system.

Table 2. Day-level characteristics.

Characteristic	N=13,954
Study day, mean (SD), (range)	44.18 (26.28), (0-91)
Weekend, n (%)	
No	9976 (71.49)
Yes	3978 (28.51)
Time since last chemotherapy (days), mean (SD), (range)[a]	11.21 (12.04), (0-90)

[a] Data missing for 1257/13954 days (9.01%).

Overall Adherence

Across participants, 41.7% (5816/13,954) of days had valid data from all 3 data streams; 33.6% (4694/13,954) had valid data from 2 data streams (1090/4694, 23.2% daily survey and smartphone, 1417/4694, 30.2% daily survey and Fitbit, and 2187/4694, 46.6% smartphone and Fitbit), 17.1% (2391/13,954) had valid data from a single data stream (449/2391, 18.8% daily survey only, 1257/2391, 52.6% smartphone only, and 685/2391, 28.6% Fitbit only), and 7.6% (1053/13,954) had valid data from no data streams. Overall adherence was higher for passive smartphone and Fitbit data streams than for patient-reported daily symptom surveys (Table 3). On average, participants were adherent to daily survey completion on 60.96% (SD 27.24%, range 0%-100%), smartphone data collection on 73.06% (SD

34.94%, range 0%-100%), and Fitbit data collection on 70.07% of enrolled days (SD 33.45%, range 0%-100%).

Table 3. Descriptive statistics of overall adherence.

Outcome	N=162, mean (SD), (range)[a]
Daily survey adherence	60.96 (27.24), (0-100)
Smartphone adherence	73.06 (34.94), (0-100)
Fitbit adherence	70.07 (33.45), (0-100)

[a] Percent of enrolled days per participant.

On average, participants included in analyses were contacted 3.67 times throughout the duration of the study with a range of 0-12 contacts per participant and the majority of contacts taking place over text. No participants had to be withdrawn due to complete noncompliance.

Univariable Models

Results of the univariable models characterizing associations between each demographic, quality of life, clinical, and time-related factor and daily adherence to daily survey completion and smartphone and Fitbit data collection are summarized in Table 4.

Table 4. Summary of results of univariable generalized estimating equations.

Predictor[a]	N	Daily survey adherence			Smartphone adherence			Fitbit adherence		
		OR (95% CI)[b]	*P* value[c]	*Q* value[d]	OR (95% CI)[b]	*P* value[c]	*Q* value[d]	OR (95% CI)[b]	*P* value[c]	*Q* value[d]
Age (years, centered at mean)	13,954	1.01 (0.99-1.02)	.34	.51	1.00 (0.97-1.02)	.81	.94	1.02 (1.00-1.05)	.03	.13
Sex	13,863	—[e]	.55	.67	—	.32	.51	—	.92	.95
Female	8485	Reference	—	—	Reference	—	—	Reference	—	—
Male	5378	0.89 (0.62-1.29)	.55	—	1.35 (0.75-2.42)	.32	—	1.03 (0.62-1.71)	.92	—
Race (collapsed)	13,954	—	.004	.02	—	.91	.94	—	.002	.02
White or Caucasian	11,631	Reference	—	—	Reference	—	—	Reference	—	—
Not White or Caucasian	2323	0.48 (0.29-0.80)	.004	—	1.04 (0.54-2.00)	.91	—	0.36 (0.19-0.68)	.002	—
Education (collapsed)	13,820	—	.41	.54	—	.57	.75	—	.15	.39
College degree or higher	6883	Reference	—	—	Reference	—	—	Reference	—	—
Less than college degree	6937	0.86 (0.61-1.22)	.41	—	0.85 (0.49-1.48)	.57	—	0.70 (0.43-1.14)	.15	—
Rural zip code	13,954	—	.80	.88	—	.94	.94	—	.88	.95
No	12,510	Reference	—	—	Reference	—	—	Reference	—	—
Yes	1444	1.08 (0.61-1.92)	.80	—	1.02 (0.60-1.73)	.94	—	0.94 (0.45-2.00)	.88	—
Phone type	13,954	—	.85	.89	—	<.001	<.001	—	.10	.30
iPhone	8433	Reference	—	—	Reference	—	—	Reference	—	—
Android	5521	0.96 (0.66-1.40)	.85	—	0.07 (0.04-0.12)	<.001	—	0.65 (0.40-1.08)	.10	—
Baseline PROMIS[f], PROPr[g]	13,756	1.08 (1.00-1.17)	.06	.25	1.07 (0.95-1.21)	.28	.49	1.06 (0.94-1.19)	.35	.58
Baseline PROMIS, cognition	13,756	0.98 (0.89-1.06)	.57	.67	0.92 (0.81-1.04)	.18	.49	1.14 (1.00-1.31)	.05	.19
Baseline PROMIS, depression	13,756	1.06 (0.96-1.16)	.25	.41	1.14 (1.00-1.29)	.046	.32	1.11 (0.94-1.31)	.21	.44
Baseline PROMIS, fatigue	13,756	1.07 (0.96-1.19)	.24	.41	1.11 (0.95-1.30)	.19	.49	1.08 (0.91-1.28)	.40	.59
Baseline PROMIS, pain	13,756	1.07 (0.99-1.17)	.10	.34	1.11 (0.98-1.25)	.09	.49	1.06 (0.95-1.19)	.31	.58
Baseline PROMIS, physical	13,756	1.06 (0.96-1.16)	.25	.41	1.09 (0.94-1.26)	.27	.49	1.00 (0.88-1.15)	.95	.95
Baseline PROMIS, sleep	13,756	1.07 (0.97-1.19)	.19	.41	1.04 (0.91-1.20)	.55	.75	0.97 (0.86-1.11)	.70	.86
Baseline PROMIS, social	13,756	1.04 (0.95-1.13)	.41	.54	1.08 (0.92-1.26)	.38	.57	0.94 (0.83-1.07)	.36	.58
Insurance plan type	13,063	—	.94	.94	—	.19	.49	—	.76	.88
Private	6621	Reference	—	—	Reference	—	—	Reference	—	—
Mixed	1911	0.98 (0.63-1.53)	.94	—	0.55 (0.28-1.08)	.08	—	1.15 (0.51-2.62)	.73	—

Predictor[a]	N	Daily survey adherence			Smartphone adherence			Fitbit adherence		
		OR (95% CI)[b]	*P* value[c]	*Q* value[d]	OR (95% CI)[b]	*P* value[c]	*Q* value[d]	OR (95% CI)[b]	*P* value[c]	*Q* value[d]
Public	4531	0.93 (0.64-1.36)	.73	—	0.70 (0.37-1.33)	.28	—	1.23 (0.70-2.17)	.47	—
Cancer type (collapsed)	13,954	—	.11	.34	—	.69	.85	—	.66	.86
Gastrointestinal tract	4810	Reference	—	—	Reference	—	—	Reference	—	—
Pancreas	3313	0.69 (0.46-1.04)	.08	—	0.75 (0.33-1.72)	.50	—	1.24 (0.65-2.36)	.51	—
Breast	2158	1.25 (0.81-1.94)	.31	—	0.74 (0.36-1.52)	.41	—	1.54 (0.70-3.37)	.28	—
Urogenital	1275	1.09 (0.59-2.03)	.78	—	0.48 (0.17-1.31)	.15	—	0.92 (0.37-2.32)	.87	—
Other	2398	1.20 (0.74-1.95)	.45	—	0.76 (0.39-1.48)	.42	—	1.54 (0.75-3.15)	.24	—
Cancer stage 4	13,681	—	.25	.41	—	.91	.94	—	.52	.72
No	4959	Reference	—	—	Reference	—	—	Reference	—	—
Yes	8722	0.81 (0.56-1.16)	.25	—	1.03 (0.62-1.72)	.91	—	0.84 (0.51-1.41)	.52	—
Time since cancer diagnosis (months)	13,954	1.01 (1.00-1.01)	.18	.41	1.01 (0.99-1.02)	.23	.49	1.01 (1.00-1.02)	.21	.44
Study day	13,954	0.99 (0.99-0.99)	<.001	<.001	1.00 (0.99-1.00)	.27	.49	1.00 (0.99-1.00)	.03	.13
Weekend	13,954	—	<.001	.002	—	.20	.49	—	.007	.05
No	9976	Reference	—	—	Reference	—	—	Reference	—	—
Yes	3978	0.89 (0.84-0.95)	<.001	—	0.94 (0.86-1.03)	.20	—	0.93 (0.89-0.98)	.007	—
Time since last chemotherapy (days)	12,697	0.99 (0.98-0.99)	<.001	<.001	0.98 (0.97-1.00)	.02	.22	0.99 (0.98-0.99)	<.001	.002

[a] For smartphone adherence outcome, adjusted for phone type.

[b] OR: odds ratio.

[c] Unadjusted Wald test *P* value for single- or multi-parameter inference.

[d] Adjusted global Wald test *P* value, corrected for multiple comparisons.

[e] Not applicable.

[f] PROMIS: Patient-Reported Outcomes Measurement Information System.

[g] PROPr: PROMIS-Preference scoring system.

For the daily survey adherence outcome, there were statistically significant effects of race, weekends, time in the study, and time since last chemotherapy treatment. The odds of completing a daily survey were significantly lower for non-White or non-Caucasian participants relative to White or Caucasian participants (OR 0.48, 95% CI 0.29-0.80; *P*=.004), on weekend days relative to weekday days (OR 0.89, 95% CI 0.84-0.95; *P*<.001), with each additional day in the study following enrollment (OR 0.99, 95% CI 0.99-0.99; *P*<.001), and with each additional day since the participant's last chemotherapy treatment (OR 0.99, 95% CI 0.98-0.99; *P*<.001).

For the smartphone adherence outcome, there were statistically significant effects of baseline depression and time since last chemotherapy treatment, after adjusting for phone type. Each 10 percentage-point increase (ie, an increase of 0.1) in baseline PROMIS preference depression subscale score, reflecting less depression, was associated with higher odds of adherence (OR 1.14, 95% CI 1.00-1.29; *P*=.046), while each additional day since the participant's last chemotherapy treatment was associated with lower odds of adherence to smartphone data collection (OR 0.98, 95% CI 0.97-1.00; *P*=.02). These effects did not survive correction for multiple comparisons (baseline depression *Q*=.32, time since last chemotherapy treatment *Q*=.22).

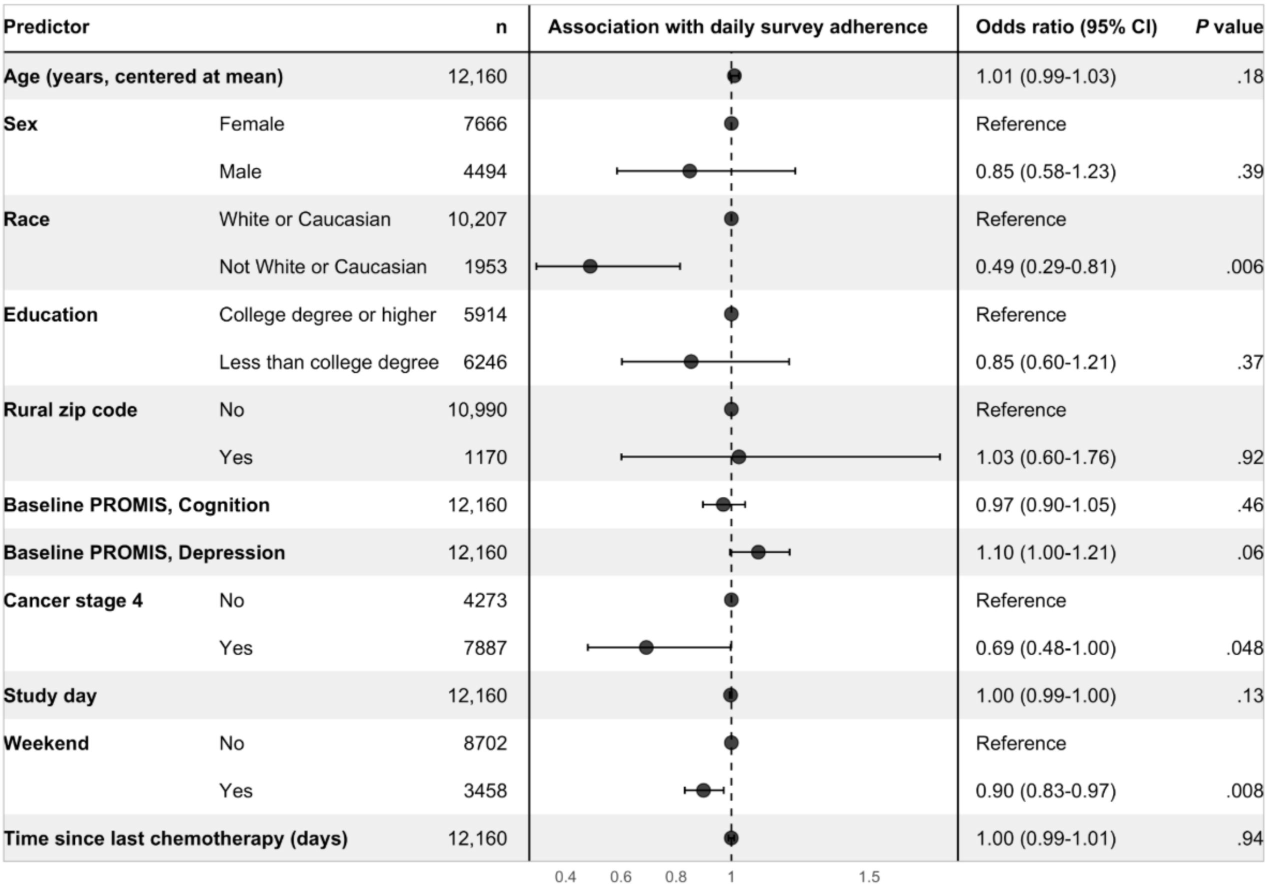
For the Fitbit adherence outcome, there were statistically significant effects of age, race, weekends, time in the study, and time since last chemotherapy treatment. Odds of adherence to Fitbit data collection increased with each additional year of age relative to the mean age of the sample (OR 1.02, 95% CI 1.00-1.05; *P*=.03). Odds of adherence to Fitbit data collection were significantly lower for non-White or non-Caucasian participants relative to White or Caucasian participants (OR 0.36, 95% CI 0.19-0.68; *P*=.002), on weekend days relative to weekday days (OR 0.93, 95% CI 0.89-0.98; *P*=.007), with each additional day in the study following enrollment (OR 1.00, 95% CI 0.99-1.00; *P*=.03), and with each additional day since the participant's last chemotherapy treatment (OR 0.99, 95% CI 0.98-0.99; *P*<.001). Effects of age (*Q*=.13), weekends (*Q*=.05), and time in the study (*Q*=.13) did not survive correction for multiple comparisons.

Multivariable Models

To determine how a purposeful subset of these predictors were together associated with adherence, we fit a single multivariable GEE, separately for each data stream. Predictors chosen a priori included (1) age; (2) gender; (3) race; (4) education; (5) rural zip code; (6) baseline PROMIS preference scores, cognition and depression subscales; (7) stage 4 cancer; (8) study day; (9) weekends; and (10) time since last chemotherapy. As with the univariable models, we additionally adjusted for phone type in the model for the smartphone data collection adherence outcome only.

Results of the multivariable models were generally consistent with those of the univariable models. For the daily survey adherence outcome (Figure 1), we again found that, adjusting for other predictors in the model, non-White or non-Caucasian participants were less likely to complete a daily survey relative to White or Caucasian participants (OR 0.49, 95% CI 0.29-0.81; *P*=.006), and participants were less likely to complete surveys on weekend days relative to weekday days (OR 0.90, 95% CI 0.83-0.97; *P*=.008). In addition, participants with stage 4 cancer were significantly less likely to be adherent to daily survey completion relative to participants with cancer in stages 0-3 (OR 0.69, 95% CI 0.48-1.00; *P*=.048). Controlling for the other predictors in the model, time in the study and time since last chemotherapy treatment were no longer significantly associated with daily survey adherence.

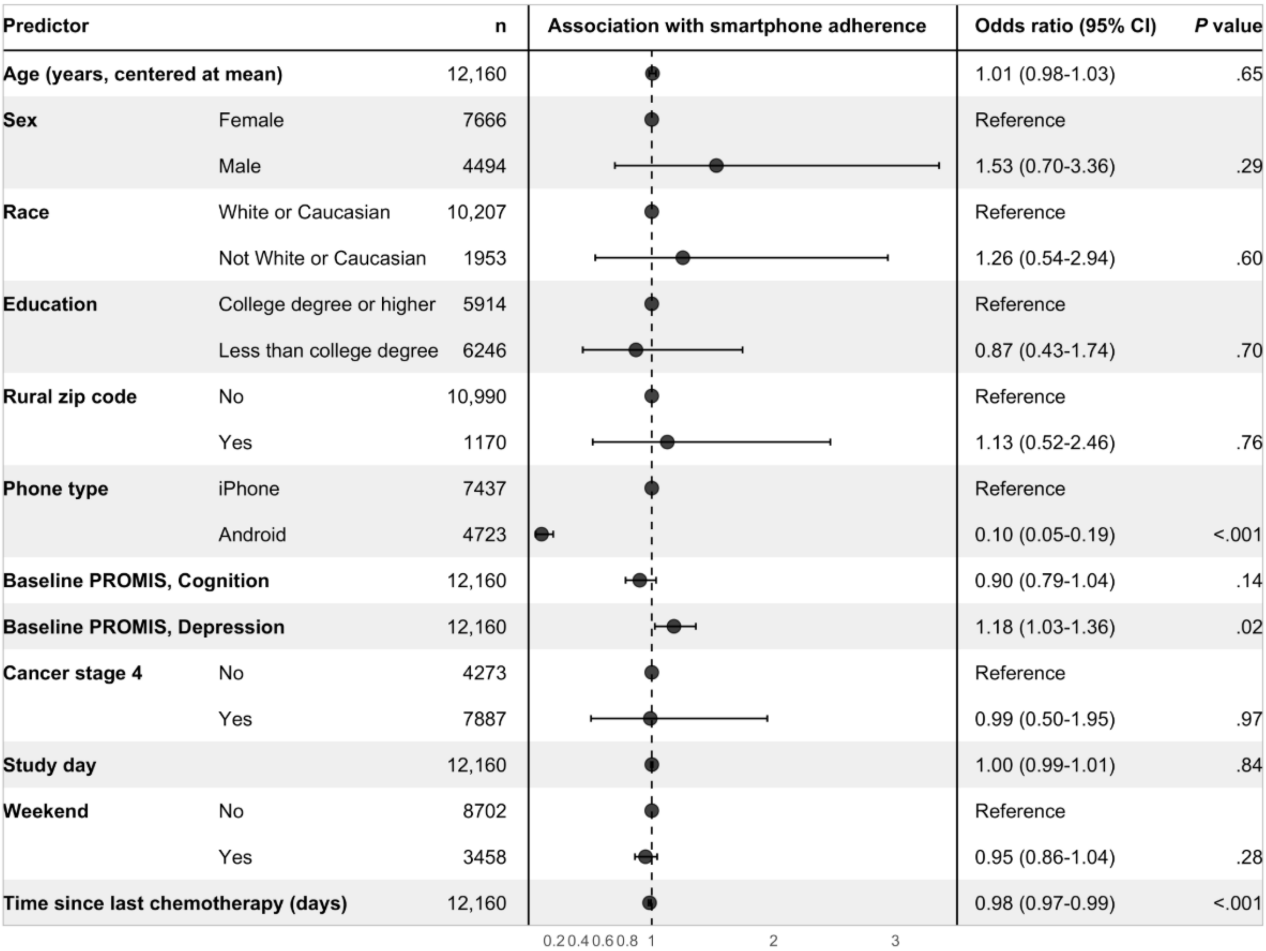
Figure 1. Results of the multivariable model for the daily survey adherence outcome. Each row corresponds to a predictor or predictor category, with separate predictors delineated by alternating gray and white bands. The center panel displays the adjusted odds ratio point estimate and 95% CI. Adjusting for other predictors in the model, odds of adherence to daily survey completion were significantly lower among non-White or Caucasian participants, participants with stage 4 cancer, and on weekend days. PROMIS: Patient-Reported Outcomes Measurement Information System.



Predictor		n	Odds ratio (95% CI)	*P* value
Age (years, centered at mean)		12,160	1.01 (0.99-1.03)	.18
Sex	Female	7666	Reference	
	Male	4494	0.85 (0.58-1.23)	.39
Race	White or Caucasian	10,207	Reference	
	Not White or Caucasian	1953	0.49 (0.29-0.81)	.006
Education	College degree or higher	5914	Reference	
	Less than college degree	6246	0.85 (0.60-1.21)	.37
Rural zip code	No	10,990	Reference	
	Yes	1170	1.03 (0.60-1.76)	.92
Baseline PROMIS, Cognition		12,160	0.97 (0.90-1.05)	.46
Baseline PROMIS, Depression		12,160	1.10 (1.00-1.21)	.06
Cancer stage 4	No	4273	Reference	
	Yes	7887	0.69 (0.48-1.00)	.048
Study day		12,160	1.00 (0.99-1.00)	.13
Weekend	No	8702	Reference	
	Yes	3458	0.90 (0.83-0.97)	.008
Time since last chemotherapy (days)		12,160	1.00 (0.99-1.01)	.94

For the smartphone adherence outcome (Figure 2), we again found that there were significant effects of phone type, baseline depression, and time since last chemotherapy treatment. Relative to participants with iPhone devices, participants with Android devices were less likely to be adherent to smartphone data collection, defined as at least 8 valid hours of data collected from any AWARE sensor, due to differences in sampling rates across device platforms (OR 0.10, 95% CI 0.05-0.19; *P*<.001). In the adjusted model, each 10 percentage-point increase (ie, an increase of 0.1) in baseline PROMIS preference depression subscale score, reflecting less depression, was again associated with higher odds of adherence (OR 1.18, 95% CI 1.03-1.36; *P*=.02), while each additional day since the participant's last chemotherapy treatment was associated with lower odds of adherence to smartphone data collection (OR 0.98, 95% CI 0.97-0.99; *P*=.001).

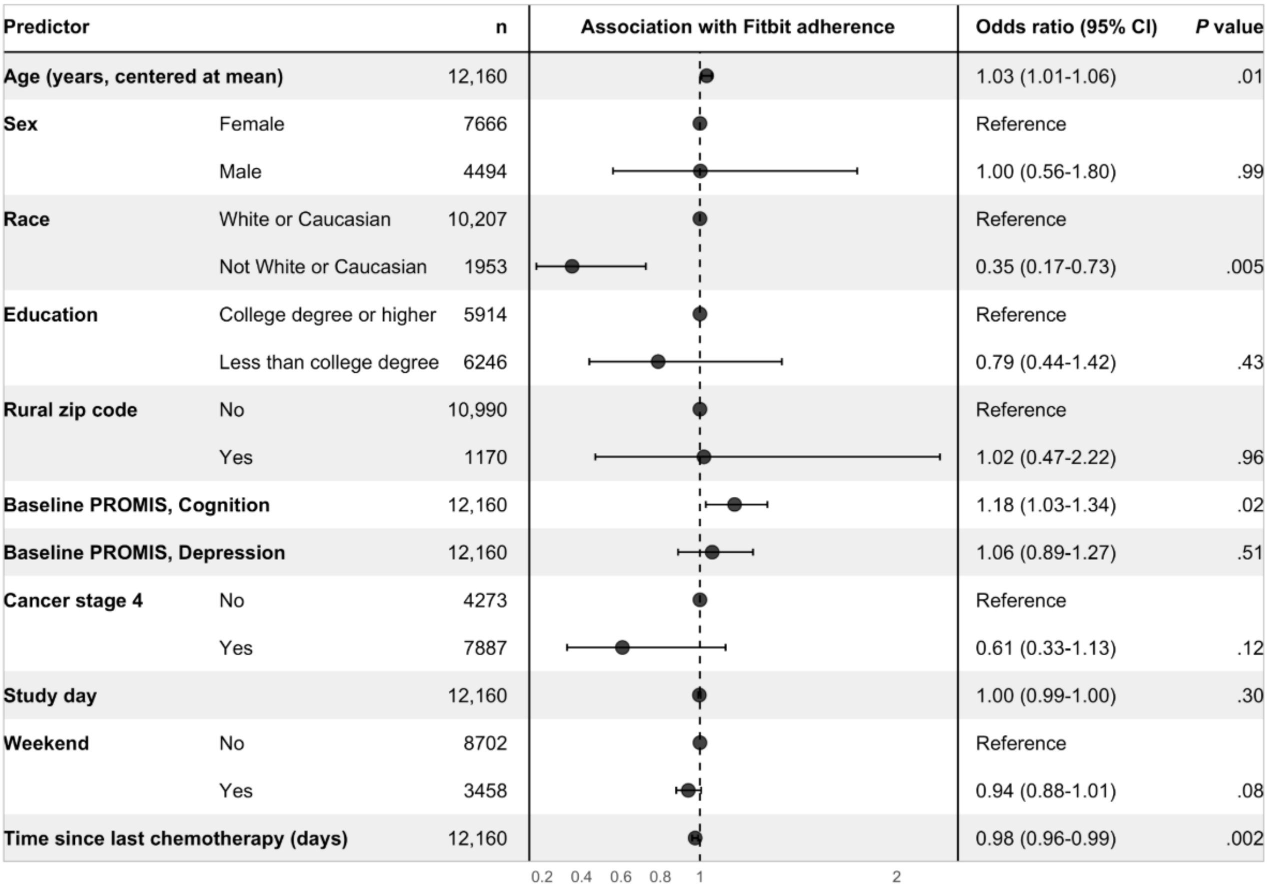
Figure 2. Results of the multivariable model for the smartphone adherence outcome. Each row corresponds to a predictor or predictor category, with separate predictors delineated by alternating gray and white bands. The center panel displays the adjusted odds ratio point estimate and 95% CI. Adjusting for other predictors in the model, odds of adherence to smartphone data collection were significantly lower among participants with Android devices and with each additional day since the participant's last known chemotherapy treatment; odds of adherence were higher among participants with higher PROMIS depression subscale scores (reflecting less depression). PROMIS: Patient-Reported Outcomes Measurement Information System.



Predictor		**n**	**Odds ratio (95% CI)**	***P* value**
Age (years, centered at mean)		12,160	1.01 (0.98-1.03)	.65
Sex	Female	7666	Reference	
	Male	4494	1.53 (0.70-3.36)	.29
Race	White or Caucasian	10,207	Reference	
	Not White or Caucasian	1953	1.26 (0.54-2.94)	.60
Education	College degree or higher	5914	Reference	
	Less than college degree	6246	0.87 (0.43-1.74)	.70
Rural zip code	No	10,990	Reference	
	Yes	1170	1.13 (0.52-2.46)	.76
Phone type	iPhone	7437	Reference	
	Android	4723	0.10 (0.05-0.19)	<.001
Baseline PROMIS, Cognition		12,160	0.90 (0.79-1.04)	.14
Baseline PROMIS, Depression		12,160	1.18 (1.03-1.36)	.02
Cancer stage 4	No	4273	Reference	
	Yes	7887	0.99 (0.50-1.95)	.97
Study day		12,160	1.00 (0.99-1.01)	.84
Weekend	No	8702	Reference	
	Yes	3458	0.95 (0.86-1.04)	.28
Time since last chemotherapy (days)		12,160	0.98 (0.97-0.99)	<.001

For the Fitbit adherence outcome (Figure 3), we again found that there were significant effects of age, race, and time since last chemotherapy treatment. Odds of adherence to Fitbit data collection increased with each additional year of age relative to the mean age of the sample (OR 1.03, 95% CI 1.01-1.06; *P*=.01). Odds of adherence to Fitbit data collection were significantly lower for non-White or non-Caucasian participants relative to White or Caucasian participants (OR 0.35, 95% CI 0.17-0.73; *P*=.005) and with each additional day since the participant's last chemotherapy treatment (OR 0.98, 95% CI 0.96-0.99; *P*=.002). In addition, adjusting for other predictors in the model, there was a significant effect of baseline cognition, with each 10 percentage-point increase in baseline PROMIS preference cognition subscale score (ie, an increase of 0.1), reflecting better cognitive abilities, associated with 18% higher odds of adherence to Fitbit data collection (OR 1.18, 95% CI 1.03-1.34; *P*=.02). Controlling for other predictors, the effects of time in the study and weekends were no longer statistically significant.

Figure 3. Results of the multivariable model for the Fitbit adherence outcome. Each row corresponds to a predictor or predictor category, with separate predictors delineated by alternating gray and white bands. The center panel displays the adjusted odds ratio point estimate and 95% CI. Adjusting for other predictors in the model, odds of adherence to Fitbit data collection were significantly lower among non-White or Caucasian participants and with each additional day since the participant's last known chemotherapy treatment; odds of adherence were higher among older participants and those with higher PROMIS cognitive subscale scores (reflecting better cognitive abilities). PROMIS: Patient-Reported Outcomes Measurement Information System.



Predictor		n	Odds ratio (95% CI)	*P* value
Age (years, centered at mean)		12,160	1.03 (1.01-1.06)	.01
Sex	Female	7666	Reference	
	Male	4494	1.00 (0.56-1.80)	.99
Race	White or Caucasian	10,207	Reference	
	Not White or Caucasian	1953	0.35 (0.17-0.73)	.005
Education	College degree or higher	5914	Reference	
	Less than college degree	6246	0.79 (0.44-1.42)	.43
Rural zip code	No	10,990	Reference	
	Yes	1170	1.02 (0.47-2.22)	.96
Baseline PROMIS, Cognition		12,160	1.18 (1.03-1.34)	.02
Baseline PROMIS, Depression		12,160	1.06 (0.89-1.27)	.51
Cancer stage 4	No	4273	Reference	
	Yes	7887	0.61 (0.33-1.13)	.12
Study day		12,160	1.00 (0.99-1.00)	.30
Weekend	No	8702	Reference	
	Yes	3458	0.94 (0.88-1.01)	.08
Time since last chemotherapy (days)		12,160	0.98 (0.96-0.99)	.002

Discussion

Principal Findings

To our knowledge, this is the first study to examine participant engagement with multiple, concurrent methods of remote patient monitoring during chemotherapy, including daily symptom reporting through smartphone, passive smartphone sensing, and wearable device data collection over a 90-day observational study. In addition, our study examined the effects that different sociodemographic, quality of life, clinical, and time-related factors had on patient engagement with each of the 3 different data streams.

Overall adherence rates support the feasibility of mobile technology–based data collection during chemotherapy, with higher rates of adherence to both smartphone sensing and wearable data collection relative to daily symptom surveys. This is likely because the daily symptom surveys required active engagement from the participant compared with the passive smartphone and wearable data collection. Upon enrollment, a member of our team worked with each participant individually to set up their Fitbit and ensure that it was working properly, which may have contributed to this difference. However, adherence metrics were lower for some participants due to various technical issues (eg, AWARE app crashing, phone being broken or replaced, and Fitbit device not syncing automatically). Overall, our results are consistent with other studies that have shown that daily symptom reporting and continuous collection of wearable device data are feasible during chemotherapy [8-15]. In our study, overall engagement with daily symptom reporting (61%) fell between adherence rates observed among other symptom tracking studies (55%-83%) [9,17], and overall adherence to collecting wearable device data (70%) similarly fell between those previously observed (45%-85%) [13,15].

Our results suggest that adherence varied based on demographic factors (age and race), clinical factors (cancer stage and patient-reported depression and cognition), and timing (including days since last chemotherapy treatment, time in study, and weekend vs weekday). Relative to White participants, non-White patients demonstrated lower levels of engagement with both the daily symptom surveys and wearable data collection, suggesting that we need new methods of engaging patients with cancer from racial and ethnic minority groups in technology-based monitoring. Patients with stage 4 cancer exhibited lower rates of engagement with daily symptom reporting than those with earlier stage disease, likely due to greater disease burden and associated life disruption. In addition, time since last chemotherapy treatment was associated with both smartphone and wearable device engagement, with participants more likely to engage with both data streams the less time that had elapsed since their last chemotherapy treatment. This association was likely due to several factors, including coordinators being able to meet with participants and troubleshoot technology difficulties during treatments. The treatments also likely served as reminders for participants to engage with the study. Consistent with previous work, participants were also less likely to complete symptom surveys on weekend days relative to weekdays [17]. Patients may have more "routine" schedules during the week, and thus are more easily able to remember to fill out the surveys. In addition, many participants had work responsibilities during the week, and thus interference related to symptoms such as fatigue may have been more salient and served as a reminder to report their symptoms.

One surprising finding was that older age was associated with better adherence to wearable device data collection, which contradicts beliefs that older adults are less likely to adopt or engage with health technology. There remains a false belief within the scientific community that older patients are unable or unwilling to engage with digital health assessments and interventions [35]. Unfortunately, due to this stigma, there is a relative lack of research in this patient population regarding their engagement with mobile health technology. Perhaps older participants, who may have been less likely than younger participants to be working or caring for children, had fewer competing demands on their time and attention and were better able to focus on the research project. We also found that better self-reported cognitive abilities at study entry predicted greater engagement with wearable Fitbit data collection, suggesting that while older adults may be more adherent, additional reminders or strategies may need to be implemented to support patients with any cognitive impairments in collecting wearable data. Interestingly, a study among patients with breast and prostate cancer of engagement levels with a symptom tracking app, similar to the survey app used in our study, also showed a positive association between age and engagement [9].

Limitations

This study is not without limitations. First, participants needed to own a smartphone that was compatible with study apps and be able to read and write in English to enroll in the study. This likely skewed our sample population to be more "tech literate" than the general population of patients receiving chemotherapy. Second, there was likely a selection bias present in our sample, as participants who were less likely to engage in our study would be more likely to decline enrollment. Third, we assessed engagement in the context of a research study where we were monitoring incoming data closely and reaching out to participants to troubleshoot technical or compliance issues frequently; it is likely that we would have lower rates of engagement without these interactions with research staff. Fourth, a participant's day-to-day symptom burden may have affected their survey response rate. Participants may have been more or less likely to fill out the surveys on days where they had particularly high (or low) symptom burden, which could skew our results; future research should examine the association between symptom burden and patient-reported outcome completion. We set a priori thresholds based on the literature and our previous work to define a day as having a completed survey (at least 50%) or sufficient wearable or smartphone sensor data (at least 8 hours), and studies that select different thresholds may draw different conclusions. We were lacking information about cancer treatments, including information about chemotherapy type and dose as well as additional treatments patients may have been receiving, such as immunotherapy or targeted therapy. The different findings observed for participants with iOS versus Android smartphones suggest there may be significant measurement bias in smartphone sensing and differences in how each operating system collected smartphone sensor data. Finally, it is important to note that the remote assessments collected as part of the current study were not shared with clinicians or used to inform clinical care, and participants were advised upon consent that data would not be shared or accessed by their clinicians. This is different from other symptom monitoring studies that incorporated clinician alerts or other communication with the care team [7]. Participants may be more motivated to engage with remote technology-based assessments when they know this information is being used to guide their cancer care. Future studies should also explore the feasibility of similar data collection methods in broader populations, including adolescents and young adults with cancer, patients receiving other forms of cancer treatment (radiation, immunotherapy, etc), and patients with nonsolid tumor cancers.

Conclusion

Despite these limitations, our study showed feasible levels of engagement with all 3 of our data streams over 90 days. These results demonstrate that collecting patient-reported symptom ratings through smartphone, passive smartphone sensor data, and wearable device data over long periods of time is feasible in cancer trials, even among older patients and patients with advanced cancer receiving active treatment. Findings provide some support for the idea that the digital divide may widen existing health disparities, with non-White participants demonstrating lower levels of engagement, but also challenge the idea that older adults will be less likely to adopt or engage with technology, as least with regard to wearable devices. Future work should experiment with different ways of optimizing engagement for all groups, including different delivery formats and schedules of reminders, onboarding and training procedures, and levels of integration with the clinical care team. More pragmatic studies should also explore levels of engagement with symptom reporting and other patient-generated health data collection in the context of routine clinical care, without research staff monitoring or intervening with participants. To our knowledge, this is the first study to examine patterns and predictors of participant engagement with daily symptom reporting, smartphone sensing, and wearable device data collection during outpatient chemotherapy, and results provide encouragement and guidance for additional work in this area.

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Data Availability

The datasets generated and analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

SM, JF, and CAL conceptualized the analyses reported in this manuscript. CAL planned the study and obtained funding. JF performed the data analyses. CB, LC, and KCD coordinated and managed the study. SM, JF, and CAL wrote the first draft of the manuscript, and CB, LC, and KCD reviewed and edited the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

ar1: first-order autoregressive
EMR: electronic medical record
GEE: generalized estimating equations
OR: odds ratio
PROMIS: Patient-Reported Outcomes Measurement Information System
PROPr: PROMIS-Preference scoring system
QIC: quasi-information criterion
RAPIDS: Reproducible Analysis Pipeline for Data Streams

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Original Paper

Artificial Intelligence for Optimizing Cancer Imaging: User Experience Study

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Abstract

Background: The need for increased clinical efficacy and efficiency has been the main force in developing artificial intelligence (AI) tools in medical imaging. The INCISIVE project is a European Union–funded initiative aiming to revolutionize cancer imaging methods using AI technology. It seeks to address limitations in imaging techniques by developing an AI-based toolbox that improves accuracy, specificity, sensitivity, interpretability, and cost-effectiveness.

Objective: To ensure the successful implementation of the INCISIVE AI service, a study was conducted to understand the needs, challenges, and expectations of health care professionals (HCPs) regarding the proposed toolbox and any potential implementation barriers.

Methods: A mixed methods study consisting of 2 phases was conducted. Phase 1 involved user experience (UX) design workshops with users of the INCISIVE AI toolbox. Phase 2 involved a Delphi study conducted through a series of sequential questionnaires. To recruit, a purposive sampling strategy based on the project's consortium network was used. In total, 16 HCPs from Serbia, Italy, Greece, Cyprus, Spain, and the United Kingdom participated in the UX design workshops and 12 completed the Delphi study. Descriptive statistics were performed using SPSS (IBM Corp), enabling the calculation of mean rank scores of the Delphi study's lists. The qualitative data collected via the UX design workshops was analyzed using NVivo (version 12; Lumivero) software.

Results: The workshops facilitated brainstorming and identification of the INCISIVE AI toolbox's desired features and implementation barriers. Subsequently, the Delphi study was instrumental in ranking these features, showing a strong consensus among HCPs ($W=0.741$, $P<.001$). Additionally, this study also identified implementation barriers, revealing a strong consensus among HCPs ($W=0.705$, $P<.001$). Key findings indicated that the INCISIVE AI toolbox could assist in areas such as misdiagnosis, overdiagnosis, delays in diagnosis, detection of minor lesions, decision-making in disagreement, treatment allocation, disease prognosis, prediction, treatment response prediction, and care integration throughout the patient journey. Limited resources, lack of organizational and managerial support, and data entry variability were some of the identified barriers. HCPs also had an explicit interest in AI explainability, desiring feature relevance explanations or a combination of feature relevance and visual explanations within the toolbox.

Conclusions: The results provide a thorough examination of the INCISIVE AI toolbox's design elements as required by the end users and potential barriers to its implementation, thus guiding the design and implementation of the INCISIVE technology. The outcome offers information about the degree of AI explainability required of the INCISIVE AI toolbox across the three services: (1) initial diagnosis; (2) disease staging, differentiation, and characterization; and (3) treatment and follow-up indicated for the toolbox. By considering the perspective of end users, INCISIVE aims to develop a solution that effectively meets their needs and drives adoption.

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KEYWORDS

artificial intelligence; cancer; cancer imaging; UX design workshops; Delphi method; INCISIVE AI toolbox; user experience

Introduction

Background

Cancer offers a unique context for medical decisions because of its diverse forms and disease evolution, as well as the requirement to consider each patient's illness, their ability to receive medical care, accurate treatment responses, early detection, tumor classification or characterization, prediction of local, recurrent, or metastatic tumor progression, precise assessment of treatment strategies and the follow-up monitoring of cancer. These hindrances persist despite advancements in technology [1].

Medical imaging plays a crucial role in the comprehensive treatment of cancer procedures as it provides valuable insights into the morphology, structure, metabolism, and functions of cancers [2,3]. Notably, medical imaging assists health care providers in defining treatment plans, assessing their effectiveness, and guiding follow-up interventions. The increasing amount and availability of collected data (cancer imaging data) and the development of novel technological tools based on artificial intelligence (AI) and machine learning, provide unprecedented opportunities for better cancer detection and classification, image optimization, radiation reduction, and clinical workflow enhancement [2].

The current imaging methods may be improved by identifying findings that are either detectable or not by the human eye and moving from a subjective perceptual skill to a more objective one [2]. To date, related existing research and innovation initiatives, are only limited to small-scale demonstrations, without adequately being validated for reproducibility and generalizability and without exploring large datasets [4]. Therefore, the INCISIVE project [5-10] has been designed to explore the full potential of AI-based solutions or technologies in cancer imaging. The main outcome of this project is to design and develop an improved AI-based technology to address the ongoing challenges of accurate and early detection of cancer, recurrence, and treatment success or failure.

The design and functionalities of the INCISIVE AI toolbox were developed by incorporating the users' perspectives and experiences. Therefore, the main objective of this study was to gain a comprehensive understanding of the needs of the users, with a specific focus on health care professionals (HCPs) who would use the INCISIVE AI toolbox. Additionally, insights from HCPs were sought to achieve consensus on crucial features of the toolbox, barriers to implementation, and potential users.

Overview of the INCISIVE Project

The INCISIVE project [5], funded by the European Union's Horizon 2020 program across 9 European nations, aims to develop and validate an AI-based toolbox to enhance the accuracy, sensitivity, specificity, interpretability, and cost-effectiveness of cancer imaging methods. The project focuses on breast, prostate, lung, and colorectal cancers [5].

Methods

Study Design

This was a 2-phase study conducted concurrently. Phase 1 entailed conducting user experience (UX) design workshops, whereas phase 2 entailed leading a Delphi study with HCPs who were the potential users of the INCISIVE AI toolbox.

Phase 1: UX Design Workshops for INCISIVE AI Toolbox Potential Users, That Is, HCPs

Study Design

A qualitative research approach was used to facilitate UX design workshops across the 5 validation countries of the INCISIVE project (Greece, Cyprus, Spain, Italy, and Serbia), in addition to the United Kingdom, which is also a partner of the INCISIVE project. The workshops followed a structured design thinking [11,12] approach, using various methodological tools to guide participants through the problem-solving process. Techniques such as empathizing with users, defining the problem, brainstorming ideas, prototyping, and testing were used. As the project was in the concept stage, the design thinking method was applied up to the ideate stage, focusing on generating innovative solutions for the development of the INCISIVE AI toolbox for cancer care.

Participants and Recruitment

A purposive sampling strategy based on the network of the INCISIVE consortium was used to recruit participants. Eligibility criteria included being a medical professional, specifically a general practitioner, radiologist, oncologist, or nuclear medicine physician. Participants were also required to have no prior involvement or affiliation with the INCISIVE project. Through nominations from the INCISIVE partners, potential participants were invited to the workshops via email, receiving a detailed participant information sheet (PIS), a consent form, and a link to access the workshop meetings. The PIS outlined this study's objectives and workshop agenda, while the consent form ensured volunteer participation. The participants were required to send their consent forms before conducting the workshops.

Data Collection Tool

Different use case scenarios (Multimedia Appendix 1) were prepared to facilitate discussion for each workshop with potential users of the AI toolbox. The use case scenarios focused on the patient journey and aimed to elicit information about practice challenges, needs, design features for the AI toolbox, and the level of AI explainability required for the different services suggested to be offered by the toolbox, which were: initial diagnosis, disease staging and characterization, and treatment and follow-up. The use case scenarios were circulated by the research team among the consortium for feedback and refinement. The definite issues (practice challenges, needs, INCISIVE AI toolbox design features, and the level of AI explainability required from the toolbox across potential services) that emerged during various work packages in the INCISIVE project were included in the workshops.

Sample Size

The sample size in this study did not depend on statistical power, but on group dynamics among experts [13]. Group discussions in UX design workshops allowed for the exploration of user's experiences, concerns, and opinions about specific topics and were distinguished by the explicit use of group interaction to generate rich experiential data. Therefore, this study involved a small number of representative end users in each workshop. This approach ensured that there was adequate time for in-depth discussions when addressing requirements. Importantly, this method followed a qualitative approach that relied on the concept of data saturation rather than on sample size.

Data Collection

Data collection took place between August and September 2021. Workshops were conducted via Microsoft Teams in a web-based format. The meeting link was sent via email by the research team. In total, 4 workshops were conducted, 1 workshop for each cancer type targeted by INCISIVE (breast, lung, colorectal, and prostate cancer). The research team facilitated and moderated workshops. Each workshop consisted of a panel of 4 participants. Some members from the INCISIVE consortium joined as observers and were able to ask questions and contribute to the discussion in the workshops via the chat functionality. Each workshop lasted an average of 60-90 (SD 20.90) minutes. The participants were provided with a small presentation about various techniques and terminologies to facilitate discussion about AI explainability during the workshops.

Data Analysis

The workshops were audio-recorded and transcribed verbatim for analysis. Transcripts were entered into the NVivo (version 12) software for data organization and management. This was followed by collating, synthesizing, and editing emergent ideas to achieve consistent terminology among items expressing similar ideas. The final step involved grouping the generated ideas and items into emerging categories.

Phase 2: Delphi Study—Identification and Prioritization of INCISIVE Features, Implementation Barriers, and Potential User Groups

Study Design

This phase used a mixed methods approach, specifically a modified Delphi approach. The Delphi approach is a systematic method for obtaining, exchanging, and developing informed opinions on a specific issue or set of issues [14]. In this study, a modified ranking-type Delphi approach was used, which aimed at developing group consensus on the relative importance of INCISIVE features, barriers, and potential user groups [13]. It consisted of four rounds. Round 1 involved administering an open-ended questionnaire to the HCPs (Multimedia Appendix 2). Round 2 entailed circulating the anonymized summaries of responses back to the experts for verification. Rounds 3 and 4 involved distilling the most important items chosen by the participants followed by ranking these items.

Participants and Recruitment

HCPs involved in cancer care were included in this phase. The recruitment of HCPs was carried out through nominations by INCISIVE partners, following the same inclusion criteria of the UX workshops. The nominated participants received the necessary documentation, including the consent form and the PIS from the research team, and were required to sign the consent form before starting this study.

Sample Size

The sample size in the Delphi method does not depend on statistical power but on group dynamics for achieving consensus among experts [13]. Thus, the Delphi literature recommends 10-18 experts for a panel or group of experts within a specific discipline [13,15].

Data Collection and Data Collection Tools

Overview

Data collection took place between August and September 2021. Delphi is a form of iterative inquiry that builds on ongoing data collection. Its primary research tool is a series of questionnaires built from participants' stepwise input [15]. Questionnaires were electronically administered via email. The sequence of administration of these questionnaires (ie, data collection) was per the Delphi literature as highlighted in Figure 1 [13,15]. The first questionnaire was sent once the participant agreed to take part and signed the consent form. Questionnaire 1, focused on item generation, required a maximum of 15 minutes to complete, while questionnaires 2 to 4, which involved verification and ranking, took no more than 10 minutes unless participants chose to provide additional explanations for their answers.

Figure 1. Delphi study administration process (adapted from [8,10]).

Phase 1: Brainstorming (discovery)

Round 1: Questionnaire 1: Ask experts to list barriers, features, and users, separately and not in any order.

Consolidate these lists from all experts.

Remove exact duplicates and unify terminology.

Round 2: Questionnaire 2: Send consolidated lists for the experts for revision and validation.

Refine final version of the consolidated lists.

Phase 2: Narrowing down (prioritizing)

Round 3: Questionnaire 3: Send the consolidated lists to each expert.

Each expert selects at least 10 items (the most important) on each list—no ranking at this stage.

For each group, retain items selected by 50% (n=6) of experts.

Selected items are consolidated into revised lists not exceeding 20 items per list.

Phase 3: Ranking

Round 4: Questionnaire 4: Ask experts to rank the items on each list (priority ranking)

Descriptive statistics (mean rank scores) are calculated for each item.

Assess level of consensus for each list within each group using Kendall W (coefficient of concordance)

If no consensus achieved as indicated by Kendall W, then share feedback with experts in each group and ask them to rerank each list

Reiterate untill consesus is reached or third iteration (ie, round 6)

Final result: 3 ranked lists for health care professional's panel

Questionnaire 1: Generation of Items or Initial Collection of Items

This questionnaire included 3 open-ended questions (Multimedia Appendix 2), about anticipated barriers to the toolbox implementation, essential features required in the INCISIVE AI toolbox, and HCPs who should use the INCISIVE AI toolbox. HCPs were asked to list at least 6 items for each question, followed by a brief explanation of their choices.

Questionnaire 2: Validation of Categorized Items

This questionnaire was designed based on the responses obtained from the first round and aimed to strengthen the construct validity according to the concept of "member checking" [15]. This questionnaire included all the consolidated lists obtained from the first questionnaire, with the corresponding categorization. For each list, each item was presented with a brief explanation based on information provided by HCPs in the first round. HCPs were sent questionnaire 2 alongside an exact copy of their responses to the first questionnaire and were asked to (1) verify their responses and confirm that items have been placed in an appropriate category and (2) review the categorizations and suggest refinements or additional items if necessary.

Questionnaire 3: Prioritizing Items or Choosing the Most Important Items

Questionnaire 3 presented the refined, consolidated lists produced from questionnaire 2. Each participant was asked to select (not rank) 10 items from each list that they considered the most important.

Questionnaire 4: Ranking Items

The questionnaire was designed based on the responses obtained in round 3. The experts were sent the relevant lists with the most important items. Each expert was instructed to rank items in numerical order (importance ranking) by putting the number 1 for the first most important item, 2 for the second most important item, 3 for the third most important item, and so on, with a lower ranking indicating more importance, hence higher ranking. Hence, each expert individually submitted a rank order of the items of each list, one for each of the relevant lists. They were also requested to provide comments justifying their rankings.

Data Analysis

Questionnaire 1

All data (items and explanations) were entered into the NVivo (version 12) software for data organization and management. The analysis entailed the removal of identical responses, and then collating, synthesizing, and editing the remaining ideas to achieve consistent terminology among items expressing similar ideas. The final step entailed grouping items into emerging categories. As a result, a consolidated preliminary version of the lists with relevant categories was created.

Questionnaire 2

Based on responses from questionnaire 1, items were further refined. This resulted in the formation of the final consolidated lists.

Questionnaire 3

Items selected by over 50% (n=6) of the experts in the panel were retained. According to the literature, the list size should not exceed 20 items to avoid burdening the participants in the next round [13,15].

Questionnaire 4

Descriptive statistics, such as mean rank scores, were calculated to assess the relative importance of items within each list, and the Kendall W coefficient of concordance was used to measure consensus among the experts. The ranking process was repeated until a strong level of agreement (W≥0.7) was achieved or until the third iteration was reached. The research team obtained 3 ranked lists, providing valuable insights and consensus on important aspects of INCISIVE implementation and the AI toolbox.

Ethical Considerations

Ethical approval for conducting this study was granted by the Research Ethics Committee at Kingston University on August 11, 2021 (reference 2877), for the UX Design Workshops and on August 16, 2021 (reference 2863), for the Delphi study. All other INCISIVE partners did not require any extra layer of ethics for this study. Informed consent forms were provided to participants before the commencement of this study. Participant information was safeguarded through coding, encryption, and secure storage practices. No compensation was provided for study participants. All methods were performed per the Declaration of Helsinki.

Results

Phase 1: UX Design Workshops for INCISIVE AI Toolbox Potential Users, That Is, HCPs

In total, 4 workshops were conducted for the INCISIVE AI toolbox; 1 workshop for each cancer type targeted in the project: breast, lung, colorectal, and prostate cancer. A total of 16 HCPs participated in the 4 workshops. Table 1 provides a summary of the participants' characteristics.

Table 1. Characteristics of health care professionals who participated in the INCISIVE AI[a] toolbox workshops (N=16).

Participants' characteristics	Number, n
Gender	
Male	8
Female	8
Country	
United Kingdom	1
Serbia	1
Italy	5
Greece	6
Spain	1
Cyprus	1
Specialty or occupation	
General practitioner or doctor	3
Radiologist	5
Oncologist	4
Radiation oncologist, therapeutic radiographer, or radiotherapist	1
Nuclear medicine physician	2
Urologist	1

[a] AI: artificial intelligence.

Features of the INCISIVE AI Toolbox, Irrespective of Cancer Type: Generic Features Required for the INCISIVE AI Toolbox

Overview

The section below details the practice challenges, needs, and generic design features required from the INCISIVE AI toolbox across the 3 main potential services.

Service 1: Initial Diagnosis

Several challenges were highlighted by the participants at this stage. These included a lack of resources for necessary tests in primary care, especially in rural areas, misdiagnosis, delay in diagnosis, lack of expertise or failure to recognize potential cancer symptoms, and low sensitivity of some imaging modalities. To tackle these issues, the participants envisaged that the INCISIVE AI toolbox can help in several ways including guiding HCPs in primary care in the management and referral of patients mainly in providing a clear protocol on the next steps to be carried out based on the available data at this stage, reduce the chances of misdiagnosis, reduce the chances of overdiagnosis as well avoiding unnecessary anxiety among patients. To promote the efficiency of the pathway, it was discussed that if all HCPs involved in the pathway have access to the INCISIVE AI toolbox, secondary care health professionals can view the tests and images that have already been performed in primary care and take appropriate action to prevent work duplication and loss of time and money. A detailed explanation of this can be found in Multimedia Appendix 3.

Service 2: Disease Staging, Differentiation, and Characterization

At this point, several issues were also brought to light, including a lack of resources, particularly imaging equipment, which can cause delays in obtaining the necessary images in a timely manner. Additionally, the proficiency of radiologists in interpreting imaging results and histopathologists in interpreting biopsy results was emphasized as a critical component. Consequently, finding the most accessible, suitable site, or area to do a biopsy, lack of experience among some radiologists and histopathologists, certain imaging modalities such as computed tomography, magnetic resonance imaging, and ultrasound, have low sensitivity, making it difficult for HCPs to distinguish between benign and malignant lesions. The participants anticipated that the INCISIVE AI toolbox would benefit them in several ways, such as enhancing the accuracy of the current imaging tests by identifying small lesions that HCPs might otherwise overlook or lesions that are difficult or confusing for them to identify using the current imaging modalities, assistance with TNM staging and categorization, advice regarding the best places to biopsy, guidance regarding the best imaging tests to run on the patient, support decision-making in cases of disagreement or contradiction of the results generated by the different imaging modalities and tests. For instance, when the results of an imaging test and a biopsy contradict. An extensive overview of this service can be found in Multimedia Appendix 4. The specific features needed for each type of tumor are detailed in Multimedia Appendix 5.

Service 3: Treatment and Follow-Up

The challenges in this stage were disease treatment for timing, best treatment options/choices and response, in addition to disease prognosis. Certain participants asserted that treatment options were typically decided on at multidisciplinary team (MDT) board meetings, which could be cumbersome to set up and coordinate per paperwork and board member availability, among other factors. This in return might lead to delay in treatment initiation for patients. Fragmentation of care occurs when HCPs are unable to see or do not have access to the detailed work performed by other HCPs, which is crucial for supporting treatment decisions.

The INCISIVE AI toolkit was envisaged by the participants to be helpful in a variety of ways at this point, such as aiding in the allocation of treatments, serving as a guide for decision support, predicting the prognosis of the disease and the response to treatment, assisting in risk stratification, and supporting MDT board meetings at institutions in both physical and web-based formats. It also enables all MDT board members to access the patient's holistic profile simultaneously. Thus again, the vision is that the INCISIVE toolbox can support electronic access to patient profiles across the journey thus promoting the integration of care allowing for continuity and efficiency. A detailed description of this service can be found in Multimedia Appendix 6.

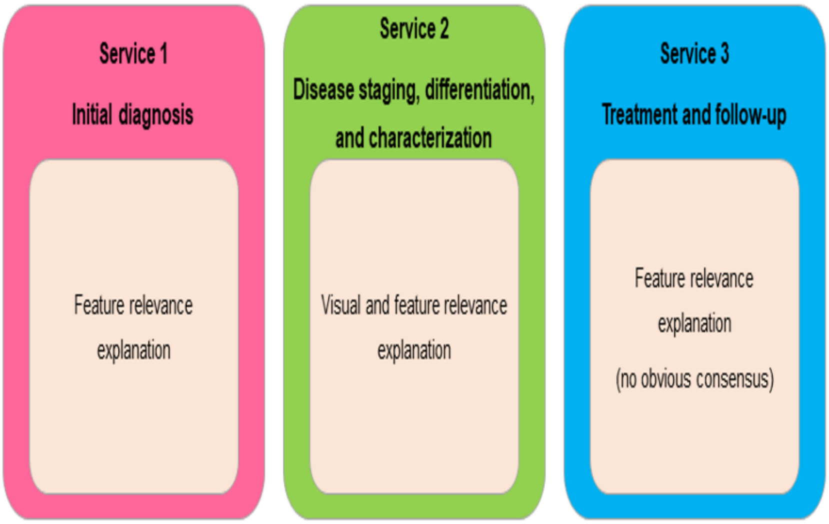
Data Input and Output Requirements of INCISIVE AI Toolbox, Irrespective of Cancer Type

Several input and output requirements were identified for each of the 3 services proposed for the INCISIVE AI toolbox. Interestingly, the participants articulated some suggestions that would make the INCISIVE toolbox more HCP-friendly across the 3 services. The data input and output requirements for the 3 services are summarized in Multimedia Appendix 7.

Explainable AI: Explainability of the INCISIVE AI Toolbox, Irrespective of Cancer Type

Participants were asked about the explainability techniques they would like to have in the INCISIVE AI toolbox at each stage or service. During the workshops, the participants were prompted with three different explainable AI techniques: (1) feature relevance explanation which attempts to explain a model's decision by quantifying the influence of each input variable (importance of input features in predicting the output), (2) visual explanation aims at generating visualizations that facilitate the understanding of a model, and (3) explanations by simplification refers to the techniques that approximate an opaque model using a simpler one, which is easier to interpret. Figure 2 explains the options selected by most participants.

Figure 2. Explainability techniques preference in the INCISIVE AI toolbox across the 3 proposed services. AI: artificial intelligence.



Potential Users or Access to INCISIVE AI Toolbox

At Initial Diagnosis

According to the participants, GPs were highlighted as the potential users of the INCISIVE toolbox at this stage and the best HCPs to access and upload information into the system. Some participants highlighted that radiologists would also benefit from having access to the INCISIVE AI toolbox at this stage especially if basic imaging modalities are carried out in primary care, for example, chest x-rays in case of lung cancer.

At Disease Staging, Differentiation, and Characterization

Radiologists, pathologists, and nuclear medicine physicians were among the suggested users at this stage. The participants highlighted a very important point which is the need for minimal data input by HCPs to make the INCISIVE AI toolbox as much HCP friendly as possible. About this, some participants suggested assigning the responsibility of data uploading to a nurse or a junior doctor/HCP in order not to increase workload. Nevertheless, the participants envisaged radiologists, pathologists, and nuclear medicine physicians as the most appropriate HCPs for accessing and data processing at this stage. This is because processing images before uploading requires expertise from radiologists and nuclear medicine physicians to identify which images are to be processed and uploaded to the system (ie, the areas of concern) and to identify which parts of the image are to be contoured. The same applies to pathologists for processing histopathological results.

At Treatment and Follow-Up

Radiologists, radiation oncologists, oncologists, and surgeons were among the suggested users at this stage. Another interesting finding that emerged out of the 4 workshops was the importance of using INCISIVE at the MDT meetings when deciding treatment options for each patient. According to the participants, all HCPs involved in patient care need to have access to the INCISIVE AI toolbox and to be able to see what other HCPs have performed during the patient's journey. According to the participants, if the INCISIVE AI toolbox can provide a comprehensive profile for the patient during the MDT meeting including all tests and imaging conducted with the relevant time points, to have all that information in 1 screen, then this would facilitate these meetings to a great extent. Again, these findings are interesting and related to features requested or desired by the participants mainly: the provision of a comprehensive profile for each patient or a complete portfolio and the ability to see the history of all entries carried out by all HCPs involved in the care of the patient.

Holistic Concerns Emanating From the Workshops

Several concerns were identified throughout the workshops. One main concern was closely intertwined with the minimal data input requirement identified earlier. The concern was related to the amount of time that HCPs will need to dedicate to the INCISIVE AI toolbox. According to participants, currently HCPs are increasingly becoming involved in what they consider nonmedical work (mainly data entry) which is affecting their workload. As such, if the INCISIVE toolbox requires too much data input and attention from HCPs (attention theft) then this would affect HCPs' willingness to use the proposed toolbox. Another concern was related to the fear that AI technologies such as the INCISIVE AI toolbox can be perceived as a replacement to HCPs in clinical decisions.

Phase 2: Delphi Study—Identification and Prioritization of Implementation Barriers, INCISIVE Features and User Groups

A total of 12 of the 16 HCPs completed the Delphi study. Participants' characteristics are summarized in Table 2.

Table 2. Characteristics of health care professionals who completed the Delphi study (N=12).

Participants' characteristics	Participants, n
Gender	
Male	6
Female	6
Country	
Serbia	2
Italy	3
Greece	5
Cyprus	2
Specialty or occupation	
General practitioner or doctor	1
Radiologist	4
Oncologist	3
Radiation oncologist, therapeutic radiographer, or radiotherapist	1
Nuclear medicine physician	2
Surgeon	1

Features of INCISIVE AI Toolbox

Overview

The first and second rounds of questionnaires (questionnaires 1 and 2) involved brainstorming potential features of the INCISIVE AI toolbox and validation. In the first questionnaire, a total of 20 features were generated by the participants and then subsequently validated with no change (via questionnaire 2). In the third round (questionnaire 3) which entailed narrowing down the list, a total of 11 features were retained and prioritized for the INCISIVE AI toolbox. In the fourth round, those 11 features were ranked by importance with a strong consensus among the participating HCPs (W=0.741, *P*<.001; Table 3).

Table 3. List of the features in order of importance (priority ranking). A lower mean ranking score indicates a more important feature.

Item importance	Item description	Rank score, mean (SD)
1	Ability to classify the lesion as benign or malignant and the probability of lesion malignancy	2.25 (2.41)
2	Automated lesion spotting and contouring (ie, annotation)	3 (1.9)
3	Automated grading and staging of the disease	3.83 (1.85)
4	Ability to suggest an appropriate course of action during diagnosis and treatment (while keeping the final decision for the clinician)	4.08 (1.37)
5	Ability to link proposed suggestions to established clinical evidence (studies or guidelines)	4.58 (1.72)
6	Ability to predict prognosis	4.75 (1.86)
7	Ability to define response to therapy or treatment	6.92 (1.56)
8	Ability to compare imaging tests and laboratory tests at different time points	7.33 (1.92)
9	Ability to predict the possibility of recurrence	8.75 (1.48)
10	Integration and display of a comprehensive patient profile	9.92 (0.79)
11	Multimodality	10.58 (0.9)

Implementation Barriers

HCPs were asked about the barriers that would affect the successful implementation of the AI toolbox proposed by INCISIVE to identify why similar AI solutions usually fail. The first and second rounds of questionnaires (questionnaires 1 and 2) involved brainstorming potential barriers to the successful implementation of the INCISIVE AI toolbox and validation. In the first questionnaire, a total of 23 barriers were identified and then subsequently validated with no change (via questionnaire 2). In the third round, a total of 10 barriers were distilled. In the fourth round, those 10 barriers were ranked by importance with a strong consensus among the participating HCPs (W=0.705, *P*<.001; Table 4).

Table 4. List of barriers to the successful implementation of INCISIVE AI[a] toolbox by importance (with priority ranking). A lower mean ranking score indicates a more important barrier.

Item importance	Item description	Rank score, mean (SD)
1	Lack of resources	1.17 (0.38)
2	Requirement of too much data input from health care professionals	2.75 (2.22)
3	Lack of organizational and management support	3.58 (1.08)
4	Medico-legal issues or concerns: accountability and liability in case of disagreement	4.25 (0.96)
5	Lack of visible advantage of the AI toolbox	5.92 (1.44)
6	Compatibility and integration concerns	6.08 (1.92)
7	Complexity and difficulty of operating the AI toolbox	6.67 (1.37)
8	Concerns related to General Data Protection Regulation (patients' privacy and confidentiality) and further legal matters in individual countries	6.92 (1.78)
9	Hardware requirements	8.33 (1.77)
10	Data entry bias and variability	9.33 (2.3)

[a] AI: artificial intelligence.

User Groups for INCISIVE AI Toolbox

The first and second rounds (questionnaires 1 and 2) involved a brainstorming of potential user groups of the INCISIVE AI toolbox and validation. In the first round, a preliminary list of 20 potential user groups was identified. After response validation in the second round, a final consolidated list of 18 potential user groups was identified. In the third round (questionnaire 3) a total of 13 user groups were retained. In the fourth round, those 13 user groups ranked by importance with a strong consensus among the participating HCPs (W=0.767, *P*<.001; Table 5). As expected, higher importance was given to physicians who are common across all tumor types starting from radiologists to nuclear medicine physicians. Whereas lower importance or ranking was provided to tumor-specific HCPs or specialists mainly: pneumologists, gastroenterologists, urologists, and gynecologists.

Table 5. The list of INCISIVE AI[a] toolbox users by priority (with priority ranking). A lower mean ranking score indicates a more important user group.

Item importance	Item description	Rank score, mean (SD)
1	Radiologists	1.5 (0.9)
2	Oncologists	2.5 (1.08)
3	Surgeons (specialized in oncology)	3.42 (1.5)
4	Radiotherapists or radiation oncologists	4.67 (2.77)
5	General medicine practitioners	5.75 (1.76)
6	Multidisciplinary team board	6.17 (2.4)
7	Pathologists	6.58 (1.44)
8	Nuclear medicine physicians	7.83 (1.85)
9	Internists (specializing in oncology)	8.92 (1.5)
10	Pneumologists	10.08 (0.9)
11	Urologists	10.33 (3.33)
12	Gastroenterologists	11.08 (0.51)
13	Gynecologists	12.17 (2.32)

[a] AI: artificial intelligence.

Discussion

Principal Findings

The results of this study focused on the specification and prioritization of features guided by the design of the INCISIVE platform. The key findings indicated that the INCISIVE AI toolbox could assist in areas such as misdiagnosis, overdiagnosis, delays in diagnosis, detection of minor lesions, decision-making in disagreement, treatment allocation, disease prognosis, prediction, treatment response prediction, and care integration throughout the patient journey. In addition, the results also provide insight into the implementation barriers that affect the success of solutions such as limited resources, lack of organizational and managerial support, and data entry variability.

The UX design workshops were an answer to many challenges and problems identified. During the stage of initial diagnosis, HCPs highlighted that the toolbox could help in reducing the chances of misdiagnosis and overdiagnosis. Studies highlighted a lack of measures to address diagnostic errors [16,17] and the far-reaching implications of misdiagnosis [18-20] and overdiagnosis [21,22]. The AI toolbox can also guide HCPs in primary care in patient management, thus addressing challenges related to delays in diagnosis, accuracy of imaging modalities, and lack of expertise. During the disease staging, differentiation, and characterization stages, HCPs highlighted that the toolbox could aid in the identification of small lesions that would otherwise be missed by HCPs or lesions that are not very straightforward or easily identified by HCPs, guidance in TNM classification and staging, and the most suitable areas for biopsy, in addition to supporting decisions in cases of disagreement among HCPs or results of the different imaging modalities and tests. HCPs also stressed that the INCISIVE AI toolbox can assist in treatment allocation, disease prognosis prediction, treatment response prediction, and MDT meetings during the third stage of the pathway, which is treatment and follow-up, by addressing issues such as lack of expertise, inaccurate imaging methods, and delays in treatment initiation. An interesting finding emanating from the current work is the vision that AI can support the integration of care across the patient journey, allowing for continuity and efficiency. A feature that proved successful in other chronic conditions in health care [22-24] but has yet to be fully adopted in cancer care in the future.

Several desired features for the INCISIVE AI toolbox were outlined through the Delphi study and the UX design workshops. Interestingly, it can be argued that some of these features apply to the patient's journey regardless of the journey stage; these include (1) integration and display of a comprehensive patient profile, (2) ability to link proposed suggestions to established clinical evidence (studies or guidelines), (3) ability to check drug interactions, (4) notification of the user of the outcome at each stage, (5) ability to see detailed input from the other HCPs involved in the care of each case, and (6) multimodality. On the other hand, and as highlighted earlier in the results section, some of the features desired by the participants are not feasible within the timeframe of INCISIVE. However, these findings are important and may be considered or viewed within the context of the future sustainability of AI in cancer care.

Some features were commonly identified from the Delphi study and the UX design workshops, and the Delphi study provided a chance to prioritize these features by importance from HCPs' perspective, which in return would guide the design of the INCISIVE AI toolbox. Mapping of these features against the users' requirements identified in the INCISIVE project is detailed in Multimedia Appendix 8.

Several barriers were identified to affect the successful implementation of the proposed INCISIVE AI toolbox, thus giving an insight into why similar solutions to the one proposed by INCISIVE usually fail. The participants initially highlighted 23 barriers, which were then distilled down to 10 barriers. Among the most important barriers were lack of resources, lack of organizational and management support, and data entry variability, which are barriers related to the organizational environment. This is not surprising given previous findings in the literature about technology implementation in health care [24]. In previous research by Odeh et al [24] exploring nurses' perceptions toward a telehealth service, the nurses reported a lack of resources, a lack of organizational support, and a lack of technical support to be among the major issues impacting the service's implementation. On the other hand, 5 of the 10 barriers were related to the technology itself, mainly hardware requirements, a lack of proven or established advantages of the AI toolbox, compatibility and integration concerns, the complexity and difficulty of operating the AI toolbox, and the requirement of too much data input from HCPs.

The concern expressed by workshop participants about the possible replacement of HCPs if the INCISIVE system or similar technologies proved successful was a noteworthy finding. This apprehension was further echoed in a cross-sectional web-based survey [23] conducted to investigate physicians' perceptions of Chatbots in health care. Another study [25] has made a positive observation, noting that clinicians demonstrate significant openness when it comes to considering the use of AI-based decision support. This finding emphasizes that AI-based technologies should not be seen as a replacement for HCPs' expertise in decision-making processes. Instead, it should be regarded as a complementary tool that can assist and augment HCPs' abilities, ultimately improving the quality and efficiency of health care delivery.

Regarding data input, the HCPs recognized the need for multiple data inputs throughout the patient journey, which can be argued to be essential for creating a holistic personalized profile for each patient. These data inputs include medical history, laboratory results, histopathological results, imaging results, etc. However, during the workshops, one recommendation made by the HCPs was to entrust the duty of data uploading to a nurse or a junior HCP. The remaining 2 barriers were related to medical and legal issues, including medico-legal issues per accountability and liability in case of disagreement and concerns related to General Data Protection Regulation (patients' privacy and confidentiality) and further legal matters in individual countries. However, this is not new; similar ethical and legal challenges posed by AI in health care have been reported in the literature [26].

Interestingly per the explainability of the proposed AI toolbox, the HCPs expressed interest in having a feature relevance explanation or a hybrid approach that combines feature relevance with visual explanation. This preference aligns with another study [27] that emphasizes the significance of visually directive data-centric explanation methods. In some instances, this preference was driven by specialty and expertise. For instance, during disease staging and characterization (ie, service 2), radiologists were more interested in a visual explanation given their specialty and as a lot of imaging tests take place during this stage of the pathway.

Strengths and Limitations

This study used both quantitative (Delphi study) and qualitative (UX design workshops) methodologies, which aided in triangulating the data and improved the reliability of the findings. HCPs from a variety of specializations participated in this study from several countries. This diverse perspective is guaranteed to be reflective of a broad spectrum of possible users and situations.

It is also essential to recognize this study's limitations. This study focused only on the specification and prioritization of features guided by the design of the INCISIVE platform, without taking into consideration what would be defined as success criteria for the overall implementation. Another notable constraint is the lack of a comparison to evaluate if the perspectives about the suggested INCISIVE AI toolkit were better or distinct from those regarding other AI solutions. Due to the limited sample size and geographical representation, the findings may not be universally applicable. The cross-sectional assessment of the user requirements sets the stage for continuous monitoring and evaluation of the user demands across time.

Conclusions

This paper outlined analysis with regards to the user requirements' definitions of the INCISIVE system. The current work has identified several features for the INCISIVE AI toolbox that are deemed important to guide in the development of the toolbox. Although some of these features may not be pertinent within the remit and duration of the INCISIVE project, they ensure the sustainability of AI in meeting user needs in the future. These features were prioritized and distilled down according to the universal MoSCoW [28] prioritization technique into 4 categories: "must-have," "should-have," "could-have," and "won't-have," or "not have right now" in follow-up research on the INCISIVE project. This step determined the features that would be achievable within the life span of the INCISIVE project and which features are part of the futuristic development of AI in cancer care. Data input and output requirements were also elicited for the INCISIVE AI toolbox. Similarly, these requirements will be prioritized according to the universal MoSCoW prioritization technique to determine what is feasible and can be achieved within the timeframe of the INCISIVE project. Additionally, this paper identified several barriers that would affect the successful implementation of INCISIVE. These barriers will be taken into consideration during the development and implementation phases of the project. Additionally, this paper provided an insight into the level of explainability required from the toolbox and potential users across the 3 services suggested for the toolbox, which are also crucial for guiding the design of the toolbox.

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Data Availability

The datasets used or analyzed during this study are available from the corresponding author upon reasonable request.

Authors' Contributions

IH, SN-G, and RK were involved in this study's design and conceptualization. IH conducted the research and collected the data. AC, ML, ES, WA, JB, and TA were also involved in data collection. Data analysis was completed by IH, SN-G, and RK. IH and LZ were responsible for drafting and finalizing this paper. All authors were involved in data interpretation, manuscript writing, and critical review. All authors read and approved the final paper.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Use case scenarios for AI toolbox users' workshops. AI: artificial intelligence.
[DOCX File , 26 KB - cancer_v10i1e52639_app1.docx]

Multimedia Appendix 2
The first Delphi questionnaire for health care professionals.
[DOCX File , 19 KB - cancer_v10i1e52639_app2.docx]

Multimedia Appendix 3
Practice challenges, needs, and generic features of the INCISIVE AI toolbox at initial diagnosis. AI: artificial intelligence.
[DOCX File , 16 KB - cancer_v10i1e52639_app3.docx]

Multimedia Appendix 4

Practice challenges, needs, and generic features of the INCISIVE AI toolbox at disease staging, differentiation, and characterization. AI: artificial intelligence.

[DOCX File , 16 KB - cancer_v10i1e52639_app4.docx]

Multimedia Appendix 5

Specific features required for the INCISIVE AI toolbox at disease staging, differentiation, and characterization. AI: artificial intelligence.

[DOCX File , 15 KB - cancer_v10i1e52639_app5.docx]

Multimedia Appendix 6

Practice challenges, needs, and generic features of the INCISIVE AI toolbox at treatment and follow-up. AI: artificial intelligence.

[DOCX File , 16 KB - cancer_v10i1e52639_app6.docx]

Multimedia Appendix 7

Data input and output requirements of INCISIVE AI toolbox. AI: artificial intelligence.

[DOCX File , 17 KB - cancer_v10i1e52639_app7.docx]

Multimedia Appendix 8

Mapping user requirements related to features of the INCISIVE AI toolbox. AI: artificial intelligence.

[DOCX File , 19 KB - cancer_v10i1e52639_app8.docx]

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Abbreviations

AI: artificial intelligence
HCP: health care professional
MDT: multidisciplinary team
PIS: participant information sheet
UX: user experience

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Original Paper

Toxic Relationships Described by People With Breast Cancer on Reddit: Topic Modeling Study

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Abstract

Background: Social support is essential to promoting optimal health outcomes for women with breast cancer. However, an estimated 12% of women with breast cancer simultaneously experience intimate partner violence (IPV; physical, psychological, or sexual abuse by an intimate partner). Women who experience IPV during breast cancer may lack traditional social support, and thus seek out alternative sources of support. Online community forums, such as Reddit, can provide accessible social connections within breast cancer–specific communities. However, it is largely unknown how women with breast cancer use Reddit to describe and seek support for experiences of IPV.

Objective: This study aims to explore how patients with breast cancer describe toxic relationships with their partners and immediate family members on Reddit.

Methods: This exploratory, cross-sectional, topic-modeling study analyzed textual data from 96 users in the r/breastcancer subreddit in February 2023. The meaning extraction method, inclusive of principal component analysis, was used to identify underlying components. Components were subjected to sentiment analysis and summative content analysis with emergent categorical development to articulate themes.

Results: Seven themes emerged related to toxic relationships: (1) contextualizing storytelling with lymph nodes, (2) toxic behavior and venting emotions, (3) abandonment and abuse following diagnosis, (4) toxic relationships and social-related fears, (5) inner strength and navigating breast cancer over time, (6) assessing social relationships and interactions, and (7) community advice and support. Toxic relationships were commonly characterized by isolation, abandonment, and emotional abuse, which had profound emotional consequences for patients. Reddit facilitated anonymous venting about toxic relationships that helped patients cope with intense feelings and stress. Exchanging advice and support about navigating toxic relationships during breast cancer were core functions of the r/breastcancer community.

Conclusions: Findings emphasized the value of Reddit as a source of social support for patients with breast cancer experiencing toxic relationships. Clinicians who understand that many patients with breast cancer experience toxic relationships and considerable psychological sequelae are better prepared to support their patients' holistic well-being. Further investigation of Reddit as a possible resource for advice, information, and support has the potential to help inform clinical practice and subsequently, patient health outcomes.

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KEYWORDS

breast cancer; intimate partner violence; meaning extraction method; Reddit; sentiment analysis; social media; social support; toxic relationships; topic modelling

Introduction

> *Breast cancer has a way of making existing cracks in relationships even wider. Just like water will fill a crack in the road, freeze, and create a larger gap, breast cancer tends to permeate all parts of our lives and distance us from people with whom we have troubled relationships.* [Original poster #85]

Projected rates of breast cancer in Canada have remained consistent over the past 5 years, with estimates that approximately 1 in 8 women will develop breast cancer in their lifetime and breast cancer will account for 25% of all new cancer cases [1-3]. Women's experiences of breast cancer are influenced by the social determinants of health, particularly their social environment [4,5]. Among patients with breast cancer, strong social relationships have been found to act as a buffer to stress [6] and help to improve treatment effectiveness, psychological functioning, coping, survival, and quality of life, as well as prevent cancer recurrence [7-9]. Conversely, weak or nonexistent social relationships have been broadly linked to long-term psychological distress [10] and an increased risk of breast cancer progression, recurrence, and mortality [11,12]. However, there is a need for research that explores connections between social relationships and breast cancer outcomes among diverse populations and social contexts.

Intimate partners (eg, spouses and significant others) and immediate family members (eg, parents and siblings) are perceived as the most important social supports for patients with breast cancer [13,14], as they provide essential social-emotional, tangible, affection, and positive social interaction support [15]. For example, partners commonly serve as the primary caregivers of patients with cancer [16]. However, not all social relationships are supportive [17]. Patients who experience intimate partner violence (IPV) may face a lack of support due to the abusive behaviors of their partner [18]. IPV, understood as physical, psychological, or sexual abuse within the context of coercive control by an intimate partner [19], concurrently affects an estimated 12.5% of patients with breast cancer [20]—and this is likely to be an underestimation given underreporting of IPV [21]. Similarly, patients may be negatively affected by an unsupportive (but not necessarily abusive) partner [22], as well as abusive or unsupportive family members [23,24]. Aside from the patients themselves, immediate female family members are often most affected by a breast cancer diagnosis; unsupportive reactions often include being in denial about the diagnosis and abandoning the patient [25].

Toxic relationships are characterized by conflict, competition, undermining, disrespect, and a lack of cohesiveness [26]. Toxic relationships encompass unsupportive and abusive dynamics in both romantic (eg, a partner) and platonic (eg, a family member) contexts and are associated with emotional distress [26], which imparts numerous downstream mental and physical health consequences [27]. To compensate for unmet support needs, patients with breast cancer may expand their social networks via the internet, including social media [28]. Online forums are a popular means of accessing information and support related to breast cancer awareness, literacy, and treatment [29-33]. The use of online breast cancer forums grew exponentially between 2006 and 2010, growing from an estimated 282,000 new posts per year to over 1,270,000 new posts per year [34] and continues to increase over a decade later [35,36]. Despite data availability and the potential for knowledge advancement [33], research on patient social media use, particularly in the context of toxic relationships, is underexplored.

Reddit, the world's third most popular social media platform, is an online forum dedicated to community-building, news dissemination, and discussion facilitation [37]. The Reddit platform consists of topic-specific subreddits (ie, forums), where all content is user-generated. Users subscribe to subreddits that interest them to see more related content. Users can post content, as well as comment and vote on others' content. To join Reddit, users create a username and password—no identifiable information is required. Reddit's capacity for anonymous participation and long-form, conversational content makes the platform a rich source of self-reported textual data [38]. The Reddit platform includes breast cancer–specific spaces that offer access to psychosocial support (eg, r/breastcancer), presenting a unique and valuable opportunity to explore how patients with breast cancer navigate toxic relationships after diagnosis. Previous research has provided preliminary insights into how patients with breast cancer use Reddit [39], but there is a notable gap in the literature regarding how patients with breast cancer describe toxic relationships and their psychosocial impacts on Reddit. Studying social media data has the potential to generate significant advances in knowledge [33], which can inform improvements to psychosocial support for patients with breast cancer experiencing toxic relationships and enhance care providers' ability to promote patient well-being. Accordingly, this study sought to explore how people with breast cancer describe toxic relationships with their partners and immediate family members on Reddit.

Methods

Design

This exploratory, cross-sectional, topic-modeling study was conducted from December 2022 to February 2023 and aimed to explore how patients with breast cancer describe toxic relationships with their partners and immediate family members on Reddit. As of February 2023, the public r/breastcancer subreddit, established in 2011, included 13,900 subscribers and self-identified as a support and information group for people who have been diagnosed with breast cancer and their caregivers and loved ones. While Reddit generally attracts young White men of high socioeconomic status [38], demographics vary by subreddit and r/breastcancer is hypothesized to be largely composed of women [40].

Ethical Considerations

This study was deemed exempt from oversight by the author's institutional ethics review board because all data were gathered from the public domain (per Article 2.2 of the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans). The subreddit at the center of this study was public at the time of data collection and writing, meaning that any person could access its content at any time. It was therefore determined that r/breastcancer users had no expectation of privacy, negating the need for oversight by an ethics review board.

Data Collection

This subreddit was scraped for textual data from posts and comments using the Python Reddit application programming interface wrapper. No date limits were imposed. An iterative approach to keyword-based searching extracted posts (n=187) related to toxic relationships with partners and immediate family members. Two keyword strings were combined to scrape data: String 1 included words associated with a toxic relationship (eg, narcissist, boundaries, abuse, violence, assault, unsupportive, cheater, affair, divorce, toxic, abandon, and manipulate) and string 2 included words that identified people of interest in the immediate family of the user (eg, abuser, spouse, partner, marriage, significant other, parent, and sibling). To be scraped, posts were required to include a minimum of 1 keyword from both string 1 and string 2 (see Textbox 1).

Textbox 1. Keywords included in the final iteration of the search strategy.

String 1

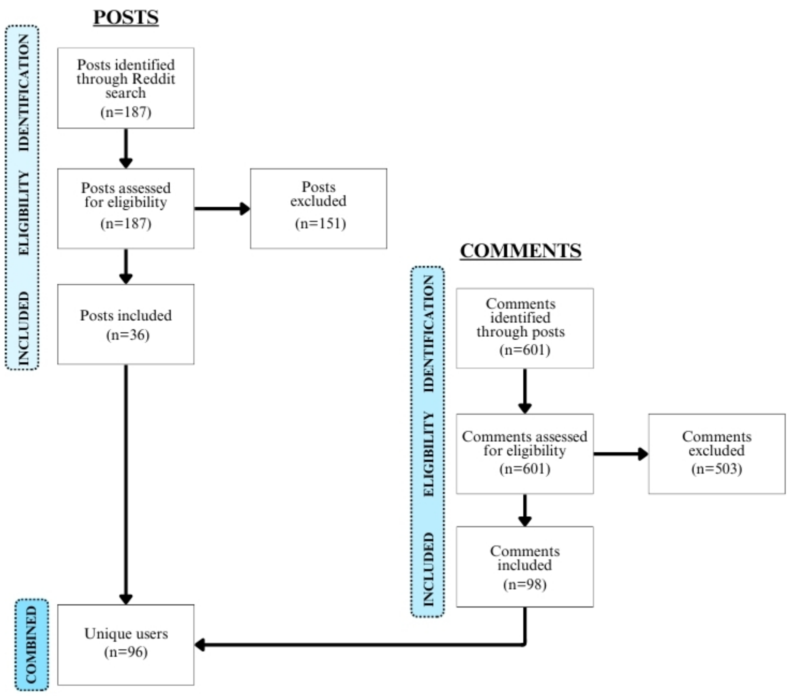
narcissist; boundaries; abuse; abusive; abusing; abused; violent; violence; assault; assaulting; assaulted; harass; harassed; harassing; lie; lied; neglect; unsupportive; not supportive; not supporting; no support; cheater; cheated; cheating; affair; divorce; divorcing; break up; breaking up; broke up; toxic; abandoned; manipulate; manipulated; emotionally unavailable; disown; alone; selfish; strained

String 2

abuser; husband; wife; partner; hubby; marriage; girlfriend; boyfriend; gf; bf; SO; significant other; spouse; mom; mother; mum; dad; father; parent; parents; sibling; sis; sister; brother

The scraped posts were then screened for eligibility by one of the authors (CAD), such that posts were ineligible if they addressed anyone other than a partner or immediate family member, were of an administrative nature posted by a moderator, were posted by a user who did not have breast cancer, aimed to exclusively seek or share medical information, or described toxic relationships outside of the context of breast cancer. After screening, 36 posts were eligible for inclusion. Eligible posts were scraped for comments (n=601), of which 98 were relevant (as determined by CAD using the eligibility criteria described above used to filter posts). Textual data were compiled into packets, where 1 packet represented the total relevant contributions (ie, posts and comments) from a single user, with an average of 260 words per packet. The final data corpus included 96 unique users with 36 posts and 98 comments (see Figure 1).

Figure 1. Final data corpus diagram.



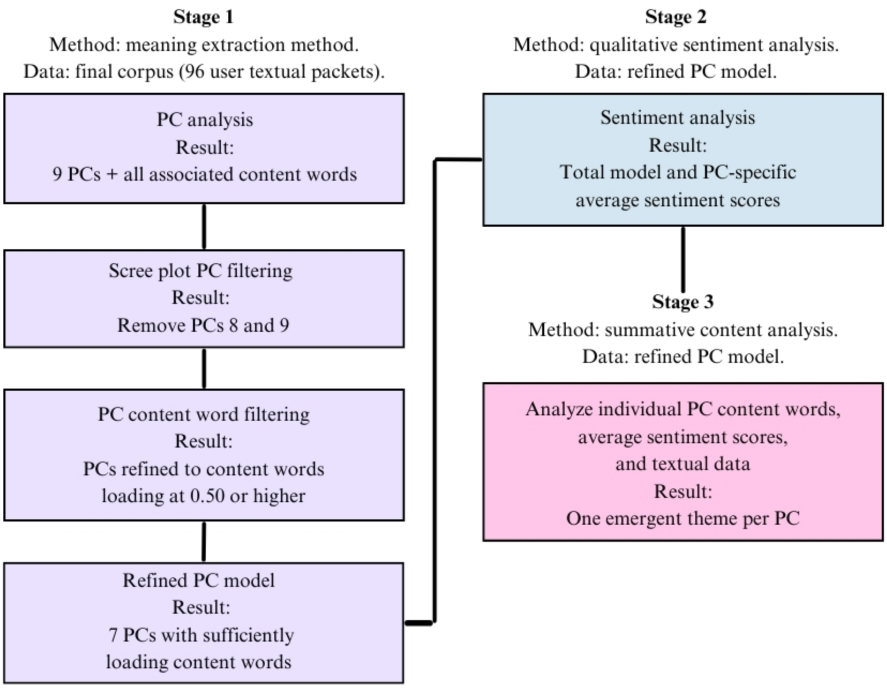
Reddit users have no expectation of privacy in public subreddits and have agreed to the platform's end user license agreement; all Reddit user content is subject to use by third parties at any time [41]. However, recommended ethical practices aim to protect participant privacy by censoring usernames and avoiding direct quotes through exclusion or paraphrasing to prevent reverse-searching [38,42]. Accordingly, within this study, users were assigned an original poster (OP) number, and reported quotes were reworded to convey their original meaning and style but protect the OP's identity. For example (fictitious), "My mom has *never* bothered checking on me" could become "My mother doesn't *ever* ask how I'm doing."

Analysis

Multistaged Approach

A 2021 systematic analysis by Proferes et al [39] identified that computational-driven textual analysis (which includes topic modeling) was the primary means of knowledge generation using Reddit data. However, the authors also identified that such analyses are enhanced by the addition of qualitative and mixed methods analyses that account for contextual details [39]. Accordingly, the data corpus was subjected to a 3-stage, mixed methods analysis that used (1) the meaning extraction method (MEM), (2) qualitative sentiment analysis, and (3) summative content analysis (Figure 2).

Figure 2. The 3 stages of analysis. PC: principal component.



Stage 1: Meaning Extraction Method

The MEM is a form of topic modeling useful for social media data exploration [43] and for generating large sample sizes of participants that are traditionally difficult to recruit [38]. Within other breast cancer–related research using Reddit data, the MEM has been described as a cost-effective means of identifying common themes described by patients [39]. The results of this method have been found to be similar in content and utility to those of traditional research methods in this domain (focus groups) [39].

The MEM identifies word clusters that co-occur in a data corpus, providing an efficient means of extracting meaningful patterns in language within high volumes of natural language data [38,43]. The Meaning Extraction Helper developed by Boyd [44] was used to analyze the textual packet data corpus, inclusive of the removal of common closed and open class words (<7.5%) and content word retention (≥5%), producing a binary output of each retained content word per OP (eg, 0=absent and 1=present). Boyd [45] also developed an open-access script for the R open-access statistical software (R Foundation for Statistical Computing), which was adapted for a principal component analysis (using a varimax rotation [43]). This produced a 9-component model that was considered acceptable (K^2=3357.40, *df*=304, *P*<2.2e–16, and KMO=0.538 [43]). Using a scree plot analysis, components 1 to 7 were retained. The 7 retained components explained 84.16% of the variance—a high proportion for a natural language application [43]. A high loading threshold of 0.50 was imposed on the content words within each component to promote thematic clarity and reduce cross-loading. The final components with refined content words were considered sufficiently strong (≥3 content words per component [46]).

Stage 2: Qualitative Sentiment Analysis

Qualitative sentiment analysis aims to assess the affective valence of components and their content words [47]. Modern qualitative sentiment analysis (ie, internet-based) is an increasingly popular and effective method of interpreting user-generated social media content [48]. Using the *syuzhet* R package [49] and Afinn sentiment lexicon of –5 (negative sentiment) to 5 (positive sentiment [50]), a total model and 7 component-specific sentiment scores were computed based on content words. The content word *tchp* was changed to *combination drug cancer therapy* for the algorithm because it cannot assess acronyms.

Stage 3: Summative Content Analysis

Summative content analysis with emergent categorical development was used to articulate patterns and themes within the textual data packets for each of the 7 refined components [51]. Component categories (referred to as themes) were inductively developed to describe their overall message, inclusive of the use of sentiment scores to contextualize positioning. The 6-step approach to trustworthy thematic analysis by Nowell et al [52], rooted in the trustworthiness theory of Lincoln and Guba [53,54] was adopted.

Summary of Analysis

Quantitative topic modeling (with MEM) was combined with qualitative sentiment and content analysis to produce a comprehensive analytical framework capable of providing an overall interpretive assessment of the data corpus. The r/breastcancer subreddit includes thousands of textual data sources, requiring the combination of complex methods to efficiently target and isolate meaningful, manageable patterns from the large volume of natural language data [38,43]. The MEM is a computational method specifically developed to facilitate efficient filtering of large textual data sets, however, a second stage of qualitative or mixed methods–based analysis is recommended to facilitate deeper exploration and interpretation in context [39]. Accordingly, sentiment analysis was applied within MEM-generated principal components to facilitate the assessment and incorporation of considerations of user's emotions and situational contexts. Following MEM and sentiment analysis, content analysis was used to deeply explore principal components through the lens of their socioemotional contexts to enrich interpretation and understanding. In sum, this combined mixed methods framework aimed to produce holistic, contextualized insights from MEM-generated categories, which is well-suited to complex, dynamic social media data.

Results

Overview of Themes

Seven distinct but related themes emerged from descriptions of toxic relationships by patients with breast cancer on Reddit, presented in order of explained variance proportion (highest to lowest) as follows: (1) contextualizing storytelling with lymph nodes, (2) toxic behavior and venting emotions, (3) abandonment and abuse following diagnosis, (4) toxic relationships and social-related fears, (5) inner strength and navigating breast cancer over time, (6) assessing social relationships and interactions, and (7) community advice and support. The overall corpus sentiment score was –4, indicative of very negative sentiment. Theme-specific sentiment scores () reflect the average valence of retained content words within each component.

Theme 1: Contextualizing Storytelling With Lymph Nodes

> *I'll have to get my lymph nodes removed next, among other things. Treatment is lonely and miserable.* [OP 2]

The first theme was classified as neutral (=0.00) and included *lymph*, *node*, and *pick* as key content words. Lymph nodes functioned as context indicators in users' stories about toxic relationships to highlight their temporality within cancer treatment. For example, one user was undergoing chemotherapy while navigating a toxic relationship with their mother. This OP prefaced their post by sharing, "After a lot of treatment, my cancer went from grade 3 to grade 1. My lymph nodes shrunk as well" (OP 66).

They then went on to disclose unsupportive behavior from their mother, stating, "My mom doesn't think I'm capable of making my own decisions–but I am. I've picked excellent physicians and made it to all of my appointments" (OP 66).

Theme 2: Toxic Behavior and Venting Emotions

> *I'm going to vent because I think it's better to write than to cry...* [OP 65]

The second theme was classified as neutral (=0.00) and described toxic relationships that the user experienced a strong emotional reaction to, which prompted them to vent their emotions on Reddit. Key content words included *boundary*, *effort*, *vent*, *upset*, and *stress*. Users reported a variety of toxic behaviors, such as boundary violations and disrespectful or abusive actions. Venting was commonly used to cope with powerful negative emotions associated with toxic relationships.

Users felt unsupported when their partners or families reacted to their diagnosis by becoming detached or distressed to the extent of relying on the patient for support. To illustrate, one user expressed disappointment in their father's silence after diagnosis, stating, "My dad isn't there for me. I guess I shouldn't be surprised, he's always been like this" (OP 45).

Other users were frustrated with bearing the emotional burden for others regarding their cancer. For example, one OP resented their husband for expecting them to manage his emotions, sharing, "I did my best to explain that I needed him to be my rock. He got upset... he wanted us to be mutually supportive. But he doesn't have cancer.... I do!" (OP 62).

Some OPs described being disrespected and emotionally abused following their diagnosis. For instance, one OP shared that their partner told them, "Lately, you aren't sexually desirable to me without your natural breasts. I miss them and how they felt... probably even more than you do" (OP 65).

Similarly, another OP disclosed experiencing emotional and verbal abuse from their partner both before and after their breast cancer diagnosis. This OP shared feeling extremely upset that just 2 weeks after their diagnosis, their partner asked them, "How long are you going to pull the breast cancer card?" (OP 85).

Toxic relationships described within this theme were strongly associated with venting, that is, posting negative, emotionally charged content. For example, an OP trying to cope with being isolated by their family prefaced their story by writing, "Heads up that this is a massive, sad vent post. Sorry but I feel like I need to shout into the void" (OP 34).

Theme 3: Abandonment and Abuse Following Diagnosis

> *Anyone else dealing with an emotionally abusive spouse before and during cancer? I'm trying to get away and he's being awful.* [OP 40]

Theme 3 was classified as slightly negative (=–1.00) and captured how patients in toxic relationships were abandoned or emotionally abused by their partners following their diagnosis. Key content words included *devastate*, *experience*, and *abuse*. Patients who navigated abandonment or abuse concurrently with a breast cancer diagnosis reported feeling emotionally devastated.

Abandonment was especially common after disclosing a breast cancer diagnosis. For example, one OP shared that their husband abandoned them on the way home from their diagnosis appointment, stating, “He said he won’t look after the kids and plans on leaving” (OP 9). Other users were abandoned as treatment began. Many users who shared stories of abandonment described emotional whiplash, characterized by a sudden, unexpected transition from feeling secure in their relationship to feeling betrayed following abandonment. As illustrated by one user, “He made me feel cared for, loved, and safe... until I said I was considering a mastectomy. Then he shut me out” (OP 12).

The emotional impacts of betrayal were devastating. An OP whose long-term partner unexpectedly broke their promise to stick by them during treatment shared, “I am completely devastated. I am infuriated. He and my body betrayed me. I am so furious” (OP 86).

Of partners who stayed following a diagnosis, many subjected the patient to emotional abuse. One OP was told that they deserved their cancer, recounting, “He used my cancer against me by saying I got it because I’m weak and that’s just natural selection at work. He told me not to bother with treatment and to just let nature run its course” (OP 76).

Other experiences involved infidelity, threats of child abandonment, accusations of faking symptoms, and coercion in treatment choices. Emotional abuse was repeatedly described as devastating. For example, an OP whose spouse had been emotionally abusive for years posted, “What can I do to stop feeling devastated that my husband feels I should be punished all the time?” (OP 40).

Theme 4: Toxic Relationships and Social-Related Fears

> *Do any of you also feel like the emotional consequences of breast cancer are almost worse to deal with than the physical?* [OP 66]

The fourth theme was classified as slightly negative (=–0.75) and focused on social-related fears associated with breast cancer. Key content words included *biopsy*, *tchp*, and *scare*. Patients’ fear stemmed from anticipating or experiencing a negative reaction to their breast cancer by a toxic family member or partner. For example, an OP who disclosed a toxic family shared dreading their reaction to their cancer, expressing, “The fear of how my family will react to my breast cancer diagnosis is nearly as overwhelming as the actual diagnosis” (OP 81).

Other users felt scared because they had already experienced an unsupportive reaction by a toxic family member or partner to their cancer. For example, one OP felt scared and hopeless after being gaslit by their partner about their diagnosis, sharing, “He was trying to tell me that my breast cancer was all in my head, despite having seen my biopsy results and meeting with multiple members of my medical team” (OP 3). Similarly, an OP whose family neglected to support them after learning of their diagnosis expressed, “My family doesn’t care about me or my breast cancer. It makes me feel scared and alone” (OP 34).

Theme 5: Inner Strength and Navigating Breast Cancer Over Time

> *I thought to myself that if my cancer ever came back, I’d rather deal with it alone than with a person like that.* [OP 32]

Theme 5 was classified as slightly positive (=1.00) and highlighted how breast cancer was disruptive to the lives of patients. Key content words included *future*, *matter*, and *strength*. Users described how health and social adversity influenced their inner strength. Toxic relationships that emerged after diagnosis were especially trying for patients. For instance, one OP expected their partner’s support as they began cancer treatment (as their partner had promised). However, the OP’s partner abruptly took back their commitment, leaving the OP to navigate cancer alone: “They sent me a message the next day and said they don’t want anything to do with me” (OP 12).

Inner strength emerged as a dynamic construct that was both challenged by experiencing a breast cancer diagnosis and toxic relationships and enhanced by surviving these adverse experiences. Many users believed that surviving breast cancer concurrently with exposure to toxic relationships was a testament to their inner strength. For example, one OP attributed their inner strength to recovering from breast cancer while navigating a lack of empathy and support from their spouse. This OP stated, “I feel 100% confident that I am a strong, intelligent woman who can face almost anything” (OP 64), while sharing that they had received a new cancer diagnosis. Inner strength also enabled users to regain a sense of control over how they were going to navigate living with a breast cancer diagnosis. For example, an OP who was abandoned by their partner after being diagnosed stated, “I finally felt strong enough to delete his contact information because I couldn’t stop myself from calling him–it was the best choice I could have made” (OP 47).

Theme 6: Assessing Social Relationships and Interactions

> *I am immensely grateful for you all for helping me navigate a chaotic and frustrating moment.* [OP 85]

The sixth theme was classified as marginally positive (=0.20) and described how OPs assessed their social relationships and interactions. Key content words included *conversation*, *response*, *listen*, *regret*, and *grateful*. Users assessed the quality of social support from family based on whether they felt judged, subjected to toxic positivity, or made to listen to unsolicited advice. For example, an OP with an emotionally unsupportive family shared, “I think a lot of family think it’s helpful when they shove positivity down our throats. What we really need is support and someone to listen without trying to solve all our problems” (OP 82).

For some users, responses to breast cancer unveiled toxic relationships that they regretted having to face. For example, an OP with unsupportive parents shared, “I regret that my breast cancer forced me to confront that my parents never have and still don’t support me how I need them to” (OP 4). However, OPs who discovered both toxic and supportive relationships during cancer expressed gratitude for the sources of support they did have. As one OP stated, “Sometimes I get jealous of people whose parents love and support them, but then I remember the rest of my friends and family who showed up for me when I needed them, and I’m grateful” (OP 32). The subreddit community was repeatedly praised by users because it was such a valuable source of support. For instance, one OP shared, “I am endlessly grateful for the knowledge and resilience of this community” (OP 53).

Theme 7: Community Advice and Support

> *I know what it feels like to be abandoned. I could tell you all the red flags in a man’s behavior... but just trust me–it’s better to be alone. You dodged a MASSIVE bullet. A person who lacks compassion about your breast cancer is NOT a good life partner. Please message me if you need someone to vent to. I really do understand...and you’ve got this.* [OP 89]

The seventh theme was classified as marginally negative (=–0.17) and characterized a core function of r/breastcancer: providing advice and support. Key content words included *money*, *quit*, and *follow*. The subreddit facilitated advice regarding various topics, especially related to navigating financial matters and treatment options in the context of a toxic relationship.

Numerous users offered money-related advice to OPs facing difficult financial situations because of toxic relationships. Situations included financial coercion, exploitation, and manipulation following cancer disclosure and managing finances during separation from a toxic partner. For instance, one OP was abandoned by their partner during a joint real estate purchase. A community member with self-professed real estate expertise strongly advised the OP against continuing with the investment, writing, “I’m begging you... please do NOT sign anything else! Lose your money... that’s not important... please do not continue with this purchase” (OP 89).

Members also counseled OPs about postmastectomy reconstruction by offering advice on how to reduce social pressure and prioritize personal preferences. For example, one OP shared how they resisted their partner’s pressure to follow reconstruction, stating, “I made him look at photos of reconstruction to show him that it’s not a free boob job and can be ugly. He changed his tune real quick” (OP 39).

Members who were ultimately pressured into reconstruction strongly encouraged OPs to follow their instincts. For example, one member who was coerced into reconstruction by their husband advised, “I constantly wish I went flat instead. If I had to do it again I would listen to my gut and go flat” (OP 8).

Similarly, it was common to share advice about treatment adherence. Many OPs struggling with a lack of support expressed wanting to quit treatment. While members empathized with users and understood their feelings, they ultimately encouraged continuing. For example, one OP shared, “I’m just sick of this. I’m pretty sure I’m done with it all” (OP 34).

The community offered empathy, such as, “When I was in the middle of your treatment, I was frustrated too and tried to quit every week” (OP 7), as well as advice, for example, “Don’t stop treatment without a good reason. It’s a gift in spite of tough side effects because it keeps us alive” (OP 48).

Discussion

Principal Results

This study explored the use of the r/breastcancer subreddit by patients to describe toxic relationships with their partners and immediate family members. Themes highlighted patients’ lived experiences of toxic relationships, emotional impacts, and support from the subreddit community. A key finding was that many people with breast cancer sought out the r/breastcancer subreddit to share their experiences of toxic relationships, often including descriptions of abandonment, isolation, and emotional abuse within this context. Further, this study presented compelling evidence that toxic relationships impart profound emotional consequences for patients and that some patients cope with these strong emotions through online venting. This work also emphasized the value of online communities like Reddit as alternative, complementary sources of support for patients experiencing toxic relationships.

Comparison With Prior Work

Abandonment and Betrayal as Common Experiences

These findings suggest that abandonment is a common experience for patients with breast cancer following diagnosis. Prior research has lacked consensus regarding the risk of abandonment among patients with breast cancer after diagnosis [55,56]. Generally, however, women are more likely to be abandoned by a partner after being diagnosed with a serious medical illness [57]. Further, distancing is the most prevalent unsupportive response experienced by a patient following their breast cancer diagnosis [23]. Fears and feelings of abandonment following diagnosis are also well-documented within breast cancer research [58-60]. Given this understanding, and considering that Reddit data can be regarded as an authentic representation of user experiences [61], it is reasonable to conclude that these findings are suggestive of an increased risk of abandonment for patients with breast cancer.

A novel finding was the occurrence of emotional whiplash, where a patient was initially promised support by their partner but was later abandoned unexpectedly. The emotional transition from security to betrayal was repeatedly reported as devastating. There is limited research describing betrayal in the context of abandonment and breast cancer, but it is known that feelings of betrayal in this context can reduce the desire for future relationships [62]. Broadly, the loss, disruption, and deterioration of social ties are some of the most stressful experiences a patient with cancer can face [6], which makes abandonment a serious risk factor for reduced mental health [63]. Comprehensive cancer care entails stress-reducing psychosocial interventions [63], but a limited understanding of the psychological effects of betrayal hinders clinicians' ability to optimally manage abandonment-related stress.

Anonymous Venting Enables Disclosure of Toxic Relationships

The central role of venting within the r/breastcancer community highlighted the unique socioemotional needs of patients with breast cancer in the context of toxic relationships. Toxic relationships impart emotional consequences that can be difficult to navigate and cope with [26]. Venting is a disinhibitory, emotion-focused strategy for coping with stress [64,65]. Venting can be considered a form of expressive writing, that is, writing that describes a deeply personal experience [66], which is well-evidenced to facilitate coping with psychological distress [67]. Online venting was consistently described as cathartic among patients in this study, aligning with prior evidence of patients with breast cancer seeking support in online communities during periods of stress [68] and perceiving reduced stress after they vent online [69]. Further, patients with breast cancer who self-manage their emotions by narrating their experiences are known to experience strong psychological benefits [70].

It might be expected that the stigma attached to breast cancer and toxic relationships would hinder disclosure [58,71], however, seeking out group-oriented support is reportedly most common for diseases considered stigmatizing [72]. The latter position is consistent with this study, as venting posts often included stigmatized thoughts and feelings (eg, wanting to 'give in' to cancer or discussing abuse without wanting to leave the relationship). Further, it appeared that Reddit's capacity for anonymity created a sense of safety that made patients comfortable disclosing information considered stigmatizing, which is consistent with existing evidence [73]. Overall, patients appeared to perceive anonymous venting via Reddit as an effective, safe strategy for coping with stress from toxic relationships. Interventions that aim to promote coping among this patient population would likely benefit from integrating anonymity to encourage uninhibited self-expression.

Advice About Navigating Toxic Relationships

Validating the feelings of other users, as well as soliciting and providing advice regarding toxic relationships, were core activities within r/breastcancer. It was previously known that participation in online forums contributes to the practical, informative, and emotional empowerment of patients with breast cancer [74]. However, this study uniquely identified that community members on Reddit often urged OPs to leave or go against the wishes of their abusive partner. While well-intentioned, this advice may not always be safe or practical. Leaving an abusive partner can be the most dangerous time in the relationship due to an increased risk of retaliation [75]. Similarly, acting in a manner that might antagonize an abuser can initiate or escalate relationship discord and consequently increase the risk of violence [76]. Furthermore, patients who depend on an abusive partner (eg, for caregiving, access to health insurance, and transportation to appointments [77]) may be unable to leave or risk the relationship by acting defiantly [78]. Resultantly, relationship advice received on Reddit by patients with abusive partners may have been incompatible with their reality or suboptimal in promoting their safety.

This indicates a knowledge gap concerning safety planning within r/breastcancer; safety planning can be understood as the development of strategies to reduce the risk of abuse and enhance support [79]. Safety planning is a proven, widely endorsed health promotion intervention that is effective both within an abusive relationship and after leaving [80,81]. Considering the prevalence of abuse among patients with breast cancer [20] and that many seek support in online forums such as Reddit [39], it could be useful to raise awareness of safety planning within r/breastcancer as a health promotion strategy. Further, considering the importance attributed to inner strength by patients in this study, building awareness of strengths-based approaches to safety planning [82] could be particularly useful. For example, community moderators could pin relationship-related resources (eg, hotlines and informative websites) as the top comment under posts about challenging, potentially toxic relationships. However, a needs assessment would be best suited to developing an IPV-related intervention considered acceptable and effective within r/breastcancer.

Clinical Implications

Psycho-oncology care teams play a critical role in optimizing health outcomes for patients with breast cancer, yet the emotional well-being of patients with cancer is often underreported and underexplored [83]. Patient-reported social media data offers real-time insights into patient experiences and needs which can be beneficial for informing clinical practice [33,83].

Clinicians who understand that many of their patients with breast cancer are negatively affected by toxic relationships are better prepared to support their emotional well-being. Acquiring knowledge about practices and resources that foster coping and inner strength, including venting and safety planning, can contribute to improved patient outcomes.

Some clinicians may be unfamiliar with the advantages of online forums for patients, but recognizing the potential benefits could enhance care [84]. Recommending Reddit as a possible source of advice, information, and support could be a valuable addition to clinical practice for patients navigating breast cancer and toxic relationships. However, because digital literacy is often overlooked in breast cancer care [85], clinicians who concurrently promote digital literacy can empower their patients to access online communities and ultimately, improve their health outcomes.

Limitations

There are limitations to this work. First, the analysis was conducted by a single researcher, which may have introduced bias in data interpretation. The analysis also relied heavily on automated methods that may have been inadequate in fully capturing nuance or interpreting context cues in textual data. Second, these data are self-reported, which may have resulted in biased perspectives. While users in this sample self-identified as patients with breast cancer, it was not possible to validate this. These data may have inadvertently included content from online robots or people without breast cancer, and thus may not accurately reflect the experiences of the target population. Additionally, these data were scraped from a single social media platform and may not be representative of the experiences of patients who use other social media platforms, do not use Reddit to discuss their personal lives, or lack access to an internet-enabled device. No demographic information was available to further contextualize findings. It is important to note that these results only relate to experiences of emotional abuse, as physical and sexual abuse were not represented in the data. Furthermore, all participants could write in English, were digitally literate, and had access to the internet, meaning that the findings may not represent the experiences of patients who are nonanglophone or lack technological access or literacy. Caution should be used when applying these findings to other patients with breast cancer.

Conclusions

This study identified that toxic relationships described by patients with breast cancer on Reddit were common and characterized by abandonment, abuse, and unsupportive behaviors. Patients often experienced profound emotional reactions to this form of social stress and anonymous venting on Reddit was described as an effective coping mechanism. Some patients described breast cancer and toxic relationships as adverse experiences that ultimately enhanced their inner strength. Overall, the r/breastcancer community appeared to be a means of exchanging advice, information, and support for patients experiencing toxic relationships. Clinicians who understand that their patients may be negatively affected by toxic relationships are better prepared to support their holistic well-being. Further investigation of Reddit as a possible source of advice, information, and support has the potential to help inform clinical practice and subsequently, improve patient health outcomes.

Data Availability

The data sets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

CAD was involved in the conceptualization, data curation, formal analysis, investigation, methodology, and both original draft preparation and review and editing of the manuscript. RB, KTJ, and TM contributed to the conceptualization, supervision, methodology, and review and editing of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

IPV: intimate partner violence
MEM: meaning extraction method
OP: original poster

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Scope, Findability, and Quality of Information About Music-Based Interventions in Oncology: Quantitative Content Analysis of Public-Facing Websites at National Cancer Institute–Designated Cancer Centers

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Abstract

Background: Music-based interventions (MBIs) are evidence-based, nonpharmacological treatments that include music therapy (MT) delivered by board-certified music therapists, as well as music services (MS) delivered by other health professionals and volunteers. Despite MBI's growing evidence base in cancer symptom management, it remains unclear how MBI-related information is presented to the public. Over 80% of people with cancer use the internet to find health-related information. In the United States, the National Cancer Institute (NCI) identifies certain Cancer Centers (CCs) as NCI-designated CCs or Comprehensive Cancer Centers (CCCs) based on their excellence in research. As NCI-designated CCs and CCCs are considered the gold standard in cancer care, their websites are viewed by the public as important sources of information.

Objective: We aimed to determine scope, findability, and quality of MBI-related information on public-facing websites of NCI-designated CCs/CCCs.

Methods: We reviewed 64 NCI-designated CC/CCC websites (excluding basic laboratories) between November 2022 and January 2023. We extracted data on the scope of information: (1) type of MBI offered (MT or MS), (2) format (individual, group), (3) method of delivery (in person or remotely delivered), (4) setting (inpatient or outpatient), (5) target population (pediatric or adult), (6) MBI practitioner qualifications, (7) clinical indications or benefits, (8) presence of testimonials, (9) cost, and (10) scheduling or referral information. We also extracted data on findability (ie, presence of direct link or drop-down menu and the number of clicks to locate MBI-related information). Based on the scope and findability data, we rated the information quality as high, moderate, or low using an adapted scale informed by prior research.

Results: Thirty-one (48%) of the 64 CC/CCCs described MBIs on their websites. Of these, 6 (19%) mentioned both MT and MS, 16 (52%) mentioned MT only, and 9 (29%) mentioned MS only. The most common format was hybrid, involving individuals and groups (n=20, 65%). The most common delivery method was in person (n=16, 52%). The most common target population was adults (n=12, 39%). The most common MBI practitioners were board-certified music therapists (n=21, 68%). The most described indications or benefits were psychological. Twenty-eight (90%) websites lacked testimonials, and 26 (84%) lacked cost information. Twenty-six (84%) websites provided scheduling or referral information. MBI-related information was found with an average of 4 (SD 1) clicks. Nine (29%) websites were of high quality, 18 (58%) were moderate, and 4 (13%) were low.

Conclusions: Based on public websites, MBIs were most commonly delivered in person by board-certified music therapists to outpatient and inpatient adults, using individual and group formats to provide psychological benefits. The findability and quality of this information should be improved to promote the dissemination of MBIs for cancer symptom management.

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KEYWORDS

music-based interventions; cancer; oncology; symptom management; music therapy; music services; National Cancer Institute

Introduction

Management of symptoms and treatment-related side effects are a key priority in oncology [1]. Undertreatment of symptoms may contribute to worse cancer-related outcomes, including treatment nonadherence, higher health care use, and increased mortality [2-9]. Medications are commonly used for managing symptoms. However, polypharmacy represents a major concern in the cancer population, with approximately 64% already taking five or more medications [10]. Polypharmacy is associated with financial toxicity, higher risk of side effects and adverse medication interactions, and poor quality of life [10,11]. These risks of polypharmacy underscore the need for effective nonpharmacological approaches for cancer symptom management [11-13]. Various nonpharmacological interventions (eg, exercise and cognitive-behavioral therapy) have demonstrated effectiveness for cancer-related symptoms, such as fatigue or psychological distress [14,15], but these options may not be optimal for all individuals. For example, barriers to physical activity are well documented in cancer populations [16]. Furthermore, some cultures view conventional psychotherapy, such as cognitive behavioral therapy, as stigmatizing [17,18]. Due to these limitations, there is a critical need for more nonpharmacological options to address the diverse needs of patients with cancer.

Music-based interventions (MBIs) are evidence-based, nonpharmacological treatment options that include music therapy (MT) and music services (MS) [19,20]. MT is delivered in individual or group-based formats by board-certified music therapists who guide patients through music experiences to achieve therapeutic goals. These music experiences may include listening to live, improvised, or prerecorded music; playing instruments; improvising music using voice or instruments; and songwriting [20]. Board-certified music therapists are trained to design and facilitate personalized therapeutic processes to address individual needs [21]. In contrast to MT, MS are not delivered by board-certified music therapists; MS is a broad category that includes music performances by volunteer musicians in medical settings and listening to prerecorded music offered by medical personnel [22].

MBIs have a robust evidence base for cancer symptom management [20], particularly for symptoms that have been identified by the National Cancer Institute (NCI) as high priority [1]. A recent Cochrane review found that MBIs demonstrated effectiveness for anxiety, depression, pain, fatigue, and quality of life [20] As a result, MBIs are recommended in several clinical guidelines for cancer symptom management [23-26]. In a recently published joint guideline from the Society for Integrative Oncology and the American Society of Clinical Oncology, MT was recommended for anxiety and depression during active cancer treatments [25]. MBIs are thought to improve cancer-related symptoms through music's effects on brain regions (eg, amygdala), psychosocial processes, as well as biological systems (eg, hypothalamic-pituitary-adrenal axis, autonomic nervous system) [27-31]. Given that music is a potent inducer of reward responses [32-34], MBIs could also potentially be more engaging for patients with cancer who find it difficult to adhere to other nonpharmacological interventions. Finally, music is found in nearly all cultures around the world [35,36]. This multicultural presence supports the unique potential of MBIs to appeal to diverse cancer populations as an option for symptom management.

Despite the growing evidence of MBIs, the availability of information about MBIs in the public sphere remains unclear. Gaps in knowledge about MBIs could limit the adoption and uptake of this evidence-based modality by patients, families, and their health care providers. One study found that most people search for health-related information online, and nearly 60% experience frustration during the online search process [37]. Another study found that over 80% of people with cancer use the internet to find health-related information [38], and they most commonly search for information related to treatment options and complementary therapies [39].

In the United States, NCI identifies certain Cancer Centers (CCs) around the country as NCI-designated CCs or NCI-designated Comprehensive Cancer Centers (CCCs) based on their scientific excellence and research capacities. NCI-designated CCs demonstrate excellence in laboratory, clinical, or population science research, whereas NCI-designated CCCs meet additional rigorous standards, including greater depth and breadth of research, access to more extensive resources, and greater transdisciplinary collaboration across basic, clinical, and population science research. Since NCI-designated CCs and CCCs are considered the gold standard in cancer care, their websites are often viewed as an important resource for health-related information. However, prior research has demonstrated key information gaps on these websites for topics relevant to patients with cancer [40,41]. Therefore, we investigated the scope, findability, and quality of MBI-related information on the public-facing websites of NCI-designated CCs and CCCs.

Methods

Study Design

This study is a quantitative content analysis of information about MBIs found on public-facing web pages of NCI-designated CCs [42,43]. Content analysis is a systematic method to code and quantify written, visual, or oral content [44]. For ease of reading, we will use the term "CC" to refer to both CCs and CCCs, except in instances where the distinction between CCs and CCCs is important to highlight.

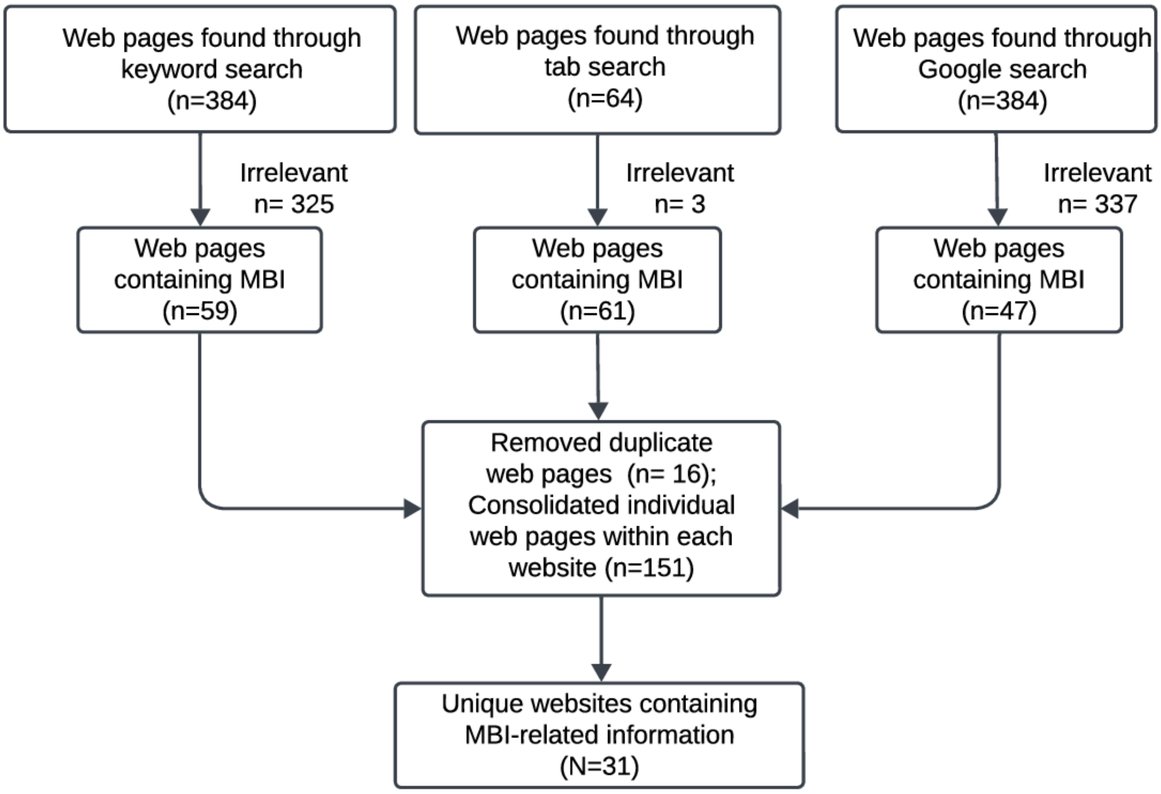
Inclusion and Exclusion Criteria for Websites

Websites were included in this study based on these criteria: (1) they belonged to an NCI-designated CCC or an NCI-designated CC. and (2) they contained MBI-related information. Websites were excluded from this study based on this criterion: (1) they were from an NCI-designated CC that was categorized as a basic laboratory.

Search Strategy

Six members of our research team executed the search strategy and data extraction (CAB, SB, AM, KS, ML, and KM). These team members included a postdoctoral researcher, as well as high school, undergraduate, and graduate students. Data extraction was completed in pairs with one person handling the initial data extraction and the second person checking the data extraction for accuracy. We reviewed 64 NCI-Designated CCs listed on the NCI website [45] between November 2022 and January 2023, excluding the seven CCs identified as basic laboratories. Following the methods from similar studies, [46,47] we used three different search strategies to identify CCs that offer MBIs: (1) keyword searching with search terms "music," "music therapy," "musician," "therapeutic music," "harp," and "sing" using the CC website's search function; (2) tab searching, which entailed systematically reviewing each menu tab or link on the website's home page (eg, "patient information" tab or "services" tab) for MBI-related information; and (3) the first page of results from Google searching using the aforementioned search terms combined with the name of the CC (Figure 1). Mentions of music that were irrelevant to MBI (eg, music fundraisers) were removed. Duplicate web pages were also removed. Individual web pages within each specific website were consolidated. Two coders used each search strategy. An Excel (Microsoft Corp) spreadsheet was used for data abstraction, with a priori determined categorical data entries as well as open text fields to allow for entry of more detailed descriptions. The team met biweekly to peer-check the coding and resolve search discrepancies through discussion.

Figure 1. Search strategy for identifying National Cancer Institute–designated Cancer Center websites containing information related to music-based interventions.



Evaluating the Scope of MBI-Related Information

We extracted the following MBI-related information from the public-facing websites of NCI-designated CCs: (1) type of MBI offered (eg, MT or MS) and the specific music activities involved (eg, music listening or group drumming), (2) format (eg, individual or group), (3) method of delivery (eg, in person or remotely delivered), (4) setting (eg, inpatient or outpatient), (5) target population (eg, pediatric or adult), (6) MBI practitioner qualifications (eg, board-certified music therapist, volunteer musician, etc), (7) clinical indications or treatment benefits (eg, reducing anxiety), (8) presence of testimonials about MBIs, (9) cost or fees, and (10) information about scheduling MBIs or referring patients for MBI.

We used the Theory of Planned Behavior (TPB) to inform our data extraction [48]. The TPB posits that an individual engages in a specific health behavior (eg, use of MBI) as a result of three key factors: (1) expected benefits or outcomes of the behavior (eg, symptom burden reduction), (2) perceived barriers to engaging in the behavior (eg, unfamiliarity or lack of knowledge about what MBIs entail, high costs associated with MBI use, limited availability of qualified MBI providers), and (3) social norms regarding the behavior (eg, information regarding for which patient populations MBIs are intended, testimonials from other patients with cancer, and recommendations from oncologists). Prior research demonstrated that these TPB factors predict the use of complementary alternative medicine by patients with cancer [49,50]. Thus, by extracting information across the three TPB domains, we were able to not only capture the scope of MBIs offered at CCs but also determine whether websites contain the critical information that influences patients' decision to seek MBIs.

Evaluating Findability of MBI-Related Information

Given that over 60% of patients experience frustration while searching for health-related information online [38,39], we evaluated findability of MBI-related information by first identifying CCs with a website home page that contained an easily identifiable link or drop-down menu to direct patients to MBI-related information. For CCs that did not contain an easily identifiable direct link or drop-down menu, we quantified the success path, a common website navigation metric, which we define here as the number of clicks needed to reach MBI-related information from a CC's home page [51,52]. Similar approaches have been used in other research to evaluate the findability of information on CC websites [41].

Evaluating Quality of MBI-Related Information

We used the scope and findability of MBI-related information to assign an overall information quality rating for each CC website (Table 1). Our scale for rating the quality of MBI-related information was adapted from the approach used by Silver et al [41] who similarly used findability and scope of information to assign a quality rating.

Table . Quality rating scale for information about music-based interventions found on National Cancer Institute–designated Cancer Center websites.

Rating	Findability	Scope of information provided
High	Success path ≤3 clicks	Web pages provide the following information: (1) type of music-based interventions offered; (2) clinical indications or treatment benefits; and (3) at least two of the following: (a) practitioner qualification, (b) referral information, (c) cost of service, (d) testimonials, (e) video of music-based intervention patient encounter, and (f) research evidence.
Moderate	Success path >3 clicks	Web pages provide the following information: (1) types of music-based interventions offered; (2) clinical indications or treatment benefits; and (3) only one of the following: (a) practitioner qualification, (b) referral information, (c) cost of service, (d) testimonials, (e) video of music-based intervention patient encounter, and (f) research evidence.
Low	Success path >5 clicks or no success locating the information with a keyword search	Web pages state that music-based interventions are offered but contain no details regarding type of music-based interventions offered; clinical indications or treatment benefits; practitioner qualifications; referral information; cost of service; testimonials; video of music-based intervention patient encounter; or research evidence.

Ethical Considerations

This study analyzed publicly available information from websites in the public domain. No human subjects were involved in this study, and no personal identifiers or confidential data were collected. Therefore, approval from an institutional review board was not required for this type of research.

Results

Characteristics of CCs With MBIs

Of the 64 CCs, we identified 31 (48%) CCs that had information about MBIs on their public-facing website. Table 2 summarizes the NCI designation and regions for the 31 CCs that offered MBIs at the time of data collection. Links to the websites of these CCs can be found at this NCI directory [45].

Table . Characteristics of 31 Cancer Centers mentioning music-based interventions on their websites.

Characteristics	Cancer Centers, n (%)
National Cancer Institute–designation	
Cancer Center	8 (26)
Comprehensive Cancer Center	23 (74)
Region	
Midwest	5 (16)
Northeast	7 (23)
Southeast	9 (29)
Southwest	3 (10)
West	7 (23)

Scope of Information About MBIs

Overview

The scope of information about MBIs found on the NCI-designated CC websites is summarized in Table 3.

Table . Scope of information about music-based interventions presented on the 31 National Cancer Institute–designated Cancer Center websites.

Characteristics	Cancer Center websites, n (%)
Type of music-based intervention	
Music therapy only	16 (52)
Music services only	9 (29)
Music therapy and music services	6 (19)
Format of music-based intervention	
Individual	2 (6)
Group	4 (13)
Both	20 (65)
Not reported	5 (16)
Method of delivery	
In person	16 (52)
Telehealth	2 (6)
Both	6 (19)
Not reported	7 (23)
Setting	
Inpatient	5 (16)
Outpatient	1 (3)
Both	19 (61)
Not reported	6 (19)
Target population	
Adult	12 (39)
Pediatric	5 (16)
Both	10 (32)
Not reported	4 (13)
Music-based intervention practitioners	
Board-certified music therapists	21 (68)
Other health professional	1 (3)
Musician	4 (13)
Other volunteers	5 (16)
Patient testimonials	
Yes	3 (10)
No	28 (90)
Cost or fee	
Free	2 (6)
Partially funded	3 (10)
No information provided	26 (84)
Scheduling or referral information	
Yes	26 (84)
No	5 (16)

Types of MBIs

Sixteen (52%) CCs listed MT services on their websites and did not appear to offer MS by nonmusic therapists. Nine mentioned only MS. Six CCs offered both MT and MS. Twenty-eight (90%) CCs provided information about the specific activities involved with MBIs. We grouped these activities into broad categories, such as listening to prerecorded music, songwriting, and lyric discussion (Table 4). The most frequently offered activities were music improvisation, playing instruments, music-guided relaxation, and songwriting.

Table . Specific music-based intervention activities described on National Cancer Institute–designated Cancer Center websites.

Interventions	Music therapy programs (n=23), n (%)	Music services programs (n=14), n (%)
Listening to prerecorded music	11 (48)	0 (0)
Music-guided relaxation	18 (78)	5 (36)
Singing	14 (61)	1 (7)
Lyric discussion	12 (52)	0 (0)
Music-guided movement	5 (22)	0 (0)
Learning or performing music	6 (26)	0 (0)
Music improvisation or playing instruments	21 (91)	2 (14)
Music making with family	5 (22)	0 (0)
Recording legacy music	6 (26)	0 (0)
Songwriting	18 (78)	0 (0)
None listed	2 (9)	1 (7)
Other[a]	7 (30)	9 (64)

[a] Includes listening to music in public spaces, neurologic music therapy, nonspecified music-based practices, and watching music videos.

Format

Twenty (65%) CCs offered MBIs in both individual and group formats. Two (6%) CCs only offered MBIs in an individual format; four (13%) CCs offered only group sessions. Five (16%) CCs did not report format information.

Method of Delivery

Sixteen (52%) CCs offered MBIs only in person. Six (19%) CCs offered both in-person and remotely offered MBIs. Two (6%) CCs offered MBIs exclusively through remote means. Seven (23%) CCs did not report on the method of delivery.

Setting

Nineteen (61%) CCs offered MBIs to inpatients and outpatients. Five (16%) CCs reported offering MBIs only in the inpatient setting; one (3%) CC reported offering MBIs only in the outpatient setting. Six (19%) CCs did not report this information.

Population

Five (16%) CCs offered MBIs to pediatric patients, 12 (39%) offered MBIs to adult patients, and 10 (32%) offered MBIs to both pediatric and adult patients. Four (13%) CCs did not specify the population.

MBI Practitioner Qualifications or Backgrounds

Twenty-one (68%) CCs had board-certified music therapists on staff. Four (13%) CCs had MBI programs that were staffed with a musician. One (3%) CC reported MBIs were provided by other health professionals. Five (13%) CCs were staffed with volunteers (including medical students). Only one (3%) CC described a relationship with a national organization that trained volunteers to provide MBIs to hospitalized patients [53]. All other centers lacked information about the type of training provided to volunteers delivering MBIs.

Clinical Indications and Treatment Benefits

Table 5 summarizes MBI treatment benefits or clinical indications described on CC websites. Due to the wide range of described benefits and indications, we grouped them into broad categories: physical (eg, symptom management, physical rehabilitation, or procedural support), psychological or emotional (eg, mood or coping, relaxation, quality of life, grief, or medical trauma), spiritual (eg, spirituality), and social (eg, communication, familial or care bond, or sense of community). Only two (6%) CCs offered a summary of research evidence for MBIs.

Table . Treatment benefits or clinical indications of music-based interventions described on National Cancer Institute–designated Cancer Center websites.

Treatment benefit or clinical indication	Music therapy programs (n=23), n (%)	Music services programs (n=14), n (%)
Physical	18 (78)	4 (29)
Psychological	21 (91)	11 (79)
Spiritual	6 (26)	2 (14)
Social	18 (78)	5 (36)

Patient Testimonials

Patient testimonials about treatment benefits were included on three (10%) web pages. We found a single testimonial by a health care provider on one (3%) website and one (3%) by a caregiver on another website. Twelve (39%) CCs provided video examples of patient encounters with MBIs.

Costs

Most of the websites did not include information about costs or fees associated with MBI services. Three (10%) websites stated MBIs were partially funded. Only two (6%) websites specified that MBIs were offered free of cost.

Scheduling and Referrals

Of the 31 CCs that offered MBIs, 26 (84%) provided referral information. MT was available via clinician referral or patient self-referral at 19 (61%) CCs. Eight (26%) websites instructed patients to contact the department responsible for offering MS.

Findability of MBI-Related Information

Of the 31 CCs that offered MBIs, none (0%) had a tab or link on their home page that led directly to information about MBI. Relevant information about MBIs was found with an average of 4 (SD 1) clicks for 29 (94%) websites. Tab searching for MBIs was unsuccessful for two (6%) CCs. The success path for finding information about MBIs through tab searching took many forms but most often started in the “for patients” tab on the home page, then to “support services,” “integrative services,” or “rehabilitative services” tabs where MBI-related links were often present. Information regarding MBIs was sometimes found in additional tabs such as “child life,” “creative arts,” “palliative care,” or “wellness.” Keyword searching using the home page search function led to successful identification of information about MBIs for 28 (90%) CCs. For three (10%) CCs, keyword searching yielded marketing or media stories and event calendars but no further information about the types of MBIs provided or how to access them. Finally, Google searching (entering the name of the CC and the aforementioned keywords) produced MBI-related search results for 29 (94%) CCs. However, Google searching often produced results irrelevant to finding center-specific MBI-related information, such as benefit concerts, news reports, fundraising events for the hospital, or outdated promotional materials.

Quality of MBI-Related Information

Using our quality rating scale (Table 1), we found that 9 (29%) CCs qualified for a high rating, 18 (58%) for a moderate rating, and 4 (13%) for a low rating.

Discussion

Principal Results

People with cancer often experience high symptom burden and are increasingly turning to the internet to find treatment options [37,54]. MBIs have a growing evidence base for cancer symptom management and are currently offered in various oncology settings [19,20,25,26,46,47,55], but there is a paucity of research on what types of MBI-related information are available on the internet. This is the first comprehensive study to examine the scope, findability, and quality of MBI-related information on the public-facing websites of NCI-designated CCs.

At the time of this study, the public-facing websites of 31 of 64 NCI-designated CCs offered information about MBIs at their respective CC. MBIs described on the CC websites varied widely by activities offered, practitioner, format, target population, and settings. These findings highlight the clinical versatility and adaptability of MBIs but also underscore the need for developing strategies and resources to help patients and families navigate the wide range of MBI-related options.

While the evidence base for MBIs continues to grow, additional research is still necessary to better understand the role of MBIs in cancer symptom management. Most websites indicated that MBIs improve outcomes in physical, psychological, spiritual, and social domains. Evidence from recent systematic reviews demonstrate that MBIs improve some physical (eg, pain or fatigue) and psychological (eg, anxiety or quality of life) outcomes listed on the websites [20,55]. However, several listed outcomes related to physical (eg, respiratory outcomes) and psychological (eg, sense of self, bereavement, self-expression, or executive function skills) domains are not yet supported by randomized controlled trials in oncology. Some CC websites also claimed that MBIs can improve outcomes in social (eg, familial bonds) and spiritual domains. These claims, however, are not yet supported by research evidence. Further, only two websites supported their stated treatment benefits with research evidence. As patients attempt to make informed treatment decisions for cancer symptom management, it is important for CCs to present accurate, evidence-informed information about the treatment benefits and clinical indications of MBIs in oncology.

At most centers, MBIs were provided by board-certified music therapists. These centers may additionally have volunteers, musicians, or other nonmusic therapist health care professionals who offered MS to patients such as listening to prerecorded or live music. Offering MS can increase access to MBIs, particularly in settings with limited availability of board-certified music therapists. However, prior research has shown that MS may produce inconsistent benefits relative to MT [19,20]. Furthermore, without proper guidance from a trained therapist, musical engagement can evoke strong emotions and memories that are undesirable or even harmful to people with cancer [19,56]. Public-facing websites often neglected to mention these risks when offering services by nonmusic therapists. Greater emphasis should be placed on educating patients about the distinction between MT and MS, as well as their relative benefits and risks.

The COVID-19 pandemic has accelerated the adoption of telehealth. However, only eight centers mentioned remotely delivered MBIs as an option on their websites. A growing body of research has documented that people with cancer experience time toxicity, which is conceptualized as the substantial amount of time spent in coordinating medical care, undergoing tests and treatments, and traveling to and from in-person appointments [57-63]. Offering more remotely delivered MBI options and emphasizing online services on CC websites may reduce time toxicity barriers and encourage patients with cancer to seek supportive care in the form of MBIs.

In parallel to increasing adoption of telehealth services, patients and families are more frequently turning to online sources for health-related information. Despite these trends in digitalization, the paucity of direct links to MBI-related information may result in fragmentation of information across multiple pages, increasing frustration for people who search online for MBI information. Furthermore, 22 CCs received a moderate or low rating for quality of MBI-related information, indicating that key pieces of information were lacking on their public-facing websites. For example, four or more websites lacked information on MBI format, delivery method, setting, target population, practitioner qualifications, scheduling, or referrals. Moreover, only three websites included patient testimonials even though testimonials have been shown to affect health behavior change [64-67]. Similarly, only five websites included information on the cost of MBIs despite costs being a well-described factor when considering the use of complementary therapies [68,69].

CCs should continually evaluate their websites for scope, findability, and quality of MBI-related information. Behavioral frameworks, such as the TPB, can help identify the key pieces of information that drive patients' treatment decision-making and their willingness to seek MBIs [70]. We recommend that CCs have a dedicated web page for MBI that is easily findable from the CC home page and includes the following information:

- Brief descriptions of MBIs, what patient participation involves, and specificity regarding whether interventions are offered individually or in group.
- Clinical indications or treatment benefits of MBIs with references to research literature and links to evidence-based resources (eg, American Music Therapy Association or Cochrane Library).
- Target populations, location of services, and method of delivery (in person or remote).
- Details about the qualifications and training of MBI practitioners, particularly those who are not board-certified music therapists.
- Costs of service.
- Instructions for scheduling MBI appointments or referring patients to MBIs.
- Testimonials by patients or health care providers, including example videos of patients engaging in MBIs.

While websites represent a key source of information that may drive treatment-seeking behavior, it is also important to consider other factors (eg, health care providers' knowledge and beliefs) that may influence the use of MBIs. For example, one study found that only 56% of health care providers in oncology settings knew about the role of MT in cancer symptom management and knew how to make referrals to MT [71]. Since most patients with cancer look to their primary oncology team to provide information about complementary or integrative health options [72], future dissemination efforts should focus on targeting health care professionals' knowledge about MBIs and establishing clear pathways for referring patients to MBIs. Fostering more seamless interprofessional collaboration between music therapists and other health care providers may also help to increase knowledge of MBIs and promote greater uptake of MBIs in oncology settings [73].

Limitations

Our study has some limitations. First, the time period of data extraction may not reflect the current website landscape. Next, descriptions on the websites may not be indicative of real-world availability of MBIs at the NCI-designated CCs. Additionally, the search strategy we employed was limited to the websites made publicly available by the CCs. Several CCs were also housed within multiple hospitals. Therefore, we may have missed some descriptions of MBIs. Furthermore, CCs may have not updated their websites with their current MBI offerings. In addition, the generalizability of our findings may be limited because we only searched the websites of NCI-designated CCs, all of which are located in the United States. Finally, a validated scale for rating the quality of MBI-related information found on websites does not exist in the literature, so we adapted a rating scale that other researchers used to evaluate public-facing websites of NCI-designated CCs [41]. While the findings should be interpreted as preliminary, our study could potentially inform future research to develop a rigorous, validated scale for rating health information found on public-facing websites.

Conclusions

Despite these limitations, our study is the first to provide a comprehensive review of MBI-related information on public-facing websites at NCI-designated CCs. NCI-designated CCs are often viewed by patients, families, and community providers as the gold standard for sources of information. In an increasingly digital world, it is critical for NCI-designated CCs to maintain a robust online presence and update their public-facing websites with evidence-informed information about MBIs. As the evidence for MBIs grows, translation of this research into accessible, actionable knowledge is critical to the real-world delivery and use of MBIs. While our study showcases the wide range of MBIs described in various oncology settings, the findings also highlight that NCI-designated CCs need to provide more detailed information about MBIs on their public-facing websites to promote the dissemination and implementation of this evidence-based option for cancer symptom management [20].

In addition to NCI-designated CC websites, future research should evaluate other key avenues through which information about MBIs is disseminated to the public. Most patients with cancer receive care in community settings [74], so it will be important to research how MBI-related information is presented in community-based clinics, hospitals, and cancer advocacy organizations. Music represents a multicultural resource [35,36], and research on the use of MBIs in cancer care has been conducted in various countries around the world [20]. Future studies should examine how MBIs are presented to the public in this global context. Researchers should also strive to develop culturally attuned approaches to disseminating MBI-related information so that patients with cancer from all cultures and backgrounds could learn about this evidence-based modality.

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Authors' Contributions

CAB, AM, JB, and KTL conceptualized the study. CAB, SB, JB, and KTL handled the methodology. CAB, SB, AM, KS, ML, and KM worked on the data extraction. CAB, SB, AM, KS, and ML carried out the data management. CAB and SB conducted the data analysis. CAB, SB, AM, KM, JB, and KTL wrote the original draft of this paper. KS and ML reviewed and edited the writing. JB and KTL supervised the team.

Conflicts of Interest

None declared.

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Abbreviations

CC: Cancer Center
CCC: Comprehensive Cancer Center
MBI: music-based intervention
MS: music services
MT: music therapy
NCI: National Cancer Institute
TPB: Theory of Planned Behavior

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Original Paper

Exploring Racial Disparities in Awareness and Perceptions of Oncology Clinical Trials: Cross-Sectional Analysis of Baseline Data From the mychoice Study

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Abstract

Background: Black/African American adults are underrepresented in oncology clinical trials in the United States, despite efforts at narrowing this disparity.

Objective: This study aims to explore differences in how Black/African American oncology patients perceive clinical trials to improve support for the clinical trial participation decision-making process.

Methods: As part of a larger randomized controlled trial, a total of 244 adult oncology patients receiving active treatment or follow-up care completed a cross-sectional baseline survey on sociodemographic characteristics, clinical trial knowledge, health literacy, perceptions of cancer clinical trials, patient activation, patient advocacy, health care self-efficacy, decisional conflict, and clinical trial intentions. Self-reported race was dichotomized into Black/African American and non–Black/African American. As appropriate, 2-tailed *t* tests and chi-square tests of independence were used to examine differences between groups.

Results: Black/African American participants had lower clinical trial knowledge ($P=.006$), lower health literacy ($P<.001$), and more medical mistrust (all P values <.05) than non–Black/African American participants. While intentions to participate in a clinical trial, if offered, did not vary between Black/African American and non–Black/African American participants, Black/African American participants indicated lower awareness of clinical trials, fewer benefits of clinical trials, and more uncertainty around clinical trial decision-making (all P values <.05). There were no differences for other variables.

Conclusions: Despite no significant differences in intent to participate in a clinical trial if offered and high overall trust in individual health care providers among both groups, beliefs persist about barriers to and benefits of clinical trial participation among Black/African American patients. Findings highlight specific ways that education and resources about clinical trials could be tailored to better suit the informational and decision-making needs and preferences of Black/African American oncology patients.

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KEYWORDS

oncology clinical trial; cancer; decision-making; racial disparity; medical mistrust

Introduction

Background

The underrepresentation of racial and ethnic minoritized populations in cancer clinical trials is well-established [1-4], particularly among Black/African American adults [5-10]. Despite federal initiatives and policies aimed at increasing cancer clinical trial enrollment and participation rates of underrepresented groups, rates have not improved among people from racial and ethnic minoritized groups, and in some cases, the rates have even declined [11]. Attributable to factors across multiple levels of influence [12], the underrepresentation of Black/African American adults in cancer clinical trials means that drugs and interventions are developed, tested, and disseminated to populations not reflective of the broader US cancer population, perpetuating health inequities [13].

For example, 1 study found that Black/African American adults comprised only 7.4% of all participants in US Food and Drug Administration clinical trials that led to new, approved cancer drugs from 2014 to 2018 [8]. The participation-to-prevalence ratio reflects the representation of Black/African American adults in the clinical trial population relative to the general cancer population, where a ratio of 1 means there is identical or equal representation between groups. Across cancer types, the estimated participation-to-prevalence ratio for Black/African American US adults was 0.31, indicating significant underrepresentation in clinical trials that result in Food and Drug Administration approvals for cancer drugs [8]. Importantly, Black/African American adults are also less likely to participate in trials of novel treatments and technologies, such as precision oncology [4,14]. These disproportionately low rates of clinical trial participation among racial and ethnic minorities result in limited understanding by medical professionals and the greater research community of how well new diagnostic technology, treatment options, and supportive care services are working for racial and ethnic minorities in comparison to the predominantly White clinical trial participant population [15,16].

In addition to underrepresentation in cancer clinical trials, inequities in cancer care and survival rates persist [17-19]. Greater inclusion of Black/African American patients in cancer clinical trials is, therefore, essential to design and test interventions to address inequities in cancer care among Black/African American patients. For example, non-Hispanic Black/African American patients have significantly greater cancer diagnosis delay [17], treatment delay [17], and likelihood of diagnosis at an advanced cancer stage [18] compared with non-Hispanic White patients. Even after accounting for cancer stage, cancer type, and other relevant covariates, Black/African American patients still have significantly lower survival rates than White patients [19].

Prior studies have found that non-Hispanic, Black/African American patients have less awareness of cancer clinical trials and hold specific attitudes and beliefs about trial participation relative to non-Hispanic, White patients [20,21]. For example, in a qualitative study of Black/African American cancer survivors who received cancer treatment at a safety-net hospital, the primary clinical trial participation barriers were (1) limited knowledge and understanding of cancer clinical trials and (2) medical mistrust, fears, and other negative perceptions of cancer clinical trials. Participants also described wanting a peer (cancer survivor of a concordant race or ethnicity group) patient navigator who was well-versed in clinical trials knowledge and who could provide other forms of social support (eg, social or emotional, faith-based or spiritual, and instrumental support) [22]. These results were consistent with other studies emphasizing the roles of knowledge or awareness, medical mistrust, and social support in clinical trial enrollment; study participation; and retention over time [23-25].

Other specific attitudes held by Black/African American patients with cancer more than White patients include lower perceived cancer susceptibility and greater doubt about the usefulness and feasibility of translating cancer clinical trial results into clinical practice [23]. Other patient-level factors associated with less knowledge and awareness of cancer clinical trials include living in a rural area [26], living farther away from universities or large hospital networks [27], older age [28], limited English language proficiency [29], lower educational attainment [21], and less annual household income [21]. Conversely, greater cancer clinical trial knowledge and the likelihood of trial participation are associated with a prior cancer diagnosis [30], having a routine source of health care (ie, primary care access) [31], and higher educational attainment [30]. Trial populations' clinical knowledge and awareness are essential constructs for researchers to be aware of because the quality of communication between clinical trial staff and prospective trial participants is, in part, dependent upon patients' clinical trial knowledge and confidence [32].

Negative attitudes toward cancer clinical trials, particularly having greater concerns, are associated with cancer fatalism [33]. Other concerns cited by Black/African American patients with cancer associated with decreased cancer clinical trial intentions are greater fear of the unknown [33], fear of death [33], prior negative health care or clinical trial experiences [22,34,35], fear of receiving an inferior treatment or placebo [22], lower health literacy [36,37], anticipated discrimination [33], and medical mistrust [33,38]. Structural racism, historical injustices, and unethical research practices have disproportionately affected Black/African American people and have perpetuated concerns of anticipated mistreatment by research personnel and broader medical mistrust [39-41]. However, levels of cancer-related knowledge and specific attitudes toward cancer clinical trials are associated with cancer clinical trial participation rates among Black/African American patients with cancer. For example, a qualitative study among Black men found that perceptions of greater research integrity and transparency were positively associated with willingness to participate in prostate cancer surveillance screening and clinical trials [38]. Other factors positively associated with willingness to participate in cancer research were having a family history of cancer, seeing greater value in screening and cancer prevention, and having more interest in learning about cancer and other health-related information [38].

At the interpersonal level, Black/African American patients with cancer have differential access to cancer clinical trial information attributable to provider biases and patient-provider communication quality. For example, clinical trials are often initially discussed with patients by their health care providers, but provider bias, including racism and discrimination, results in less information sharing and discussion about cancer screenings, clinical trials, and cancer treatment options for Black/African American patients than for White patients [42]. At the clinic level, limited hiring of providers with language fluency beyond English reduces clinic access and decreases the feasibility of within-session information sharing about clinical trials for patients and families with limited English language proficiency [43]. Importantly, many Black/African American patients report not being offered a trial during their cancer care [44-46], despite overall positive perceptions of clinical trials, further exacerbating the inequity [47].

Finally, it should be noted that individual-level awareness of clinical trials is only minimally helpful as an interventional target when structural and systemic factors more strongly drive participation rates. For example, studies have repeatedly demonstrated that some of the greatest barriers to clinical trial enrollment are inequitable clinical trial referrals and enrollment practices [48] and stringent trial eligibility criteria [49-52]. Recent programs and initiatives implemented to increase awareness of cancer clinical trials among Black/African American patients have recognized that awareness must be addressed at multiple levels of influence to advance health equity. For example, a June 2022 article published by the American Society of Clinical Oncology suggests that clinics and health care facilities use 1 of 2 standardized clinic self-assessment tools to review their enrollment practices and patient-, provider-, and system-level barriers to clinical trial enrollment [52-56].

This study is a cross-sectional analysis of the baseline data from a parent randomized controlled trial (RCT) designed to evaluate the impact of a multicultural, clinical trial preparatory digital health tool (mychoice) or standard National Cancer Institute information for patients with cancer. mychoice was conceptualized and developed by a team of investigators at Fox Chase Cancer Center and the Temple University College of Public Health through extensive formative research with Black/African American patients, expertise in health disparities and clinical trial participation, commercial marketing techniques (perceptual mapping and vector message modeling), and best practices in digital health and patient engagement [47,57]. Although founded on clinical trial participation barriers significant to underrepresented patients, the tool is designed to be appropriate for all patients with cancer and to represent diverse patient perspectives.

Objectives

A diverse sample of patients enrolled in the parent RCT completed a baseline survey before viewing the decision-making tool, providing an opportunity to explore racial disparities in a variety of factors previously linked to clinical trial participation rates and the clinical trial participation decision-making process. On the basis of the conducted formative work with Black/African American patients to inform the digital health tool used in the parent RCT, this study sought to confirm whether factors identified in the formative work were, in fact, salient to Black/African American patients with cancer relative to non–Black/African American patients with cancer at baseline. Findings will help explain Black/African American versus non–Black/African American participant responses to the culturally tailored, clinical trial decision-making tool and also help identify factors that could help further refine the decision-making tool. In addition, findings can be used to tailor and prioritize topics in provider education and training to better support the needs of Black/African American patients with cancer in cancer clinical trial decision-making.

Methods

Participants

The analytical sample at baseline included patients with cancer from 4 leading cancer centers in Philadelphia (Fox Chase Cancer Center, Temple University Hospital, University of Pennsylvania's Abramson Cancer Center, and Thomas Jefferson University's Sidney Kimmel Cancer Center) who consented to participate in the parent RCT (NCT03427177) and completed the baseline survey. Moreover, 3 of the 4 recruitment sites are National Cancer Institute–designated cancer centers. Eligible patients were actively being treated for cancer or in follow-up care (ie, within 6 months of definitive treatment), aged ≥18 years, able to speak and read English, and had not participated in a therapeutic clinical trial. The parent RCT had been planned to enroll 270 participants. In total, 257 participants consented and 249 (96.9%) completed the baseline survey. Patients of all racial and ethnic groups were eligible for the RCT, but only 244 (98%) of the 249 completed baselines reported valid or nonmissing data for their race and were analyzed in this study.

Instruments

Overview

The survey was developed using both validated instruments and study-related measures from formative work, including both qualitative interviews and surveys with Black/African American patients with cancer [47,57-59]. Variables included in the present analyses were sociodemographic characteristics (ie, age, race, ethnicity, gender, income, educational attainment, insurance type, and cohabitation status), dichotomized race group (Black/African American vs non–Black/African American), clinical characteristics (ie, cancer stage and treatment status), general clinical trial knowledge, health literacy, cancer clinical trial perceptions (awareness, benefits, concerns, and cancer and health care experiences beliefs about health care providers and health), patient activation in cancer care, patient self-advocacy, self-efficacy in health care interactions, decisional conflict, and clinical trial intentions.

General Knowledge of Clinical Trials

General knowledge of clinical trials was assessed using 16 revised items from Knowledge of Clinical Trials scale by

Campbell et al [60]. Response options were "true" or "false" and were scored for accuracy. Scores were generated using the percentage of questions answered correctly, ranging from 0% to 100%.

Health Literacy

Health literacy was assessed with a single item from the Single Item Literacy Screener, which specifically identifies adults who may need assistance reading and understanding health materials [61]. The item says, "How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy?" Response options were rated on a 5-point Likert scale, ranging from a score of "1" reflecting "never" to "5" reflecting "always." On the basis of psychometric testing, scores >"2" reflect people with limited health literacy in reading and comprehending written health information [61].

Cancer Clinical Trial Perceptions

Perceptions of cancer clinical trials were evaluated using 48 items developed by the primary investigators through formative work, reflecting domains of (1) awareness, (2) benefits, (3) concerns, (4) cancer and health care experiences, and (5) beliefs about health care providers and health [47,57-59]. Response options were rated on an 11-point Likert scale ranging from 0 to 10 where "0" indicated strong disagreement and "10" indicated strong agreement. Item-level analyses were conducted in this study.

Patient Activation in Cancer Care

Patient activation for cancer care decision-making was measured with 10-item Decisional Engagement Scale [62]. This instrument was developed specifically to understand patients' level of involvement in their cancer care and engagement with active decision-making processes around treatment and care options [62]. Response options were rated on an 11-point Likert scale, ranging from 0 to 10 where "0" meant "doesn't describe you at all" and "10" meant "perfectly describes you." In psychometric evaluation, the 10-item Decisional Engagement Scale has demonstrated strong factor structure, reliability, and concurrent validity with health-related quality of life, shared decision-making preferences, and clarity about cancer care preferences [62].

Patient Self-Advocacy

Patient self-advocacy was measured with 12-item Patient Self-Advocacy Scale [63]. Response options were rated on an 11-point Likert scale, ranging from 0 to 10. In addition, 1 item ("I don't get what I need from my physician because I am not assertive enough") was reverse coded before calculating an average summary score. The scale has demonstrated good internal consistency, construct validity, and criterion validity [63].

Health Care Self-Efficacy

Self-efficacy to engage with health care providers was measured with 10-item Perceived Self-Efficacy in Patient-Physical Interactions scale [64]. Items asked about confidence to do specific health care–related tasks, such as confidence to get a physician to listen to them, confidence in ability to know what questions to ask a physician, and confidence in ability to get a physician to take their health concerns seriously. Response options ranged from 1 to 5, where "1" indicated least confidence and "5" indicated most confidence [64].

Decisional Conflict

Decisional conflict about clinical trial participation was measured with 13-item Decisional Conflict scale proposed by O'Connor [65]. Response options were rated on a 5-point Likert scale, ranging from 0 to 4 where "0" reflected "strongly agree" and "4" reflected "strongly disagree." Scoring of 4 subscales (uncertainty, informed, value clarity, and decision support) was done by summing the items within the subscale, dividing by the number of items within that subscale, and multiplying by 25. This resulted in a score ranging from 0 to 100. A total score for all items was also calculated by summing all items, dividing by 13, and multiplying by 25. This, too, led to a total score ranging from 0 to 100. In psychometric testing, the scale had good discriminant validity between those who choose versus those who do not choose to engage in a health behavior. Other psychometric properties were determined to be acceptable [65].

Clinical Trial Participation Intentions

Intentions to participate in a cancer clinical trial were assessed with a single, modified item from the Choice Predisposition Scale proposed by O'Connor [66]. The item read, "We would like to know what your opinion is about your cancer treatment options at present. When your doctor asks you to make a choice about treatment methods, please indicate how strongly you agree or disagree that you would choose to participate in a clinical trial, if offered." Response options ranged from 0 to 10, where "0" indicated strongly disagree," a "5" meant "neither agree nor disagree," and "10" indicated "strongly agree." This scale has good psychometric properties, such as high test-retest validity, good construct validity, high sensitivity to change, and discriminant validity [66].

Procedures

Prospective participants were screened for eligibility (aged ≥18 years, cancer diagnosis, receiving current or follow-up care, English speaking, and had not previously participated in a clinical trial). Participants provided verbal informed consent either in person or over the phone. Consent was verified via an e-consent using REDCap (Research Electronic Data Capture; Vanderbilt University), a web-based application developed to capture data for research [67,68]. Consented patients were randomized to intervention conditions via REDCap and completed a baseline survey prior to viewing any intervention content. The baseline survey assessments were web-based and were conducted through REDCap. Patients could either complete the study at the hospital using a study iPad (Apple Inc) or at home on their own devices. The baseline survey took approximately 45 minutes.

Statistical Analysis

Univariate statistics using means, SDs, and percentages are presented to characterize the participant sample. Differences in sociodemographic and clinical characteristics between dichotomous race groups (ie, Black/African American and non–Black/African American patients) were evaluated using chi-square tests of independence and independent sample 2-tailed *t* tests, as appropriate. Independent sample *t* tests were also used to examine for differences between Black/African American and non–Black/African American patients' clinical trial knowledge, attitudes toward cancer clinical trials, and intentions to participate in a clinical trial. While some variables (eg, health literacy and self-efficacy in health care interactions) were highly skewed, *t* tests were still used as opposed to nonparametric testing because *t* tests are robust to skewed distributions when the sample size is >200 [69]. Homogeneity of variances between groups was evaluated for each item before running independent samples *t* tests, and the appropriate *t* test assumptions were applied accordingly. All data analyses were conducted in StataSE (version 17.0; StataCorp).

Ethical Considerations

The study protocol was approved by the Fox Chase Cancer Center's institutional review board (#17-8013). All procedures involving human participants were in accordance with the ethical standards of the institutional or national research committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. All participants provided verbal informed consent. Verification of consent with e-consent and all other study data were collected in REDCap, a secure web-based application developed to collect and store research data [67,68]. To protect participants' privacy, the data were coded before analysis using unique participant study identifiers and no direct identifiers were in the analytic data set. Participants were compensated US $25 for completing the baseline survey, educational intervention, and the posttest survey. However, this paper describes results from the baseline survey data only.

Results

Overview

Table 1 compares sociodemographic and clinical characteristics by dichotomous race group. Tables 2-4 show results of all remaining independent sample *t* tests for differences in average general clinical trials knowledge, health literacy, perceptions of cancer clinical trials, patient activation, patient advocacy, health care self-efficacy, decisional conflict, and clinical trial intentions by race group.

Table 1. Sociodemographic and clinical characteristics of study participants by race at baseline (N=244).

Characteristics	Total[a] (N=244)	Non–Black/African American (n=149)	Black/African American (n=95)	Chi-square (*df*) or *t* test (*df*)	*P* value
Gender, n (%)				7.465 (1)	.006
Female	154 (63.1)	84 (56.4)	70 (73.7)		
Male	90 (36.9)	65 (43.6)	25 (26.3)		
Age (y), mean (SD)	60.89 (10.24)	61.62 (11.13)	59.28 (10.24)	1.866 (242)	.06
Educational attainment, n (%)				59.509 (2)	<.001
Less than high school	29 (11.9)	8 (5.4)	21 (22.1)		
High school or GED[b]	74 (30.3)	26 (17.4)	48 (50.5)		
Some college or more	141 (57.8)	115 (77.2)	26 (27.4)		
Insurance type, n (%)				17.379 (1)	<.001
Private	92 (38.3)	72 (48.7)	20 (21.7)		
Medicare or Medicaid	148 (61.7)	76 (51.3)	72 (78.3)		
Race, n (%)				—[c]	—
American Indian or Alaskan Native	1 (0.4)	1 (0.7)	0 (0)		
Asian	2 (0.8)	2 (1.3)	0 (0)		
Black/African American	95 (38.9)	0 (0)	95 (100)		
White	136 (55.7)	136 (91.3)	0 (0)		
More than 1 race	10 (4.1)	10 (6.7)	0 (0)		
Ethnicity, n (%)				2.775 (1)	.09[d]
Hispanic/Latino	10 (4.7)	9 (6.5)	1 (1.4)		
Non–Hispanic/Latino	202 (95.3)	130 (93.5)	72 (98.6)		
Annual household income (US $), n (%)				78.660 (2)	<.001
<15,000	60 (26.7)	13 (9.5)	47 (53.4)		
15,000-50,000	66 (29.3)	34 (24.8)	32 (36.4)		
>50,000	99 (44)	90 (65.7)	9 (10.2)		
Cohabitation status, n (%)				2.697 (1)	.10
No	55 (22.9)	28 (19.3)	27 (28.4)		
Yes (lives with >1 people)	185 (77.1)	117 (80.7)	68 (71.6)		
Cancer stage, n (%)				0.020 (1)	.89
Early	108 (56)	65 (55.6)	43 (56.6)		
Late	85 (44)	52 (44.4)	33 (43.4)		
Treatment status[e], n (%)				8.993 (1)	.003
Receiving treatment	165 (73)	88 (65.7)	77 (83.7)		
Receiving follow-up care	61 (27)	46 (34.3)	15 (16.3)		

[a] Percentages are rounded and, therefore, may not add up to 100%. Missing or invalid data were excluded from this table for insurance type (n=4), ethnicity (n=32), income (n=19), cohabitation status (n=4), cancer stage (n=51), and treatment status (n=18).

[b] GED: General Educational Development.

[c] Not applicable. This was because the table is split by binary race, so examining race by race is nonsensical.

[d] Fisher exact test was used when one or more of the expected cell counts was <5.

[e] Receiving treatment includes treatment types, such as chemotherapy, radiation, surgery, and any other types of cancer treatment. Follow-up care includes posttreatment care within 6 months of the last receipt of treatment.

Table 2. Baseline knowledge, health literacy, awareness of clinical trials for Black/African American versus non–Black/African American oncology patients (N=244).

	Non–Black/African American patients (n=149)		Black/African American patients (n=95)		*t* test (*df*)	*P* value
	Mean (SD)	95% CI	Mean (SD)	95% CI		
General clinical trial knowledge[a]	80.70 (14.73)	78.32-83.09	75.59 (12.86)	72.97-78.21	2.775 (242)	.006
Health literacy[b,c]	1.47 (0.72)	1.35-1.58	2.06 (1.11)	1.84-2.29	–4.650 (145.36)	<.001
Awareness of clinical trials[d]						
I had heard about clinical trials before I was diagnosed.	7.61 (3.33)	7.06-8.15	5.19 (3.96)	4.39-6.01	5.075 (238)	<.001
I know where to get information about clinical trials.	5.30 (3.59)	4.71-5.89	4.44 (3.70)	3.68-5.19	1.801 (237)	.07
I know someone who has been part of a clinical trial who I can talk to about whether I should participate or not.	3.42 (3.69)	2.81-4.02	2.78 (3.53)	2.05-3.50	1.335 (238)	.18
I understand what clinical trials are and how they work.	4.41 (3.68)	3.80-5.02	4.31 (3.83)	3.52-5.09	0.204 (236)	.84
I do not have enough information about clinical trials to make a decision.	5.93 (3.55)	5.35-6.51	4.55 (3.63)	3.80-5.29	2.920 (238)	.004
My doctor gave me enough information to make a decision about being part of a clinical trial.	3.68 (3.70)	3.06-4.29	3.76 (3.60)	3.02-4.51	–0.179 (233)	.86
Being part of a clinical trial means I get all or part of my medical care and medication for free[d].	4.99 (3.38)	4.44-5.55	4.65 (4.15)	3.79-5.50	0.677 (167.75)	.50

[a] Clinical trials knowledge was a percentage ranging from 0 to 100.

[b] Health literacy ranged from 0 to 4, where higher values reflected lower health literacy.

[c] Variances were not equal between groups, so an independent sample *t* test with unequal variances was used.

[d] Response options for awareness items ranged from 0 to 10, where 0 indicated strong disagreement and 10 indicated strong agreement.

Table 3. Baseline perceived benefits and concerns about cancer clinical trials for Black/African American versus non–Black/African American oncology patients (N=244).

	Non–Black/African American patients (n=149)		Black/African American patients (n=95)		*t* test (*df*)	*P* value
	Mean (SD)	95% CI	Mean (SD)	95% CI		
Benefits of clinical trial participation[a]						
I have a better chance of living longer if I am part of a clinical trial[b].	5.37 (2.79)	4.91-5.83	4.30 (3.74)	3.53-5.06	2.396 (158.44)	.02
Being part of a clinical trial improves my quality of life[b].	5.16 (2.69)	4.72-5.60	4.24 (3.45)	3.53-4.95	2.184 (161.70)	.03
I believe the benefits of being in a clinical trial outweigh the possible side effects[b].	5.37 (2.73)	4.92-5.82	4.43 (3.56)	3.71-5.16	2.176 (164.88)	.03
Being part of a clinical trial offers the best treatment available for my cancer[b].	5.48 (2.87)	5.01-5.95	4.43 (3.78)	3.65-5.20	2.299 (160.87)	.02
Being part of a clinical trial can give a person a sense of purpose in life[b].	6.15 (2.57)	5.73-6.57	4.76 (3.62)	4.01-5.50	3.246 (152.86)	.001
If my doctor said a clinical trial was the best option for me, I would follow their advice[b].	7.91 (2.37)	7.52-8.30	6.93 (3.45)	6.22-7.63	2.429 (151.87)	.02
Being part of a clinical trial will improve my community’s trust in medical research[b]	5.94 (2.74)	5.49-6.39	5.17 (3.55)	4.44-5.90	1.785 (162.08)	.08
Being part of a clinical trial could help find a cure for cancer[b].	8.24 (1.77)	7.95-8.53	6.99 (3.21)	6.34-7.64	3.468 (131.55)	<.001
Being part of a clinical trial would help my doctor and their research[b].	8.05 (2.05)	7.71-8.38)	7.27 (3.18)	6.61-7.92	2.103 (141.08)	.04
Being part of a clinical trial could help my children or grandchildren in the future[b].	8.27 (2.05)	7.94-8.61	7.27 (3.10)	6.63-7.91	2.760 (142.89)	.007
Being part of a clinical trial could help other people with my type of cancer[b].	8.51 (1.82)	8.21-8.80	7.84 (2.73)	7.29-8.40	2.090 (148.21)	.04
Concerns of cancer clinical trial participation[a]						
I am worried that my health insurance won’t pay for me to be part of a clinical trial.	5.00 (3.31)	4.46-5.54	5.27 (3.66)	4.53-6.02	–0.602 (240)	.55
I believe that taking part in a clinical trial will cause more side effects than my current treatment.	4.47 (2.54)	4.06-4.89	3.82 (3.04)	3.20-4.44	1.798 (238)	.07
I believe that my medical care is not as good if I take part in a clinical trial.	2.77 (2.78)	2.31-3.23	2.70 (3.00)	2.09-3.32	0.181 (236)	.86
My religious beliefs could keep me from taking part in a clinical trial[b].	0.58 (1.72)	0.30-0.86	1.73 (2.92)	1.13-2.33	–3.445 (132.69)	<.001
God has already decided what will happen so being part of a clinical trial would not help[b].	0.84 (2.10)	0.50-1.19	2.95 (3.70)	2.19-3.71	–5.015 (132.15)	<.001
No one talked to me about being part of a clinical trial.	5.23 (4.07)	4.56-5.90	4.49 (3.80)	3.72-5.27	1.402 (236)	.16
I’m too upset about my cancer diagnosis to think about being part of a clinical trial.	1.70 (2.71)	1.25-2.14	2.23 (2.82)	1.66-2.81	–1.474 (237)	.14
I’m afraid I’ll get a sugar pill (placebo) instead of real medicine in a clinical trial.	4.00 (3.66)	3.40-4.60	2.72 (3.35)	2.03-3.40	2.750 (239)	.006
I’d worry that I’d be treated like a number, not a person, in a clinical trial.	2.66 (2.85)	2.20-3.13	2.84 (3.27)	2.18-3.51	–0.446 (239)	.66
I believe I would be treated like a “guinea pig” in a clinical trial[b].	2.30 (2.74)	1.85-2.75	3.12 (3.39)	2.42-3.82	–1.944 (166.51)	.05
I believe I would not be told important information about my health if I was part of a clinical trial[b].	2.23 (2.74)	1.79-2.69	2.67 (3.29)	2.00-3.34	–1.066 (172.53)	.29

[a] Response options for perception items ranged from 0 to 10, where 0 indicated strong disagreement and 10 indicated strong agreement.

[b] Variances were not equal between groups, so independent sample *t* test with unequal variances was used.

Table 4. Baseline health care experiences, health care beliefs, patient self-advocacy, patient activation, health care self-efficacy, decisional conflict, and intentions to participate in cancer clinical trials for Black/African American versus non–Black/African American oncology patients (N=244).

	Non–Black/African American patients (n=149)		Black/African American patients (n=95)		*t* test (*df*)	*P* value
	Values, mean (SD)	95% CI	Values, mean (SD)	95% CI		
Cancer health care experiences and perceptions[a]						
I feel confident in my decisions about treatment[b].	8.57 (1.90)	8.26-8.88	8.32 (2.51)	7.81-8.83	0.836 (160.96)	.41
I have someone close to me I can talk to about my diagnosis and treatment options.	8.15 (2.97)	7.66-8.65	8.35 (2.72)	7.79-8.90	–0.508 (236)	.61
I have a lot of support from my family and friends.[b]	9.06 (1.94)	8.74-9.37	8.48 (2.69)	7.94-9.03	1.790 (157.03)	.08
I have a pastor or other religious leader that I trust and can talk to.	5.29 (3.96)	4.63-5.95	7.03 (3.88)	6.24-7.83	–3.336 (234)	.001
I have had someone close to me die of cancer.	8.12 (3.19)	7.59-8.64	7.55 (3.65)	6.80-8.30	1.260 (238)	.21
I have family members or close friends who have had cancer and been successfully treated.	7.58 (3.48)	7.01-8.15	6.59 (3.90)	5.79-7.39	2.038 (236)	.04
I trust the doctor treating me for my cancer.[b]	9.13 (1.70)	8.85-9.41	8.71 (2.38)	8.23-9.20	1.476 (153.83)	.14
It is important to get treated as soon as you are diagnosed to help prevent the cancer from coming back.[b]	9.26 (1.51)	9.01-9.51	9.05 (2.05)	8.63-9.47	0.849 (157.67)	.40
I researched information on my own about treatment options.	7.27 (3.11)	6.76-7.78	6.38 (3.55)	5.66-7.10	2.050 (237)	.04
I feel confident being able to research information on my own about treatment options.	6.65 (3.19)	6.12-7.17	6.78 (3.44)	6.07-7.48	–0.294 (237)	.77
Beliefs about health care providers and health[a]						
I go to the doctor for regular checkups.	9.11 (2.01)	8.78-9.44	9.04 (1.70)	8.70-9.39	0.271 (239)	.79
I get my cancer screenings whenever they are recommended.[b]	9.23 (1.66)	8.95-9.50	8.91 (2.02)	8.49-9.32	1.296 (173.79)	.20
Growing up we used a lot of home remedies.	3.56 (3.28)	3.02-4.10	6.03 (3.54)	5.30-6.77	–5.485 (235)	<.001
I believe using alternative therapies is important while being treated for cancer.	5.56 (3.38)	5.10-6.12	5.42 (3.86)	4.64-6.21	0.292 (236)	.77
I think that doctors mislead patients[b].	1.37 (2.32)	0.99-1.75	2.50 (3.15)	1.85-3.15	–2.991 (156.97)	.003
I don’t trust medical researchers[b].	1.23 (2.40)	0.83-1.62	2.69 (3.02)	2.07-3.31	–3.956 (167.01)	<.001
I believe racial/ethnic minorities are discriminated against in medical research studies[b].	1.64 (2.66)	1.21-2.08	3.27 (3.46)	2.56-3.97	–3.876 (162.46)	<.001
I don’t trust drug (pharmaceutical) companies.	3.84 (3.27)	3.31-4.38	3.98 (3.25)	3.31-4.64	–0.316 (238)	.75
Patient activation in cancer care (DES-10[c]) [a]	8.00 (1.33)	7.78-8.22	7.85 (1.51)	7.54-8.15	0.841 (239)	.40
Patient self-advocacy (PSAS[d]) [a]	6.07 (1.49)	5.82-6.31	6.07 (1.69)	5.73-6.41	–0.009 (238)	.99
Health care self-efficacy (PEPPI[e])	4.45 (0.64)	4.34-4.55	4.44 (0.76)	4.28-4.59	0.109 (239)	.91
Decisional conflict[f]						
Certainty (range 0-100)	36.24 (25.76)	32.08-40.46	25.62 (22.17)	21.08-30.16	3.284 (237)	.001
Informed (range 0-100)	31.91 (20.75)	28.51-35.30	36.44 (24.95)	31.32-41.55	–1.523 (238)	.13
Values clarity (range 0-100)	37.84 (27.67)	33.32-42.37	41.31 (28.58)	35.46-47.17	–0.936 (238)	.35

	Non–Black/African American patients (n=149)		Black/African American patients (n=95)		*t* test (*df*)	*P* value
	Values, mean (SD)	95% CI	Values, mean (SD)	95% CI		
Support (range 0-100)	21.52 (20.94)	18.09-24.94	22.61 (21.54)	18.19-27.02	–0.389 (238)	.70
Overall decisional conflict (range 0-100)	31.74 (19.80)	28.50-34.98	30.81 (19.66)	26.78-34.83	0.357 (238)	.72
Intentions to participate in clinical trial, if offered[a,b]	7.03 (2.60)	6.60-7.46	6.38 (3.16)	5.73-7.02	1.662 (174.01)	.10

[a] Response options for perception items, patient activation, patient self-advocacy, and clinical trial intentions ranged from 0 to 10, where "0" indicated strong disagreement and "10" indicated strong agreement.

[b] Variances were not equal between groups, so an independent sample *t* test with unequal variances was used.

[c] DES-10: 10-item Decisional Engagement Scale.

[d] PSAS: Patient Self-Advocacy Scale.

[e] PEPPI: Perceived Efficacy in Patient-Physician Interactions; health care self-efficacy ranged from 1 to 5, where higher values reflected greater self-efficacy.

[f] Decisional conflict was a percentage ranging from 0 to 100.

Sociodemographic and Clinical Characteristics

More than a third (95/244, 38.9%) of participants self-identified as Black/African American. Participants were aged a mean 60.89 (SD 10.24) years but did not vary by dichotomous race group. More than half (141/244, 57.8%) had at least some college or more, but educational attainment varied significantly between Black/African American and non–Black/African American participants (*P*<.001). Moreover, 63.1% (154/244) of the sample included female participants, but a greater percentage of the Black/African American patients were female (70/95, 73%) compared to the non–Black/African American patients (84/149, 56.4%; *P*=.006). Other significant differences between groups were observed for insurance type (ie, a greater percentage of Black/African American patients on Medicare or Medicaid), annual household income (ie, higher household income reported by non–Black/African American patients), and treatment status (ie, greater percentage of Black/African American patients still receiving treatment as opposed to follow-up care compared with non–Black/African American patients).

General Clinical Trials Knowledge and Health Literacy

Compared to the Black/African American patients (mean 75.6, SD 12.7), the non–Black/African American patients (mean 80.7, SD 14.7) had significantly higher general clinical trial knowledge scores (t_{242}=2.775; *P*=.006). Health literacy (greater values reflect lower health literacy) was also higher among non–Black/African American patients (mean 1.47, SD 0.72) than Black/African American patients (mean 2.06, SD 1.11; $t_{145.36}$=−4.650; *P*<.001).

Awareness of Cancer Clinical Trials

Non-Black patients (mean 7.61, SD 3.33) were significantly more likely to have heard about clinical trials before their cancer diagnosis compared with Black/African American patients (mean 5.19, SD 3.96; t_{238}=5.075; *P*<.001). However, non–Black/African American patients (mean 5.93, SD 3.55) felt more strongly than Black/African American patients (mean 4.55, SD 3.63) that they did not have sufficient information to decide whether to participate in a cancer clinical trial (t_{238}=2.920; *P*=.004). There were no differences between groups on all other awareness-related items, including information gathering, support for accessing and consuming cancer-related health information, and receiving sufficient information about cancer clinical trials from their health care providers.

Benefits of Clinical Trial Participation

Black/African American patients consistently rated the benefits of cancer clinical trial participation lower than non–Black/African American patients. Specifically, Black/African American patients rated 10 out of 11 items about perceived benefits lower than non–Black/African American patients, all of which were statistically significant (*P* values were .02, .03, .03, .02, .001, .02, <.001, .04, .007, and .04). Benefits of cancer clinical trial participation rated lower included having better survival odds, improving quality of life, increasing access to high-quality treatment, having a greater sense of purpose, and helping to find treatments and cures for family members or the public. In fact, the only benefits-related item that did not yield significant differences between groups at α=.05 level was belief that clinical trial participation would improve their community's trust in medical research ("Being part of a clinical trial will improve my community's trust in medical research").

Concerns of Clinical Trial Participation

Concerns about cancer clinical trials that varied between racial groups were religious beliefs as barriers, fatalistic beliefs about cancer, and fears of receiving a placebo or sugar pill. Compared to non-Black patients, Black/African American patients with cancer were significantly more likely to believe that their religion or fatalistic beliefs (ie, "God has already decided what will happen so being part of a clinical trial would not help") would keep them from participating in a clinical trial. However, non–Black/African American patients (mean 4.00, SD 3.66) were significantly more concerned than Black/African American patients (mean 2.72, SD 3.35) about potentially receiving a placebo and not real medicine (t_{239}=2.750; *P*=.006).

Cancer and Health Care Experiences

Religious leaders were more strongly endorsed as a form of social support for Black/African American patients than non-Black patients. For example, non-Black patients (mean 5.29, SD 3.96) were less likely than Black/African American patients (mean 7.03, SD 3.88) to say they have a pastor or other religious leader that they trusted and could talk to (t_{234}=–3.336; *P*=.001). However, non-Black patients (mean 7.27, SD 3.11) were more likely to report independently researching treatment options than Black/African American patients with cancer (mean 6.38, SD 3.55; t_{237}=2.050; *P*=.04). In addition, non-Black patients (mean 7.58, SD 3.48) more strongly endorsed agreement with having family or close friends who had been diagnosed with cancer and who were successfully treated than Black/African American patients (mean 6.59, SD 3.90; t_{236}=2.038; *P*=.04).

Beliefs About Health and Health Care Providers

Non-Black patients reported less frequent use of home remedies for medical care growing up than Black/African American patients (t_{236}=–5.485; *P*<.001). In addition, 3 items of distrust of health care providers and medical mistrust were also endorsed more strongly by Black/African American patients (“I think that doctors mislead patients,” “I don’t trust medical researchers,” and “I believe racial/ethnic minorities are discriminated against in medical research studies”). However, ratings in both groups remained low and below a score of neutral (ie, “5”), reflecting overall low levels of medical mistrust in this sample.

Patient Activation, Patient Self-Advocacy, and Health Care Self-Efficacy

There were no significant differences in average patient activation in cancer care, patient self-advocacy, or health care self-efficacy between Black/African American and non–Black/African American patients (all *P*>.05).

Decisional Conflict

Of the 4 domains of decisional conflict, only certainty was significantly different between Black/African American and non–Black/African American patient groups. Black/African American patients with cancer (mean 25.62, SD 22.17) reported lower certainty in their clinical trial decision-making than non–Black/African American patients (mean 36.24, SD 25.76; t_{237}=3.284; *P*=.001). The remaining 3 decisional conflict domains (informed, value clarity, and support) and summary decisional conflict score were nonsignificant between groups at the α=.05 level.

Intentions to Participate in Clinical Trial, if Offered

Intentions to participate in a cancer clinical trial, if offered, did not differ significantly between Black/African American patients (mean 6.38, SD 3.16) and non–Black/African American patients (mean 7.03, SD 2.60) at the α=.05 level ($t_{174.01}$=1.662; *P*=.10).

Discussion

Principal Findings

This analysis of baseline data from the mychoice randomized control study focused on patient perceptions regarding cancer clinical trials comparing Black/African American patients to non-Black patients. Some results are consistent with other research while also suggesting some unexpected findings that might shift the focus on how best to increase participation among Black/African American patients with cancer. Results indicate that addressing preparation for decision-making, community context, and the opportunity to reframe perceptions about interest in considering clinical trials are important constructs to target in efforts to reduce barriers to participation for Black/African American patients.

Comparisons to Prior Work

Clinical trial decision-making is complex. As suggested by Wenzel et al [70], the Model of Cancer Clinical Trial Decision-Making provides a framework to explore these findings from the patient perspective including information gathering, intrapersonal and interpersonal factors that influence the decision-making process, all of which ultimately impact decisional outcomes.

Our findings suggest that there are differences at the start of the clinical trial decision-making process between Black/African American and non-Black patients. We found non–Black/African American patients had significantly higher levels of clinical trial knowledge, health literacy, and positive experiences with cancer outcomes, while Black/African American patients were less likely to hear about clinical trials before their diagnosis, creating inequities from the start. More challenging is combating the realities of later-stage disease at diagnosis and unequal oncology care in many communities of color where cancer outcomes are less positive [71,72]. These findings are consistent with the current literature and highlight the need for more community education and awareness about clinical trials using plain language and health communication approaches appropriate for all levels of health literacy [73]. As progress is made to address these inequities, it is important to emphasize these gains in our educational initiatives and share stories from survivors and clinical trial participants from these communities [74].

Our study findings are also consistent with other research highlighting that the potential benefits of participation are less likely to resonate with Black patients, including the notion that participation is a benefit to their community. One factor is a higher level of level of general medical mistrust found in the Black/African American community [75], which is associated with expectations of lower care quality and poorer treatment experiences [76].

Consistent with existing literature, Black/African American patients with cancer more frequently endorse fatalistic beliefs about the condition [77]. As noted in the model proposed by Wenzel et al [70], increased fatalism is an important factor in this decision-making process. Addressing these deep-rooted beliefs and experiences requires deeper, authentic discussions with community leaders, providers, and other stakeholders. Religious leaders, specifically, can be messengers to balance these beliefs because they can play an important role in individuals' decision-making process [78]. To improve self-efficacy in cancer clinical trial decision-making and to improve clinical trial experiences overall, prior evidence-based recommendations have been made to establish long-term partnerships between not only the health care providers but also with other patients, patient advocates, researchers, clinical trial sponsors, and other community-based organizations (eg, faith-based groups and social services organizations) [55,79] as well as to form community advisory boards [80].

We found few differences in facilitators to clinical trial participation by race. Indeed, patients reported that they were confident in gathering support, trusted their physicians, and could get information from their physicians about clinical trials. Although general mistrust was more prevalent in Black/African American patients, their trust in their physician and their ability to get information about clinical trials was similar to non-Black patients. This was a much more nuanced view of medical mistrust and may vary significantly among Black/African American patients, depending on a range of sociodemographic factors and life experiences. In addition, it is important to note that general mistrust might be mitigated by the providers providing direct care, which could include providers from a variety of specialties and primary care. Therefore, initiatives and interventions to educate a broad range of providers about clinical trials and emphasize their role in this decision-making process are essential to increasing participation.

An unexpected finding was that non-Black patients reported higher levels of concerns about receiving a placebo and felt they did not have sufficient information to decide about participation. This may be related to their higher levels of clinical trial knowledge that might initially raise more questions and concerns, recognizing the complexity of the process. As more comprehensive education is conducted in Black/African American communities, we might expect that these will be issues that need to be specifically addressed.

Perhaps most importantly, there were no differences between Black/African American and non-Black patients in their intention to participate if offered a clinical trial. This was true despite having found important differences in perceived barriers to participation by race. However, provider and system barriers may impact the ability of patients to turn intention into decision-making and participation. If a trial were available and yet not offered, there is an unwarranted bias that they would not be interested. If a trial is not available, then there is no decision to make. This expands the Wenzel model beyond the patient [70], focusing on the multilevel influences on this decision-making process. Future research could include both the mychoice patient tool and provider training and interventions to increase cultural competency and change the knowledge and attitudes of providers and study staff, as well as providing culturally tailored education initiatives to increase education and awareness of clinical trials among racial and ethnic minoritized populations [81-83]. Our own work developing the mychoice web-based tool to assist diverse patients in the decision-making process serves as an example [58].

Future Directions

We recognize that patients' knowledge, attitudes, and interest in clinical trial participation are only one facet of this complex process. Availability of clinical trials in local settings, systematic barriers to care, language and cultural barriers, provider attitudes, and trial eligibility requirements all must be addressed as well. To date, many programs and interventions have been implemented at multiple levels or at the organization or systems levels to address systemic factors that drive the continued underrepresentation of people from racial and ethnic minoritized groups in research. For example, 1 system-level approach is the creation of the US Cancer Centers of Excellence and an inventory of successful strategies for increased inclusion of people from racial and ethnic minoritized groups in clinical trials [84,85]. Specifically, leaders from 8 US cancer centers met to determine best practices for increasing enrollment and retention of clinical trial participants from racial and ethnic minoritized groups. Topics discussed included hiring practices; cultural changes in research organizations; and education or training on equity, diversity, and inclusion among people who study and work in cancer clinical trials [55,84,85]. These changes are important because patient-provider identity concordance can motivate greater interpersonal trust, cancer care engagement, and care quality [86-88], yet Black oncologists remain significantly underrepresented within the health care workforce, with Black oncologists making up only 3% of all oncologists in the United States as of 2021 [87].

Finally, studies should also publish data more frequently on the racial and ethnic composition of their study participants in their published clinical trial reports and in registry results [55]. While applicable to public health and medical fields beyond oncology, increased transparency about the demographic composition of clinical trials will assist with monitoring of diversity, equity and inclusion progress and support future meta-analytic research. For example, among the 197 precision oncology clinical trials in the United States from 2004 to 2017 reported on ClinicalTrials.gov, fewer than half (n=97, 49.2%) provided race or ethnicity data [4]. Similarly, recent systematic reviews found that only 57% of the 155 head and neck cancer clinical trials between 2010 and 2020 [89] and only 4.4% of the 544 bladder cancer clinical trials published between 1970 and 2020 had race or ethnicity demographic data [90].

Limitations

This study has several limitations. First, this was a cross-sectional analysis that limits inferences to causality. Second, generalizability is limited to people already receiving care for cancer. This is noteworthy because cancer disparities exist before this point (ie, detection, treatment provision, etc), meaning that there may be different beliefs and attitudes associated with patients who have not engaged with cancer treatment services. This may also limit generalization to some specific patient populations, such as recent immigrants, without adequate health insurance and health care access. Moreover, this was a baseline sample of patients diagnosed with cancer recruited from cancer treatment centers for an RCT. Thus, this sample of participants likely already has higher acceptance of clinical trials because they had already consented to be in a behavioral trial. In addition, results also suggest that these participants may have higher acceptance of Western medicine and health care providers because they are already receiving care at a cancer treatment center. This sample reported low levels of health care provider medical mistrust and few reports of negative health care experiences across both the Black/African American and non-Black groups, which is likely not representative of the US adult cancer population, especially Black adults [46,91,92].

While social desirability bias can contribute to underreporting of negative health care experiences and other negative health care attitudes and beliefs, the web-based, self-administered survey format may have mitigated the extent to which social desirability bias could have impacted the validity of participant responses. Another potential limitation is that these analyses did not control for multiple comparisons made on the same data set. While some researchers suggest using the Bonferroni adjustment to control for the possibility of finding false positives when making multiple comparisons, there is criticism of its unilateral use in multiple comparison studies [93]. That said, there remains some potential for inflated type 1 error (ie, false positives) given the number of hypotheses tested. Finally, there are also additional barriers to cancer clinical trial participation that are not accounted for in the present analysis. For example, older age, insurance type (ie, Medicaid and uninsured vs private insurance), greater medical comorbidities, and greater distance to treatment are associated with lower rates of clinical trial participation [94] and high-quality, guideline-concordant cancer care [95]. Thus, covariate-adjusted analysis methods should be considered for subsequent work.

Conclusions

The findings from the baseline survey of the mychoice randomized trial highlight that although clinical trial participation among diverse populations remains low, there were no significant differences in interest in clinical trials, and trust in individual providers was high in both Black/African American and non-Black patients with cancer. However, persistent beliefs about barriers to and benefits of participation in clinical trials exist. Our findings suggest that we need more outreach, discussion, and introduction of clinical trials to diverse oncology patients who may be more interested than presumed. This does not preclude the considerable work that needs to be done to address access to clinical trials and addressing the systemic barriers to participation. Importantly, the findings from this study suggest that current interventions have not significantly moved the needle in broadening the appeal of clinical trials in Black/African American patients with cancer, and further work in effectively increasing participation rates is still needed.

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Data Availability

The data sets generated during and analyzed during this study are not publicly available because they contain information that could potentially identify patients but are available from the corresponding author on reasonable request.

Authors' Contributions

AH contributed to formal analysis, writing the original draft, and reviewing and editing the manuscript. LF contributed to conceptualization, data curation, funding acquisition, investigation, methodology, project administration, supervision, writing the original draft, and reviewing and editing the manuscript. CK contributed to project administration, supervision, reviewing and editing the manuscript. PJAK contributed to project administration and reviewing and editing the manuscript. XM contributed to formal analysis. JW contributed to methodology and formal analysis. CG contributed to conceptualization and reviewing and editing the manuscript. AEL contributed to conceptualization and reviewing and editing the manuscript. MA and PD contributed to investigation. ZL contributed to reviewing and editing the manuscript. SBB contributed to conceptualization, data curation, funding acquisition, investigation, methodology, project administration, supervision, writing the original draft, and reviewing and editing the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

RCT: randomized controlled trial
REDCap: Research Electronic Data Capture

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Original Paper

Development of an Educational Website for Patients With Cancer and Preexisting Autoimmune Diseases Considering Immune Checkpoint Blockers: Usability and Acceptability Study

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Abstract

Background: Patients with cancer and an underlying autoimmune disease who are considering immune checkpoint blockers (ICBs) need to know about the benefits and risks of severe immune-related adverse events and flares of the autoimmune condition.

Objective: This study aims to develop and alpha test an educational website for patients with cancer.

Methods: Learning topics, images, and website architecture (including flow and requirements) were developed and iteratively reviewed by members of a community scientist program, a patient advisory group, and content experts. Alpha testing was performed, measuring the site's usability using the Suitability Assessment of Materials and its acceptability using the Ottawa Acceptability Measure.

Results: The website included a home page; general information about ICBs; comprehensive modules on the benefits and risks of ICBs for patients with cancer and preexisting autoimmune diseases; general wellness information; and features such as a quiz, additional resources, and a glossary. For the alpha testing, 9 users assessed the newly developed website. Patient reviewers (n=5) had rheumatoid arthritis, Crohn disease, Sjogren syndrome, or vasculitis. Health care provider reviewers (n=4) were medical oncologists or rheumatologists. The median Suitability Assessment of Materials rating was 75 (IQR 70-79; range 0-100) for patients versus 66 (IQR 57-72; range 0-100) for providers (scores ≥70 indicate no substantial changes needed). Recommendations for improvement, mostly involving navigation and accessibility, were addressed. All participants expressed that the website was acceptable and balanced in terms of discussion of benefits and harms. Because half (2/4, 50%) of the providers suggested we increase the amount of information, we extended the content on the impact of having an autoimmune disease when considering ICB treatment, the probability of flares, and the management of flares in this context.

Conclusions: The feedback led to minor revisions to enhance readability, navigation, and accessibility, ensuring the website's suitability as a decision-making aid. The newly developed website could become a supporting tool to facilitate patient-physician discussion regarding ICBs.

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KEYWORDS

immune checkpoint inhibitors; patient education; usability testing; cancer; autoimmune diseases; mobile phones; user testing; usability; user experience; immunotherapy; websites; development; acceptability; autoimmune; immunology; oncology; architecture; iterative; vasculitis; Crohn disease; Sjogren syndrome; educational; web-based resource; health information; rheumatology; arthritis; web design; eHealth; adverse events; patient care; treatment

Introduction

Health information can motivate patients to become involved in their health care and facilitate discussions between patients and health care providers [1]. Informed patients also have better treatment adherence and satisfaction with their care [2,3]. Although web-based information can be helpful, it can also be harmful as it may contain conflicting, biased, or incomplete information, causing confusion on the part of the patient. For instance, requests for interventions that may not be appropriate or may have unforeseen harms may emerge from unbalanced, poor-quality information that presents an overly positive picture [4].

Immune checkpoint blockers (ICBs) are immunotherapy drugs that enhance the immune system's ability to target cancer by inhibiting specific pathways that regulate immune cell activity, such as programmed cell death protein 1, programmed death ligand 1, and cytotoxic T-lymphocyte–associated protein 4 [5]. These pathways are often exploited by cancer cells to evade immune detection. By blocking these checkpoints, ICBs unleash T-cells to attack cancer more effectively, significantly benefiting patients with various malignancies, including melanoma, nonsmall cell lung cancer, renal cell carcinoma, and others [6]. However, this approach can also trigger immune-related adverse events, as the heightened immune response may affect normal tissues [7].

Because ICBs have the potential to cause severe immune-related adverse events or exacerbate underlying autoimmune conditions, patients with cancer and a preexisting autoimmune disease who undergo treatment with ICBs need balanced information about ICBs [8-10]. Results from our prior learning needs assessment in this population suggest that some patients like to learn on their own to allow time to digest information and ask questions later [11]. We found that most patients preferred educational materials in multiple formats (eg, video, audio, graphics, and text), suggesting that websites or smartphone apps would be the most convenient delivery channels [11]. Clinicians also agreed that the optimal delivery of health information should include multiple formats; however, crucial requirements identified by providers were accuracy, simplicity, and standardized information (as opposed to individualized or nonlinear information) [12].

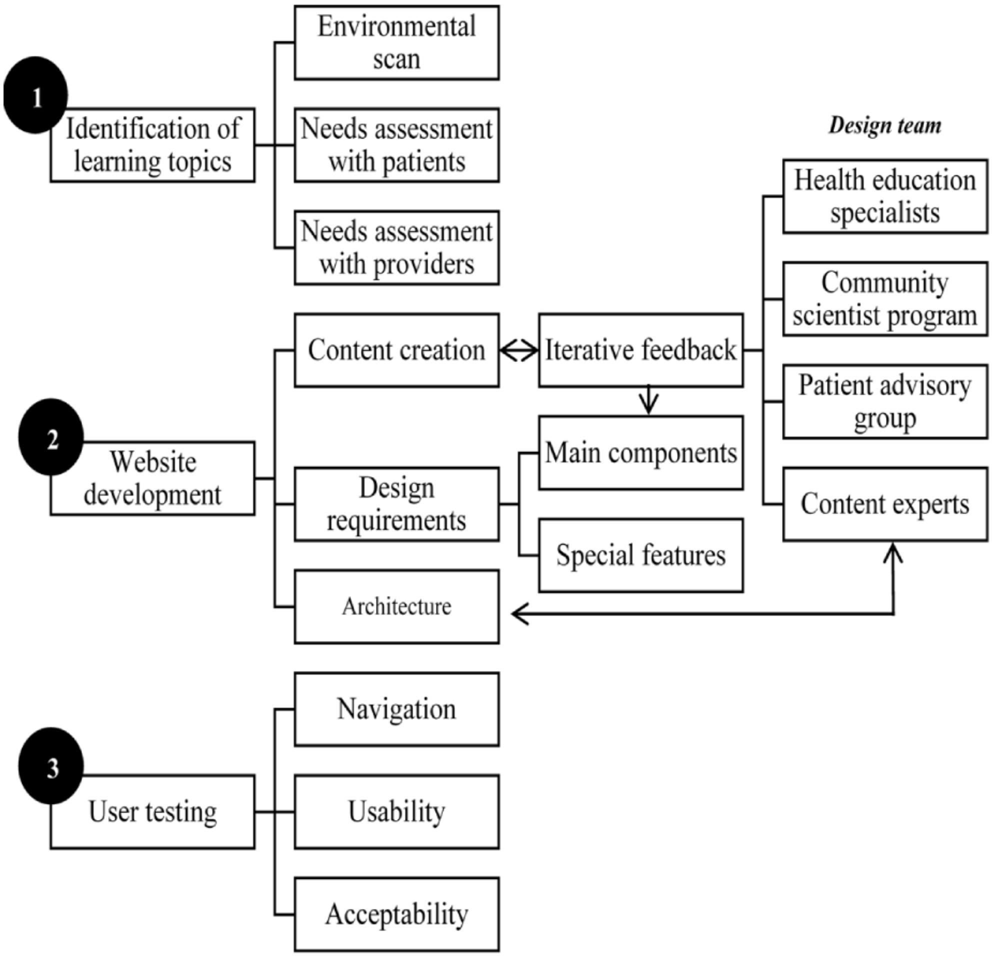
To our knowledge, there currently exists no web-based information containing specific content for patients with cancer and a preexisting autoimmune disease who are considering ICBs. Current websites provide only general information about cancer and ICBs, with few providing balanced information between benefits and potential risks [13]. We developed and alpha tested an educational website designed to inform patients with cancer and underlying autoimmune diseases who are considering ICBs and to facilitate patient-provider discussions.

Methods

Design

We followed a user-centered approach to develop and test our website [14]. Our study process, depicted in Figure 1, involved 3 main sequential phases: identification of learning topics, website development, and user testing.

Figure 1. Study design.



Identification of Learning Topics

The process for identification of the key points to include in the educational content has been described elsewhere [12,13]. Briefly, an environmental scan was conducted to assess the quality and content of web-based information about ICBs [13]. Concurrently, we interviewed patients with cancer and a preexisting autoimmune disease who were considering or already had received ICBs, as well as the providers caring for these patients [11,12]. We asked both patients and providers about their preferred formats and channels to deliver information.

Website Development

Two review authors (ME and MALO) created educational content based on the identified learning needs and current informational gaps. Two patient health education specialists helped to ensure that the content readability was at a sixth-grade level or below. We then focused on the website architecture and design requirements, including colors, layout, and text formatting. We identified the main components and special features to be included (ie, medical illustrations, glossary of terms, quiz based on the educational content, and links to other relevant URLs). For the mockup website, the informational components were categorized into basic, key, and other health-related information. A medical illustrator created visual representations of the concepts related to the immune system, immune cells, immune checkpoint proteins, and autoimmune diseases.

The learning topics; images that were relevant to the educational content; and website architecture, including flow and requirements, were iteratively reviewed by health education specialists, members of a community scientist program, a patient advisory group (ie, 3 patients who had received ICBs and 2 caregivers), and content experts (ie, 3 oncologists, 4 rheumatologists, and 1 decision scientist). Four Zoom (Zoom Video Communications, Inc) meetings were held with members of the community scientist program (an institutional resource to gain consumers’ input on research projects), which includes patients with cancer, survivors, and caregivers (the number of participants in each of these groups differed for every meeting, n=8-12). Moderators of the meetings took written notes, and this information was used to modify the website content. Feedback on the mockup website from the patient advisory group and the content experts was received through individual interviews and email communications, and a disposition report was created that summarized all comments and how they were addressed. Screenshots of the mockup website are shown in the Multimedia Appendix 1.

Patient and Provider Testing of the Prototype

After developing the mockup website, we conducted an extensive evaluation of the prototype (alpha testing). Nielsen studies suggest that 5 users from any user group will elicit 80%

of interface usability problems [15]. The purpose of the testing was primarily to assess visual elements, content of the website, navigation, functionality, acceptability, and usability.

Recruitment

Participants were recruited from a large comprehensive cancer center. We posted flyers in participating clinics. In addition, research staff identified potentially eligible patients by reviewing clinic schedules and through a chart review. Patients met eligibility criteria if they were diagnosed with an underlying autoimmune disease, had already received ICBs, were fluent in English, and had access to a device with Zoom conferencing capabilities. Providers were eligible if they were medical oncologists or internal medicine specialists caring for these patients. Potential participants were contacted by phone, message, or email by a member of the research team and invited to participate.

Ethical Considerations

The study was approved by the institutional review board at The University of Texas MD Anderson Cancer Center (protocol #2020-0843). All participants provided verbal consent to participate. Informed consent was obtained from all participants involved in the study. Members of the patient advisory board and patients completing the alpha testing were compensated ($180 gift card for members of the advisory board and $30 for patients). Study data were collected and managed using a secure, web-based software platform, REDCap (Research Electronic Data Capture; Vanderbilt University) hosted at The University of Texas MD Anderson Cancer Center [16,17].

Procedures

After providing informed consent, participants navigated the website using computers connected to the internet at their homes using Zoom or in the clinic on mobile devices. Two investigators (MALO and GFD or VT) led the user testing session, with MALO sitting in on most sessions to take notes. We used 3 different approaches for testing as follows.

- Navigation testing: During cognitive interviews, we asked participants to describe how they were navigating through the website [18]. Written notes were taken of participant reactions and behaviors. We asked questions about the general look and feel of the mockup website (eg, language and terminology, information layout, and images), menu options and pathways, and how they would normally access the website (smartphone or PC). We instructed participants to complete some basic tasks to find information on the website to test its functionality. In addition, we asked about the appropriateness of the content and images (see Section S1 inMultimedia Appendix 2). Navigation sessions lasted between 52 and 64 minutes for patients and 30 to 60 minutes for providers. They were conducted between March 2023 and July 2023.
- Usability: We used the Suitability Assessment of Materials (SAM) to evaluate the adequacy of the content, literacy demand, graphics, layout and typography, learning stimulation and motivation, and cultural appropriateness [19]. Each item in SAM has 3 possible responses: “not adequate,” “adequate,” and “superior.” A “superior” response scores 2 points for that item; an “adequate” response scores 1 point; and a “not adequate” response scores 0 points. These points are then added up and divided by the maximum possible total score (ie, 44) to obtain a percentage rating (hereafter referred to as the SAM score). A SAM score of 70 to 100 is considered superior with no need for revisions. A SAM score of 40 to 60 is considered suitable, but revisions may be needed for any items considered unsuitable. A SAM score of less than 40 is considered not suitable [20,21].
- Acceptability: The Ottawa Acceptability Measure was used to obtain patient ratings of various features of the educational tool, including length and amount of information, type of information (balanced or not), and likelihood to help people with cancer and autoimmune diseases who are considering ICBs. Responses can be reported descriptively in terms of proportions responding positively or negatively on each criterion. The scale also includes an open-ended question about the overall satisfaction with the website [22].

Other measures collected included patient demographics (ie, age, sex, race, ethnicity, language, and education), health literacy using the Single Item Literacy Screener to identify patients who have difficulty reading health-related materials [23], and preferred decision-making role (the patient is the primary decision maker [active], the provider is the primary decision-maker [passive], or the provider and patient make the decision together [collaborative]) using the Control Preferences Scale [24].

Analysis

We used a mixed methods approach for data analysis. Notes from the navigation testing with participants and the responses to the Ottawa Acceptability Measure open-ended questions were collated and categorized into themes related to acceptability, usability, accessibility, navigation, and functionality of the website. Changes were made if more than 2 patients or providers suggested areas of improvement. We used descriptive statistics to summarize the characteristics of the participants and the data from the usability and acceptability scales.

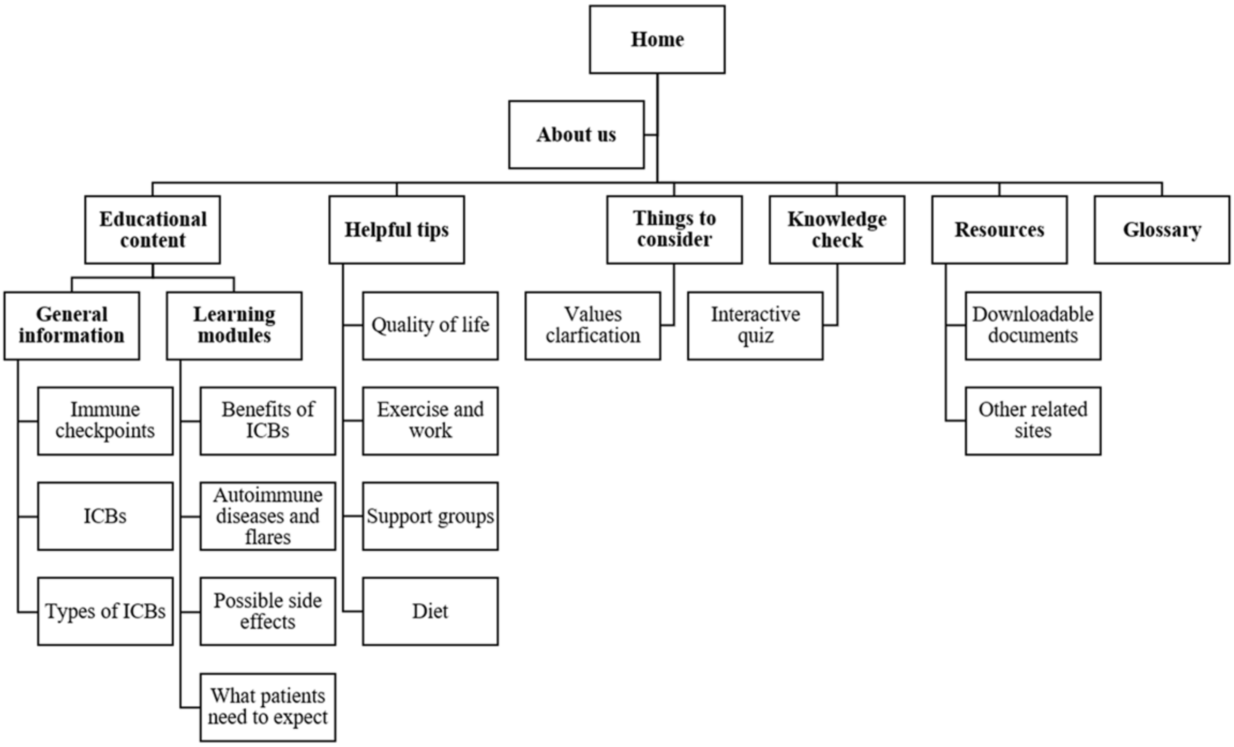
Results

Website Components

Figure 2 shows the components included in the website. The final site map includes a page with general information about ICBs (ie, “What cancer is?” “What the immune system is?” “What T-cells are?” “How the immune system responds to cancer?” “What immunotherapy is?” “What immune checkpoints are?” ICB mechanisms of action, and types of ICBs) and learning modules covering (1) benefits of ICBs (ie, choice of treatment, benefits of ICBs, ICB treatment vs other cancer treatments, and ICB therapy vs chemotherapy); (2) receipt of ICBs in the context of autoimmune disease (ie, “What autoimmune diseases are?” “What flares are?” “How can ICBs affect autoimmune diseases?” importance of autoimmune disease control when considering ICB treatment, risk of flares during ICB treatment, possible symptoms, treatment options, and appointment with autoimmune disease specialist); (3)

possible side effects (ie, side effects that are not flares of the autoimmune disease, symptoms that require immediate attention, permanent or fatal side effects, and when to call a doctor); and (4) what patients should expect before, during, and after treatment with ICBs (ie, discussion with doctor, tumor markers, ICB treatment process, length of ICB treatment, ICB monotherapy vs combination, ICB combined with other cancer treatments, and causes of ICB discontinuation). An additional page includes information about the potential impact of ICBs on quality of life as well as exercise and daily activities, support groups, and maintaining a healthy diet. The site also includes a quiz, a values clarification booklet with possible questions to ask doctors, a glossary page with definitions of the medical terminology used throughout the site, and a resources page with links to downloadable documents and related sites. The "About Us" page includes the names and affiliations of those involved in the development and production of the website, a health information disclaimer, and the sources of funding.

Figure 2. Site map for the newly developed website. ICB: immune checkpoint blocker.



Website Maintenance

The website displays an update date to inform users of the most recent revisions. To ensure the website remains up-to-date and relevant, the content will be reviewed and updated every 24 months or more frequently as new evidence emerges. Updates will be managed by the research team, which maintains a database of relevant medical literature on the topic [25,26]. Specific updates will include incorporating new ICB indications, advances in toxicity management, and any critical findings relevant to autoimmune disease risks.

Patient and Provider Testing of the Prototype

Patient participants (n=5) had a mean age of 59.2 (SD 11.6) years; 3 (60%) were female, 2 (40%) had diagnosis of rheumatoid arthritis, 1 (20%) had Crohn disease, 1 (20%) had Sjogren syndrome, and 1 (20%) had granulomatosis with polyangiitis. The following malignancies reported were each reported once (n=1, 20%): lung cancer, prostate cancer, melanoma, colon cancer, and breast cancer. The ICB administered, education level, race, ethnicity, health literacy, and preferred decision-making role of the participants are summarized in Table 1.

Table 1. Characteristics of patient participants (n=5).

Characteristic	Values
Age (years), mean (SD)	59.2 (11.6)
Sex, n (%)	
Female	3 (60)
Education level, n (%)	
Less than high school diploma	1 (20)
High school diploma or higher degree	4 (80)
Race or ethnicity, n (%)	
Hispanic White	1 (20)
Non-Hispanic White	4 (80)
Health literacy, n (%)	
Adequate	3 (60)
Inadequate	2 (40)
Preferred decision-making role , n (%)	
Collaborative	4 (80)
Active	1 (20)
Immune checkpoint blocker administered , n (%)	
Durvalumab	2 (40)
Nivolumab	2 (40)
Pembrolizumab	1 (20)

Provider participants (n=5) comprised 4 (80%) melanoma medical oncologists and 1 (20%) rheumatologist. Three (60%) were female, 3 (60%) were White, and 2 (40%) were Asian, with a median of 18 (IQR 16-20) years of practice. The median SAM score for patient participants was 75 (IQR 70-79; range 0-100). For provider participants, the median SAM score was 66 (IQR 57-72; range 0-100). Providers reported seeing an average of 20-200 patients who are receiving ICBs, and providers spent 20% to 75% of their time in clinical practice. All reported being confident in managing patients with cancer and preexisting autoimmune diseases.

Usability

The median SAM score for patient participants was 75 (IQR 9.1; range 0-100). For provider participants, the median SAM score was 64 (IQR 14.2; range 0-100). The number of patients and providers rating specific items on SAM as adequate or superior is shown in Table 2 [19]. Only 2 items were considered for revision: consistently providing context before presenting new information and adding step-by-step directions for the interpretation of medical illustrations used. We did not consider making changes to the typography because our text met the criteria for suitability (ie, consistent use of upper and lower case with serif font type, font size of at least 12 points, bolding and change of color, and size used to emphasize key points).

Table 2. Proportion of participants rating each item on the Suitability Assessment of Materials as adequate or superior.

Item	Patients (n=5), n (%)	Providers (n=4[a]), n (%)
Content subscale		
Purpose is evident	5 (100)	4 (100)
Content	5 (100)	4 (100)
Scope is limited	5 (100)	4 (100)
Summary of review included	5 (100)	4 (100)
Literacy demand subscale		
Reading grade level	5 (100)	3 (75)
Writing style, active voice	5 (100)	4 (100)
Vocabulary with common words	5 (100)	3 (75)
Context given first	4 (80)	4 (100)
Learning aids via “road signs”	5 (100)	4 (100)
Graphics subscale		
Cover graphic showing purpose	5 (100)	3 (75)
Type of graphics	5 (100)	4 (100)
Relevance of illustrations	5 (100)	3 (75)
Lists and tables explained	4 (80)	3 (75)
Captions used for graphics	5 (100)	4 (100)
Layout and typography subscale		
Layout easy to follow	5 (100)	4 (100)
Typography appropriate	4 (80)	4 (100)
Subheading “chunking” used	5 (100)	4 (100)
Learning stimulation and motivation subscale		
Interaction used	5 (100)	4 (100)
Behaviors modeled and specific	5 (100)	4 (100)
Motivation and self-efficacy	5 (100)	4 (100)
Cultural appropriateness subscale		
Match in logic, language, experience	5 (100)	4 (100)
Cultural image and examples	5 (100)	4 (100)

[a] One clinician provided only verbal suggestions after navigation.

Acceptability

Patient participants agreed that the website was acceptable, with good or excellent information regarding the impact of preexisting autoimmune diseases in the context of ICB therapy and risk of flares (Table 3). Patients perceived the information as balanced (benefits or harms ratio) and containing enough information to be helpful for making a decision regarding the use of ICBs (Table 3). Providers were neutral about the length of information, preferring more information in general, especially about treatment options. As a result of this feedback, we expanded the amount of information provided about treatment options, ICB infusions, and disease flares of underlying autoimmune diseases.

Table 3. Proportion of participants rating each item on the Ottawa Acceptability Measure as good or excellent.

Ottawa Acceptability Measure item	Patients (n=5), n (%)	Providers (n=4[a]), n (%)
Type of information presented		
Impact of preexisting autoimmune disease	5 (100)	2 (50)
Risk of flares	4 (80)	2 (50)
Treatment options	3 (60)	2 (50)
Right length of information	4 (80)	2 (50)
Right amount of information	4 (80)	2 (50)
Balanced information	5 (100)	4 (100)
Educational tool useful at the time of first discussing treatment with immune checkpoint inhibitors	5 (100)	4 (100)
Enough information to help patients decide whether to use immune checkpoint inhibitors	5 (100)	3 (75)

[a] One clinician provided only verbal suggestions after navigation.

Qualitative Synthesis of Suggestions

Patient participants appreciated the ICB overview. Most comments were favorable; patients expressed that having this website before starting ICB therapy would have made it easier to understand the information and their decisions. One participant commented, “It was really informative. I wish I had it to know what I was getting into.” Another commented, “I was able to read it. I like it was in common words that I could understand.” Other participants commented on the amount of information. For example, a participant stated, “I think it was just right what was in there. Not too much, not too little. It gave enough info to decide.” Others commented on the additional pages, such as the glossary of terms and features of the site (“crisp” images, breakdown of the content, and ability to move from 1 module to another).

Table S1 in Multimedia Appendix 2 contains a summary of the suggested website changes. Recommendations for improvement mostly involved minor changes to the content to improve readability and expand information to include more details about the immune system and autoimmune diseases and treatment. Other recommendations involved navigation (eg, adding a home page button and site map), accessibility (eg, enlarging images and including activities), and functionality (eg, adding a link to the institutional patient portal for direct messaging to the clinic).

Discussion

Principal Findings

This paper details the design, development, and evaluation of an educational website with information tailored for patients with cancer and preexisting autoimmune diseases considering treatment with ICBs. The website included comprehensive information on ICBs, their benefits and risks, and the implications for patients with autoimmune conditions, alongside tools such as a quiz and a glossary. Both patient and provider participants found the website usable and acceptable. Patients appreciated the clarity and relevance of the content, while providers suggested expanding information on treatment options. Minor improvements were recommended to enhance readability, navigation, and functionality, indicating the website’s potential as a valuable resource for informed decision-making in this patient population.

In the United States, more than 1 in 3 individuals currently access web-based health information [27], and its use has grown substantially over the past decade [28,29]. Therefore, the creation of a dedicated website for patients with cancer and preexisting autoimmune disease appears to be a cost-effective and widely accessible solution to address some of the unmet informational needs of this patient population [11]. Reliable web-based information can complement the role of clinicians in health education, making web-based information a valuable supportive tool in the overall health care process [30-32]. Furthermore, web-based information platforms can play a crucial role in supporting individuals in remote areas and those without access to health care education services. In clinical settings with vast demand and insufficient time to allocate to ensure that patients comprehend the information received by the health care team, web-based information can also play an important role.

Relying on Google or other search engines for health information can cause problems when the information available is inaccurate, of low quality, not relevant to the individual’s needs, or inconsistent across various sources. In fact, such poor information may have negative effects on communication between patients and health care providers [30,31]. In our previous research, patients expressed a desire for trustworthy sources of information that align with their health care provider’s recommendations. Similarly, health care providers welcomed patients sharing web-based health information if it was accurate and relevant to their medical needs [11,12].

Based on the previous research findings, we designed our website to address the specific needs of patients with cancer and preexisting autoimmune diseases. Our research indicated that these patients face challenges in obtaining comprehensive and reliable information about ICBs and the potential for immune-related adverse events and autoimmune disease flares [11,13]. Both patients and clinicians expressed a desire for a trustworthy and easily accessible source of evidence-based information, which our website aims to provide [12,13]. Our past research has also shown that although patients are given information about immune-related adverse events and flares from their clinicians at the time of the first encounter, patients often fail to understand or remember it [11]. In addition, current information about ICBs is not specific for patients with preexisting autoimmune disease, thus clinicians cannot offer resources with specific information for patients to review after their encounter [13].

During the design and development phases, the research team recommended creating a user-friendly site with content that met the plain language guidelines for patients with low health literacy, in addition to presenting high-quality, evidence-based information. The objectives were achieved successfully because the design, content, illustrations, and language used were well received by the users. The prototype testing revealed that the website was user-friendly and easy to navigate. Additionally, participants found the content highly suitable for their needs.

A strength of our study was the adoption of a user-centered design approach, effectively addressing users' requirements for a website that was easy to use, comprehensive, evidence-based, and backed by reputable experts and health care providers. Another strength was the engagement of a diverse group of multidisciplinary expert clinical advisors and a design team with extensive knowledge and experience in user-centered design.

As with any research study, ours also had some limitations. First, our team has limited representation of participants with low health literacy, who may have provided different feedback than that from our participants. However, we addressed this by including health literacy experts among the production group. Second, for assessing the website's usability and acceptability, patients were deliberately selected from individuals who had already received ICBs to ensure an in-depth experience. However, it is important to acknowledge that this sampling approach may not fully represent the feedback that we could have received from individuals who have not yet been exposed to ICBs. Nonetheless, the recommendations collected closely aligned with those from our patient advisory board and the community scientist program, both of which include individuals without previous knowledge of immunotherapy or autoimmune diseases. Finally, the type of web-based platform chosen to address users' needs was predetermined before the study began because previous research indicated a preference for channels that would allow delivery of the information in multiple formats [33]. It is possible that a smartphone app or the electronic health record system could have been used to deliver text and illustrations and include interactions but the chosen format was based on our preliminary work [11,12].

Ongoing data collection will provide more information to evaluate the effectiveness of the newly developed website in enhancing knowledge, facilitating patient-provider discussions, and continuing to meet the end users' needs. Additionally, further research is planned to enhance specific sections of the website, incorporating more complex features to address users' requests. To improve accessibility, we also aim to translate the content into other languages.

Conclusions

We used a human-centered design approach, involving the user throughout the design process to ensure that the final website met the needs and requirements of the targeted population. The research team, encompassing multiple stakeholders (ie, patients, caregivers, educators, physicians, and researchers), was involved throughout the design process. Our newly developed website was acceptable for patients and has the potential to become a supporting tool to facilitate patient-provider discussions regarding ICBs.

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Data Availability

The datasets generated during and/or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

MALO conceptualized the study, obtained funding, managed the project, conducted all statistical analyses, conducted provider interviews, and drafted the original manuscript; MESA contributed to the study's conceptualization and critically reviewed website content; GFD recruited patient participants and conducted interviews; MC drafted the original website content; HL, CC, MA, HT, AM, COB, and AD provided feedback during website content and contributed by reviewing and editing the manuscript; VBL assisted with regulatory compliance, website production, and contributed to reviewing and editing the manuscript; and RJV developed the study methodology, website production, and participated in reviewing and editing the manuscript. All authors reviewed the final manuscript and approved it for submission.

Conflicts of Interest

CC reports speakers' bureau from AstraZeneca and Sanofi, and consulting fees from AstraZeneca, Sanofi, and Lilly. MA received research funding (to institution) from Genentech, Nektar Therapeutics, Merck, GlaxoSmithKline, Novartis, Jounce Therapeutics, Bristol Myers Squibb, Eli Lilly, Adaptimmune, Shattuck Lab, Gilead, Verismo therapeutics, Lyell. In addition, he is part of Advisory Boards from GlaxoSmithKline, Shattuck Lab, Bristol Myers Squibb, AstraZeneca, Insightec, Regeneron and has received speaker fees from AstraZeneca, Nektar Therapeutics, SITC. He reports participation in the safety review committee for Nanobiotix-MDA Alliance, Henlius.

Multimedia Appendix 1
Screenshots of the mockup website.
[DOCX File , 950 KB - cancer_v10i1e53443_app1.docx]

Multimedia Appendix 2
Interview guides and website design recommendations.
[DOCX File , 22 KB - cancer_v10i1e53443_app2.docx]

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Abbreviations

ICB: immune checkpoint blocker
REDCap: Research Electronic Data Capture;
SAM: Suitability Assessment of Materials

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Designing Positive Psychology Interventions for Social Media: Cross-Sectional Web-Based Experiment With Young Adults With Cancer

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Abstract

Background: Young adults (ages 18 - 39 years) with cancer face unique risks for negative psychosocial outcomes. These risks could be lessened with positive psychology interventions adapted for social media if intervention messages encourage intentions to do the activities and positive message reactions and if young adults with cancer perceive few downsides.

Objective: This study aimed to assess whether social media messages from evidence-based positive psychology interventions encouraged intentions to do the intervention activities and intended positive message reactions, overall and among sociodemographic or cancer characteristic subgroups. We also aimed to identify perceived downsides of the activity that would negatively impact the interventions' feasibility.

Methods: Young adults (ages 18 - 39 years, cancer diagnosis ages 15 - 39 years) were randomized to a between-persons web-based experiment. Participants viewed a social media message with social context cues (vs not) for 1 of 2 types of intervention (acts of kindness vs social connectedness). Participants reported intentions to do the activity, along with their perceived social presence in the message (how much they felt the sense of others) and forecasted positivity resonance (whether they would experience socially connected positive emotions when doing the activity), with 5-point items. Participants also reported their self-efficacy (how certain they can do the intervention activity) with a 0 - 100 item and potential downsides of the activity categorically.

Results: More than 4 out of 5 young adults with cancer (N=396) reported they "somewhat" (coded as 3) to "extremely" (5) intended to do the intervention activity (336/396, 84.8%; mean ranged from 3.4 - 3.6, SD 0.9-1.0), perceived social presence in the messages (350/396, 88.4%; mean 3.8, SD 0.7), and forecasted positivity resonance (349/396, 88.1%; mean 3.8 - 3.9, SD 0.8). Participants reported having self-efficacy to complete the activity (mean 70.7% of possible 100%, SD 15.4% - 17.2%). Most (320/396, 80.8%) did not think of the downsides of the interventions. Messages with social context cues (vs not) and both intervention types were rated similarly (all $P>.05$). Black young adults reported lower intentions, perceived social presence, and forecasted positivity resonance than White young adults (all $P<.001$). Participants in active treatment (vs completed) reported greater intentions to do the activities ($P<.001$).

Conclusions: Positive psychology intervention messages adapted for social media were perceived as acceptable and feasible among young adults with cancer. The social media–based messages encouraged increasing one's social connectedness and performing acts of kindness. Young adults with cancer also predicted they would have feelings of positive social engagement (positivity resonance) when doing the interventions—the key ingredient for experiencing the health benefits of these activities. This study provides promising evidence for the development of age-appropriate, highly scalable interventions to improve psychosocial health among young adults with cancer.

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KEYWORDS

young adult; cancer survivors; social media; positive psychology; acceptability; feasibility; youth; cancer; psychosocial; self-efficacy; social connection; positive emotion; emotion; social engagement

Introduction

Young adults (ages 18 - 39 years) with cancer need tailored interventions to improve their psychosocial health. Young adults who receive any cancer diagnosis often struggle with poor psychosocial health [1,2], more than non-cancer peers [3-5]. Young adults with cancer experience social isolation that is made worse by debilitating life disruptions (eg, extended school and work absences [6-9]) throughout the cancer experience and into survivorship [10,11]. Lack of social connectedness in this population is linked with poor psychological functioning, greater sensitivity to stressors, lower physical functioning, and worse quality of life [12]. Conversely, young adults with cancer who have frequent positive, in-person social interactions have better psychological and health outcomes [13].

The science of positive psychology offers a roadmap to meet the needs of young adults with cancer. Ample evidence demonstrates how behavioral interventions, collectively termed “positive psychology interventions,” can increase people’s day-to-day positive activities to improve their psychosocial health [14-18]. Among the most widely studied is an act of kindness intervention: a meta-analysis of 27 randomized controlled trials (combined N=4045) found people who increase their everyday kind acts show reliable increases in well-being [19].

Recent work identifies positive experiences of social connectedness as a key active ingredient in acts of kindness interventions [20], a result consistent with other large-scale studies showing that socially engaged pursuits predict increases in well-being [18]. Social connectedness interventions target this active ingredient directly, by assigning people to increase their positive connections with others, even brief ones with acquaintances and strangers encountered in person in daily life [21]. These interventions stem from recent theory and evidence that the collective emotional state of “positivity resonance” functions to build individual psychosocial health and caring communities [21-27]. In-person social connections vary in their positivity resonance, with high quality marked by a fusion of shared positive emotions, mutual kindness, and synchrony [25,28]. A recent randomized controlled trial of various social connectedness interventions produced increases in nightly reports of positivity resonance across 35 days and demonstrated links between this socially engaged state and altruism and other prosocial tendencies [21]. Despite the promise of positive psychology to meet the unique psychosocial needs of young adults with cancer, there are currently few age-appropriate resources available [29,30].

Evidence-based positive psychology interventions should be adapted for young adults with cancer in their design and delivery. Young adults with cancer consistently report needing digital support and reducing social isolation as top priorities [31,32]. Most young adults in the United States (94%) own a smartphone [33], 85% are on the internet daily [34], and 71% use more than 1 social media platform [35]. Daily, millions of young adults turn to social media, to seek health information and lifestyle advice to improve their well-being [36], including those seeking cancer support [37-39]. Delivered via social media, positive psychology interventions designed for young adults with cancer can reach isolated populations where they are *online* to offer advice on how to foster meaningful, in-person social interactions [40].

Visuals and text about others (termed “social context cues”) are important social media message elements to increase motivation to engage with digital interventions [41,42]. Social context cues that are visual (eg, peer photographs) and text-based (eg, personal stories) communicate psychosocial information about others’ thinking and experiences [43]. Visuals of people are social context cues that provide rich peer information, which may be especially important for young adults with cancer who want to see images of peers’ positive experiences or success stories (eg, enjoying life despite treatment or posttreatment) to feel hopeful [37,38]. Personal stories are text-based social context cues that provide salient cause-and-effect stories [44-47], which can include life advice young adults with cancer are looking for: managing negative mental health (eg, a reminder to stop doomscrolling and get out to connect in real life) or adjusting to a new “normal” of reconnecting and building community (eg, offer a sincere compliment to brighten someone’s day) [37,38].

Social context cues increase young adults’ perceived social presence in digital interventions [43,48]. Social presence is the feeling of being with others in mediated contexts. Social presence is driven by exposure to social context cues that signal information about peers and allow individuals to feel the personalness and human sensitivity of others through mediated channels. Social context cues increase motivation and use of web-based information for health behaviors because advice is perceived as more useful when it is from or endorsed by a community of peers [41,49], especially from young adults who “get it” because of a cancer diagnosis [42].

In this study, we adapted social media messages to include enhanced social context cues (ie, peer images, stories) for 2 different positive psychology interventions—acts of kindness and social connectedness—and assessed message reactions. This work is guided by our conceptual framework that our existing positive psychology interventions [21,50] can be optimized for young adults with cancer with the addition of attention-getting, relevant social context cues [41,43]. Social context cues are an important motivator for engagement with and intentions to do the behavior in intervention messages [41,51]. Following the advice to create more in-person social encounters allows for the emergence of positivity resonance [25,28], which in turn builds psychosocial health, a vital asset for young adults with cancer [52-54].

Our goal was to assess whether our social media messages encouraged intentions to do the intervention activities with the attendant positive reactions. We conducted a cross-sectional web-based experiment with 396 young adults with cancer (ages 18 - 39 years) viewing mock Instagram intervention messages. We hypothesized that enhanced social context cues (vs not) would lead to greater intentions to do the activity (hypothesis 1), greater perceived social presence in the messages (hypothesis 2), higher forecasted positivity resonance for the activity (hypothesis 3), and higher self-efficacy for the activity (hypothesis 4) across 2 different intervention types. We examined whether the type of intervention activity (acts of kindness vs social connectedness) impacted acceptability, asking (research question 1) whether intervention type impacted intentions. We also examined (research question 2) whether intervention type impacted perceived social presence, forecasted positivity resonance, or self-efficacy. We explored the feasibility of (research question 3) whether social cues or intervention type increased perceived downsides of the activity. Last, we explored whether intervention message reception (with enhanced cues vs not) differed by sociodemographic or cancer characteristics.

Methods

Participants

We recruited young adults with cancer, ages 18 - 39 years, to participate in a cross-sectional web-based experiment in December 2021. This experiment to assess reactions to evidence-based positive psychology interventions optimized for social media was part of a larger, unrelated study to better understand support needs of young adults with cancer. The sample size was calculated for the parent study where participants viewed a peer support app prototype and shared their social media use for cancer support (396 participants had 80% power to detect a small-to-medium effect, Cohen d=0.25, with a 2-tailed, independent samples t test and a critical α of 0.05) before participating in this experiment; results of those efforts will be reported elsewhere.

Young adults were eligible if they (1) were 18 - 39 years old and (2) had received any cancer diagnosis between 15 - 39 years. Participants had to report a cancer diagnosis from a multiselect list (see *Measures*) or select “other” and fill in their cancer type and select “yes” to receiving a cancer diagnosis between ages 15 - 39 years to be considered eligible. There were no eligibility restrictions for number of years since diagnosis or current treatment status (eg, completed treatment). There were no other exclusion criteria. Eligible participants were recruited by market research companies Opinions for Good and Slice MR [55]. Opinions for Good and Slice MR use their propriety web-based panels of survey respondents to reach a wide range of health care audiences and provide customized recruitment for each research study. Opinions for Good and Slice MR also use unique recruitment incentive methods to reach cancer populations through organization partnerships; participants can directly give back some of their incentive to benefit a nonprofit and advocacy organization of their choice, which encourages partnership among Opinions for Good and Slice MR with advocacy organizations to connect with individuals interested in participating in research.

Ethical Considerations

This study was reviewed and determined exempted by the University of North Carolina Institutional Review Board (#19 - 2715). We preregistered the procedure and analyses on AsPredicted (#79697). After accessing the survey link, participants provided informed consent by reading the approved consent form. Participants then had to respond “Yes” to participate in the research study, and to confirm they had (1) read the consent form, (2) voluntarily agreed to participate, (3) were 18 - 39 years of age, and (4) had a previous cancer diagnosis. Participants received incentives based on the reward amount set by the Opinions for Good and Slice MR (eg, approximately US $20) with the opportunity to give a portion to a nonprofit of their choice. To protect the privacy and confidentiality of participants, all publicly available quantitative data are deidentified, and open-ended responses are not included in those public repositories.

Stimuli

Four different posts were created using a mock Instagram interface and accounts created by the team (all shown in Figure 1 with black bars to anonymize the stimuli). To assess the impact of enhanced social context cues on social media posts, we paired the intervention instructions with different post images. In the social context cues conditions, each activity was paired with an image of a smiling young adult. In the image, we also added a personal story with specific examples of their positive experiences (eg, giving a compliment to make someone smile, or having a dog brighten someone’s day). In the no cues conditions, positive activity instructions were paired with nonhuman imagery (eg, hearts) without any additional text (ie, no testimonial). All other elements of the mock Instagram posts were the same, including who posted, the number of interactions (eg, likes, comments), and the social media background.

The post message text was adapted from the emailed verbal instructions used in 2 types of evidence-based positive psychology interventions encouraging acts of kindness [50] or social connectedness [21]. All messages suggested that young adults with cancer do 3 positive actions the following day. In the acts of kindness conditions, messages shared, “Research shows acts of kindness can improve your and others’ well-being. Tomorrow, try to do three nice things you wouldn’t normally do for others.” In the social connectedness conditions, messages shared, “Research shows connecting with people you barely know can improve your and others’ well-being. Tomorrow, try to create three positive connections with people, beyond what would be your norm.” Each post then had a few examples, a statement about next-day follow-up (as would occur in an intervention), and a commonsense caution to not put oneself in danger.

Figure 1. Stimuli.

[redacted]

met a wonderful person today who sadly just lost her dog :(let's just say i was more than happy to let ollie give her kisses and brighten her day

sam_wood Research shows acts of kindness can improve your and others' well-being.

Tomorrow, try to do three nice things you wouldn't normally do for others.

You could cook dinner for friends or family, do a chore for someone, write a thank you letter, or whatever works for you. These acts of kindness don't need to be for the same person and the people may or may not be aware of the acts.

The next day, we'll ask you about it.

Common sense caution: Don't do anything that might put you or others in danger.

sam_wood Research shows acts of kindness can improve your and others' well-being.

Tomorrow, try to do three nice things you wouldn't normally do for others.

You could cook dinner for friends or family, do a chore for someone, write a thank you letter, or whatever works for you. These acts of kindness don't need to be for the same person and the people may or may not be aware of the acts.

The next day, we'll ask you about it.

Common sense caution: Don't do anything that might put you or others in danger.

[redacted]

i told a customer i LOVED her earrings that she apparently made herself! she couldn't stop smiling and made both our days :) it's the little things

sam_wood Research shows connecting with people you barely know can improve your and others' well-being.

Tomorrow, try to create three positive connections with people, beyond what would be your norm.

Try making eye contact and smiling, asking them about their day, offering a sincere thank you to a service person, or whatever works for you.

The next day, we'll ask you about it.

Common sense caution: Don't do anything that might put you or others in danger.

sam_wood Research shows connecting with people you barely know can improve your and the others' well-being.

Tomorrow, try to create three positive connections with people, beyond what would be your norm.

Try making eye contact and smiling, asking them about their day, offering a sincere thank you to a service person, or whatever works for you.

The next day, we'll ask you about it.

Common sense caution: Don't do anything that might put you or others in danger.

Procedure

After accessing the Qualtrics link from Opinions for Good and Slice MR invitations, participants answered eligibility questions (current age, diagnosis, age at diagnosis) and provided informed consent. Participants then completed items for the parent support app needs experiment (noted above) before beginning this study. Participants were given a transition prompt to set up this study: "In this next section, we want to show you a social media message for an activity and get your thoughts. Below is an example message for activities that involve social interaction. Please read the message and respond to the items below."

Young adults with cancer were then randomized to view an intervention message from 1 of 2 options for the first manipulation of social context cues (enhanced social context cues vs no enhanced cues) and for 1 of 2 options in the second manipulation of intervention types (acts of kindness vs social connectedness). Participants viewed one of the 4 messages from the respective social cue or intervention type conditions shown in Figure 1 (ie, acts of kindness message with and without social context cues, social connectedness message with and without social context cues). Participants were randomized to their study conditions, and which message they would view, with the randomization feature in the Qualtrics survey flow.

Participants were shown the intervention message at the top of the survey web page. With the stimuli shown, participants were asked to report (1) their intentions to do the activity, (2) perceived social presence in the message, (3) forecasted positivity resonance for emotions they would feel if they engaged in the activity, (4) their self-efficacy for undertaking the activity, and (5) any downsides for the activity. Items within scales were shown in a randomized order.

Measures

Intentions

We captured intentions to do the activity with an adapted single item [56]: "If this activity was assigned to you, how likely would you be to complete it tomorrow?" Response options were "not at all" (coded as 1), "a little" (2), "somewhat" (3), "quite a bit" (4), or "extremely" (5).

Perceived Social Presence

Participants rated the feelings of others in the message with 5 established items [57,58], including "There is a sense of personalness in the message." Response options were "not at all" (1), "a little" (2), "somewhat" (3), "quite a bit" (4), or "extremely" (5).

Forecasted Positivity Resonance

We assessed the degree to which participants anticipated socially engaged positive emotions by inquiring about forecasted personal enjoyment and adapting (for forecasted vs experienced affect) the Perceived Positivity Resonance Scale [23,27]. Items were “If you were to do this activity tomorrow, to what degree would you anticipate…,” followed by 3 items: “…personally enjoying the activity?,” “…experiencing a mutual sense of warmth and concern toward one another?,” and “feeling ‘in sync’ with the other(s)?” Response options were “not at all” (1), “a little” (2), “somewhat” (3), “quite a bit” (4), or “extremely” (5).

Self-Efficacy

Participants reported their self-efficacy or confidence in their ability to complete the activity with the single item [59]: “Please indicate how certain you are that you can do the activity from the message.” Responses were captured with a slider that was labeled with “cannot do at all” (0), “moderately can do” (50), and “highly certain can do” (100).

Potential Downsides

To better understand potential unintended consequences of the intervention messages we developed new items for this study. Specifically, we asked, “Do any downsides immediately come to mind when thinking about doing this activity?” Response options: “yes” (1), “no” (2), and “not sure” (3). If participants responded yes or not sure, they were asked to select from a multiselection item all the relevant downsides, including “would take too much time” (1), “would cost too much money” (2), “I already do these things and don’t need this prompt” (3), and given a chance to “fill in any other downsides not listed” (4) in an open-ended text box.

Cancer Characteristics

Participants reported their cancer diagnosis with a multiselect item: “What cancer diagnosis have you received?” Response options included 15 cancers (“brain tumor,” “breast,” “cervical”, “colon,” “Hodgkin Lymphoma,” “Leukemia,” “lung,” “non-Hodgkin Lymphoma,” “ovarian,” “rectal,” “sarcoma,” “testicular,” “thyroid,” “uterine/endometrial”), an “other” option with text entry, “prefer not to answer” (not eligible), or “I never had a cancer diagnosis” (not eligible). In addition to confirming eligibility (“yes”/”no”) for a cancer diagnosis between ages 15 - 39 years, participants also reported their age of diagnosis for all cancer types selected. For each cancer selected, participants also reported their cancer stage, “If your [cancer] diagnosis was staged, with which stage were you diagnosed,” and response options of “I,” “II,” “III,” “IV,” and “unknown/not applicable.” For each cancer selected, participants reported their current treatment status, “Which of the following best describes your current treatment status with your [cancer] diagnosis?” Participants had either “completed treatment” or were considered in active treatment (ie, “in treatment,” “ongoing therapies (hormonal, immunotherapy, etc),” “chronic disease (in/out of treatment),” or “not yet started treatment”).

Data Analyses

We first ensured reliability via Cronbach α for the multi-item outcome scales was sufficient (>0.70). We also ensured our continuous variables were within normal distribution thresholds (skewness within SD 2, kurtosis within SD 7) [60]. We then inspected distributions to exclude extreme outliers (>3 SDs from the mean) and then computed descriptive statistics for all outcomes (ie, means, SDs, and proportions) by study condition. For all our predictions with continuous outcomes, we conducted ANOVAs, one for each outcome. The predictors were social context cues (present vs absent) and intervention type (acts of kindness vs social connectedness). We conducted chi-square tests for categorical outcomes (ie, downsides). We used a Bonferroni-corrected critical α of 0.005 and 2-tailed statistical tests for planned comparisons.

We next explored participant characteristics as moderators where sufficient subgroup sample sizes were allowed. This included age (18-24, 25-29, 30-34, and 35-39 years), race (Black vs White), gender (women vs men), and treatment status (completed vs active treatment). Each subgroup was included as a predictor, along with social context cues condition (present vs absent), in separate ANOVAs for intentions, social presence, forecasted affect, or self-efficacy. We omitted the intervention type and used a Bonferroni-corrected critical α of 0.002 and 2-tailed statistical tests for exploratory moderation. Per our preregistration, we conducted serial mediation analyses with PROCESS (SPSS macro) to examine mediated effects of social presence on our outcomes, but only reported in the web-based Multimedia Appendix 1, since we did not have main effects on our proposed mediator.

Results

Participant Characteristics

Young adult participants’ (N=396) average age was 31 (SD 5.2) years, with an average age of 27 (SD 5.1) years at diagnosis (Table 1). Participants mostly identified as male (251/396, 63.4%), White (246/396, 62.1%), or Black or African American (95/396, 24%). Young adults were from all 50 United States (392/396, 99%) and Canada. Cancer diagnoses included lung cancer (85/396, 21.5%), brain tumors (62/396, 15.7%), leukemia (37/396, 9.3%), breast cancer (32/396, 8.1%), testicular cancer (32/396, 8.1%), colon cancer (30/396, 7.6%), cervical cancer (30/396, 7.6%), rectal cancer (28/396, 7.1%), and thyroid cancer (20/396, 5.1%), among others. Participants had either completed treatment (73/396, 18.4%) or were in active treatment, including reporting they were in treatment (160/396, 40.4%), ongoing therapies (139/396, 35.1%), in and out of treatment (15/396, 3.8%), and not yet started treatment (11/396, 2.8%). Participants did not differ by age, race and ethnicity, gender, or treatment status across experimental conditions.

Table . Participant demographics (N=396).

Demographics	Values
Current age (in years), mean (SD)	31.1 (5.2)
18 - 24, n (%)	45 (11.4)
25 - 29, n (%)	90 (22.7)
30 - 34, n (%)	121 (30.6)
35 - 39, n (%)	132 (33.3)
Age at diagnosis (years), mean (SD)	26.8 (5.1)
Gender, n (%)	
Women	131 (33.1)
Men	251 (63.4)
Nonbinary, gender queer, or questioning	2 (0.6)
Transgender, n (%)	
Yes, transgender	38 (9.6)
No, not transgender	345 (87.1)
Race and ethnicity, n (%)	
White	246 (62.1)
Black or African American	95 (24.0)
Hispanic, Latino, or Spanish	26 (6.6)
Asian	9 (2.3)
American Indian or Alaska Native	8 (2.0)
Some other race or ethnicity	2 (0.5)
Multiracial	10 (2.5)
Diagnosis[a], n (%)	
Brain tumor	62 (15.7)
Breast cancer	32 (8.1)
Cervical cancer	30 (7.6)
Colon cancer	30 (7.6)
Hodgkin lymphoma	18 (4.5)
Leukemia	37 (9.3)
Lung cancer	85 (21.5)
Non-Hodgkin lymphoma	2 (0.5)
Ovarian cancer	15 (3.8)
Rectal cancer	28 (7.1)
Sarcoma	6 (1.5)
Testicular cancer	32 (8.1)
Thyroid cancer	20 (5.1)
Uterine/endometrial cancer	14 (3.5)
Other cancers	9 (2.3)
Stage[a], n (%)	
I	140 (35.4)
II	188 (47.5)
III	54 (13.6)

Demographics	Values
IV	16 (4.1)
Treatment status, n (%)	
Active (in treatment, ongoing therapies, in/out of treatment, or not yet started)	322 (81.3)
Completed	73 (18.4)

[a] Most (95%) participants reported one diagnosis; 20 participants reported between 2 and 4 diagnoses.

Most Young Adults With Cancer Reported Intending to Do the Intervention Activity (Hypothesis 1, Research Question 1a)

Most young adults with cancer (336/396, 84.8%) reported that they were "somewhat" (3) to "extremely" (5) likely to carry out the recommended intervention activity with means ranging from 3.4 to 3.6 on a 5-point scale. See Table 2 for condition means, SDs, and results from ANOVAs. Messages with social context cues (peer images, personal stories) and those without cues encouraged young adults to intend to enact the intervention behavior similarly. Although the highest means were observed when cues were shown, this condition difference was not significant, *P*=.05 (hypothesis 1 unsupported). Young adult participants were similarly encouraged to engage in the activity regardless of intervention type; there were no differences in intentions between acts of kindness activity (eg, do a chore for someone, write a thank you letter) and a social connectedness activity (eg, making eye contact and smiling, offering a sincere thank you), *P*=.36 (research question 1a).

Table . Effects of social context cues and type of intervention (N=396).

	Social context cue condition		*F* test (*df*)	Chi-square (*df*)	*P* value	Intervention type condition		*F* test (*df*)	Chi-square (*df*)	*P* value
	With enhanced cues	No enhanced cues				Acts of kindness	Social connectedness			
Intentions, mean (SD)	3.6 (0.9)	3.4 (0.9)	3.8 (1,388)	—[a]	.05	3.6 (0.9)	3.5 (1.0)	0.8 (1,388)	—	.36
Social presence, mean (SD)	3.8 (0.7)	3.8 (0.7)	0.1 (1,392)	—	.75	3.8 (0.7)	3.8 (0.7)	0.1 (1,392)	—	.72
Forecasted positivity resonance, mean (SD)	3.9 (0.8)	3.8 (0.8)	1.0 (1,392)	—	.32	3.9 (0.8)	3.8 (0.8)	0.4 (1,392)	—	.51
Self-efficacy, mean (SD)	72.0 (15.9)	69.5 (16.6)	2.3 (1,369)	—	.13	70.5 (15.4)	71.0 (17.2)	0.1 (1,369)	—	.75
Downsides, n (%)				2.6 (2)	.27				3.3 (2)	.19
Yes	11.6 (23)	31 (15.8)	—			28 (14.3)	26 (13.1)	—		
No	167 (84.3)	153 (78.1)	—			162 (82.7)	158 (79.8)	—		
Not sure	8 (4.0)	12 (6.1)	—			6 (3.1)	14 (7.1)	—		

[a] Not applicable.

Participants' race and treatment status influenced intentions to do any of the intervention activities, with main effects for these subgroups (Table 3). Overall, Black participants had lower intentions to engage in any of the activities from the messages compared with White participants, $F_{1,333}$=18.8, *P*<.001.

Participants in active treatment, including in treatment, ongoing therapies, in/out of treatment, or not yet started, had greater intentions to do any of the activities shown compared with participants who completed treatment, $F_{1,387}$=20.2, *P*<.001.

Table . Outcomes by participant characteristic subgroups.

	Intentions, mean (SD)	Social presence, mean (SD)	Forecasted positivity resonance, mean (SD)	Self-efficacy, mean (SD)
Age (years)				
18 - 24	3.4 (0.9)	3.8 (0.7)	3.8 (0.9)	70.0 (16.6)
25 - 29	3.4 (1.0)	3.7 (0.7)	3.7 (0.9)	68.1 (17.1)
30 - 34	3.5 (0.9)	3.7 (0.7)	3.8 (0.8)	70.3 (17.0)
35 - 39	3.7 (0.9)	4.0 (0.6)	4.0 (0.6)	73.1 (14.4)
Race				
Black or African American	3.2 (0.8)	3.6 (0.6)	3.7 (0.7)	68.3 (15.5)
White	3.6 (0.9)	4.0 (0.6)	4.0 (0.8)	72.1 (16.3)
Gender				
Women	3.6 (1.0)	3.7 (0.8)	3.8 (0.9)	69.7 (17.3)
Men	3.5 (0.9)	3.9 (0.6)	3.9 (0.7)	71.8 (15.4)
Treatment status				
Active treatment	3.6 (0.9)	3.8 (0.7)	3.9 (0.8)	70.6 (16.2)
Completed treatment	3.1 (0.9)	3.7 (0.8)	3.7 (0.8)	70.7 (16.3)

Alongside these significant subgroup differences, we note that mean intention ratings remained above 3 (on our 1 - 5 scale) for Black participants (mean 3.2) and those who had completed treatment (mean 3.1). There were no main effects for age or gender. There were no interactions for social context cues and any subgroups for intentions to do the activity.

Most Young Adults With Cancer Reported Perceived Social Presence, Forecasted Positivity Resonance, and Self-Efficacy for the Intervention Messages (Hypotheses 2-4, Research Question 2)

Over 4 of 5 young adults with cancer (350/396, 88.4%) reported "somewhat" (3) to "extremely" (5) feeling the presence of someone in the messages (perceived social presence) with a mean of 3.8 across all conditions and reliability of $\alpha=.8$ across items. There were no differences for perceived social presence with the enhanced social context cues (vs no cues), $P=.75$ (hypothesis 2 unsupported). Perceived social presence was also similar across intervention type, $P=.72$ (research question 1b). There was a main effect and interaction by race for perceived social presence in the messages. Black participants had lower perceived social presence across all messages than White participants, $F_{1,337}=28.7$, $P<.001$; when decomposing the interaction we find that whereas White participants reported higher social presence with enhanced social context cues (vs not), $P=.02$, no effect for cues emerged for Black participants, $P=.33$. There were no main effects of age, gender, nor treatment status, as well as no interactions with age, gender, nor treatment status for social presence.

Most young adults with cancer (349/396, 88.1%) also forecasted they would be "somewhat" (3) to "extremely" (5) likely to experience feeling states linked to positivity resonance, that is, enjoying the activity, feeling mutual warmth, and feeling "in sync" with others, with reliability of $\alpha=.7$ across items. Means for forecasted positivity resonance ranged from 3.8 to 3.9, on our 1 - 5 response scale. Messages were rated similarly with (vs without) social context cues, $P=.32$ (hypothesis 3 unsupported), and for both intervention types, $P=.51$ (research question 1c). There was a main effect for race on forecasted positivity resonance, with Black participants forecasting lower positivity resonance (mean 3.7) across all messages than White participants (mean 4.0), $F_{1,337}=10.9$, $P=.001$. There were no main effects for age, gender, or treatment status on forecasted positivity resonance, nor were there interactions among any subgroups.

Young adults with cancer, on average, reported having self-efficacy to complete the intervention activity, with a mean of 70.7% on a 0 - 100 scale (excluding 3 outliers of >3 SDs). There were no differences in self-efficacy with the enhanced social context cues (vs no cues), $P=.13$ (hypothesis 4 unsupported) nor intervention type, $P=.75$ (research question 1d). There were no main effects nor interaction by age, race, gender, or treatment status for self-efficacy.

Few Young Adults With Cancer Reported Downsides to the Intervention Activities (Research Question 3)

Most young adults with cancer (320/396, 80.8%) did not report downsides to doing the intervention activity. Potential downsides did not differ with the enhanced social context cues (vs no cues), $P=.27$, nor for intervention type, $P=.19$ (research question 2). Among participants who thought of downsides (n=54) or were not sure (n=20), reasons included the following: would cost too much money (n=41), would take too much time (n=38), and not needing prompt because already doing these things (n=24).

Discussion

Overview

Young adults with cancer are an underserved population with few age-appropriate support resources for their unique psychosocial health needs [29,30]. To address this need, we adapted evidence-based positive psychology interventions for presentation to young adults with cancer via social media. We found intervention messages adapted for social media were well received among young adults with cancer. More than 80% of young adults with cancer reported they would do the intervention activity if prompted (intentions), reported intended message reactions (perceived social presence, forecasted positivity resonance, self-efficacy), and did not think of downsides.

Principal Findings for Positive Psychology Interventions as Social Media Messages

Young adults were largely willing to engage in both intervention activities—to carry out acts of kindness or increase their social connectedness. Evidence for the positive reception of 2 interventions is valuable because positive activity assignments are known to be most effective when they involve variety and good "person-activity fit" [16]. Young adults in cancer treatment, inclusive of those in-and-out of treatment, not yet having started treatment, and in ongoing therapies, had greater intentions to do the intervention activity compared with those who had completed treatment. This promisingly signals these positive psychology interventions could be adapted for people at all stages of the cancer experience. With highly scalable distribution through social media, the interventions would not need to be "saved" or held for a later date when young adults have completed their cancer treatment. Given the unmet needs of young adults with cancer for interventions to improve psychosocial health, our initial evidence for 2 low-cost, age-appropriate interventions is encouraging. Both intervention types provide researchers, clinicians, and practitioners with valuable options to disseminate through their organization's presence on the web.

Most young adults with cancer also thought the messages signaled peers (perceived social presence), which increases trust and motivation to use web-based health interventions [41,42]. We did not find differences in perceived social presence between intervention messages with enhanced social context cues and those without. This could be because, with messages designed to mimic Instagram posts, the control condition included many standard social context cues (eg, profile pictures, post likes) known to signal others and peer communities among young adults [41,49].

Most young adults with cancer expected to enjoy the recommended activities and anticipated that doing them would bring feelings of mutual warmth and of being "in sync" with others, core facets of the uplifting, socially connected state of positivity resonance. Growing evidence shows that the frequency of people's daily experiences of positivity resonance promotes health and well-being [26] and is linked to better mental health, increased resilience, and a greater sense of meaning [22-24].

Most young adults with cancer were confident they could do these intervention activities with few perceived downsides. Their reported self-efficacy to do the activities is encouraging with the COVID-19 pandemic and related psychological pressure contributing to poor psychosocial outcomes in young adults with cancer [61]. Fewer than one in seven participants thought of any downsides. The few downsides reported were resource concerns—money or time—that could be alleviated by revising intervention activity prompts (eg, shorter activities) and providing financial support for costs incurred (eg, coffee or meal gift cards).

Moderation by Race for Positive Psychology Interventions as Social Media Messages

Although the positive psychology interventions developed for young adults with cancer, broadly, were well received, these messages did not work equally well for all. We should prioritize critical frameworks in intervention development to reach health disparity populations who may receive great benefit [62], such as Black young adults who face a disproportionate burden of disease compared with White young adults [63]. All too often, evaluations of interventions do not disaggregate data to address inequalities by race—a critical step to reduce health disparities. Looking at differences by race in this study, Black young adults had lower intentions and forecasted positivity resonance for the activities in the messages compared with White young adults. Moreover, our interaction for perceived social presence indicates social context cues only had an impact among White participants when images of individuals who appeared White were shown. These findings highlight a need to prioritize optimizing intervention messages for Black young adults. Literature supports the development of culturally tailored messages across the cancer continuum [64-66]. Culturally tailored messages should be designed with visuals and text that incorporate shared beliefs, language, and representation of the cancer experience as a Black young adult. A failure to account for cultural context may lead to ineffective health communication messages for some of the most vulnerable youth, further exacerbating existing cancer disparities. Enhancing the effectiveness of positive psychology interventions requires intentional efforts to ensure Black young adults and members of other disparate subgroups, not examined here due to subgroup size, can "see" themselves in the messages, to increase relevance and potential impact.

Strengths and Limitations

Our recruitment methods allowed us to reach a large, diverse sample of participants willing to engage in research about web-based cancer support, including those with cancers that have disproportionately poor outcomes (eg, lung cancer). However, our recruitment had limitations. First, this is a convenience sample that should not be interpreted as representative of young adults with cancer in the United States. Second, research with young adults with other demographics, cancer characteristics, or more variability in their willingness to use social media for cancer support may yield different results. Third, while we used measures from previous research, when possible, the adapted versions of these items for our specific study context were not pre-tested among young adults with cancer. Fourth, for our study design, a limited number of social context cues (ie, peer images, personal stories) were used in these messages; other message content with more culturally or age-relevant behavioral tips, stories, and peer images could have greater or different effects. Future research should include young adults with cancer in the image selection and personal story generation process to identify effective content with a human-centered process for intervention message optimization. Specifically, Black young adults with cancer and other disparate groups should be directly involved in the content creation, refinement, and selection of message images and text to ensure the message images and text are optimized to reach and have the intended impact among our most vulnerable populations.

Conclusion

This study provides promising evidence that positive psychology intervention messages adapted for social media were perceived as acceptable and feasible among young adults. More than 4 in 5 participants thought they would do the activity, with confidence in their ability to do so, and did not perceive downsides. Moreover, young adults with cancer thought the interventions delivered on social media would improve their psychosocial health. Most participants anticipated doing these intervention activities would raise their positive emotions and feelings of social connection. As the need for age-appropriate resources for young adults with cancer continues, this encouraging evidence for 2 low-cost, highly scalable interventions provides options to address their unique needs and improve psychosocial health.

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Data Availability

The datasets generated or analyzed during this study are available in the Carolina Digital Repository [67].

Authors' Contributions

AJL, HBN, CS, ND, and BLF contributed to the conceptualization of the study. Data curation and formal analysis were conducted by AJL, who also secured funding for the project. The investigation was carried out by AJL, RNV, and MP. The methodology was developed by AJL, JZ, and BLF. Project administration was managed by MP, with supervision provided by AJL and BLF. AJL and RNV wrote the original draft, and the manuscript was reviewed and edited by AJL, RNV, JZ, HBN, MP, CS, ND, and BLF.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Preregistered mediation analyses.
[DOCX File, 37 KB - cancer_v10i1e48627_app1.docx]

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Abbreviations

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Original Paper

Exploring Web-Based Information and Resources That Support Adolescents and Young Adults With Cancer to Resume Study and Work: Environmental Scan Study

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Abstract

Background: Adolescents and young adults (AYAs) diagnosed with cancer experience physical, cognitive, and psychosocial effects from cancer treatment that can negatively affect their ability to remain engaged in education or work through cancer treatment and in the long term. Disengagement from education or work can have lasting implications for AYAs' financial independence, psychosocial well-being, and quality of life. Australian AYAs with cancer lack access to adequate specialist support for their education and work needs and report a preference for web-based support that they can access from anywhere, in their own time. However, it remains unclear what web-based resources exist that are tailored to support AYAs with cancer in reaching their educational or work goals.

Objective: This study aimed to determine what web-based resources exist for Australian AYAs with cancer to (1) support return to education or work and (2) identify the degree to which existing resources are age-specific, cancer-specific, culturally inclusive, and evidence-based; are co-designed with AYAs; use age-appropriate language; and are easy to find.

Methods: We conducted an environmental scan by searching Google with English search terms in August 2022 to identify information resources about employment and education for AYAs ever diagnosed with cancer. Data extraction was conducted in Microsoft Excel, and the following were assessed: understandability and actionability (using the Patient Education and Materials Tool), readability (using the Sydney Health Literacy Laboratory Health Literacy Editor), and whether the resource was easy to locate, evidence-based, co-designed with AYAs, and culturally inclusive of Aboriginal and Torres Strait Islander peoples. The latter was assessed using 7 criteria previously developed by members of the research team.

Results: We identified 24 web-based resources, comprising 22 written text resources and 12 video resources. Most resources (21/24, 88%) were published by nongovernmental organizations in Australia, Canada, the United States, and the United Kingdom. A total of 7 resources focused on education, 8 focused on work, and 9 focused on both education and work. The evaluation of resources demonstrated poor understandability and actionability. Resources were rarely evidence-based or co-designed by AYAs, difficult to locate on the internet, and largely not inclusive of Aboriginal and Torres Strait Islander populations.

Conclusions: Although web-based resources for AYAs with cancer are often available through the websites of hospitals or nongovernmental organizations, this environmental scan suggests they would benefit from more evidence-based and actionable resources that are available in multiple formats (eg, text and audio-visual) and tailored to be age-appropriate and culturally inclusive.

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KEYWORDS

adolescent; cancer; education; employment; information needs; oncology; online information; quality of life; resource; return to work; school; study; supportive resources; treatment; young adult

Introduction

A diagnosis of cancer in adolescence and the young adult years can lead to significant and long-lasting disruptions to key developmental milestones [1-3]. Adolescents and young adults (AYAs) with cancer are at risk of poor long-term medical and psychosocial outcomes due to delays in diagnosis and lagging improvements in survival rates compared with those diagnosed as children or adults [1]. Symptoms and late effects from cancer treatment can negatively impact AYAs' education and work engagement [4-7]. A weakened immune system, nausea, fatigue, neuropathy, poor cognitive functioning, poor social well-being, and mental health challenges such as depression and social anxiety are just some of the physical symptoms and late effects AYAs must contend with [3-9]. Challenges with education and work engagement may also drive distressing symptoms such as poor social well-being and depression [3,9,10].

Poorer outcomes are exacerbated by the limited age-appropriate services targeting their unique needs [11]. During adolescence and the young adult years, broadly defined as the ages of 15-39 years, young people are expected to participate in and complete education and training, obtain employment, and achieve financial independence, all while navigating social and intimate relationships to develop and evolve their identity [12]. A cancer diagnosis and treatment during adolescence and the young adult years can interrupt or delay these developmental tasks [12].

Extended absences and difficulties engaging with education or work are common for survivors of AYA cancer and can have a lifelong negative impact on AYAs' educational and work goals, quality of life, and psychosocial and financial well-being [2]. survivors of AYA cancer miss significantly more days of school than their peers [11]. AYAs may miss 40-60 days of school within the first year following their diagnosis [13], and Australian data suggest nearly 50% of survivors of AYA cancer have not fully returned to education or work up to 24 months post diagnosis [14]. Nearly 40% of AYAs report their employment goals were negatively affected by cancer [15], and survivors of AYA cancer are more likely than peers without a history of cancer to report an increased number of missed workdays as a result of illness or disability (11.9% of survivors vs 6.7% of controls) [16]. survivors of AYA cancer are also more likely than peers without a history of cancer to report employment disability (being unable to carry out employment or work requirements at all or needing to do so with disability provisions; 34.1% of survivors vs 23.9% of controls) [16]. However, qualitative studies suggest that survivors of AYA cancer experience trouble navigating public support, education, and employment systems, which puts them at a disadvantage by contributing to increased financial hardship, fear, and uncertainty around their education and employment situations. Financial hardship in itself serves as a barrier to AYAs achieving their education goals by making it difficult for AYAs to afford education, particularly at a university level, or to keep up with repayment of education-related debts [17].

In contrast, AYAs who are able to remain more engaged with their education or work report decreased psychological distress [18] and improved social well-being [1,19]. Yet, few interventions supporting AYAs to remain engaged with education or work have been systematically evaluated [2]. The only such service evaluated in Australia is an educational and vocational counseling service based in a major cancer center in Victoria, Australia, which provides in-depth, tailored support through trained advisors to AYAs diagnosed with cancer between the ages of 15 and 25 years [20]. To date, 209 AYAs have received support through this program. By completion, 73% of AYAs were able to engage in education or vocation or were receiving support through an external source [20]. Access to such personalized programs may be limited due to cancer centers' resources and AYAs' distance to their treatment centers [21,22]. Individualized consultation requires synchronous engagement, usually during school or work hours, which may further prevent uptake for AYAs who have some level of participation in education or work [23].

The average Australian AYA spends approximately 14 hours per week on the internet, and survivors of AYA cancer are highly engaged with social media as well as web-based cancer resources [24,25]. Many Australians with cancer living in rural or remote locations rely on web-based resources to navigate the impacts of a cancer diagnosis and its treatment on their education or career [26,27]. Given this reliance on web-based information, it is critical to consider the extent to which web-based information resources are equitably accessible by Australian AYAs. Previous studies and reviews have defined equity of access to web-based information as the provision of web-based information that is easy to find, provided in a range of formats (eg, text, video, and audio), understandable or readable for individuals with varying abilities and health literacy levels, and culturally and linguistically inclusive [28-30]. The importance of equitable access to health information for Australians is paramount, considering how many people live in rural locations and the cultural and linguistic diversity of the country. Approximately 3.2% of the population identify as Aboriginal and Torres Strait Islander peoples, 30% were born overseas, and 21% of families speak a language other than English at home [31].

Ensuring equitable access to web-based information resources requires consultation with target populations (ie, co-design of information resources with a culturally and linguistically diverse group of AYAs diagnosed with cancer), as well as a focus on providing information that is evidence-based. However, no previous research has assessed what web-based information resources exist to support Australian survivors of AYA cancer in their engagement with education or work, and to what extent resources are equitably accessible. Therefore, this study aimed to determine the following: (1) What web-based resources exist for engaging with education or work after a cancer diagnosis that AYAs with cancer are likely to encounter when conducting a Google search? and (2) Of the identified resources, to what degree are they understandable, actionable, readable, easy to locate, evidence-based, co-designed with survivors of AYA cancer, and culturally inclusive?

Methods

Overview

Web-based resources for AYAs with cancer are typically provided through hospitals and nongovernmental organizations (NGOs) rather than through academic journals or research databases. Therefore, we chose to conduct an environmental scan rather than a systematic review, using a standard search engine rather than academic databases. Environmental scans have demonstrated usability in identifying health information resources across a range of health disciplines [32,33]. While there is no consensus regarding optimal methods for conducting an environmental scan of health information resources, environmental scans take a higher-level approach than systematic reviews or qualitative evaluation studies to identify available resources, tabulate yes or no responses to whether web-based resources possess certain qualities, and determine the basic usability of resource content [33,34]. We opted to follow similar methods used by Ruble et al [32] in their 2019 publication assessing web-based resources to support children returning to school during or after cancer treatment and methods used by Schiffman et al [35] in their 2006 study on internet use among survivors of AYA cancer. In keeping with these previous studies, 2 researchers led the search and data extraction, and we used validated measures of understandability, actionability, and readability to conduct a basic assessment of available resources. We also tabulated whether resources were easy to locate, evidence-based, developed through co-design with AYAs, and culturally inclusive of Indigenous populations. We conducted structured searches through Google and extracted data in Microsoft Excel (Microsoft Corporation).

Consumer Involvement

Consumer involvement in the design of this study was central to our methods. Chief investigators included the researcher and clinician chief investigators in addition to 2 survivors of AYA cancer (authors CES and NS) and 1 parent of a survivor (author JO). Together, the chief investigator team met in November 2021, March 2022, and May 2022, to develop the environmental scan protocol, including search terms and methods.

Searches

We searched Google Australia with English search terms between August 8 and 19, 2022 (Textbox 1). No limits were applied to the country, as we wanted to replicate the way survivors of AYA cancer currently access information to support their return to education or work.

Textbox 1. Environmental scan search terms as per both themes.

Adolescents and young adults with or surviving cancer

- AYA cancer
- Teen cancer
- Adolescent cancer
- Young adult cancer

Returning to study or work

- Study
- School
- Education
- University
- College
- Work
- Employment
- Career

Search terms were created by combining search words from 2 themes. The first theme designated the target population of AYAs with or surviving cancer, and the second designated information and resource content related to "returning to study or work." Using the words listed in Textbox 1, CES and GD independently conducted 24 unique searches combining the 2 groups of search terms with "AND" (eg, "adolescent cancer AND school"). Before and between each new search, the browser cache was reset. All searches were conducted from Sydney, New South Wales, Australia. However, to identify whether there may be any difference in search results based on location in Australia, GD also conducted 6 of the 24 searches using a virtual private network and changed the search location to Perth, Western Australia, which is located on the opposite side of Australia from Sydney.

Resource Selection

Typically, a Google search will present 10 results per page, meaning 50 results would be presented across 5 pages. Although the average internet user will only click on results appearing in the first 10 Google search results [36], we opted to maximize, the identification of relevant results by reviewing the first 50 results for eligibility (CES and GD) [37]. Eligible websites, documents, videos, and audio-visual resources were those that provided text-based information, video, or audio-visual information in English and were directed primarily toward AYAs returning to study (any level) or work after a cancer diagnosis. Websites, documents, and videos or audio-visual resources targeting parents or family members of AYAs were excluded. Academic papers, media stories, and blogs were also excluded.

Data Extraction

An Excel spreadsheet was developed to include drop-down menus to record key data (Table 1). Data extraction fields were partially based on a previous review of web-based resources conducted by Ruble et al [32] in 2020.

CES and GD independently conducted data extraction and recorded the addresses of websites meeting eligibility criteria in separate Excel spreadsheets, reconciled their searches, and removed duplicates.

Table 1. Data extraction fields and response options.

Field	Response option
Target audience	AYA[a]-specific or other
Setting	Education (inclusive of secondary or tertiary) or employment
Source creator	• Nongovernmental organization • Cooperative group or professional organization • Health care institution • State or federal government organizations • Media publications
Country of origin	Country name
Access to website	Publicly available, subscription, or user profile
Purpose of website	Information, advertising, support, or intervention
Date of last review of information	Date
Cancer type	Diagnosis name, resource designed for AYAs with chronic illness more broadly but includes cancer, or no cancer type specified
Media used to convey information	Written descriptive text, video or YouTube, images, stories or vignettes, quotes from consumers, or other
Support, tools, or information provided by the resource	Checklists, letter templates, strategies, access to career or education counseling, support group or network, or other
Evidence-based	Yes or no
Co-designed	Yes, no, or unclear: describes consultation with survivors but not methods for this consultation

[a] AYA: adolescent and young adult.

Assessment of Resources and Data Synthesis

Was the Resource Understandable and Actionable?

For both text and audio-visual resources, we used the Patient Education Materials Assessment Tool (PEMAT) [38] to assess the understandability and actionability of the resources. Understandability refers to whether the meaning is comprehensible, taking multiple elements into account, such as word complexity and the layout or structure of the information [38]. Actionability refers to whether or not a resource provides content in a way that consumers can easily determine what they need to act on or do based on the content presented [38]. PEMAT for written materials consists of 17 items assessing understandability and 17 items assessing actionability, all of which are scored as agree, disagree, or unsure [38]. The PEMAT for audio-visual materials includes 13 items assessing understandability and 4 assessing actionability. The PEMAT generates percentage scores (0%-100%) which is the proportion of the responses assessed as having been met (agree). Scores of 100% indicate optimal understandability or actionability; scores of 70% indicate adequate understandability or actionability [38,39]. The PEMAT has been used previously in a review of information resources for students with cancer [32] and an evaluation of other web-based information for many illnesses, including cancer [37]. The PEMAT demonstrates good reliability and ease of use, with interrater reliability scores of 0.92 for understandability and 0.93 for actionability, and 92% of raters agreeing on its ease of use [40].

Was the Resource Readable?

We also assessed the readability (reading level) of text resources using the Sydney Health Literacy Laboratory (SHeLL) Health Literacy Editor. Optimal readability on the SHeLL Editor is indicated by a score of 8 or below, equating to a grade 8 reading level [41,42]. Generally, health information designed for the general population or patients is recommended to be readable at a grade 8 level or lower [43]. The SHeLL Editor enables the pasting of exact text from a resource into its reading level calculator to provide a specific reading level for text.

How Easy Was It to Locate the Resource?

The ease of locating the resource was assessed by determining whether a resource appeared within the first 10 search results on the first page of results on Google. This is based on evidence suggesting the average internet user will only click on results appearing in the first 10 Google search results [36].

Was the Resource Evidence-Based?

Resources were evaluated as being evidence-based according to whether or not supporting evidence was cited and accurately represented to support the information they provided, or if they indicated in any background content whether research was involved in the development of the resource content.

Was the Resource Developed Through Co-Design With Survivors of AYA Cancer?

Co-design refers to methods used to engage, consult, and work in collaboration with young people to develop research questions, resource content, or interventions [44]. We assessed whether resources were co-designed with survivors of AYA cancer based on whether or not they described using a co-design method to develop the information they provide. We note as “unclear” any resources indicating content was developed in consultation with AYAs with cancer, but the exact co-design methods used or extent of engagement with AYAs is not clearly described.

Was the Resource Culturally Inclusive?

To our knowledge, no tool exists to assess the cultural inclusivity of international web-based health resources. Therefore, to measure the cultural inclusivity of the resources we identified, we used 7 criteria that were codeveloped by 3 Aboriginal and Torres Strait Islander researchers (including AG) and 2 non-Aboriginal and Torres Strait Islander researchers (including AD) [45]. All researchers involved in the development of these criteria have a strong track record in Indigenous health research [45-51]. Due to the criteria being designed solely for the evaluation of the cultural inclusivity of resources for Aboriginal and Torres Strait Islander peoples in Australia, we only evaluate the cultural inclusivity of resources created by and for Australians [45].

The criteria for cultural inclusivity were as follows [45]: (1) Does the resource include any visual aids (photos, animations, infographics, or charts) that depict or contain information about Aboriginal and Torres Strait Islander peoples? (2) Does the resource include any information or data about Aboriginal and Torres Strait Islander peoples? (3) Does the resource include any Aboriginal and Torres Strait Islander design or artwork? (4) Does the resource provide any evidence of leadership, involvement, or governance by peoples, communities, or organizations that identify as or represent populations that are Aboriginal and Torres Strait Islander? (5) Is the resource available in any Aboriginal and Torres Strait Islander languages? (6) Is any of the language used strengths-based and respectful to Aboriginal and Torres Strait Islander peoples? and (7) Does the resource include a contact (phone number, email, or website) for any culturally relevant or personalized support and information for Aboriginal and Torres Strait Islander peoples?

AG, a Pakana woman from Lutruwita (Tasmania), reviewed all resources to determine their relevancy to Aboriginal and Torres Strait Islander peoples. As this tool is not validated, there is no clear minimum number of criteria that should be achieved to determine the cultural competency of a resource. As such, we report the number of criteria that were met descriptively and describe the strengths and shortfalls of the resources.

Results

Research Question 1: What Web-Based Resources Exist for Engaging With Education or Work After a Cancer Diagnosis, That AYAs With Cancer Are Likely to Encounter When Conducting a Google Search?

A total of 24 AYA-specific resources met eligibility criteria and were included (Table 2). Most were published by NGOs (n=19, 79%). All resources focused on information provision rather than advertising, support, or intervention, with content shared through text information, text and video stories from other AYAs with cancer, contact details for support organizations, or lists of strategies to navigate education and work challenges. A total of 8 resources were from the United States [52-59], 8 from Australia [60-67], 6 from the United Kingdom [68-73], and 2 from Canada [74,75]. A total of 7 resources focused on education, 8 on work, and 9 on both. There was no difference in search results between searches conducted in Sydney and Perth.

Most resources did not target specific cancer types or stages of the cancer trajectory, although 4 were developed for people diagnosed with blood cancer [59,66,69,74]. There was little consistency in the topics covered across resources, with only a few common topics covered (Table 3).

Table 2. Cultural inclusivity of resources identified through the environmental scan [45].

Criteria	Resources meeting each criterion, n
Does the resource include any visual aids (photos, animations, infographics, or charts) that depict or contain information about Aboriginal or Torres Strait Islander peoples?	0
Does the resource include any information or data about Aboriginal or Torres Strait Islander peoples?	0
Does the resource include any Aboriginal or Torres Strait Islander designs or artwork?	4
Does the resource provide any evidence of leadership, involvement, or governance by people, communities, or organizations that identify as or represent populations that are Aboriginal or Torres Strait Islander?	0
Is the resource available in Aboriginal or Torres Strait Islander languages?	0
Is any of the language used strengths-based and respectful to Aboriginal and Torres Strait Islander peoples?	6
Does the resource include a contact (phone number, email, or website) for any culturally relevant or personalized support and information for Aboriginal and Torres Strait Islander peoples?	2

Table 3. Common information and strategies covered in resources.

Topic covered	Resource explored topic in relation to education, work, or both
Disability rights and accessing accommodations or provisions (n=16) [52-55,58,61-63,65-67,71,72,74]	Both
Telling people or talking about your cancer (n=13) [52-55,60-63,65-67,70-72]	Both
Applying for jobs or changing careers (n=11) [52,61,64,66,67,69,71-75]	Both
Managing physical or cognitive impacts of cancer treatment (n=7) [54,57,65-67,71,75]	Both

Research Question 2a: Were Resources Understandable?

Understandability of all text and resources was very good, with all but 1 resource [68] scoring 80% or more on the PEMAT (Table S1 in Multimedia Appendix 1 [52-75]).

Research Question 2b: Were Resources Actionable?

Actionability varied greatly across resources, ranging from 40%-100% on the PEMAT (Table S1 in Multimedia Appendix 1 [52-75]). Less actionable text resources tended to be those focused on broad information and strategies, such as tips on how to tell your employer about your diagnosis and the suggestion to seek counseling support through a university campus student services center, rather than advice on when and how AYAs can take specific steps to address their concerns. In general, video resources were the least actionable in that most involved AYA survivors telling their own personal stories related to education and work challenges after a cancer diagnosis, rather than providing advice or strategies to other AYAs.

Research Question 2c: Were Text Resources Also Readable?

Readability for all 23 text resources was very poor, with reading levels ranging between grades 8.5 and 16.0 (mean 12, SD 1.97), indicating that, on average, the included resources require completion of a high school degree to comprehend. No resources were assessed to be the optimal reading level of grade 8 or lower (Table S1 in Multimedia Appendix 1 [52-75]).

Research Question 2d: Were Resources Easy to Locate?

Resources were difficult to locate, with 22 out of 24 (90%) relevant resources appearing on the second or third page of the Google search results (Table S1 in Multimedia Appendix 1 [52-75]). Results of the Google search prioritized resources related to younger children diagnosed with cancer and their engagement with school, as well as older adults returning to work. AYA-specific resources were scattered in between these less relevant results, as well as other, less relevant results, such as academic journal publications, links to hospital-based cancer services, and information about specific types of cancer.

Research Question 2e: Were Resources Evidence-Based?

No resources cited any research-based evidence to support the information provided (Table S1 in Multimedia Appendix 1 [52-75]). Most resources did not describe how the content was developed. Where any description was provided, resources tended to be developed through consultation with expert informants, such as career counselors, oncologists, hematologists, and social workers.

Research Question 2f: Were Resources Co-Designed?

No resources specifically discussed co-design methods used to develop resource content in collaboration with AYAs.

Research Question 2g: Were Resources Culturally Inclusive?

The number of cultural inclusivity criteria each resource addressed is summarized in Table S1 in Multimedia Appendix 1 [52-75]. The number of resources meeting specific criteria in the cultural inclusivity checklist is summarized in Table 2. Generally, cultural inclusivity of Aboriginal and Torres Strait Islander peoples was very poor, with only 2 out of 7 inclusivity criteria met by 1 or more resources: inclusion of Aboriginal or Torres Strait Islander cultural design or artwork and an acknowledgment on the web page recognizing Aboriginal and Torres Strait Islander peoples (minimally reflecting the use of strengths-based language that is respectful of Aboriginal and Torres Strait Islander peoples).

In reviewing all resources, both Australian and internationally-designed, we noticed several further equity, access, diversity, and representative issues with resources that were not initially part of our aims, that are important to highlight. Pictures and videos presented in resources almost exclusively portrayed heterosexual relationships, women were more commonly represented in pictures than men, and women were more commonly shown to be young, White, and of thinner build. Settings also showed middle-class, suburban, or urban areas rather than lower-socioeconomic, rural, or remote settings. Most resources also primarily assumed internet access and support from family or friends were available to AYAs. Lastly, language was not gender neutral and tended to assume heterosexual, 2-parent families.

Discussion

Overview

This environmental scan aimed to (1) determine what web-based resources exist to support survivors of AYA cancer in their engagement with education or work and (2) assess the understandability, readability, actionability, and cultural inclusivity of resources, as well as how easy resources were to locate, whether they provide evidence-based information, and whether they were co-designed with survivors of AYA cancer. We found few high-quality resources on the topic of returning to education or working for AYAs with cancer in Australia.

Although the understandability of most resources was high, the readability of text-based resources was poor, with most text resources requiring reading levels at the university education level or higher. This discrepancy may be due to the understandability criteria being quite broad (eg, text “material uses common, everyday language” or “material ‘chunks’ information into short sections”) and not directly providing criteria against which age-appropriate understandability could be assessed. For example, a resource might include everyday language for a young adult in small sections, but sentence structures or legal terminology related to education or work rights may be more complicated, thus affecting readability. Our findings on poor readability of resources are consistent with literature indicating most AYAs with cancer who access web-based resources report the resources require high health literacy and present information that is difficult to understand, critically evaluate, and act on [76,77].

We also found most web-based resources limited in their modes of information provision, primarily using text to provide lists of information and strategies. Few resources involved audio-visual content that may be preferable for the AYA population [35]. Where audio-visual content was provided, it was often focused on individual stories and experiences rather than the provision of guidance to AYAs and actionable strategies to navigate the return to education or work after cancer.

It is therefore unsurprising that the actionability of resources was moderate, with resources scoring 60%-100% on actionability. The focus on broad information and strategies in most of the resources reviewed may feel overwhelming to AYAs, given that it can be difficult for a young person to review a long list of suggestions and determine what they should act on given their individual health status, needs, and education or work goals [25]. Previous studies have provided evidence that Australian survivors of AYA cancer report low confidence in their ability to assess the reliability and validity of health-related information [77]. From a developmental standpoint, adolescents may not have fully developed their critical thinking skills yet [77]. This underscores the importance of providing information to AYAs that is both understandable and actionable.

It is also important to note that no resources cited an evidence base (ie, peer-reviewed scientific literature) for their information or recommendations, nor did any resource specify co-design of any content with survivors of AYA cancer. Instead, most resources assumed a certain level of understanding and self-motivation to act on the provided information or strategies. Most resources were also difficult to locate, appearing on multiple pages in a Google search. However, reliance on evidence-based information and co-design of resources with AYA survivors are widely acknowledged as critical to ensuring that information content and delivery methods are optimized for the specific needs of this age group [78-81].

Lastly, few resources met more than 1 criterion for cultural inclusivity. The lack of culturally inclusive resources for Aboriginal and Torres Strait Islander peoples may exacerbate existing health inequalities in people with cancer [82]. While there is no research, to our knowledge, describing specific concerns related to return to work or education for Aboriginal and Torres Strait Islander AYAs with cancer, financial distress is a common area of unmet need for Aboriginal and Torres Strait Islander adults with cancer in Queensland [83]. Considering the employment and educational disparities that are known within this population broadly [84,85], it stands to reason that Aboriginal and Torres Strait Islander AYAs with cancer may be in particular need of information to support their educational and employment endeavors. However, resources were generally not inclusive of Aboriginal and Torres Strait Islander peoples. In turn, the literature suggests that such limited inclusivity in health information can lead to feelings of isolation, feeling misunderstood by health services, and reduced self-efficacy in patients to follow medical advice [86]. There is an urgent need to address this gap in resources available to Australian AYAs through co-designing and testing the impact of resources with Aboriginal and Torres Strait Islander survivors of AYA cancer.

Comparison to Previous Work

While some NGOs and health care institutions provide lists of web-based resources for AYAs with cancer on their website, no previous research has specifically collated and evaluated web-based resources to support AYAs’ return to education or work after cancer. This environmental scan is the first to evaluate the age appropriateness, accessibility, understandability, and cultural inclusivity of web-based resources specifically targeting the education and work needs of AYAs with cancer in Australia.

Limitations

There were some limitations worth noting. The search strategies used were constructed to mirror typical searches AYAs might conduct with a select set of keywords. However, these strategies may not capture all modes of searches AYAs might conduct, such as asking questions in the Google search or using other terms not featured, and we did not include results such as blogs or social media posts from which AYAs may also seek information. We only conducted searches in English and did not find or include resources published in other languages that may be relevant. Furthermore, there are some limitations associated with assessing the cultural inclusivity of international resources using a tool designed specifically for Australia. However, it is important to note that, to our knowledge, no international tools exist to assess the cultural inclusivity of web-based health information resources, and we, therefore, opted to use the Australian tool and focus specifically on assessing the cultural inclusivity of resources for Aboriginal and Torres Strait Islander Australians. We also aimed to optimize the reach of our searches by using 24 unique search term combinations, as well as by conducting the searches from both Sydney (where the investigators are located) and Perth (through a virtual private network). Finally, given that AYAs use web-based resources and information, an important next step will be understanding what AYAs themselves think about available web-based resources in terms of appropriateness or usefulness, which was beyond the scope of the current environmental scan conducted here.

Conclusions

AYAs diagnosed with cancer frequently turn to the internet to seek information related to their diagnosis, treatment, and psychosocial needs [24,25,76,87]. Information accessed on the internet can play a major role in AYAs' decisions to seek care or support to address their specific needs and concerns [24,25,76,87]. Findings from this environmental scan suggest AYAs diagnosed with cancer in Australia would benefit from more tailored, evidence-based, and culturally inclusive web-based resources that are easy to locate, are provided in multiple formats (eg, text as well as audio-visual), are presented at the reading level of someone in year 8 or below and are easy to act on. While some resources describe their development as being done in consultation with survivors of AYA cancer, it is unclear to what extent a co-design approach was taken. A co-design approach would be beneficial to at least ensure the understandability, readability, actionability, and cultural inclusivity of any future resources developed.

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Data Availability

The data sets generated during this study are available from the corresponding author on reasonable request.

Authors' Contributions

All authors contributed to project conceptualization, methodology, writing, reviewing, and editing. Authors CES, JEF, GD, AD, and AG contributed to data curation and formal analysis. CES wrote the original manuscript with supervision from JEF.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Resources identified.
[DOCX File , 23 KB - cancer_v10i1e47944_app1.docx]

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Abbreviations

AYA: adolescent and young adult
NGO: nongovernmental organization
PEMAT: Patient Education Materials Assessment Tool
SHeLL: Sydney Health Literacy Laboratory

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Original Paper

Evaluation of the e–Mental Health Intervention Make It Training From Patients' Perspectives: Qualitative Analysis Within the Reduct Trial

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Abstract

Background: Make It Training is an e–mental health intervention designed for individuals with cancer that aims to reduce psychological distress and improve disease-related coping and quality of life.

Objective: This study evaluated the experienced usefulness and usability of the web-based Make It Training intervention using a qualitative approach.

Methods: In this study, semistructured interviews were conducted with participants at different cancer stages and with different cancer entities. All participants had previously taken part in the Reduct trial, a randomized controlled trial that assessed the efficacy of the Make It Training intervention. The data were coded deductively by 2 independent researchers and analyzed iteratively using thematic codebook analysis.

Results: Analysis of experienced usefulness resulted in 4 themes (developing coping strategies to reduce psychological distress, improvement in quality of life, Make It Training vs traditional psychotherapy, and integration into daily life) with 11 subthemes. Analysis of experienced usability resulted in 3 themes (efficiency and accessibility, user-friendliness, and recommendations to design the Make It Training intervention to be more appealing) with 6 subthemes. Make It Training was evaluated as a user-friendly intervention helpful for developing functional coping strategies to reduce psychological distress and improve quality of life. The consensus regarding Make It Training was that it was described as a daily companion that integrates well into daily life and that it has the potential to be routinely implemented within oncological health care either as a stand-alone intervention or in addition to psychotherapy.

Conclusions: e–Mental health interventions such as Make It Training can target both the prevention of mental health issues and health promotion. Moreover, they offer a cost-efficient and low-threshold option to receive psycho-oncological support.

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KEYWORDS

psycho-oncology; eHealth; digital health; cancer; Reduct trial; oncology

Introduction

Background

Cancer is one of the leading causes of death worldwide, and its prevalence is constantly increasing [1]. Worldwide, 19.3 million new cases of cancer were diagnosed in 2020 [2]. By 2024, a total of 27.5 million new cases of cancer are expected each year [2]. Receiving a cancer diagnosis and undergoing cancer treatment are associated with a high psychological burden [3,4]. Approximately every second individual diagnosed with cancer experiences high psychological distress, and one-third of all individuals across different cancer stages and types meet the criteria for at least one mental health disorder [5-7].

Due to the high psychological burden associated with cancer, a significant number of individuals seek psycho-oncological support [8-10]. Previous research has proven the efficacy of psycho-oncological treatment on different outcomes such as distress, fatigue, depression, anxiety, and quality of life [11-16]. However, receiving proper psycho-oncological support is difficult due to various barriers within the health care system [10,17,18]. These include geographic barriers, the stigma of seeking mental health services, financial constraints, continuity of health care, and the limited availability of mental health professionals [19-21]. Thus, efforts are required to expand access to mental health support for patients with cancer [4,8].

eHealth interventions offer a cost-efficient approach to overcome barriers in psycho-oncological care [16,22,23]. Most of these eHealth interventions consist of (web) applications that are based on psychotherapeutic approaches such as cognitive behavioral therapy (CBT) [24-28]. Existing research has demonstrated the efficacy of psychological eHealth interventions for individuals with cancer on outcomes such as distress, depression, anxiety, fatigue, and quality of life [16,25-27].

Most of the studies evaluating psycho-oncological eHealth interventions have proven their efficacy by adapting a quantitative research approach [16,25-27], wherein statistical analyses are conducted to investigate the pre- and postintervention scores of standardized questionnaires to assess statistically significant differences [29]. Although this approach is considered the gold standard for efficacy research, it does have some limitations [30]. These limitations include missing information on individual experiences, as well as missing in-depth information on the mechanisms behind the change that led to the statistical significance displayed in the data [31]. The inclusion of qualitative research offers an in-depth understanding of these mechanisms [32-34]. Considering research findings from both qualitative and quantitative approaches allows for a more holistic understanding of not only whether an intervention works but also how and why [35,36]. Thus, it offers in-depth knowledge of change mechanisms and the possibility of optimizing existing interventions. Moreover, assessment of eHealth interventions using a mixed methods approach is associated with increased adaptation to patients' needs and demands compared to solely using quantitative assessments [37-39].

This paper reports qualitative analyses conducted as part of the Reduct trial (German Clinical Trial Register DRKS00025213) [40]. The Reduct trial is a multicenter randomized controlled trial to assess the efficacy of the web-based Make It Training intervention (mindfulness and skill-based distress reduction training in oncology). To date, it is one of the largest efficacy trials in the field of psycho-oncology. Make It Training is a self-guided (web-based) application aimed at reducing distress in individuals with cancer [40,41]. It is based on CBT, acceptance and commitment therapy (ACT), and mindfulness-based stress reduction (MBSR). Over 4 months, individuals are supported by Make It Training through skill training, psychoeducation, interactive exercises, mindfulness, and psychotherapeutic techniques. Make It Training aims to reduce psychological distress, improve disease-related coping, and improve quality of life. It was developed to bridge the gap in the lack of psycho-oncological support in the health care system that currently exists in certain regions. The papers by Bäuerle et al [40] and Heinen et al [41] outline the study and intervention protocols, respectively.

Study Objectives

Taking on a qualitative stance, this study examined the experienced usefulness and usability of Make It Training from patients' perspectives. The aim of this study was to obtain a more holistic view and enrich the understanding of individuals' experiences concerning Make It Training beyond the boundaries of quantitative data [35,36]. When referring to the experience of usefulness, this study took on a psychotherapeutic perspective and referred to the patients' general evaluation of Make It Training, changes experienced while completing the intervention, attribution of these changes, specific aspects of the intervention that they found particularly useful or hindering, and recommendation to other individuals with cancer. On the basis of the study by Gould and Lewis [42] and the Health IT Usability Evaluation Model [43], the term usability comprises the patients' experienced user-friendliness, efficiency, accessibility, and practicability of the intervention.

Methods

Study Design and Procedure

This study was based on the guidelines of Levitt et al [44] and the COREQ (Consolidated Criteria for Reporting Qualitative Research) guidelines [45]. It consisted of one-on-one semistructured interviews. The interviews were conducted by a trained female interviewer who was experienced with qualitative research. To avoid any potential bias, the interviewer was not part of the core research team of the Reduct trial. There was no previous relationship established between the interviewer and the participants before the study began. Moreover, the participants did not have personal knowledge of the researcher. In total, 33% (2/6) of the participants completed the interviews in person, and 67% (4/6) did so digitally. Apart from the interviewer and the interviewee, there was no other person present during the interviews. All participants were interviewed once. To focus on the dialogue between the interviewee and the interviewer, no field notes were taken during the interviews. No transcripts were returned to the participants for comments or corrections. The COREQ checklist can be found in Multimedia Appendix 1 [45].

Recruitment

The participants of 1 study center that completed the Make It Training intervention within the Reduct trial [40] between May 2022 and September 2022 were contacted via email and telephone and invited to participate in this study. Purposive sampling (ie, completion of Make It Training) was carried out to obtain information-rich participants as well as in-depth experiences with Make It Training [34,46,47]. Recruitment took place in an early phase of the Reduct trial, so 11 participants were eligible to be contacted in total. Of these 11 participants, 5 (45%) either did not respond or could not participate for personal reasons. The final sample consisted of 6 participants. On the basis of Crouch and McKenzie [48], a small sample size was selected to put emphasis on the relationship between the researcher and the participant, as well as to explore the patients' lived experiences with Make It Training in depth.

For the inclusion, exclusion, and completion criteria (eg, current cancer diagnosis, command of the German language, internet connection, age of >18 years, and no psychotherapy during the intervention period) of the Reduct trial, we refer to the study protocol by Bäuerle et al [40]. This study was based on the inclusion and exclusion criteria of the Reduct trial.

Ethical Considerations

This study was approved by the Ethics Committee of the Medical Faculty of the University of Duisburg-Essen (22-10,902-BO). All interviews were conducted on the premises of the university and audiotaped with the interviewees' consent. The data were pseudonymized. The data protection–compliant audio files and identifying information were stored in a password-protected database. After providing written informed consent, the participants were interviewed. The participants had the option to be interviewed either in person at the clinic or digitally through a data protection–compliant software for clinicians [49]. There was no compensation or any form of reimbursement.

Semistructured Interview

The interview questions were divided into 9 segments. The first segment focused on explaining the study background and gathering sociodemographic information. In the second to ninth segments, interviewees were asked about the following: general experience with Make It Training, changes that they noticed since completing the intervention, attribution of these changes, content of the intervention that they perceived as particularly helpful or not helpful, content that was perceived as missing, the motivation to participate in the intervention, usability, and recommendation of the intervention to other individuals with cancer.

The interview questions were developed based on the Client Change Interview (CCI) [50] and the Health IT Usability Evaluation Scale (Health ITUES) [51]. The CCI was chosen as it is an established interview within psychotherapy research to assess self-perceived changes and attribution of changes related to psychotherapy [50]. In addition, it helps to identify perceived helpful or unhelpful components of psychotherapeutic interventions [50].

The Health ITUES is a questionnaire used to evaluate the usability of eHealth technologies among people with chronic diseases [52]. It was chosen as it is a validated assessment instrument to evaluate the feasibility and usability of eHealth interventions.

The full version of the semistructured interview is provided in Table S1 in Multimedia Appendix 2 [50,51].

In addition, self-generated questions were included (Textbox 1).

Textbox 1. Self-generated questions of the semistructured interview.

- How did you perceive the operation and user-friendliness of the Make It Training?
- How did you perceive the additional service in the form of reminder emails and contacts in the event of technical difficulties?

Data Analysis

The data were analyzed using thematic codebook analysis [53,54]. Thematic analysis was chosen due to its wide application across paradigms [54-56]. An overall deductive approach was chosen because it is an established approach to evaluate user experiences with digital interventions [57]. Moreover, it is helpful in organizing and categorizing meaningful data in conjunction with the existing literature [34,35,54]. The data were coded partly deductively by 2 independent researchers in 2 rounds of analysis. As the research team was interested in the participants' in-depth lived experiences with Make It Training rather than general thematic cohesion over the sample, a bottom-up inductive analysis was conducted first, which was then captured in the deductive structure in the second round of analysis.

The analyses were conducted iteratively; that is, they were carried out in a cyclical manner to refine and deepen the understanding of the data through the following steps:

1. Each coder open coded the first 2 transcripts, and individual memos were written.
2. The codes were compared and revised through multiple iterative rounds among the research team to obtain different perspectives. Both coders met to compare their findings, particularly regarding the codes; discuss discrepancies to

ensure consensus on the application of finalized codes and, if applicable, add new codes; and develop a codebook.

3. Both coders agreed that saturation had been attained in the first 2 open-coded transcripts.
4. The finalized codes were divided into categories and themes [56] and tested on the 4 remaining transcripts.

Chronemics (such as hesitation or silence) were taken into account as nonverbal information in the analysis. Overall, there was a high level of agreement (approximately 70%) between the researchers during the evaluation process, and discrepancies were critically discussed during meetings with the research team to reach a consensus. For publishing purposes, all interview quotes were translated from German into English, and the analysis process was reviewed by the research team. All interviews were transcribed using the f4x transcription software and then analyzed using the MAXQDA computer program (VERBI GmbH) [58]. On the basis of the decision to include a small sample size, the research team defined saturation according to Legard et al [59], meaning that saturation was assessed based on whether there was a consensus among the participants regarding the general evaluation of Make It Training and whether the research team felt that they had reached an understanding of the participants' lived experiences with Make It Training.

Quality Control

All researchers involved had a background in clinical psychology, psycho-oncology, psychosomatic medicine, and psychotherapy with different research experiences (full-time professors, assistant professors, postdoctoral researchers, PhD candidates, and graduate students).

On the basis of Creswell and Miller [60], validity guidelines were followed to ensure the validity of this study. These included triangulation by searching for convergence among diverse sources of information (eg, the lens of the researcher and systematic paradigm) to form themes or categories in a study [60]. Finally, validation procedures included seeking assistance through peer debriefing, which was realized by involving an auditor. The auditor was a senior qualitative researcher with extensive experience in clinical psychology and efficacy research but without familiarity with the Reduct trial and the Make It Training intervention. They audited the first round of findings by reading written findings, questioning the researchers on their procedures, and challenging interpretations and thematic structure. Subsequently, the researchers conducted another iterative round of analysis to synthesize and sensitize the data and fine-tune the findings accordingly. To establish credibility, we ensured to provide a thick and rich description of the setting, participants, and themes of the qualitative study [61].

Results

Overview

A total of 6 (mean 34 min, SD 7 min 56 s; range 20-45 min) one-on-one interviews were conducted. The demographic characteristics of the participants are presented in Table 1.

Table 1. Sociodemographic and diagnosis-related characteristics of the participants (N=6).

Characteristics	Participants, n (%)
Gender[a]	
Identified as a woman	4 (67)
Identified as a man	2 (33)
Age range (y)[a]	
49-56	4 (67)
57-66	2 (33)
Cancer type[b]	
Breast cancer	1 (17)
Lymphatic; blood-forming tissue	1 (17)
Skin cancer	2 (33)
Colon cancer	1 (17)
Musculoskeletal tumors	1 (17)
Year of initial cancer diagnosis[b]	
2010	1 (17)
2018	1 (17)
2019	1 (17)
2020	2 (33)
2022	1 (17)
Recurrence[b]	
Yes	5 (83)
No	1 (17)
Metastasis[b]	
Yes	3 (50)
No	3 (50)

[a] Sociodemographic characteristic.

[b] Medical characteristic and etiopathology.

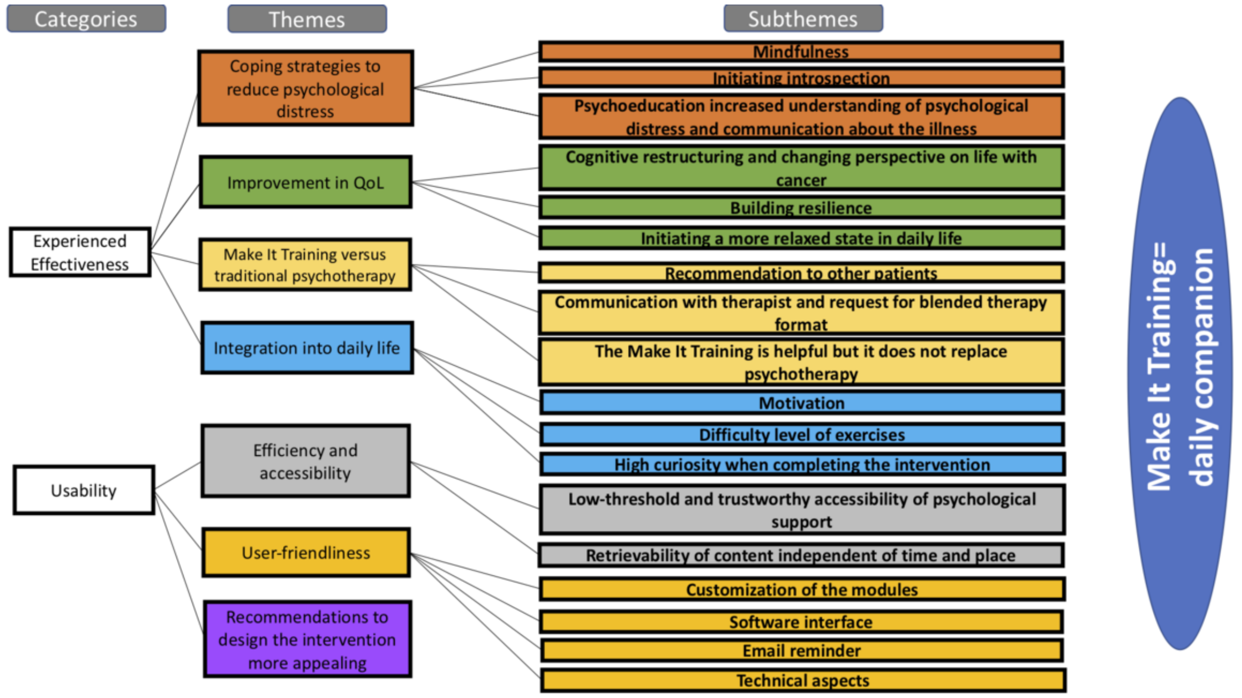
Theme Classification

Overview

The previously selected categories were divided into 7 themes that were used to focus the qualitative analyses. The themes were used deductively to select excerpts in the interviews that appeared relevant to these themes. Within the selections per theme, excerpts were coded using line-by-line coding and grouped to form information-rich subthemes. All themes and subthemes are reported in the following sections using representative quotes. Further information on the theme classification can be found in Figure 1, whereas Table S2 in Multimedia Appendix 2 summarizes all representative quotes.

The consensus regarding the Make It Training intervention was that it was described as a “daily companion” that integrates well into daily life and that it has the potential to be routinely implemented within oncological health care either as an intervention itself or in addition to psychotherapy (Table S2 in Multimedia Appendix 2, quote 1).

Figure 1. Themes and subthemes from the codebook analysis. Graphic display of the overarching categories, themes, and subthemes that emerged during the data analysis process. The term daily companion refers to the term that was commonly used by the participants to describe the Make It Training intervention. QoL: quality of life.



Category 1: Experienced Usefulness

Theme 1: Developing Coping Strategies to Reduce Psychological Distress

Overview Theme 1

This theme is centered on the development of functional coping strategies that participants described as a change related to Make It Training. All participants reported that Make It Training helped them develop a repertoire of coping strategies, which was helpful in reducing psychological distress.

For example, the improvement in emotion regulation was described as such a strategy (Table S2 in Multimedia Appendix 2, quote 2). Another commonly described coping strategy was redefining the relationship with cancer (Table S2 in Multimedia Appendix 2, quote 3).

Subtheme 1.1: Mindfulness Exercises

The increased practice of mindful behavior stood out as a described coping strategy, and it was attributed to the mindfulness exercises provided in Make It Training. The participants strongly embraced the variety of mindfulness exercises provided in the intervention. Interviewee 6 would have preferred even more exercises within Make It Training (Table S2 in Multimedia Appendix 2, quote 4).

The mindful breathing exercises were most commonly described as helpful. They were perceived as a new coping skill that could be integrated into daily life for stress management and tension reduction. One of the participants also positively noted the long-term advantages of breathing exercises (Table S2 in Multimedia Appendix 2, quote 5). This statement illustrates the advantages of mindful breathing exercises as part of the coping repertoire. Moreover, it demonstrates the practical application of the techniques in daily life as well as the interviewees' subjective perception of improvement.

Subtheme 1.2: Initiating Introspection

Most participants reported that Make It Training helped initiate introspection, which was described as supportive in dealing with difficult situations. It was further described as developing the skill to observe and interpret one's own thinking patterns, emotions, and behavior and not just be overwhelmed by them (Table S2 in Multimedia Appendix 2, quotes 6 and 7). Moreover, being able to observe one's inner world (ie, introspection) can help shift attention to positive aspects in difficult phases (Table S2 in Multimedia Appendix 2, quote 8).

Subtheme 1.3: Psychoeducation Increased Understanding of Psychological Distress Associated With Cancer and Communication About the Illness

Many participants experienced the psychoeducational components within the intervention as helpful because they led to a better understanding of cancer and its associated psychological distress and somatic restrictions. The participants reported that they were able to learn not only about personal circumstances but also how to communicate better and more effectively approach family members. In this regard, the expert videos provided, where health care professionals reported on each topic, were perceived as useful (Table S2 in Multimedia Appendix 2, quote 9).

Theme 2: Improvement in Quality of Life

Overview Theme 2

All participants reported that Make It Training helped increase their quality of life. This was described as redefining perspectives on life circumstances and cancer. Moreover, health-related behavior change, increase in resilience, and enhanced practice of mindful behavior were described as positively contributing to quality of life (Table S2 in Multimedia Appendix 2, quote 10).

Subtheme 2.1: Cognitive Restructuring and Changing Perspective on Life With Cancer

Participants reported that Make It Training helped modulate existing thinking patterns. This was commonly described as changing perspectives on life with cancer, as well as on the cancer diagnosis itself (Table S2 in Multimedia Appendix 2, quote 11). Another participant described a redefined relationship with pain (Table S2 in Multimedia Appendix 2, quote 12).

Subtheme 2.2: Building Resilience

Participants reported that Make It Training helped them become more resilient, which was described as developing the ability to better deal with unpleasant situations such as chemotherapy (Table S2 in Multimedia Appendix 2, quote 13).

Subtheme 2.3: Initiating a More Relaxed State in Daily Life

The participants described that the intervention was helpful to experience a more relaxed state in daily life, which positively contributed to their quality of life (Table S2 in Multimedia Appendix 2, quotes 14 and 15).

Theme 3: Make It Training Versus Traditional Psychotherapy

Overview Theme 3

While evaluating the Make It Training intervention, some participants drew a comparison between Make It Training and traditional psychotherapy. In total, 33% (2/6) of the participants had previous psychotherapeutic experience. Even though Make It Training was perceived as a helpful and easily accessible format to receive psycho-oncological support, 83% (5/6) of the patients reported that it did not replace traditional psychotherapy (Table S2 in Multimedia Appendix 2, quote 16). In contrast, one participant reported preferring Make It Training to traditional face-to-face psychotherapy (Table S2 in Multimedia Appendix 2, quote 17).

Subtheme 3.1: Recommendation to Other Patients

All participants had been diagnosed with different cancer entities and stages (Table 1). Overall, all reported recommending Make It Training to others as they were convinced that other individuals with cancer could benefit from the intervention as well. Some of them suggested that a psycho-oncological eHealth intervention such as Make It Training should be offered as a routine intervention within oncological health care.

Multiple participants argued that particularly individuals with a first-time cancer diagnosis would substantially benefit from the intervention. One participant hypothesized that providing individuals with a first-time diagnosis of cancer with an eHealth application such as Make It Training would help them process and better deal with the cancer diagnosis (Table S2 in Multimedia Appendix 2, quotes 18 and 19).

Subtheme 3.2: Communication With Therapist and Request for Blended Therapy Format

Make It Training is a purely self-guided eHealth intervention. Some participants wished for more communication with a therapist. In this context, they stressed the importance of a patient-therapist interaction. Some participants reported that Make It Training might be even more beneficial with additional therapist guidance. In this regard, additional therapist consultations via phone or email were suggested. Moreover, participants reported that these options would offer the opportunity to better voice challenges, misunderstandings, and questions. A total of 50% (3/6) of the participants expressed a preference for a blended format (ie, a combination of Make It Training with traditional face-to-face psychotherapy; Table S2 in Multimedia Appendix 2, quote 20).

Theme 4: Integration Into Daily Life

Overview Theme 4

The intervention was described as a “daily companion” (interviewee 4) or “a wonderful companion for everyday life” (interviewee 2) that could help a lot of individuals with cancer. Make It Training provided participants with a variety of psychoeducational information, psychotherapeutic exercises, and skill training that were perceived as suitable for integration into daily life. All participants reported that they had incorporated the received information or skills that they found valuable and implementable (see Table S2 in Multimedia Appendix 2, quotes 21 and 22, for examples of how participants integrated the skills into their daily lives).

Subtheme 4.1: Motivation

In the initial phase, all participants reported being motivated to complete the intervention. However, there were divided opinions regarding motivation after that initial phase. Some experienced Make It Training to be action activating because “it was a meaningful engagement with the disease” (interviewee 2). For others, the motivation gradually declined.

One participant brought up an analogy from sports to describe their motivation. They addressed the fact that, over time, they lacked the motivation to continue through Make It Training. However, the reminder emails helped keep the participant motivated (Table S2 in Multimedia Appendix 2, quote 23). In contrast, there were participants who did not need an external motivator (Table S2 in Multimedia Appendix 2, quotes 24-26).

Subtheme 4.2: Difficulty Level of Yoga Exercises

Make It Training comprised physical exercises in the form of yoga. There were mixed opinions on the difficulty level of these exercises as some participants perceived them as physically exhausting, whereas others did not. An older participant reported that some physical exercises were too straining due to restrictions caused by a lack of mobility because of the cancer (Table S2 in Multimedia Appendix 2, quote 27).

Subtheme 4.3: High Curiosity When Completing the Make It Training Intervention

Curiosity was high among all participants to see “what’s new there?” (interviewee 1) when a new module was unlocked. Curiosity was described as high because one had to wait a week to unlock a new module, which was perceived as exciting (Table S2 in Multimedia Appendix 2, quotes 28-30). Overall, participants seemed to support the format in which content is unlocked incrementally as it generates curiosity.

Category 2: Usability

Theme 5: Efficiency and Accessibility of the Make It Training Intervention

Overview Theme 5

The digital setup allowed all participants to work through the modules independent of time and place. Because of that, Make It Training was perceived as an efficient and easily accessible format to receive psycho-oncological support (Table S2 in Multimedia Appendix 2, quote 31).

Subtheme 5.1: Low-Threshold and Trustworthy Accessibility of Psychological Support

The content provided during the intervention was perceived as professional and trustworthy. It was reported that having access to Make It Training was not associated with barriers that were previously experienced by some participants when seeking psychotherapy. This was perceived as very positive (Table S2 in Multimedia Appendix 2, quotes 32-34).

Subtheme 5.2: Retrievability of Content Independent of Time and Place

All participants positively outlined the retrievability of the content. This refers to the possibility to flexibly retrieve the contents of Make It Training independent of time and place. When a module is activated, the participants can choose when and for how long they want to work on it, as well as on what parts. This was perceived as useful as it offers the flexibility to work on the modules independently of physicians' appointments, operations, or other medical examinations. Thus, Make It Training was considered "really timely-ideal" (interviewee 4; Table S2 in Multimedia Appendix 2, quote 35).

Participants also reported that the retrievability of the content helped them assess whether a skill that was learned could actually be internalized as well, which was perceived as a benefit (Table S2 in Multimedia Appendix 2, quotes 36 and 37).

Theme 6: User-Friendliness

Overview Theme 6

There were mixed opinions regarding the user-friendliness of Make It Training. Overall, participants considered the application user-friendly. One of the most common reasons why the intervention was described as user-friendly was that it was perceived as not requiring much guidance when using it (Table S2 in Multimedia Appendix 2, quote 38).

One participant criticized the user-friendliness of Make It Training because they perceived the software interface as confusing (Table S2 in Multimedia Appendix 2, quote 39).

Subtheme 6.1: Customization of the Modules

Make It Training follows a certain chronology in the order of the modules, which is not customizable. This was experienced by most participants as very limiting, and they would have liked to be able to work through the modules in their own order (Table S2 in Multimedia Appendix 2, quote 40).

Subtheme 6.2: Software Interface

There were mixed opinions regarding the software interface of Make It Training. Some participants perceived the layout of Make It Training as clear and stimulating. In contrast, others pointed out the unclear and childish presentation of the modules. One participant also came up with an analogy to a "kids board game" (interviewee 5). In general, the rather playful approach was appreciated (Table S2 in Multimedia Appendix 2, quotes 41 and 42).

Subtheme 6.3: Email Reminder to Increase Adherence

There were mixed opinions regarding the reminder emails that all participants received throughout the intervention. Most perceived them as a helpful addition that encouraged them; however, some of the participants perceived them as a bother (Table S2 in Multimedia Appendix 2, quote 43).

Subtheme 6.4: Technical Aspects

Most of the participants did not report any significant technical difficulties or perceived deficiencies. Common technical issues included internet connection or low-resolution quality of the videos.

Theme 7: Recommendations to Design the Make It Training Intervention to Be More Appealing

The participants gave feedback on how to design the Make It Training intervention to be more appealing. One module that focused on the family members of individuals with cancer was regarded by 33% (2/6) of the participants as lacking sensitivity. They reported that working through this module seemed inappropriate and upsetting for those without family members (Table S2 in Multimedia Appendix 2, quotes 44 and 45).

As another recommendation, some participants expressed the need to adapt the modules to the stage of cancer and the current treatment phase (Table S2 in Multimedia Appendix 2, quote 46).

Regarding usability, participants reported minor technical issues or design shortcomings that affected their navigation of and interaction with the program (eg, struggle to remember their position or progress within the program and challenges in finding the right areas to click or interact with). Clearer indicators or visual cues to help users track their progress and easily identify their current location within the program's content or structure were suggested (Table S2 in Multimedia Appendix 2, quotes 47-49).

Discussion

Principal Findings

This study examined the experienced usefulness and usability of Make It Training from patients' perspectives using a qualitative approach, which was accomplished through thematic analysis of interviews conducted with individuals with cancer at different stages of severity. Analysis of their experience of the usefulness of Make It Training resulted in 4 themes (developing coping strategies to reduce psychological distress, improvement in quality of life, Make It Training vs traditional psychotherapy, and integration into daily life) with 11 subthemes. Analysis of their experienced usability resulted in 3 themes (efficiency and accessibility, user-friendliness, and recommendations to design the Make It Training intervention to be more appealing) with 6 subthemes. All participants positively evaluated Make It Training. Moreover, all participants reported that they experienced positive changes while completing the Make It Training intervention and attributed these changes to the intervention itself. The overall usability of Make It Training was experienced as positive as well, although the experiences showed variation due to personal preferences. Overall, the results of this study point to a high satisfaction with Make It Training.

The themes that were discussed as perceived changes during the Make It Training intervention are consistent with its overall goal, which is to support individuals with cancer with disease-related coping, improvement in quality of life, and reduction in psychological distress [40,41]. Moreover, the aforementioned results are in line with those of the study by Ringwald et al [62], who assessed the acceptance of and satisfaction with a previous version of the Make It Training intervention in a pilot study. In this study, the acceptance and satisfaction rates of Make It Training were high, and 87% of the participants reported that they would recommend the intervention to other individuals with cancer [62]. Overall, the results from both the study by Ringwald et al [62] and our study point to a high acceptance of and satisfaction with Make It Training. Because of their satisfaction with Make It Training, the participants stated that it should be implemented as a routine intervention within health care. Previous research has shown that there is a relationship between acceptance of eHealth interventions and their actual use [63-67]. Acceptance is also an important factor for adherence [68]. Thus, given the acceptance of and satisfaction with Make It Training, it might have potential as an eHealth intervention to be routinely implemented in oncological health care as a medical device. In Germany, for example, there is a more recent regulation that eHealth interventions can be prescribed by health care professionals.

The Make It Training was described as a low-threshold and efficient format to receive psycho-oncological support. This was perceived as extraordinarily helpful as some participants had previously experienced difficulties with receiving proper psycho-oncological support, which is known to be a common problem in certain regions [10,17,18]. In this regard, the retrieval of content independent of time and place was described as being helpful with internalizing learned skills and accessing psychological support quickly when needed. These results further support the implementation of eHealth interventions such as Make It Training as an integral part of oncological health care. Digital interventions, if they are accepted among users, can overcome barriers associated with receiving psychological support, thereby improving mental health care and aftercare in oncology [19-21]. As individuals with cancer show elevated levels of distress both during and after cancer treatment, access to (digital) mental health care within this field is of great importance for both prevention and health promotion [4,8].

Despite mixed opinions regarding the software interface, Make It Training was generally rated as user-friendly. The participants most commonly argued for the usability of Make It Training by discussing that high technological literacy was not a requirement for completing the intervention. This finding is consistent with those of previous research showing a link between the use and acceptance of eHealth interventions and users' technological literacy [23,66,67]. Even though eHealth interventions have the potential to improve health care and aftercare, their implementation often fails because patients face barriers when wanting to make use of these interventions [23,66,67,69]. These barriers include low technological literacy, limitations in technological access, limitations in usability, and limited education in digital advice [69-72]. In addition, there are demographic barriers based on differences in age, socioeconomic status, educational level, language, and culture. Overall, existing barriers to receiving digital interventions due to demographic or structural differences can foster insensitivity within health care [72-74]. Certain individuals with cancer are at risk of being excluded from digital interventions because this population tends to have a higher median age (>60 y) [75], whereas the disease affects individuals with all kinds of demographic characteristics (ie, different cultural backgrounds, socioeconomic statuses, and educational levels). In addition, individuals commonly experience cognitive and physical restrictions during cancer treatment [76]. Thus, for more inclusive health care for individuals with cancer, eHealth interventions need to be designed as barrier free as possible (ie, they should depend less on the user's technological literacy as well as on other potentially exclusive factors).

Make It Training was compared by the participants to traditional face-to-face therapy even though it was not a specific topic in the interviews. In this regard, Make It Training was described as a helpful intervention, although it was noted that it could not replace traditional psychotherapy. The participants reported the missing therapist interaction as the main reason. In this regard, there was a desire for more therapist interaction within the Make It Training. In addition, a blended therapy format (ie, a combination of the Make It Training with additional face-to-face psychotherapy) was described as the "ideal" format to receive psycho-oncological support. This is in line with previous research supporting the adaptation of blended therapy approaches in psycho-oncology as well [77]. Efficacy research shows that purely self-guided eHealth interventions are associated with smaller effect sizes with a lower completion rate compared to blended therapy interventions, which can be attributed to the missing therapist interaction [78,79]. The results of this study, along with existing research, indicate that it is highly important to adapt eHealth interventions to the patients' needs [80]. Thus, it is suggested to put emphasis on therapist interaction (ie, blended format) in psycho-oncological eHealth interventions.

In this study, a qualitative approach was chosen as we believe that the inclusion of qualitative analyses within efficacy research (ie, the Reduct trial; Bäuerle et al [40]) provides more scientifically sound and transportable results. In this regard, it is important to look beyond surface or aggregate-level evidence to allow for inter- and intrapersonal nuances [81]. These are often missed in efficacy research but are rather important for a holistic understanding of usefulness in clinical practice [81]. Including qualitative research allows for an investigation of these inter- and intrapersonal nuances as well as for scrutiny of the level of experience, which is an important aspect when evaluating health care interventions such as the Make It Training. Another important strength of this study is the heterogeneity of the sample (ie, all participants were diagnosed with different cancer types and stages), which positively contributed to the generalizability of the evaluation of the Make It Training. In addition, this study provided the research team with information-rich descriptions of the participants' lived experiences regarding the Make It Training. It was also possible to obtain in-depth feedback on how to design the Make It Training intervention to be more appealing from a patient's perspective. Practical implications derived from this study are, from patients' perspectives, the potential of psycho-oncological eHealth interventions such as the Make It Training to improve oncological health care by offering a low-threshold option that provides psychological support independent of time and place and does not interfere with the already time-consuming oncological treatment. However, for routine implementation, they need to be adapted to the patients' needs and designed to be barrier free and should not require high technological literacy to interact with them. Moreover, even though eHealth interventions do offer efficient psycho-oncological support, they do not replace traditional psychotherapy, and it is suggested to use them as a first-step psychological support in a stepped-care health care approach.

Limitations and Recommendations for Future Research

This study has some limitations. Even though a qualitative approach offers valuable insights into participants' in-depth experiences, there are limitations regarding qualitative research itself, particularly concerning its generalizability and objectivity [82]. In this study, the decision to use a small sample size might have had a negative impact on the generalizability of the results even though the research team made efforts to select a highly heterogeneous sample. Moreover, a small sample size leads to a smaller data corpus, which can negatively impact the achievement of full thematic saturation. Other limitations include the use of a deductive analysis approach [54] and the risk of selection bias. Moreover, most of the research team members have a background primarily in quantitative methodology. Even though attempts were made to reduce this potential bias by actively involving an expert in qualitative research, this should still be considered a limitation. On the basis of the results of this study, it is suggested that future research put more emphasis on the barrier-free design of interventions and include patients' perspectives when designing and evaluating eHealth interventions. Moreover, it is suggested that future research investigate blended therapy approaches (ie, a combination of digital psycho-oncological interventions and face-to-face psychotherapy) as this format seems to be appealing for individuals with cancer.

Conclusions

The Make It Training was evaluated as a user-friendly intervention that is helpful for developing functional coping strategies to reduce psychological distress and improve quality of life among individuals with cancer. It has the potential to be implemented as a routine eHealth intervention in oncological health care. Overall, the results of this study, along with the existing literature, support the paradigm shift of including digital mental health care in the treatment of somatic and mental health disorders. e–Mental health interventions such as Make It Training can target both prevention of mental health issues and health promotion and offer a cost-efficient and low-threshold option to receive psycho-oncological support. Moreover, they allow for the retrieval of mental health support content independent of time and place. However, for psycho-oncological eHealth interventions to be actually used, they need to be designed to be barrier free and adapted to the users' needs.

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Data Availability

The data sets generated during and analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

JBK contributed to conceptualization, methodology, data curation, writing—original draft preparation, and investigation. FT contributed to conceptualization, methodology, writing—review and editing, and supervision. MT contributed to conceptualization, investigation, writing—review and editing, and supervision. TL contributed to data curation, investigation, and writing—original draft preparation. JH, CS, YE, and JG contributed to conceptualization, investigation, and writing—review and editing. MP contributed to software and writing—review and editing. AB contributed to conceptualization, methodology, writing—original draft preparation, investigation, and supervision.

Conflicts of Interest

None declared.

Multimedia Appendix 1
COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist.
[PDF File (Adobe PDF File), 420 KB - cancer_v10i1e53117_app1.pdf]

Multimedia Appendix 2
Semistructured interview questions and quotes.
[DOCX File , 36 KB - cancer_v10i1e53117_app2.docx]

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Abbreviations

ACT: acceptance and commitment therapy
CBT: cognitive behavioral therapy
CCI: Client Change Interview
COREQ: Consolidated Criteria for Reporting Qualitative Research
Health ITUES: Health IT Usability Evaluation Scale
MBSR: mindfulness-based stress reduction

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Original Paper

Differing Content and Language Based on Poster-Patient Relationships on the Chinese Social Media Platform Weibo: Text Classification, Sentiment Analysis, and Topic Modeling of Posts on Breast Cancer

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Abstract

Background: Breast cancer affects the lives of not only those diagnosed but also the people around them. Many of those affected share their experiences on social media. However, these narratives may differ according to who the poster is and what their relationship with the patient is; a patient posting about their experiences may post different content from someone whose friends or family has breast cancer. Weibo is 1 of the most popular social media platforms in China, and breast cancer–related posts are frequently found there.

Objective: With the goal of understanding the different experiences of those affected by breast cancer in China, we aimed to explore how content and language used in relevant posts differ according to who the poster is and what their relationship with the patient is and whether there are differences in emotional expression and topic content if the patient is the poster themselves or a friend, family member, relative, or acquaintance.

Methods: We used Weibo as a resource to examine how posts differ according to the different poster-patient relationships. We collected a total of 10,322 relevant Weibo posts. Using a 2-step analysis method, we fine-tuned 2 Chinese Robustly Optimized Bidirectional Encoder Representations from Transformers (BERT) Pretraining Approach models on this data set with annotated poster-patient relationships. These models were lined in sequence, first a binary classifier (no_patient or patient) and then a multiclass classifier (post_user, family_members, friends_relatives, acquaintances, heard_relation), to classify poster-patient relationships. Next, we used the Linguistic Inquiry and Word Count lexicon to conduct sentiment analysis from 5 emotion categories (positive and negative emotions, anger, sadness, and anxiety), followed by topic modeling (BERTopic).

Results: Our binary model (F_1-score=0.92) and multiclass model (F_1-score=0.83) were largely able to classify poster-patient relationships accurately. Subsequent sentiment analysis showed significant differences in emotion categories across all poster-patient relationships. Notably, negative emotions and anger were higher for the “no_patient” class, but sadness and anxiety were higher for the “family_members” class. Focusing on the top 30 topics, we also noted that topics on fears and anger toward cancer were higher in the “no_patient” class, but topics on cancer treatment were higher in the “family_members” class.

Conclusions: Chinese users post different types of content, depending on the poster- poster-patient relationships. If the patient is family, posts are sadder and more anxious but also contain more content on treatments. However, if no patient is detected, posts show higher levels of anger. We think that these may stem from rants from posters, which may help with emotion regulation and gathering social support.

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KEYWORDS

cancer; social media; text classification; topic modeling; sentiment analysis; Weibo

Introduction

Background

Breast cancer is 1 of the most common forms of cancer, with an estimated 2 billion people being affected worldwide in 2020 (according to statistics released by the World Health Organization [WHO]), and is consequently a disease familiar to many people. It is a chronic disease with a high mortality rate, which poses a serious threat to human life [1]. For this reason, breast cancer is often viewed negatively, and new diagnoses often trigger sadness, fear, and even psychopathological comorbidities, such as depression [2]. In recent decades, the number of new diagnoses has continued to rise, despite important improvements in medical technologies worldwide [1]. In China, more than 400,000 people were diagnosed with breast cancer in 2020, with approximately 100,000 deaths (according to WHO) [1]. Behind these diagnoses are numerous stories emerging from the experiences of patients or the people around them who are closely intertwined [3]. Therefore, it is not unusual for one to come across discussions on breast cancer in daily life—be it learning about the diagnosis of a loved one or acquaintance or coming across news on a celebrity with breast cancer or even struggling to accept the diagnosis of a close relative. Therefore, a lot of these breast cancer–related narratives take place on social media–lived experiences of people who may have been diagnosed with or who know of someone struggling with breast cancer.

Social media is indispensable in the daily life of billions worldwide; almost everyone is a user of a social media platform [4]. On these platforms, people can share snippets of their lives with other people around them, which double as autobiographical records of their life events. As a social tool, one can smoothly interact and communicate with one’s friends and family over the internet, be it synchronously or asynchronously [5,6]. Such activity leaves digital traces all over the internet, and researchers have since begun using social media posts as resources for uncovering social phenomena [5]. Particularly in the medical field, social media analyses have also been used to great effect, for example, in examining and predicting the epidemiological spread of infectious diseases, such as seasonal influenza and COVID-19 [7,8]. Recently, researchers have also analyzed social media to learn about the perspectives and needs of patients with certain diseases. For example, Kamba et al [9] analyzed a Japanese social media forum (Yahoo Japan) for posts relating to breast cancer and found that the most frequently mentioned concerns pertain to symptoms, screening, and lack of knowledge, to name a few (see also Refs. [10,11]).

However, much of this research has been conducted on Western social media platforms, such as Twitter and Reddit, which have limited penetration in the Chinese market. Chinese internet users have their own social media ecosystems and platforms: Sina Weibo is 1 of the most widely used and popular social platforms in China and has been called by some as the “Chinese version of Twitter” [12]. Given our research interest in Chinese social media users, we focused our paper specifically on Weibo. As a widely used platform, the number of monthly active users reached 511 million in 2020; Weibo is known by almost everyone in China [13], and posts are known to reflect the diversity of opinions and perspectives by everyday Chinese [14]. Often, users discuss and post about all kinds of topics on Weibo, including topics pertaining to breast cancer. With the large number of users and the diversity of content, Weibo data appear to be a valuable corpus for research on Chinese perspectives from the bottom-up.

Sentiment Analysis on Social Media

To accommodate the large volume of data on the internet, conventional methods, such as qualitative coding, may be too time-consuming and costly. Therefore, modern sociological researchers frequently use computational methods, such as sentiment analysis and topic modeling, to analyze the data. Originating from the field of natural language processing (NLP), sentiment analysis is optimized to deal with the detection and classification of sentiments in (a large number of) texts. By using sentiment analysis, we can infer whether a given text has a positive, negative, or more fine-grained emotional orientation in a given context [15]. In studying social media, researchers analyze the data on social media to obtain public perceptions on a specific topic in contribution to the study and advancement of society [16]. Some researchers have also applied sentiment analysis to measure customers’ needs from their social media posts, thereby obtaining unique insight to improve a brand’s products or services [15]. Researchers have also applied sentiment analysis on social media to predict mental health issues, for example, Wang et al [17] used sentiment analysis to detect users with depression on social networking services.

Regarding breast cancer, sentiment analysis may play a more important role in exploring the patients’ psychological state, such as their perceptions, cognitions, and emotions [18]. Through analyses of tweet sentiments, previous research has confirmed that patients with breast cancer have different polarities (valence) of emotional expression for topics related to breast cancer [19]. For example, support seeking and treatments are associated with positive sentiment, but health care and insurance are associated with negative sentiment. Moreover, posters may not necessarily be patients themselves posting about their experiences or concerns but could be posting about a loved one, a relative, or an acquaintance with breast cancer. Accordingly, posters’ emotional expressions on social media may not only display differences in sentiment, depending on their specified content or aspects (eg, treatment stage or success), but also show differences, depending on their relationship with the patient [20] or if the posters themselves are the patients. In this paper, we define this as the “poster-patient relationship.” Therefore, in studying the usage of social media for emotional expression in the context of breast cancer, we propose the necessity to distinguish the poster-patient relationships for each post—whether posts originate from patients themselves or from their friends and relatives or other people.

The Research

Before examining emotional expressions and sentiment, we intended to discern the relationships between poster and patient through the post. Due to the large volume of data, we turned to machine learning for this task. "Machine learning" is the term used to describe both the academic discipline and the collection of techniques that allow computers to undertake complex tasks, and recent advances in machine learning have driven advances in the development of NLP and artificial intelligence (AI) [21]. In NLP, the past 5 years have seen rapid advances in the transformer-based framework, resulting in cutting-edge pretrained language models, such as Bidirectional Encoder Representations from Transformers (BERT) [22], Robustly Optimized BERT Pretraining Approach (RoBERTa) [23], and Generative Pretrained Transformer (GPT)-3 [24], which have greatly improved the effectiveness of downstream tasks (eg, text classification), opening up new avenues for researchers to study society and language [25].

Our aim was to study how users on the Chinese social media platform Weibo post about breast cancer–related topics on social media. Although we took a hypothesis-blind, exploratory approach to data analysis, we focused our discussion on topics surrounding the issue of emotional expression by examining differences in emotional expression, depending on poster-patient relationships. In step 1, we collected data from Weibo and determined poster-patient relationships through 2 stages of classification: first, we identified whether a post references a patient with breast cancer (as opposed to posts that mention breast cancer without naming a specific patient), followed by the poster-patient relationship classification that determined the relationship between the mentioned patient and the author of the post (poster). Ultimately, these 2 stages in step 1 constituted a single classification pipeline to identify poster-patient relationships: whether the post authors are themselves the patients or (1) a family member (*family_members*); (2) a friend or relative (*friends_relatives*); (3) an acquaintance (*acquaintances*); (4) from a parasocial relationship, such as a celebrity or public figure (*heard_relation*); or (5) no patient mentioned (*no_patient*). In step 2, we used the LIWC-based dictionary to count the word frequency for each post, with 5 emotional categories (sadness, anger, anxiety, positive, and negative), thereby expanding our target beyond just positive and negative sentiments. Despite the lack of discreet positive emotion categories in the LIWC dictionary, we chose it because it is 1 of the most widely used and accessible sentiment dictionaries in psycholinguistic research. Next, we used topic modeling to further examine the main topics discussed between each class and how these topics differ across classes. This will allow us to see how social media narratives for patients and posters differ, while shedding light on possible implications for emotional expression via social media.

Methods

Ethical Considerations

As all data used in this study are publicly available and no personal identifiers were obtained, our study was exempt from institutional ethics review. Where applicable, all posts included in this analysis have been paraphrased so that they cannot be traced back to the user. No identifying information (eg, usernames, IDs, or pictures) are included in the main manuscript or in the supplementary material.

Step 1: Poster-Patient Relationship Classification

Data Collection

Since Sina Weibo does not maintain a public application programming interface (API), we used a previously constructed web crawler to request publicly available Weibo posts. Our web crawler simulates a user visiting Weibo's official website and searches for relevant posts (see the next paragraph for the search procedure). Through this approach, each web search request can obtain up to 50 posts before reinitiating a new search request to retrieve a new set of posts. In our crawler, we were able to set adjustable parameters to specify keywords, the publishing date, location, and interval times between 2 search requests.

We conducted 2 searches with different queries: "breast cancer ('乳腺癌')" and "sadness ('悲伤')", as well as "breast cancer ('乳腺癌')" and "record ('记录')" in Chinese, from January 1, 2018, to December 31, 2021. For both queries, the interval time was set to 15 seconds and the location was unspecified, meaning that we searched for posts from across China. Finally, for the 2 searches with different queries, we obtained 160,182, and 144,125 posts, respectively. For each post, we additionally obtained the user id, username, user type, publish time, post text, location, number of comments, likes, and reposts, which were removed before commencement of analyses.

Next, for the data-cleaning phase, we combined the search results of the 2 queries into a single data set. Duplicate posts were removed through string matching, and obvious advertisements and irrelevant posts were removed by manually checking the data set. This was to ensure the posts were related to narrative accounts pertaining to breast cancer. Finally, this resulted in a cleaned data set containing relevant breast cancer–related narratives from individual users, for a total of 10,322 posts.

Poster-Patient Relationship Classification Criteria

First, we set up 6 categories based on the relationship of the mentioned patient and the author of the post: "post_user," where the authors are themselves the patients (coded as 0); "family_members," where the authors mention a family member (eg, parent) as the patient (coded as 1); "friends_relatives," where a friend or nonimmediate relative (eg, cousins, aunt) is the patient (coded as 2); "acquaintances," where a colleague or neighbor (social relationships) is the patient (coded as 3); "heard_relation," where the author may be posting about a celebrity or a famous patient with cancer (coded as 4); and "no_patient," where breast cancer is mentioned generally without being associated with a specific person (coded as 5).

Data Annotation

We randomly portioned 3000 (29.1%) of the 10,322 posts for manual annotation based on the classification criteria, with each data point (post) assigned a label from the 6 aforementioned categories. In the process of labeling, first we determined whether there was a patient in the post (binary classification task), and then we determined whether the poster-patient relationship could be inferred and labeled according to the prespecified classification criteria (multiclass classification task). All data labeling was performed by 1 of the authors who is a native Chinese speaker. See Table 1 for the annotation proportions, and Table S1 in Multimedia Appendix 1 for examples of annotated posts.

To verify that our annotations were objectively labeled and free of subjective bias, we randomly selected 600 (20%) of the 3000 annotated posts, and these were reannotated in the same procedure by another native Chinese annotator who was not part of the research team. Across the 6 categories, the interannotator agreement was good (Cohen κ=0.67) [26], and the original annotations were used to train the classification model.

Table 1. Distribution of annotated posts.

	Posts, n
No_patient	1089
Heard_relation	509
Family_members	443
Acquaintances	356
Post_user	338
Friends_relatives	265

Data Preprocessing

In our study, we chose the pretrained Chinese-RoBERTa-wwm-ext (Chinese RoBERTa) [27] model as our classification model. The Chinese RoBERTa is a large language transformer model based on the RoBERTa architecture [23], trained on a large corpus of the in house–collected extended data containing an encyclopedia, news articles, and web forums, which has 5.4 billion words and is over 10 times bigger than the Chinese Wikipedia [27], and is frequently used for Chinese NLP tasks. To improve the accuracy of the multiclass text classification, we decomposed the classification task over 2 stages (see Ref. [28]): a binary classification task to determine whether a patient was mentioned, followed by a multiclass classifier on posts where a patient was mentioned in order to identify the poster-patient relationship.

The pretrained language model (Chinese RoBERTa) has a limited input character length of 512, and 522 posts in our data set were longer than this character length limit. As such, we used automated text summarization to condense the text length to within 512 characters for these 522 posts using SnowNLP, a Python library that can perform Chinese word segmentation, part-of-speech tagging, sentiment analysis, text categorization, *pinyin* conversion, traditional simplification, text keyword extraction, text summarization, sentence segmenting, and text similarity estimation [29]. The SnowNLP tool segments posts by sentence and using the TextRank algorithm [30] calculates the weight of each sentence in the post according to the extent to which the content of the sentence represents the content of the text. Finally, all the small units are sorted in reverse order according to their weight scores. When implementing this tool, by setting a number parameter, the corresponding number of sentences is output accordingly, resulting in summarized texts. In Multimedia Appendix 2, we included some examples of automatic summarization.

Classifier Training

Following annotation and data preprocessing, 2 classifiers were constructed for this study in a 2-stage process. In the first stage, a binary classification model was trained to identify whether a patient is mentioned. This was followed by training a multiclass classification model to identify the poster-patient relationship for each post where a patient was mentioned in 1 of 5 classes: post_user, family_members, friends_relatives, acquaintances, and heard_relation. This resulted in a total of 6 classes corresponding to the annotations, with the inclusion of the "no_patient" class from the earlier binary classification model. In constructing the 2 classifiers, we specified the task of the RoBERTa model as classification. We monitored the training performance for each epoch through cross-entropy loss. Fine-tuning was implemented under the Pytorch framework, where we used the Amda Optimizer to optimize and update model parameters for training purposes. For testing, sklearn metrics were used to evaluate the binary classification and multiclass classification. In addition, 2400 (80%) of the 3000 annotated posts were used to train the model, and the main parameters for the model training were as follows: batch size=16, learning rate=1.0×10^{-5}, and training epochs=5. We used 600 (20%) posts to test the fine-tuned model.

In the second stage, we removed the "no_patient" class from the annotated data. In total, 1515 (50.5%) posts were used to fine-tune the Chinese RoBERTa model. The main parameters were similar to the binary classifier, with batch size=16, learning rate=1.0×10^{-5}, and training epochs=5. For validation, we used 396 (13.2%) posts to test the trained model.

Step 2: Examining Differences in Emotional Expression

Analysis 1: Sentiment Analysis Based on the LIWC

The LIWC program is a text analysis program that calculates the degree of use for different categories of words across a wide array of texts [31]. This tool was originally developed in English, but researchers have since produced a Chinese version of the LIWC dictionary based on the same criteria [32]. We used an open source Python package to access the Chinese LIWC dictionary. The LIWC dictionary has proved extremely useful in a number of different disciplines and has had a large impact on our understanding of how lexical elements related to cognition, affect, and personal concerns can be used to better understand human behavior [33].

In our study, we focused on the emotion categories to implement the sentiment analysis in our corpus of Weibo posts. We used the LIWC program and its Chinese dictionary to examine 5 emotion categories available in the Chinese LIWC dictionary: positive emotions, negative emotions, sadness, anger, and anxiety. The LIWC dictionary operates by counting the number of terms in each post that corresponds to its internal dictionary for each emotion category, and outputs a score representing the ratio of relevant terms to all identified terms in the post. We then conducted Kruskal-Wallis tests to determine whether positive emotion terms, negative emotion terms, anxiety terms, sadness terms, and anger terms significantly differed between each poster-patient relationship class. If there was a significant effect of the emotion category, we conducted post hoc Dwass-Steel-Critchlow-Fligner (DSCF) pairwise comparisons to compare differences between specific categories.

In this paper, our data are in Chinese, so we had to tokenize our data. We used Jieba for tokenization, which is 1 of the most popular Chinese tokenization tools in NLP [34]. To clean out the noise, we excluded more than 2000 stop words, which were collected from an open source Chinese dictionary of stop words.

Analysis 2: Topic Modeling

Making sense of a large unstructured corpus through qualitative means is difficult. Therefore, we used topic modeling to better assist us in interpreting data. Topic modeling is a widely used approach to extract common, recurring themes from large amounts of text data through identification and clustering of repeated patterns in words and sentences. In this paper, we adopted the open source BERTopic algorithm [35] to achieve this. BERTopic leverages transformers and class-based term frequency–inverse document frequency (c-TF-IDF) to create dense clusters of words, allowing for easily interpretable topics, while keeping important words in the topic descriptions [35]. Past research [36] has also found that BERTopic-based topic modeling generally yields more theoretically interpretable results than other forms of topic modeling (eg, latent Dirichlet allocation or Top2Vec). As the BERTopic algorithm only assigns 1 topic to every document (post), we were able to compute topics per class, which allowed uniform comparison of topic distribution for every class (poster-patient relationships), enabling us to observe general trends: which topics are more frequently observed in which class of poster-patient relationship. As long texts are more suitable for modeling and there is no limit to the length of input sentences, during the topic modeling, we replaced the summarized sentences with the original ones. For identified topics, we deliberated on the schema associated with as many words in the topic as possible. Note that this process is largely subjective, so we encourage readers to additionally reference the words contained in each topic, rather than relying solely on the authors' labels.

In this paper, our data are in Chinese and because the BERTopic model is based on the clustering of individual words to implement topic modeling; therefore, in the process of topic modeling, similar to the sentiment analysis, we needed to tokenize our Chinese data. We again used Jieba for tokenization [34]. To obtain meaningful entities from the topic models, we excluded more than 2000 stop words, which were collected from an open source Chinese dictionary of stop words.

Results

Step 1: Poster-Patient Relationship Classification

Binary Classifier

This model was trained to distinguish each post as either mentioning ("patient" class) or not mentioning ("no_patient" class) a patient. We merged the "post_user," "family_members," "friends_relatives," "acquaintances," and "heard_relation" classes into a superordinate "patient" class. The model achieved a high F_1-score (see Table 2).

Table 2. Binary classifier's metrics report.

Class	Precision	Recall	F_1-score	Support
no_patient	0.90	0.90	0.90	204
patient	0.95	0.95	0.95	396
Macro average	0.92	0.92	0.92	600

Multiclass Classifier

Next, we constructed a multiclass classifier to focus on patient classification: "post_user," "family_members," "friends_relatives," "acquaintances," and "heard_relation." Results are reported in Table 3.

Table 3. Multiclass classifier's metric report.

Class	Precision	Recall	F_1-score	Support
acquaintances	0.76	0.67	0.71	75
heard_relation	0.83	0.83	0.83	102
famliy_members	0.93	0.90	0.91	86
post_user	0.86	0.91	0.89	82
friends_relatives	0.74	0.84	0.79	51
Macro average	0.82	0.83	0.83	396

Post Classification

After excluding the annotated data, we were left with 7322 (70.9%) of the 10,322 data points (posts). These posts then underwent the 2-stage classification process. The first stage included a binary classifier to determine whether patient information was identifiable from the post (patient and no_patient), and if a patient was detected, the post then passed to the second stage. This included a multiclass classifier to classify the relationship between the patient and the Weibo poster. In the first stage, 4494 (61.4%) posts were classified as having a patient and 2828 (38.6%) posts as having no patient. Of the former, the relation classifications were as follows (Table 4): the patient was identified as a friend or relative (friends_relatives; n=667, 14.8%), as the poster (post_user; n=705, 15.7%), as an acquaintance (acquaintances; n=781, 17.4%), as a family member (family_members; n=961, 21.4%), and as someone they had only heard about (heard_relation; n=1380, 30.7%).

As Tables 1 and 4 show, the rankings of categories by the number of relevant posts were similar regardless of whether the data were manually labeled or predicted by our classifier. The ranking list was no_patient > heard_relation > family_members > acquaintances > post_user > friends_relatives. We noted that the "no_patient" class that did not mention a specific patient was the majority class, which accounted for one-third of the total number of posts (n=2828, 38.6%). We think that posters use the target words ("breast cancer") to share some personal thoughts, not necessarily about specific instances of breast cancer or for a targeted patient. Alternatively, they may feel no need to talk about the patient due to the content and style of the post. Except for this class, the distribution of the other poster-patient relationship classes was relatively balanced in the data set.

Table 4. Distribution of predicted posts.

	Posts, n
No_patient	2828
Heard_relation	1380
Family_members	961
Acquaintances	781
Post_user	705
Friends_relatives	667

Step 2: Examining Differences in Emotional Expressions

Sentiment Analysis

For subsequent analyses, our aim was to maximize the information we could extract from the data, so manual annotations were combined with the machine-learned predictions for a total of 10,322 posts. We applied the LIWC and the matched Chinese dictionary to count the emotion-related words for each tokenized post. We mainly focused on positive emotion, negative emotion, sadness, anger, and anxiety categories. We calculated the ratio of each emotion category in each post (number of emotion words/number of all tokens). To visualize broad emotional differences among the classified poster-patient relationship classes, we plotted the mean scores for 6 identity categories in each of the 5 emotion categories.

For positive emotions, the "friends_relatives" class had a relatively higher value than the other 5 classes (Table 5). For negative emotions, the "no_patient" class had a relatively higher value than the other 5 classes. For angry terms, the "no_patient" class had a significantly higher value than the other 5 classes, which had almost the same values. For anxiety terms, the "family_members," "no_patient," and "post_user" classes had a higher value than the other 3 classes; the "heard_relation" class had the lowest value. For sadness terms, the "family_members," "no_patient," and "post_user" classes had a relatively higher value than the other 3 classes.

Table 5. Emotion distribution for each class in the 5 emotion categories (positive emotions, negative emotions, anger, anxiety, and sadness).

	Mean ratio of each emotion category in each post[a]
Positive emotions	
no_patient	0.05567
heard_relation	0.05785
family_members	0.05469
acquaintances	0.06581
post_user	0.05382
friends_relatives	0.07490
Negative emotions	
no_patient	0.11920
heard_relation	0.09202
family_members	0.09933
acquaintances	0.09118
post_user	0.09759
friends_relatives	0.09386
Anger	
no_patient	0.01020
heard_relation	0.00490
family_members	0.00467
acquaintances	0.00479
post_user	0.00469
friends_relatives	0.00489
Anxiety	
no_patient	0.00699
heard_relation	0.00389
family_members	0.00674
acquaintances	0.00465
post_user	0.00595
friends_relatives	0.00430
Sadness	
no_patient	0.01094
heard_relation	0.00894
family_members	0.01107
acquaintances	0.00845
post_user	0.01110
friends_relatives	0.00928

[a] Number of emotion words/number of all tokens.

Next, we statistically examined differences in emotions across poster-patient relationships. Kruskal-Wallis tests showed significant effects for positive emotions (posemo: χ^2_5=185.9, *P*<.001), negative emotions (negemo; χ^2_5=156.8, *P*<.001), anxiety (anx; χ^2_5=50.6, *P*<.001), anger (anger; χ^2_5=38.2, *P*<.001), and sadness (sad; χ^2_5=56.8, *P*<.001). This suggests that for all emotion categories, significant effects were detected across the 6 poster-patient relationship classes. Table 6 reports the post hoc DSCF pairwise comparisons.

Although there were a number of significant effects, here we comment primarily on consistent patterns of results that may be indicative of broader trends in Weibo users with respect to the emotional language used when posting about breast cancer.

We noticed that the “friends_relatives” class had significantly higher positive emotions than all other poster-patient relationship classes, and this was followed closely by the “acquaintances” class, which had higher positive emotions than the other remaining poster-patient relationship classes.

Table 6. Pairwise comparisons for the 5 emotion categories.

Class 1	Class 2	Positive emotions		Negative emotions		Anxiety		Anger		Sadness	
		W[a]	*P* value	W	*P* value	W	*P* value	W	*P* value	W	*P* value
acquaintances	family_members	–7.87	<.001[b]	3.94	.06	7.55	<.001[b]	1.05	.98	6.42	<.001[b]
acquaintances	friends_relative	5.67	<.001[b]	1.87	.77	1.29	.94	1.75	.82	3.02	.27
acquaintances	heard_relation	–6.75	<.001[b]	0.64	0.99	0.91	.98	1.81	.79	2.47	.50
acquaintances	no_patient	–10.73	<.001[b]	12.13	<.001[b]	2.65	.42	6.38	<.001[b]	–0.46	.99
acquaintances	post_user	–8.49	<.001[b]	3.13	.23	5.15	.004[b]	1.74	.82	5.16	.004[b]
family_members	friends_relatives	13.42	<.001[b]	–1.83	.79	–5.90	<.001[b]	0.86	.99	–3.01	.27
family_members	heard_relation	1.78	.81	–3.96	.06	–7.94	<.001[b]	0.81	.99	–4.81	.01[b]
family_members	no_patient	–2.62	.43	8.63	<.001[b]	–6.92	<.001[b]	5.71	<.001[b]	–8.88	<.001[b]
family_members	post_user	–1.08	.97	–0.61	.99	–2.13	.66	0.86	.99	–0.87	.99
friends_relative	heard_relation	–12.65	<.001[b]	–1.54	.89	–0.57	.99	–0.21	.99	–1.04	.98
friends_relative	no_patient	–16.21	<.001[b]	9.41	<.001[b]	0.94	.98	4.01	.05	–4.23	.03[b]
friends_relative	post_user	–13.68	<.001[b]	1.19	.96	3.69	.09	–0.07	.99	2.02	.71
heard_relation	no_patient	–5.15	.004[b]	14.14	<.001[b]	2.01	.72	5.55	.001[b]	–4.14	.04[b]
heard_relation	post_user	–2.76	.37	2.98	.28	5.02	.005[b]	0.12	.99	3.47	.14
no_patient	post_user	1.29	.94	–8.31	<.001[b]	3.76	.08	–4.23	.03[b]	6.98	<.001[b]

[a] Standardized Wilcoxon statistic from Dwass-Steel-Critchlow-Fligner (DSCF) pairwise comparisons.

[b] Significant *P* values.

In addition, we found that “no_patient” posts had consistently higher negative emotions than the posts in all other poster-patient relationship classes, but no strong and consistent pattern of difference was observed between other poster-patient relationship classes. This pattern was mirrored strongly in the anger emotion category, suggesting that “no_patient” posts were higher on anger compared to posts in the other poster-patient relationship classes. As “negative emotions” is a broad emotion category containing many other negative emotion words in its dictionary, we think that strong differences observed in anger could be driving the significant difference found in the negative emotions category.

Furthermore, we noticed that with the exception of the “post_user” class, the “family_members” class was generally significantly higher in anxiety than the “acquaintances,” “friends_relatives,” “no_patient,” and “heard_relation” poster-patient relationship classes and higher in sadness than the “acquaintances,” “no_patient,” and “heard_relation” poster-patient relationship classes.

Clustered Topics

To gain an overview of why some poster-patient relationship classes were consistently higher in some emotions than other classes, we turned to topic modeling. Using the *topics per class* function of the BERTopic model, we aimed to compare topical relationships that mirrored some of the identified effects from the sentiment analysis.

We initially found that 139 topics were automatically generated from BERTopic, but this included several topics of low significance, where post counts numbered less than 50. As we wanted to focus on topics of greater relevance, we narrowed our analysis to include only the top 30 (21.6%) topics by topic prevalence across the entire data set, which was sufficient to cover more than 6000 (58.1%) posts. In Table 7 and in Table S2 in Multimedia Appendix 3, we list the top 30 topics with top 30 representative terms and provide a summarized theme for each topic. These are represented by an ID, which represents the ranked prevalence of each topic, while the topic number represents the topic labels assigned for the initial generation. We also visualized the distribution of (poster-patient relationship) classes per topic, which was used to identify topics that were more prevalent in a particular class for the analysis. These visualizations are available in our GitHub repository [37].

Table 7. Top 30 terms of top 30 topics from topic modeling.

ID	Topic number	Label	Top 30 representative words (Chinese)	Top 30 representative words (translated into English)
0	0	Anger	生气,脾气,气死我了,情绪,真的	angry, temper, I'm angry, emotions, really
1	1	Laments	去世,家里,回来,生活,记得	passed away, at home, come back, life, remember
2	3	Symptoms	乳腺,乳房,肿块,增生,结节,	breast, breast, lump, hyperplasia, node
3	4	Hospital stays	医生,病人,主任,医院,手术	doctor, patient, director, hospital, surgery
4	7	Hope and prayers	希望,幸福,生活,人生,幸运	hope, happiness, life, life, lucky
5	6	Hospitalization	手术,医院,化疗,住院,医生	surgery, hospital, chemotherapy, hospitalization, doctor
6	8	Lamenting hospitalization	病房,医院,病人,恐惧,患者	ward, hospital, patient, fear, patient
7	2	Dreams and nightmares	梦里,梦见,梦到,昨晚,做梦	dream, dreaming, dreaming, last night, dreaming
8	10	Diagnosis	一年,手术,去年,确诊,希望	a year, surgery, last year, diagnosed, hope
9	5	Chinese dramas	刘静,女主,男主,欢喜,英子	Liu Jing, heroine, hero, cheerful, Yingzi
10	13	School	老师,学生,家长,班主任,上课	teacher, student, parent, classroom, lesson
11	20	Friends	朋友,闺蜜,离婚,聊天,命理	friend, bestie, divorce, chat, numerology
12	18	Sleep-wake cycles	熬夜,睡觉,晚上,睡不着,睡着	stay up, sleep, night, sleepless, sleep
13	12	Passing	去世,消息,难过,死者,刚刚	passed away, news, sad, deceased, just
14	26	Treatment processes	放疗,化疗,结束,治疗,转移	radiotherapy, chemotherapy, end, treatment, metastasis
15	33	Treatment effects	治愈,治疗,方案,效果,患者	cure, treatment, protocol, effect, patient
16	113	Appeal to emotion	开心,心情,事情,几率,难过	happy, mood, things, odds, sad
17	42	Initiative	面对,压力,生活,健康,人生	face, pressure, life, health, life
18	11	*A Little Red Flower* (a popular Chinese movie released in 2020)	小花,一朵,千惠,小红花,病魔	little flower, a, Chie, little red flower
19	45	Suspicion of breast cancer	怀疑,焦虑症,返祖,胸痛,检查	suspicion, anxiety, revert, chest pain, examination
20	48	Other cancers	肺癌,肝癌,胃癌,肠癌,吸烟	lung cancer, liver cancer, stomach cancer, bowel cancer
21	64	Anxiety	焦虑,担心,烦躁,考研,心情	anxiety, worry, irritable, exam, mood
22	17	Metastasis of cancer cells	转移,癌症,癌细胞,患者,闫宏微	transfer, cancer, cancer cells, patient, Yan Hongwei
23	22	Weibo follows	关注,微博,抗癌,荔枝,记录	concern, microblogging, anti-cancer, lychee
24	23	Weibo usage	微博,媽媽,努力做到,更新,不想	microblogging, mom, trying to do, update, don't want
25	85	Treatment side effects	头发,假发,化疗,光头,掉头发	hair, wig, chemotherapy, bald, lose hair
26	27	Check-up	姐夫,电话,昨天,医生,回去	brother-in-law, phone, yesterday, doctor, go back
27	63	Female physiology	没事,预防,增生,例假,一去	Nothing, prevention, hyperplasia, period, a go
28	9	Public figures	陈晓旭,李明,伤官,林黛玉,李婷	Chen Xiaoxu, Li Ming, hurt official, Lin Daiyu, Li Ting
29	58	Treatment stages	化疗,第二次,第三次,结束,白细胞	chemotherapy, second, third, end, white blood cells

Notable Topics

Negative Emotions and Anger

The sentiment analysis suggested that the “no_patient” class had consistently higher negative emotions and anger than all other poster-patient relationship classes. Next, we examined the top 30 topics to identify topics with a similar pattern, which were topics 0, 2, 3, 18, 13, 23, 42, 45, 48, 64, and 113. These spanned a number of overlapping themes. Topic 0, for example, contained terms that directly expressed anger and also appeared to carry the speculation that anger is a cause of breast cancer. Similarly, topics 42, 64, and 113 comprised emotive posts about being positive or hopeful in the face of breast cancer, as well as the anxiety and stress it causes. Posts on topics 3, 48, and 63 contained physiological and medical terms, particularly cancer-related terms, their comorbidities, and their antecedents, and posts on topic 45 appeared to express anxiety at the poster facing a possible cancer diagnosis. Finally, topics 2 and 18 contained posts about the user having a nightmare about breast cancer while sleeping, and topics 13 and 20 were about cancer in everyday life. A guiding theme for these topics is that they seem to relate to the posters’ fears and anger toward cancer in general.

Sadness and Anxiety

Topics 26 and 58 resembled the patterns of relationship classes for sadness and anxiety, in that with the exception of the “post_user” class, the “family_members” class was more prevalent than the other poster-patient relationship classes. These topics shared a common theme, in that they discussed treatment options for breast cancer (eg, chemotherapy, immunotherapy). One explanation could be that immediate family members, as caregivers, were more concerned about breast cancer treatment.

Error Analysis for Machine Learning Classification

Although our classifiers predicted posts well to some extent, we noticed that some cases were mistakenly classified into other categories, according to the metrics from Tables 3 and 6. To explore the possible reasons behind this misclassification, we implemented error analysis.

We found that 1 common reason for these errors was when the patient in a post was unclear and what they said needed to be inferred through semantic understanding. In Table S3 in Multimedia Appendix 4, for example, in post I, the breast cancer patient in the post was the post author (we inferred that the patient should be the poster from reading the post), so according to our classification definition, the true label would be “post_user,” but the predicted label from our classifiers was “acquaintances.” We think that this could be attributed to a mention of a colleague at the beginning of the post and was mistakenly classified into the “acquaintances” class instead. We observed another reason for errors was when the patient was clearly mentioned but there were multiple other actors mentioned in the post as well. Such appearances can greatly affect the classifiers’ prediction. In post II, based on our understanding, the patient appeared to be the poster, but there were many other family members present (eg, father, baby, son, daughter-in-law, granddaughter, grandma). Therefore, post II was mistakenly classified into the “family_members” class instead of the “post_user” class.

Discussion

Principal Findings

Step 1: Poster-Patient Relationship Classification

We fine-tuned the pretrained language model Chinese RoBERTa on our annotations on poster-patient relationships to construct a classification model capable of identifying patients’ relationships with the posters of Weibo posts concerning breast cancer. We subsequently used those classifiers to implement a 2-stage classification process. Both classifiers performed well, and we were generally able to classify poster-patient relationships with moderate-to-high accuracy. This comprised step 1, the poster-patient relationship classification, which was essential to our research question of examining differing Weibo posting styles across poster-patient relationships.

Step 2: Principal Results for Sentiment Analysis and Topic Modeling

In step 2, we used sentiment analysis to compare emotion expressiveness across the 6 poster-patient relationship classes, followed by topic modeling to connect topic content with the emotional difference among identity categories in order to gain an overall understanding. Although this offers only an approximate attempt to interpret the findings of the sentiment analysis, it nevertheless offers an early window into how Weibo posts on breast cancer differ according to the relationship the patient has with the poster. Here, we remind readers that (1) sentiment analysis was calculated based on broad trends in emotion categories, in that for a specific emotion category, having a higher performance in a relationship class meant that it had a higher frequency across all data, and (2) the distribution of topics per class was performed using the corresponding frequency number of each category across all data, which effectively presented the participation for each relationship class in each topic. In other words, among the 6 relationship classes, the correspondence between each relationship class for each emotion category and the correspondence between each relationship class for each topic can only approximately connect both results to contextualize the emotion from the topic when the relevance is consistent. It does not, however, directly represent the actual relationships between topics and emotion terms, so we caution readers against overinterpreting these results.

Anger and Negative Emotions in “no_patient” Posts

One strong result observed from the sentiment analysis was that “no_patient” posts were consistently higher on anger and negative emotions in general. Considering the topics that are more closely associated with the “no_patient” posts, our interpretation is that posts that omit explicit mentions of patients could indicate the poster’s apprehension, anxiety, or anger toward breast cancer. For example, this could come in the form of a rant. Ranting on social media is a common behavior for expressing stress and dissatisfaction with certain aspects of life. For some users, ranting on a social media platform encourages social support from other users [38] and is therefore more preferable than ranting in closed media (eg, a diary). Second, ranting on social media has a cathartic effect on the individual with regard to anger reduction [39]. This may thus be a constructive outlet [40] for posters to reduce their negative emotions when feeling particularly angry or anxious toward breast cancer. In these types of posts, we think that the poster may omit explicit mentions of the patient, as these posts are not necessarily of an autobiographical nature but of an expressive nature instead (eg, flow-of-thought writing) and may occur in any situation in which the poster may have a reason to be angry at cancer. For example, posters may be angry at a diagnosis (or prospect) of cancer in themselves or their loved ones, or they may be angry at the problems in society that arise from cancer and associated treatments, which do not necessarily need a target patient.

Sadness and Anxiety in “family_members” Posts

In contrast, sadness and anxiety were consistently higher in posts where close family members (eg, parents) were the patients. This also corresponded with more mentions of treatment options. Past research has documented the significant emotional burden placed on close family members as caregivers of patients with cancer [41]. Moreover, this could be exacerbated by cultural factors: family members are more closely linked to the concept of the self in China, which is largely consistent with interdependent self-construal and collectivistic cultural orientation [42]. In Chinese society, the burden of caregiving often falls to family members, such as adult children [43]. Moreover, (lack of) familial support has been linked to depression and loneliness in elderly Chinese, suggesting the importance of family ties as relational aspects of one’s well-being (eg, interdependent happiness [44]). This may explain the greater mentions of treatment options, and the sadness and anxiety, in Weibo posts where the patient was identified as a family member of the poster; the patient was considered relationally closer and more important to their self-identity, and the poster would also more likely be engaged in caregiving.

This could also be a unique cultural aspect of Chinese individuals. Previous studies have shown that American individuals (elderly) have more independent self-construal, and familial ties, being obligatory, are often less important to the self than friendship ties [44,45]. However, more research is needed to examine similar posts on Western social media platforms for proper cross-cultural examination.

Implications and Future Directions

Our research identified how emotion expression and content change according to the poster’s relationship with the patient, and aligns closely with past research on the stresses and risks family caregivers face for depression and anxiety disorders [36]. This is particularly exacerbated in Chinese culture, where the strain of caregiving is often intensified through cultural norms surrounding filial piety [46]: this means that caregivers often must maintain a patient and positive outlook when interacting with their patients so as not to put an additional burden on the patients. Moreover, discussions about cancer are often seen as taboo in Chinese society, so caregivers cannot easily access social support from their friends and family. However, as social media provides an opportunity for sharing experiences and outreach, it holds immense potential for community building and social support, particularly for familial caregivers (see Ref. [47]). Therefore, we think that social media opens up new opportunities for caregivers (and patients) to seek social support, with reduced fears of breaking social norms and facing judgment from their community. This may even be above and beyond the benefits of social media–based social support in comparatively open Western societies, and we encourage further studies to examine how Chinese internet spaces should be designed to facilitate such social support.

Limitations

To obtain our target data set (long narratives pertaining to breast cancer), we needed to contextualize our initial Weibo queries with additional keywords, in this case “sadness.” Although this enhanced the quality of our data set, it would have biased the data toward more negative sentiments. Nevertheless, despite the overt bias toward negative posts in our sample, significant differences were still observed in poster-patient relationship classes.

During our classification process, we constructed 2 classifiers based on language models. For the binary classifier, the model reached an F_1-score of 0.9, and for the multiclass classifier, the model reached an F_1-score of 0.8 on average. Although these values are good, there is still some room for improvement for our classifiers. One possibility would be to use a better model for multiclass classification.

In sentiment analysis, we implemented a LIWC-based tool based on the lexical matching of terms for word frequency. Moreover, since only 5 broad affective categories (positive emotions, negative emotions, anger, anxiety, and sadness) were included in this tool, we focused only on these in our study. We think that with newer and more powerful sentiment analysis tools and a larger number of affect categories, the accuracy and granularity of sentiment analysis can be further improved for more valuable insight from the text corpus.

For topic modeling, we used the BERTopic tool to cluster topics, and we found that all the generated topics only had subtle distinctions, which led to several overlaps in similar content among topics. For a better understanding of topics, a qualitative assessment of posts would have yielded deeper insights into the data, but this would not have been practical, given the size of the data set.

Conclusion

In this paper, we studied breast cancer–related narratives on the Chinese social media platform Weibo. Using a pretrained transformer language model (Chinese RoBERTa) as the base model, we fine-tuned 2 models on an annotated subset of the data to classify poster-patient relationships in those posts in a sequential process. Ultimately, we classified all posts according to the identified poster-patient relationships (post_user, family_members, friends_relatives, acquaintances, heard_relation, or, if no patient was identified, no_patient).

Next, we implemented sentiment analysis. We used the Chinese LIWC lexicon to examine the sentiment among 6 categories, focusing on positive emotions, negative emotions, anger, anxiety, and sadness. Through statistical comparisons, we found that emotional expressions present differences among different poster-patient relationship classes. For example, the “no_patient” class had a significantly higher level of anger compared to other classes.

To contextualize these results, we also conducted topic modeling using BERTopic. This showed that posts had different topical content according to the different poster-patient relationships. For example, the “no_patient” class presented more anger in the discussions, while the “family_members” class showed more care for hospitalization and treatment. In sum, our results indicate that patient-poster relationships show differing content and language on Weibo.

Acknowledgments

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Data Availability

As data contain social media posts that may be linked to individuals, data will be made available upon request to the authors.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Annotation sample.
[DOCX File , 18 KB - cancer_v10i1e51332_app1.docx]

Multimedia Appendix 2
Examples of automatic summarization of long Weibo posts.
[DOCX File , 37 KB - cancer_v10i1e51332_app2.docx]

Multimedia Appendix 3
Top 30 terms of top 30 topics from topic modeling.
[DOCX File , 31 KB - cancer_v10i1e51332_app3.docx]

Multimedia Appendix 4
Examples of error analysis.
[DOCX File , 15 KB - cancer_v10i1e51332_app4.docx]

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Abbreviations

BERT: Bidirectional Encoder Representations from Transformers
DSCF: Dwass-Steel-Critchlow-Fligner
LIWC: Linguistic Inquiry and Word Count
NLP: natural language processing
RoBERTa: A Robustly Optimized BERT Pretraining Approach
WHO: World Health Organization

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Original Paper

Evaluating the Quality of Cancer-Related WeChat Public Accounts: Cross-Sectional Study

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Abstract

Background: WeChat (Tencent) is one of the most important information sources for Chinese people. Relevantly, various health-related data are constantly transmitted among WeChat users. WeChat public accounts (WPAs) for health are rapidly emerging. Health-related WeChat public accounts have a significant impact on public health. Because of the rise in web-based health-seeking behavior, the general public has grown accustomed to obtaining cancer information from WPAs. Although WPAs make it easy for people to obtain health information, the quality of the information is questionable.

Objective: This study aims to assess the quality and suitability of cancer-related WeChat public accounts (CWPAs).

Methods: The survey was conducted from February 1 to 28, 2023. Based on the WPA monthly list provided by Qingbo Big Data, 28 CWPAs in the WeChat communication index were selected as the survey sample. Quality assessment of the included CWPAs was performed using the HONcode instrument. Furthermore, suitability was measured by using the Suitability Assessment of Materials. A total of 2 researchers conducted the evaluations independently.

Results: Of the 28 CWPAs, 12 (43%) were academic and 16 (57%) were commercial. No statistical difference was found regarding the HONcode scores between the 2 groups (P=.96). The quality of the academic and commercial CWPAs evaluated using the HONcode instrument demonstrated mean scores of 5.58 (SD 2.02) and 5.63 (SD 2.16), respectively, corresponding to a moderate class. All CWPAs’ compliance with the HONcode principles was unsatisfactory. A statistically significant difference between the 2 groups was observed in the Suitability Assessment of Materials scores (P=.04). The commercial WPAs reached an overall 55.1% (SD 5.5%) score versus the 50.2% (SD 6.4%) score reached by academic WPAs. The suitability of academic and commercial CWPAs was considered adequate.

Conclusions: This study revealed that CWPAs are not sufficiently credible. WPA owners must endeavor to create reliable health websites using approved tools such as the HONcode criteria. However, it is necessary to educate the public about the evaluation tools of health websites to assess their credibility before using the provided content. In addition, improving readability will allow the public to read and understand the content.

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KEYWORDS

cancer; big data; social media; health literacy; WeChat; China; public health

Introduction

According to the International Agency for Research on Cancer (IARC), cancer is the first or second leading cause of premature mortality in over 90 countries. China accounts for 23.7% of global new cases and 30% of deaths. In China, the age-standardized incidence and mortality rates of all cancers were 201.7 per 100,000 and 130.1 per 100,000 in 2018, respectively [1]. In recent decades, the cancer burden in China has increased, posing a serious threat to public health.

Moreover, with the rapid development of the internet, social media has remarkably changed people's lifestyles [2]. Similar to Facebook, WeChat, released in 2011 by Tencent Inc, has become the most widely used social networking platform in China, reporting 1299 million users in 2022 [3]. WeChat public accounts (WPA) are application accounts supplied by administrators that can be used for communication and interaction with specific groups via text, pictures, videos, and so forth. Members can follow the WPAs of interest to receive relevant information or messages. In early 2020, more than 1 million papers were posted daily on WeChat [4]. WeChat is one of the most important sources of information for the Chinese public. Pertinently, various health-related information is continuously transmitted among WeChat users. Health-related WeChat public accounts (HWPAs) are being rapidly developed [5]. HWPAs have an important impact on public health status. Although it is convenient for people to obtain health information from WPAs, the quality of the health information is questionable [6]. Therefore, it is important to evaluate the quality of the HWPAs. Previous studies have explored the use of WPAs in health education [7-9]. However, few have focused on the quality of HWPAs. Wang et al [10] examined 93 HWPAs to evaluate their quality and found that they were substandard according to the Net Foundation Code of Conduct (HONcode) conformity. Furthermore, there is still a lack of general understanding regarding the quality of cancer-related WeChat public accounts (CWPAs). Owing to increasing web-based health-seeking behaviors, the public has become accustomed to obtaining cancer information through WPAs. Therefore, this study was conducted to evaluate the quality of CWPAs. Our study aims to assess the quality and suitability of CWPAs.

Methods

Data Collection

The data used in this study were derived from the Qingbo Big Data platform, the largest third-party evaluation platform for new media in China. Qingbo Big Data Technology Co, Ltd (Beijing, China) was established in October 2014. The company provides big data technology services to the Chinese government, top Chinese news media, and large multinational enterprises [11]. The WeChat communication index (WCI), proposed by Qingbo Big Data, is the most widely used standard for evaluating the influence of WPAs [10]. The WCI comprises 4 primary indicators (the overall paper spread rate, average spread rate of each paper, title spread rate, and peak spread rate), 8 secondary indicators, and a set of calculation formulas for standardized scores [12]. A higher WCI value indicates a larger WPA influence. We searched for new media in the cancer category of the WPA monthly list (February 1 to 28, 2023) provided by Qingbo Big Data. The CWPAs in the WCI were selected as the survey sample. The exclusion criteria for CWPAs were as follows: (1) having been completed for commercial purposes, and (2) no papers released during the survey period. As a result, 18 CWPAs were excluded according to the criteria. Finally, 28 CWPAs were included in this study (Multimedia Appendix 1). We analyzed 1503 papers released by each CWPA on the survey dates.

Evaluation Tools

Quality assessment of the included CWPAs was performed using the HONcode instrument. Health on the Internet is an independent organization that provides health information guidelines for websites based on 8 principles: authoritativeness, complementarity, privacy, attribution, justifiability, transparency, financial disclosure, and advertising policies [13] (Multimedia Appendix 2). The introduction of the HONcode in 1996 was a milestone for web-based health information, as evidenced by the numerous references to the HONcode in the Health Informatics literature. The HONcode has often been used as a major indicator of content accuracy in scientific studies [14]. As CWPAs are used to disseminate cancer-related health knowledge to the public, these WPAs should also comply with the HONcode principles. Thus, we believe analyzing the credibility and reliability of the information on CWPAs using the HONcode instrument is appropriate. We adopted a similar HONcode scoring system to that previously published [15]. For each CWPA, the respect or no respect to each HONcode principle was scored as 0 (nonconformity) or 1 (conformity). As a result, the quality of the CWPAs was classified as low (HONcode 0-2), moderate (HONcode 3-5), or high (HONcode 6-8).

The Suitability Assessment of Materials (SAM) created by Doak et al [16] was designed to assess educational material. Applying the SAM can pinpoint specific deficiencies in suitability, and if the material is still in the developmental stage, these deficiencies can be corrected. The SAM comprises 22 criteria in 6 categories: content, literacy demand, graphics, layout and typography, learning stimulation and motivation, and cultural appropriateness (Multimedia Appendix 3). Within these categories, according to how well they meet the criteria for each item, individual items are rated as follows: not applicable, 0 (not suitable), 1 (adequate), or 2 (superior). The sum of the ratings obtained was divided by the total possible score and transformed into percentages. A total of 3 levels are used to categorize the percentage score: 70%-100%, "superior"; 40%-69%, "adequate"; and 0%-39%, "not suitable" [16]. The SAM has been tested and validated in individuals of various cultural backgrounds [17]. In a study by Chang et al [18], the SAM was proven valid and reliable for evaluating the suitability of health-education materials in Chinese. Therefore, in this study, we used the SAM to evaluate health information released by CWPAs. These CWPAs were classified into academic WPAs and commercial WPAs according to a study by Valizadeh-Haghi et al [19]. The findings of this study revealed that there was a significant association between the website category and the credibility of health websites.

A total of 2 researchers conducted the evaluations. These 2 raters independently evaluated CWPAs' compliance with the principles of the HONcode and the suitability of the papers released by the CWPAs using the SAM scale. Any controversial assessment results were resolved through real-time negotiations. Cohen κ test assessed interrater reliability, with a score of 0.83 indicating almost perfect agreement [20].

Statistical Analysis

Statistical analysis was performed using SPSS (version 26.0; IMB Corp). Numerical variables are reported as mean (SD) or median (IQR) values. We tested the normality of the distribution of the numerical variables using the Shapiro-Wilk test before proceeding with a parametric or nonparametric test. Parametric variables were compared using the Student *t* test and nonparametric continuous variables were evaluated with the Mann-Whitney *U* test. Categorical variables were presented as numbers (n) and percentages (%). Fisher exact test was used to compare categorical variables. Statistical significance was set at *P*<.05.

Ethical Considerations

According to Article 32 of the ethical review guideline of life science and medical research, which was issued by the National Health Commission of the People’s Republic of China on February 18, 2023, because only publicly available data were involved in our study, the ethical review could be exempted [21]. All data were anonymized.

Results

Characteristics of the CWPAs

The general characteristics of the CWPAs are listed in Table 1. Of the 28 CWPAs, 12 (43%) were academic and 16 (57%) were commercial. A statistically significant difference between the 2 groups was observed in the SAM scores (*P*=.04). The commercial WPAs reached an overall 55.1% (SD 5.5%) score versus the 50.2% (SD 6.4%) score reached by academic WPAs. The suitability of academic and commercial CWPAs was considered adequate. Statistical differences were also found regarding views (*P*=.04), likes (*P*=.03), and WCI (*P*=.03). Notably, the numbers of views, likes, and WCI were higher for commercial WPAs than for academic WPAs. Although no statistical difference was found regarding the HONcode scores between the 2 groups (*P*=.96), commercial WPAs seemed more compliant than academic WPAs. The quality of the academic and commercial CWPAs evaluated using the HONcode instrument demonstrated mean scores of 5.58 (SD 2.02) and 5.63 (SD 2.16), respectively, corresponding to a moderate class.

Table 1. Analysis of cancer-related WeChat public account characteristics by ownership.

Characteristics	Academic CWPAs[a]	Commercial CWPAs	*P* value
Number of papers	322	1181	N/A[b]
Number of views, median (IQR)	59,109 (1534.2-60,643.2)	420,237.75 (19,762-439,999.75)	.04
Number of likes, median (IQR)	226.25 (5.25-231.5)	1640.25 (82.75-1723)	.03
WCI[c], mean (SD)	453.57 (255.46)	700.09 (300.20)	.03
HONcode scores, mean (SD)	5.58 (2.02)	5.63 (2.16)	.96
SAM[d] scores (%), mean (SD)	50.2 (6.4)	55.1 (5.5)	.04

[a] CWPA: cancer-related WeChat public account.

[b] N/A: not applicable.

[c] WCI: WeChat communication index.

[d] SAM: Suitability Assessment of Materials.

Health on the Net Foundation Code of Conduct Conformity

The HONcode compliances of the 28 CWPAs according to ownership are listed in Table 2. Except for the advertising principle (*P*=.02), there were no statistical differences regarding the other 7 principles between the academic and commercial groups. CWPAs’ compliance with the HONcode principles was not ideal. Most academic and commercial WPAs failed to meet the principles of transparency and financial disclosure (58% vs 62% and 58% vs 69%, respectively). One-third of academic (4/12, 33%) and almost half of the commercial WPAs (7/16, 44%) did not respect this attribution principle. All academic WPAs and 94% (n=15) of the commercial WPAs received a full score on the justifiability principle. Compliance was also uneven for authoritative and complementarity principles. A greater proportion of academic WPAs achieved full scores in the authoritative and complementarity principles (10/12, 83% and 11/12, 92%, respectively), compared with commercial WPAs (11/16, 69%). Finally, only 25% (n=3) of academic WPAs received a full score in the advertising policy principle, compared with commercial WPAs (12/16, 75%); that is, three-quarters of the academic WPAs did not clearly distinguish advertising from editorial content.

Table 2. Evaluating HONcode scores according to ownership.

HONcode principles	Proportion of academic CWPAs[a] with full score (n=12), n (%)	Proportion of commercial CWPAs with full score (n=16), n (%)	*P* value
Authoritative	10 (83)	11 (69)	.66
Complementarity	11 (92)	11 (69)	.19
Privacy	12 (100)	16 (100)	N/A[b]
Attribution	8 (67)	9 (56)	.71
Justifiability	12 (100)	15 (94)	.38
Transparency	5 (42)	6 (38)	.82
Financial disclosure	5 (42)	5 (31)	.69
Advertising policy	3 (25)	12 (75)	.02

[a] CWPA: cancer-related WeChat public account.

[b] N/A: not applicable.

Suitability of Papers From WPAs

Table 3 presents the analysis of the CWPAs' readability using the SAM. Among the 6 categories, a statistically significant difference was found between academic and commercial WPAs in literacy demand (*P*=.02). In most cases, the mean scores of academic WPAs were lower than those of commercial WPAs, except for the cultural appropriateness items. However, no statistical differences were found between the 2 groups regarding content (*P*=.53), graphics (*P*=.07), layout and typography (*P*=.84), learning stimulation and motivation (*P*=.95), or cultural appropriateness (*P*=.78). None of the CWPAs achieved a superior score on the SAM items. The percentages of criteria met in each of the 6 SAM categories ranged from the lowest for learning stimulation and motivation to the highest for content.

Table 3. Evaluating Suitability Assessment of Materials scores of papers on the cancer-related WeChat public account according to ownership.

SAM[a] items	Academic CWPAs[b], mean (SD)	Commercial CWPAs, mean (SD)	*P* value
Content (purpose is evident, content regarding behavior, scope is limited, and summary or review included)	5.08 (0.51)	5.25 (0.86)	.53
Literacy demand (reading grade level, writing style, active voice, vocabulary uses common words, context is given first, and learning aids via "road signs")	4.58 (0.79)	5.56 (1.15)	.02
Graphics (cover graphic shows purpose; type of graphics; relevance of illustrations; list, tables, etc explained; and captions used for graphics)	4.67 (1.15)	5.63 (1.41)	.07
Layout and typography (layout factors, typography, and subheads used)	3.83 (0.58)	3.88 (0.50)	.84
Learning stimulation and motivation (interaction used, behaviors are modeled and specific, and motivation [self-efficacy])	1.67 (0.98)	1.69 (0.79)	.95
Cultural appropriateness (match in logic, language, and experience; cultural image; and examples)	2.25 (0.62)	2.19 (0.54)	.78

[a] SAM: Suitability Assessment of Materials.

[b] CWPA: cancer-related WeChat public account.

In the content category, most WPAs stated their purpose in the titles and contained related information within the necessary scope. However, some (8/28, 28.6%) of the WPAs contained behavior-related context in presenting content; that is, the content mainly included facts about cancers and not guides for readers' behavior or decision-making. Additionally, 14% (n=4) of WPAs did not include a summary or review. Regarding literacy demand, 1 WPA was classified as not suitable, 26 as adequate, and only 1 was superior. The cover graphics for most papers released by the WPAs were rated as superior. However, 68% (n=19) of the WPAs used illustrations inappropriately. Moreover, one-quarter (7/28, 25%) of the papers did not include captions that detailed the information in the tables and graphs. The layouts of most papers received high scores; for example, most were adequate and superior regarding typography and font size. Lower ratings were caused by the tendency to include too much information under the subheadings. The learning stimulation and motivation categories had the lowest ratings. None of the studies provided web-based learning stimulation. The content for behavioral modeling and self-efficacy of 93% (n=26) of the WPAs was adequate or not suitable. Most WPAs (26/28, 93%) were rated as adequate or superior for using positive images and examples for the cultural appropriateness category.

Discussion

Principal Findings

WeChat is the most popular platform for acquiring health information. Health information acquisition via WeChat is more convenient, timely, and cost-effective; moreover, it protects privacy and avoids embarrassment. Furthermore, the technical development of big data and the Internet of Things allows individuals to access, track, and customize health information. To a certain extent, WeChat contributes to greater freedom regarding individual health decisions.

The public encounters problems through the internet via an overload of information. In our study, searching for “cancer” in the Qingbo search engine generated 46 WPAs. Worryingly, the information presented in these WPAs is not sufficiently credible; that is, valid and valuable information is obscured by irrelevant and misleading information. To our knowledge, this was the first study to evaluate the quality and readability of WPAs concerning cancer. Our study mirrored other studies’ findings on various topics [22-24].

The HONcode instrument for health-related web resources has been available for 20 years. A failure to comply with the HONcode criteria indicates that users may encounter websites that are not sufficiently reliable. These websites may contain inaccurate, misleading, and inadequate information, which can influence preventive actions and decision-making regarding cancer treatment choices.

This study’s findings revealed that all CWPAs’ compliance with the HONcode principles was unsatisfactory. Although one could intuit that the information found in academic CWPAs would yield the highest quality information, our study found this was not always true. Specifically, there was no statistical difference between academic WPAs and commercial CWPAs regarding HONcode sum scores and most HONcode categories. Thus, academic institutions must take substantial steps to improve the credibility of their WPAs to comply with the HON principles.

Compliance with the authority criterion reflects the credibility of the information source because this principle proves that the information provided by experts is reliable [25]. In this study, one-quarter (7/28, 25%) of the surveyed CWPAs did not specify the names or expertise of the authors. In a similar study evaluating Persian language health websites on Ebola, the authorities obtained the lowest score [22]. While the public needs sufficient information about the author’s identity to assess the trustworthiness of information, CWPAs must pay more attention to this criterion to increase trustworthiness for their readers. The complementarity aspect of web-based medical information should be clearly stated on health websites as such information is intended to provide support and training for readers and should not be a substitute for direct medical advice [19]. Nevertheless, 21.4% (n=6) of the surveyed CWPAs did not consider this criterion, which may have led to misuse of information. Moreover, CWPAs should describe their privacy policies and define how they handle users’ private information such as email addresses and content. This policy is among the 7 core issues in website usability design and is particularly important for creating effective websites [26]. Satisfactorily, all CWPAs assessed in this study identified their privacy policies. According to the attribution principle, the publication date and most recent content updates should be posted on the website. Adherence to this principle can ensure the credibility of health websites. This study revealed that the attribution principle was considered in more than half (17/28, 61%) of the CWPAs. Nevertheless, 39% (n=11) of the CWPAs did not pay sufficient attention to this principle. The justifiability criterion indicates that any information on a website must support claims regarding the benefits or performance of a particular treatment, medication, or medical device. Overall, in this study, the adherence to the justifiable principle was good. The transparency principle states that when additional information is required, people must be able to connect with content editors and communicate with webmasters. Unfortunately, based on the present findings, this principle was only considered in 39% (n=11) of the CWPAs. Financial disclosure and advertising principles imply that there should be a clear distinction between commercial and scientifically edited content presented on CWPAs. If advertising is a source of funding for a WPA, the financial disclosure policy for presenting such content should be clearly stated. Moreover, failure to comply with advertising policies indicates that individuals may be unable to distinguish advertisement information from the main content. Access to such WPAs may guide readers toward unreliable information that may threaten their health. However, only 36% (n=10) of the surveyed CWPAs considered financial disclosure principles. More importantly, 75% (n=9) of the academic WPAs failed to comply with the advertising policy. In contrast, only 25% (n=4) of commercial WPAs failed to comply with this principle.

The content provided to the public must not only meet the reliability standard but also be at the required reading level that allows people of all educational levels to understand and process information related to their disease and treatment options [27]. Notably, lower overall health literacy is associated with increased complications, hospitalizations, poor understanding of the disease, and increased health care costs [28]. This study determined the CWPAs’ information suitability to be “adequate.” Cultural and linguistic differences inevitably lead to differences in people’s health-related behaviors and understanding of web-based health information. Thus, website owners must consider additional acculturation factors when publishing health information. However, this creates higher requirements for user cultural literacy [11].

Regarding scoring dimensions, most papers published by the CWPAs had appropriate cover pictures and attractive titles that clearly described the paper’s purpose, a good layout and typography, and were culturally suitable. However, the nonstandard use of charts and the lack of charts used as illustrations were common problems. More than half of the papers included pictures with weak relevance to the content of the papers or even harmful overstatements and stereotypical cultural characteristics. In addition, regarding vocabulary, readers had difficulty reading papers generated by professional WPAs because they usually use more scientific terms.

The cultural appropriateness of health-education materials is enhanced when readers view illustrations and graphics that are easily recognizable and depict people similar to themselves and those around them. Many factors affect health care including cultural beliefs and practices [17]. Thus, it is important to consider these factors when designing health education materials.

We are particularly interested in examining the facilitation of self-efficacy. Applying the concept of self-efficacy is an effective means of promoting positive health behaviors and informed decision-making. Self-efficacy theory explains and predicts how people influence their motivation and behavior; to enhance self-efficacy, materials must model the desired behavior using someone similar to the intended audience [17]. Very few of the reviewed materials used appropriate methods to enhance readers' self-efficacy.

Based on our findings, although the suitability of health information released by CWPAs was at a moderate level, the overall quality of accessible information on CWPAs was inadequate. Failure to comply with all HONcode criteria in these CWPAs shows that while searching for WPAs, users will encounter impressive websites, and consequently, low-quality information that can affect their health care practices for cancer. Reliable and readable information is essential for overcoming the potential negative aspects of web-based health information. Providing information in shorter sentences with simple words and using figures or videos may help improve the public's understanding of cancer and cater to people with varying levels of health literacy. This highlights the importance of understanding the quality of CWPAs by providers and guiding the public toward reliable sources. Finally, it is recommended that the papers of CWPAs be subjected to some form of peer review, similar to those used for journal paper submissions, before the final upload. This would create a core set of high-quality, publicly available information.

Limitations

This study has some limitations. The study was conducted between February 1 and 28, 2023; therefore, it does not completely and comprehensively represent other studies conducted at different times. However, owing to the dynamic characteristics of the web, search results vary at different times and places. New websites are constantly being created, while some websites are being disbanded. Second, there are many evaluation indices for WPAs; however, horizontal comparisons of these indices are lacking. We chose the WCI proposed by Qingbo Big Data as the ranking basis for the influence of WPAs, which may have resulted in selection bias. Finally, this study was conducted only on Chinese websites. Therefore, the results of this study may differ from those conducted in other languages.

Conclusions

This study revealed that CWPAs are not sufficiently credible. WPA owners must endeavor to create reliable health websites using approved tools such as the HONcode criteria. However, it is necessary to educate the public about the evaluation tools of health websites to assess their credibility before using the provided content. In addition, improving readability will allow the public to read and understand the content.

Data Availability

The data sets generated or analyzed during this study are available from the corresponding author upon reasonable request.

Authors' Contributions

PP and CY participated in the conceptualization of the paper. TD, HT, XH, and WM conducted the data searches on the internet. JL and WY conducted data evaluation. YX performed statistical analysis. TL critically reviewed the manuscript for important intellectual content. PP structured and wrote the paper. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Raw data of the cancer-related WeChat public accounts.
[XLSX File (Microsoft Excel File), 16 KB - cancer_v10i1e52156_app1.xlsx]

Multimedia Appendix 2
The HONcode principles.
[DOCX File , 17 KB - cancer_v10i1e52156_app2.docx]

Multimedia Appendix 3
The Suitability Assessment of Materials criteria and descriptions.
[DOCX File , 20 KB - cancer_v10i1e52156_app3.docx]

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Abbreviations

CWPA: cancer-related WeChat public account
HWPA: health-related WeChat public account
IARC: International Agency for Research on Cancer
SAM: Suitability Assessment of Materials
WCI: WeChat communication index
WPA: WeChat public account

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Original Paper

Engagement With a Relaxation and Mindfulness Mobile App Among People With Cancer: Exploratory Analysis of Use Data and Self-Reports From a Randomized Controlled Trial

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Abstract

Background: Mobile health (mHealth) apps offer unique opportunities to support self-care and behavior change, but poor user engagement limits their effectiveness. This is particularly true for fully automated mHealth apps without any human support. Human support in mHealth apps is associated with better engagement but at the cost of reduced scalability.

Objective: This work aimed to (1) describe the theory-informed development of a fully automated relaxation and mindfulness app to reduce distress in people with cancer (CanRelax app 2.0), (2) describe engagement with the app on multiple levels within a fully automated randomized controlled trial over 10 weeks, and (3) examine whether engagement was related to user characteristics.

Methods: The CanRelax app 2.0 was developed in iterative processes involving input from people with cancer and relevant experts. The app includes evidence-based relaxation exercises, personalized weekly coaching sessions with a rule-based conversational agent, 39 self-enactable behavior change techniques, a self-monitoring dashboard with gamification elements, highly tailored reminder notifications, an educational video clip, and personalized in-app letters. For the larger study, German-speaking adults diagnosed with cancer within the last 5 years were recruited via the web in Switzerland, Austria, and Germany. Engagement was analyzed in a sample of 100 study participants with multiple measures on a micro level (completed coaching sessions, relaxation exercises practiced with the app, and feedback on the app) and a macro level (relaxation exercises practiced without the app and self-efficacy toward self-set weekly relaxation goals).

Results: In week 10, a total of 62% (62/100) of the participants were actively using the CanRelax app 2.0. No associations were identified between engagement and level of distress at baseline, sex assigned at birth, educational attainment, or age. At the micro level, 71.88% (3520/4897) of all relaxation exercises and 714 coaching sessions were completed in the app, and all participants who provided feedback (52/100, 52%) expressed positive app experiences. At the macro level, 28.12% (1377/4897) of relaxation exercises were completed without the app, and participants' self-efficacy remained stable at a high level. At the same time, participants raised their weekly relaxation goals, which indicates a potential relative increase in self-efficacy.

Conclusions: The CanRelax app 2.0 achieved promising engagement even though it provided no human support. Fully automated social components might have compensated for the lack of human involvement and should be investigated further. More than one-quarter (1377/4897, 28.12%) of all relaxation exercises were practiced without the app, highlighting the importance of assessing engagement on multiple levels.

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KEYWORDS

mobile health; mHealth; digital health; eHealth; smartphone; mobile phone; implementation; adherence; self-guided; unguided; fully automated; conversational agent; chatbot; behavior change; tailoring; self-care; cancer; app development

Introduction

Background

Mobile health (mHealth) apps offer unique opportunities to deliver self-care interventions and support behavior change, but poor user engagement and retention rates pose substantial challenges. mHealth apps are a convenient approach to facilitate behavior change with the potential to reach large numbers of people [1-3]. However, in the same manner that mHealth apps provide easy access with a low barrier to start an intervention, they also provide a low barrier to stop using an intervention, turning a great advantage of mHealth apps into a fundamental challenge [2]. Low engagement is problematic because mHealth apps that support healthy behaviors can only be effective if people take an active role, learn the necessary skills to change their behavior, and apply the skills to everyday life, making engagement a pivotal prerequisite to health behavior change [4-8]. In studies using mHealth apps, poor engagement can also confound the outcome and impact the validity of the results as study dropouts may differ from completers [2,9]. While many mHealth apps have significant issues with sustained engagement [10-17], this is particularly true for fully automated mHealth apps without any human support, also termed unguided or self-guided mHealth apps. A high level of human support in guided mHealth apps is typically associated with better engagement rates but at the cost of reduced scalability [18,19]. Hence, to increase the effectiveness of behavior change interventions and improve mHealth studies, it is critical to better understand what makes people stay engaged with mHealth apps [2,20-22] and especially with fully automated mHealth apps as the latter are more likely to be disseminated widely [23].

User engagement has been conceptualized differently across disciplines, but there is a consensus that engagement with an mHealth app needs to be examined on different levels [7,24]. The different levels stem from the crucial distinction between moment-to-moment engagement with the intervention at the *micro* level (ie, app use and user experience) and engagement with the broader intervention goal at the *macro* level (ie, target behavior) [5,7]. The micro and macro levels are closely interlinked, and engagement at the different levels can vary over time [5]. For example, during the initial use phase of mHealth apps, moment-to-moment engagement with the app may serve as preparation for behavior change. In a later phase, when people apply the skills they learned to everyday life, use of the app may no longer be required for engagement with the targeted behavior. Hence, reduced app use could be a sign of success rather than failure [2], highlighting the importance of comprehensively assessing engagement.

Most mHealth studies assess engagement with system use data at the micro level but do not consider engagement measures at the macro level. At the micro level, system use data such as the number of log-ins or the amount and type of content used are frequently applied as the only measure of engagement with an mHealth app. However, although system use data undoubtedly provide valuable information on certain aspects of microlevel engagement, these data are not considered a valid measure of engagement on their own [24]. Greater efforts are needed to combine different data sources, such as pairing system use data with self-report data or qualitative methods, to better understand the user experience [5,6,17,24]. At the macro level, assessing engagement remains a challenge and is often neglected in mHealth studies. To support research in this area, recent reviews have provided a valuable overview of available measures for exploring engagement in the behavior change process in daily life [5,6,24]. The listed measures to assess macrolevel engagement include sensor data to track behavior in real-life settings, analysis of social media patterns, and the repeated assessment of psychological constructs that are hypothesized to be important determinants of behavior change (eg, self-efficacy) [24]. Changes over time in psychological constructs such as self-efficacy could indicate engagement in the behavior change process [24]. Given the complexity of engagement as a construct, other measures of macrolevel engagement might be useful depending on the specific research context. Thus far, little research has been conducted applying these or other measures at the macro level of engagement and exploring their use in an mHealth behavior change setting [24].

Objectives

We examined engagement at both a micro and a macro level with a newly developed relaxation and mindfulness app to reduce distress in people with cancer (CanRelax app 2.0) within a fully automated randomized controlled trial (RCT) over 10 weeks. The CanRelax app 2.0 is based on a first app version piloted in a feasibility study [25] and now includes more relaxation resources, a conversational agent, gamification elements, and 39 behavior change techniques (BCTs) translated into designed app features. The aims of this paper were to (1) describe the theory-informed development of the CanRelax app 2.0, (2) describe engagement with the app over 10 weeks as total app use and user feedback (micro level) and as self-efficacy and reported relaxation practices without using the app (macro level), and (3) examine whether engagement was related to user characteristics.

Methods

Study Design

The presented data originated from a larger RCT with an additional nonrandomized third arm. The study aimed to evaluate the effectiveness of the CanRelax app 2.0 in reducing distress in people with cancer who experience high distress compared with a waitlist control group. The primary end point was distress after 10 weeks assessed using the Patient Health Questionnaire Anxiety and Depression Scale [25]. Secondary outcomes were well-being (5-item World Health Organization Well-Being Index [26]), self-regulation (Multidimensional Assessment of Interoceptive Awareness Self-Regulation subscale [27]), and the course of distress over time (4-item Patient Health Questionnaire [28] and Distress Thermometer [29]; Multimedia Appendix 1 [25-31]). Eligible participants who self-reported high distress at baseline (Distress Thermometer score of ≥5 [29]) were randomized using 1:1 block randomization stratified by sex; those who self-reported low distress at baseline (Distress Thermometer score of <5 [29]) were included in a third arm as a nonrandomized intervention group to further explore user engagement. This nonrandomized intervention group received immediate access to the app (the same app as the randomized intervention group); the waitlist control group received full access to the app after 10 weeks. All groups were allowed to continue usual care and other interventions (including self-care interventions) as needed. As per sample size calculation, the target sample size was 210 participants in the randomized study arms (105 per arm); the sample size was not predefined for the nonrandomized third arm. The study was registered a priori at the German Clinical Trials Register (DRKS00027546; registration date: February 23, 2022). For this paper, data were taken from participants randomly assigned to the intervention group and participants assigned to the nonrandomized third arm. Further information on the study design and assessments is provided in Multimedia Appendix 1 [25-31]. The results of the RCT will be reported elsewhere.

Inclusion Criteria

People were eligible to participate in the study if they (1) had received a cancer diagnosis within the last 5 years regardless of the type of cancer or stage at diagnosis, (2) were aged ≥18 years, (3) were fluent in German, (4) had a smartphone with regular internet access, and (5) gave informed consent to participate in the study. The exclusion criteria were suicidal ideation and known pregnancy according to participants' self-reports. For this study, we analyzed an exploratory sample of the first 100 study participants who received full access to the CanRelax app 2.0 at inclusion. This corresponds to the sample needed to detect a meaningful difference (effect size d=0.8) in engagement between subgroups (high, 67/100, 67%, vs low, 33/100, 33%, distress) with a power of 0.95 (α=.05). The study was advertised for distressed individuals with cancer. Hence, we expected more high-distress than low-distress participants and assumed a ratio of approximately 2:1. Participants were excluded from the analysis if they withdrew from the study and requested that we exclude their data. In these cases, we included the next participant who received full access to the app at inclusion so that we had data from 100 participants for analysis.

Recruitment Procedure

We launched the app in July 2022 through the Apple App Store and Google Play Store in Switzerland, Germany, and Austria. At the same time, we established a project website to facilitate recruitment. The website presented a summary of the study with key information such as the eligibility criteria, pictures of the app, and audio samples. It also included QR codes containing web links to the CanRelax app 2.0 in both app stores. We used social media sites (ie, Facebook, Twitter, and LinkedIn) and more traditional approaches (eg, consultations with health care providers, printed flyers, newsletters, and a press release by the University Hospital Zurich) to recruit study participants. Interested individuals could download the app free of charge and start by completing the app onboarding process as a first introduction to the app and the study. From the beginning, users were explicitly informed that they were interacting with a conversational agent, not a person. All study processes were fully automated; screening questions, study information and consent, enrollment, data collection, and all steps up to completion of follow-up were managed entirely through the CanRelax app 2.0. Participants had no contact with the research team at any time during the study unless they contacted the research team to ask questions before consenting or in case of technical issues. The RCT completed recruitment successfully in February 2023. Data collection was ongoing at the time of writing this paper.

Intervention

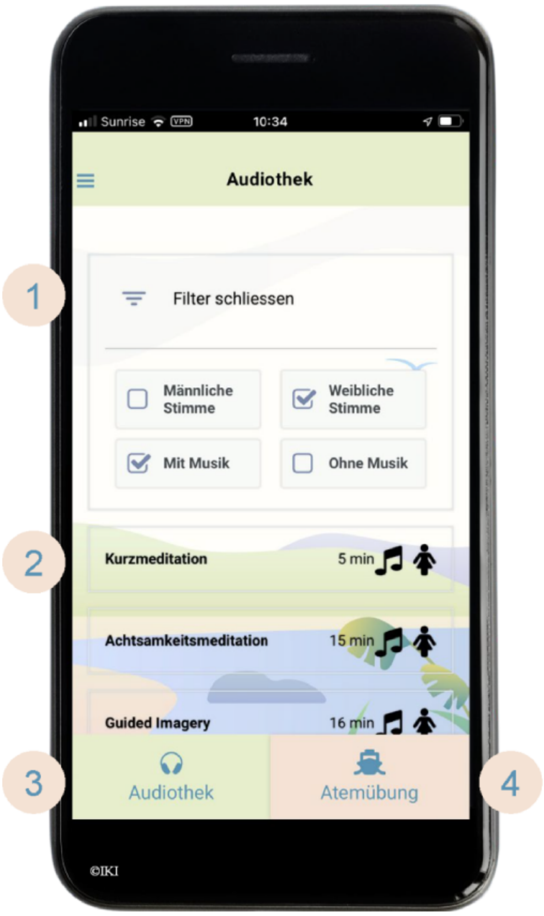
Overview

The intervention was a fully automated mHealth app designed specifically to improve distress in adults with cancer through one type of self-care behavior (relaxation). Participants had access to the CanRelax app 2.0 over 20 weeks (10 weeks of intervention and 10 weeks of follow-up). On day 1, participants selected an outcome goal from a 5-item list in the app, including "find inner peace" (default if no choice was made), "improve coping strategies," "build self-confidence," "increase joy in life," and "just curious." Participants were periodically reminded of this goal during the intervention, and it was displayed in the dashboard of the app. During the intervention, participants could also set weekly relaxation goals in terms of a targeted number of relaxation exercises per week (with 1 exercise per week at minimum and a default of 3 exercises per week irrespective of the type of exercise). Weekly coaching sessions with a text-based conversational agent called Lumy provided motivational input for effective and lasting behavior change (integration of relaxation into daily life). Participants were encouraged to set small, realistic relaxation goals for themselves, choose and practice any relaxation exercise at their convenience to meet their goals, and chat with Lumy each week. The minimum expectation for participation in this intervention was completing at least one relaxation exercise and one coaching session per week over the 10-week intervention period.

Technical Implementation of the CanRelax App 2.0

The app was built using MobileCoach (version 21.9.1), an open-source software platform for digital biomarker and health intervention research [32,33]. Conceptually, the app implements the Talk-and-Tools paradigm, which was applied successfully in the domain of mHealth behavior change interventions [34]. The app offers a user interface with a conversational agent (the *talk*) and a broad range of *tools* (Multimedia Appendix 2). Our conversational agent Lumy is visually represented by a neutral (nonhuman) avatar (Multimedia Appendix 3). By choosing a nonhuman avatar, we aimed to create an inclusive experience for all app users and followed best practices and design principles of popular commercial mindfulness and relaxation apps (eg, Headspace). The tools include evidence-based relaxation exercises, a self-monitoring dashboard with metrics on participants' goals and progress, an educational video clip, personalized in-app letters, frequently asked question (FAQ) sections on the mechanisms and benefits of relaxation as well as on creating healthy habits, and tailored reminder notifications to support regular relaxation practice and engagement with the app. Screenshots of the app can be found in Figures 1-3.

Figure 1. Screenshot of the CanRelax app 2.0—resource library with relaxation exercises. (1) Filter for exercise characteristics (male or female voice with or without background music), (2) search results (can be scrolled for further exercises), (3) audio files, and (4) breathing training.


Filter schliessen

☐ Männliche Stimme
☑ Weibliche Stimme
☑ Mit Musik
☐ Ohne Musik

Figure 2. Screenshot of the CanRelax app 2.0—interaction with the conversational agent Lumy (reviewing and adjusting goals). (1) Lumy: “Well done, Robin. Now let’s talk about the goal you want to set for yourself in the coming weeks.” (2) Answer options: “Okay” or “I prefer to skip this part.”.

Chat mit Lumy

Geplant: 6 Ruhepunkte

Erreicht: 6 Ruhepunkte

13:27

Geschafft!

13:28

Super gemacht, Robin. Weiter so!

13:28

Nun würde ich gerne noch besprechen, welches Übungsziel Du Dir für die kommenden Wochen setzen willst.

13:28

Figure 3. Screenshot of the CanRelax app 2.0—dashboard. (1) Intervention start date, current week, and next chat appointment with Lumy; (2) collected points in the current and previous week and in total; and (3) personal relaxation goals (number of relaxation exercises) in the current and previous week and outcome goal of the participant.

Dashboard

18.10.22 Dein CanRelax Startdatum	Woche 3 Aktuelle Woche (Di - Mo)	Di 9:00 Nächste Sitzung mit Lumy

Deine gesammelten Ruhepunkte

0 Ruhepunkte in Woche 3	4 Ruhepunkte in Woche 2	6 Gesamtzahl Ruhepunkte

Deine geplanten Ziele

3 Ruhepunkte in Woche 3	3 Ruhepunkte in Woche 2	Innere Ruhe Übergeordnetes Ziel

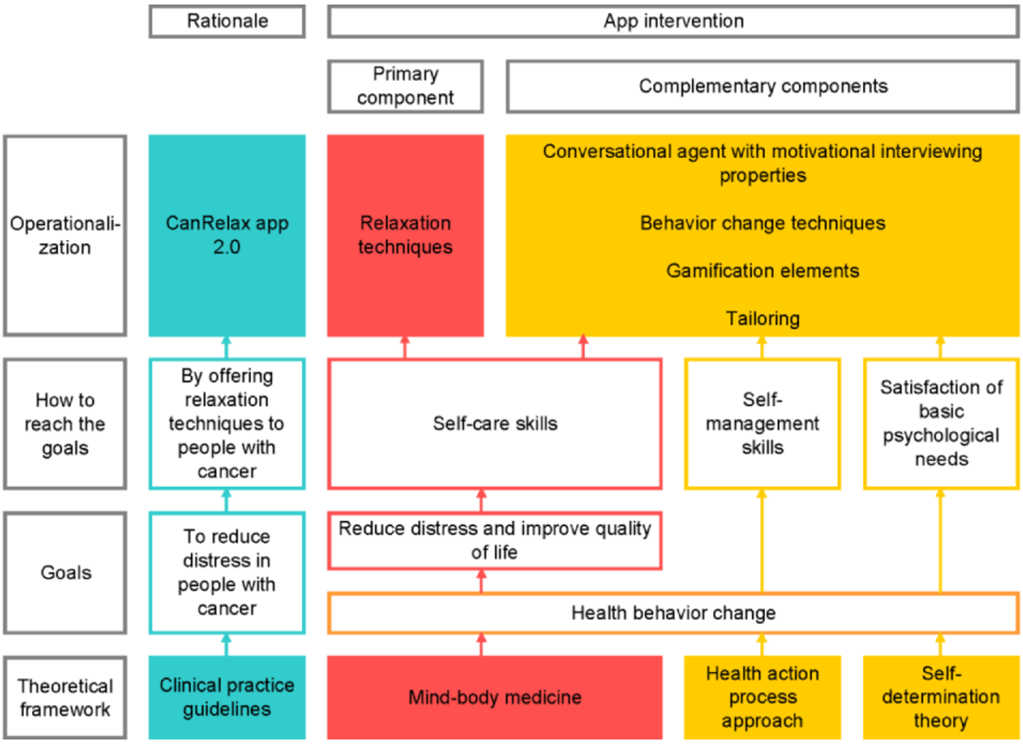
Deine Wochenbilanz

Theoretical Principles and Operationalization

Overview

The CanRelax app 2.0 implements clinical practice guidelines [35,36]; is grounded in mind-body medicine (MBM) [37,38], the Health Action Process Approach (HAPA) [39], and self-determination theory (SDT) [40]; and includes 39 BCTs (Multimedia Appendix 4 [41]) translated into app features and content. BCTs are active components of behavior change interventions [42] that can influence users' engagement at both the micro and macro levels. At the micro level, BCTs such as prompts or cues can increase user engagement with the app itself. At the macro level, BCTs can increase engagement with the target behavior (relaxation practice), for example, by using goal setting or self-monitoring features [6,7]. The underlying concept of the intervention flow and the structure of the coaching sessions are informed by generic principles of face-to-face coaching sessions, and we used motivational interviewing (MI) [43,44] aspects as a communication approach. To support the integration of relaxation into everyday routines, we applied the complementing principles of MBM, the HAPA, and SDT as outlined in Figure 4 and detailed in the following sections.

Figure 4. Theoretical framework and operationalization of the CanRelax app 2.0.



Clinical Practice Guidelines

The CanRelax app 2.0 aims to identify and address distress according to clinical practice guideline recommendations on distress management in people with cancer [35,36] by offering a relaxation and mindfulness intervention specifically designed for individuals with cancer, including initial assessment and monitoring of distress using validated tools such as the Distress Thermometer [29].

MBM Approach

MBM is a resource-oriented approach centered on empowering individuals and supporting healthy, sustainable behaviors [37,38]. Relaxation and mindfulness are widely used self-care interventions in MBM. The CanRelax app 2.0, being a mind-body intervention, provides the opportunity to learn different relaxation techniques along with educational material on distress during cancer, relaxation, and creating healthy habits.

HAPA Framework

Healthy behavior change is at the core of the HAPA. The HAPA focuses on the difficulty of behaving according to one's intentions and suggests to bridge this intention-behavior gap through perceived self-efficacy, action planning, and coping planning [39]. The CanRelax app 2.0 seeks to enhance self-efficacy and self-management skills through self-enactable BCTs with practical examples of use, such as problem-solving, positive reframing, behavioral experiments, graded tasks, prompts, and self-kindness [41]. Among automatically preselected themes and BCTs (triggered by participants' interaction with the app), participants can pick the components and topics most relevant to them. The app encourages participants to try new BCTs, determine what works for them, and use these techniques in their daily lives to stay motivated. Participants can also set their own relaxation goals and choose the support they wish to receive from Lumy.

SDT Approach

SDT sees healthy behavior change as closely linked to the satisfaction of basic psychological needs for autonomy, competence, and relatedness [40]. The CanRelax app 2.0 supports these basic needs by offering meaningful rationales and choices, using autonomy-supportive language, acknowledging people's preferences, recognizing their efforts, and promoting a feeling of being cared for through supportive coaching sessions and peer support. Peer support is implemented through personalized letters in the app from semifictional people with cancer sharing their struggles and strategies for overcoming obstacles. Personal preferences are acknowledged, for example, by tailoring emojis to participants' preferred skin tone and providing all chat content in 3 gender options (woman; man; and a gender-neutral option using the gender star, an asterisk placed within German words such as in "Liebe*r Andrea"). Participants select both the skin tone of their emoji and their preferred gender option during the onboarding process. We also let individuals choose their nickname and a form of address they are comfortable with (formal or informal), showing respect for their personal preferences in relation to language use [45].

MI Approach

MI is a person-centered communication approach that relates to the selected behavior change theories in that it aims to create a collaborative environment, draws on people's own goals and values, and supports their autonomy [43,44]. Examples illustrating the integration of MI principles into the app are provided in the *Coaching Sessions and Tailoring* section.

Relaxation Exercises

The app offers 7 different types of relaxation exercises recommended as evidence-based interventions to reduce distress in people with cancer [35,36,46,47]. The relaxation exercises include guided audio recordings of a short meditation (5 minutes), walking meditation (5 minutes), mindfulness meditation (15 minutes), guided imagery (15 minutes), progressive muscle relaxation (15 minutes), body scan (40 minutes), and slow-paced breathing training with visual guidance through gameful visualizations (2-5 minutes; Breeze 2 [48]). The audio files are available in male and female voices with and without background music. The FAQ sidebar submenu in the app provides a selection aid with more information about the different types of relaxation exercises.

Self-Monitoring Dashboard With Gamification Elements

The CanRelax app 2.0 tracks relaxation exercises and rewards participants with points as a gamification element. Earned points count toward participants' self-set weekly relaxation goals. Participants can also earn points by practicing relaxation exercises without the CanRelax app 2.0 (using a different app or without using any app) provided they add this information manually when prompted by Lumy during the coaching sessions. A self-monitoring dashboard illustrates earned points as progress circles. It also provides an overview of the relaxation goals and includes other useful information such as the date and time of the next coaching session.

Coaching Sessions and Tailoring

Lumy was developed as a friendly conversational agent that guides participants through the intervention via a series of rule-based, predefined, and personalized conversational turns that simulate the back-and-forth of a real-life conversation. A full coaching session consists of approximately 60 conversational turns (counted in pairs, with one conversational turn consisting of one message from Lumy and one from the participant in response). The conversational flow adapts to the responses chosen by the participants and is enhanced through various ways of tailoring (Textbox 1).

We adopted the structure of a typical face-to-face behavioral coaching session to build the chat sessions in the app [51]. The sessions start with a greeting, followed by small talk about a neutral topic (eg, about the weather) or a "how are you?" sequence and an introduction to the session (including a snooze option to postpone the session). The core part includes assessing the participants' current state, reviewing previously discussed topics and experiences with BCTs (if applicable), and applying coaching techniques based on MI [43,44]. The implemented techniques focus on building confidence for change (eg, scaling questions, shifting focus away from obstacles and barriers, reframing to offer new and positive interpretations, expressing empathy, affirming, and expressing respect by asking for permission before the conversation starts or before information is shared). After participants have set new relaxation goals, the sessions are summarized to reflect back the main points of the session. An outlook serves as a bridge to the next session, and participants are again encouraged to try out the selected BCTs before the next session (if applicable). The sessions close with the option to adjust the reminder settings and a farewell.

Textbox 1. Implementation of tailoring concepts according to the extended model of tailoring [49].

Tailoring concepts and their implementation in the CanRelax app 2.0

- Feedback: Lumy gives *feedback* on goal setting, goal achievement, and participants' self-efficacy toward goal achievement. When participants reach their relaxation goals, Lumy celebrates their achievements, and when things do not go well, Lumy tries to offer support.
- Interhuman interaction: in case of urgent need, Lumy encourages *interhuman interaction* through built-in support to contact relevant services that offer advice and support. Inspired by human coaches, we programmed Lumy to show great attention and commitment, listen with curiosity, reflect, and encourage participants to overcome obstacles. When participants report a challenge they came up against in their practice, they have the option to learn about tips and techniques (behavior change techniques [BCTs]) that can help overcome that challenge. They can choose to skip this section or pick a topic they find interesting among 3 preselected BCTs. Selected BCTs are delivered through personalized in-app letters from semifictional peers, which is another way of supporting *interhuman interaction.*
- Adaptation: the BCTs are *adapted* precisely to the reported challenge, and the preselected options are renewed in each coaching session to help keep the sessions interesting.
- User targeting: the concept of *user targeting* attempts to give participants the impression that the conversation was designed especially for them [49]. We incorporated this concept by identifying participants by their nicknames. We also regard participants' chosen pronouns (formal or informal), gender identity terms, and emojis as expressions of how participants construct their web identity in the context of the CanRelax app 2.0 [50] and match the chat conversations and the app accordingly.
- Goal setting: *goal setting* is a BCT that can be used to tailor an intervention and give participants a feeling of progress over time [49]. In CanRelax 2.0, participants' own weekly relaxation goals and objectives are at the center of the intervention.
- Context awareness: the tailoring concept *context awareness* aims at providing relevant information considering participants' (external) situation [49]. We incorporated this by tailoring greeting and farewell messages to the time of day and small talk topics to the season of the year, where applicable.
- Self-learning: CanRelax 2.0 is a *self-learning* app in the sense that it *learns* from the interactions with the participants and updates the intervention accordingly. For example, it records the obstacles that participants report and the BCTs they select and uses this information as a bridge to future sessions. To give continuity, the subsequent coaching sessions take up previously discussed topics and include a recap of experiences and learnings (if any) with the new BCTs between sessions.

Iterative Development and Testing

We developed the CanRelax app 2.0 in iterative processes involving input from people with cancer, health professionals, and an interdisciplinary team. The CanRelax app 2.0 builds on a basic app version, which provided relaxation exercises and a reminder function but no other tools or a conversational agent [52]. In version 2.0, we included new features, enhanced functionality, and a solid theory base. During the development process, we conducted usability testing with people with cancer to determine whether they understood and enjoyed the app and whether the app features met their needs. We submitted the usability testing study synopsis to the ethics committee of Zurich, Switzerland, and after review, they stated that the study did not fall under the regulation of the Human Research Act of Switzerland (ethics ID: 2020-00224). A total of 9 individuals with cancer consented to test a prototype of the app, of whom 3 provided detailed feedback, 3 did not test the app in the given time frame, and 3 had technical issues or privacy concerns regarding the test environment. Originally, we planned to conduct the usability tests in person, but due to circumstances related to COVID-19, we had to switch to a fully web-based approach using self-reports. In addition, we thoroughly and repeatedly pretested the app content and features with a multidisciplinary team. The team consisted of professionals with expertise in software engineering, computer science, psychology, psychotherapy, medicine, MBM, nursing, and teaching. Most user feedback was centered on the scripted coaching dialogues with Lumy. We clustered the comments into two main categories and iteratively implemented (1) more variety, in-depth responses, and tailored follow-up questions in the conversation (eg, adjusted the wording of unsatisfactory conversational turns, extended sets of predefined answer options, added links to previously discussed topics, and created unique session openings); and (2) more active choice options with possibilities to skip parts of the conversation, the ability to select topics of personal relevance and interest, the ability to formulate own reminders, and a snooze feature. All improvements were continually refined and tested over 2 years until user satisfaction was achieved.

Assessments

We collected self-reported data (through Lumy and structured in-app questionnaires) and objective app use data at different time points during the 10-week study period. Only the relevant measures considered for this analysis are described in detail in this paper; the measures of the larger study are reported in Multimedia Appendix 1.

Distress and Sociodemographics

At screening and baseline, we collected participants' self-reported level of distress using a well-known and validated instrument (Distress Thermometer [29]) and sociodemographics such as age, educational attainment, and sex assigned at birth using a structured in-app questionnaire. In the first chat with Lumy, we stored the selected gender identity terms, emoji skin tone modifiers, and preference for formal or informal pronouns ("Du" or "Sie" for "you" in German) to personalize the chat sessions and assessed participants' initial motivation for downloading the app (outcome goal; 5 forced-choice answer options; see the *Intervention* section).

Macrolevel Engagement

To answer the research questions of this paper, we combined engagement data on different levels. Data on macrolevel engagement were gathered in the weekly coaching sessions with Lumy. In each session, we asked about relaxation techniques practiced without using the CanRelax app 2.0. The exact wording changed slightly from week to week to help keep the conversation natural (example wording if at least one relaxation exercise was completed in the app: “Did you practice in any other way last week, besides using the CanRelax app?” If no relaxation exercise was completed in the app, the wording was as follows: “Have you practiced in a different way instead, without the CanRelax app?” An example follow-up question if participants answered “yes” would be the following: “In the past seven days, how often have you practiced without using the CanRelax app?”). We assessed reasons for practicing relaxation exercises without the app (if applicable) once per participant and participants’ self-efficacy toward self-set relaxation goals biweekly using a single-item measure developed with the recommended wording for assessing a specific health behavior [53] (“How confident are you that you will reach your relaxation goal next week, even if it gets difficult?”; participants responded on a visual analog scale implemented as a horizontal slider with values from 0 [*not at all confident*] to 10 [*very confident*]).

Microlevel Engagement

At the micro level, we collected participants’ feedback on the app at week 10 with single-choice questions about their favorite feature and the features they would like to change in the app (7 forced-choice answer options in random order) and an option to provide additional information in a free-text field. In addition, the CanRelax app 2.0 tracked the use of different app components (relaxation exercises in the app and coaching sessions with Lumy) over the entire intervention period. Relaxation exercises were considered completed when they were played for 66% of their total run time, and weekly coaching sessions were considered completed when the session closing was reached. We counted the chat sessions 1 to 11 as coaching sessions but not session 0 (onboarding) as completing this session was a requirement for enrollment.

Adherence Definition

We used an adherence definition of at least one relaxation exercise or one coaching session per week for 80% of the weeks during the study period to identify participants who complied fully with the app use suggestions.

Analyses

We conducted descriptive and exploratory data analyses to investigate the data set and thematic analysis of free-text comments. Descriptive statistics were used to report the baseline characteristics of the participants, participants’ self-set goals and self-efficacy, and quantitative in-app feedback. Data visualization methods, supplemented by numerical measures, were used to summarize the main characteristics of the data collected on engagement. We tested for differences in the number of completed relaxation exercises and coaching sessions between prespecified subgroups (distress level at baseline, sex, educational attainment, and age). For this purpose, we conducted a Mann-Whitney *U* test (in the case of 2 groups) or a Kruskal-Wallis test (for >2 groups) after a detailed investigation of descriptive statistics, checking for outliers using box plots and testing normality using a Shapiro-Wilk normality test and *Q-Q* plots. Qualitative free-text feedback was analyzed thematically using an inductive approach with the feedback statements as a coding unit, coded into multiple categories where applicable [54].

All analyses were conducted for the entire sample, including those participants who never used the app after onboarding, except for the comparison of relaxation exercises completed using the app versus without using the app. We expected no missing values in baseline variables as completing the questionnaires was a prerequisite for enrollment and participants could not skip questions. Nevertheless, 1 educational attainment response was missing from 1 participant for unknown reasons. Missing values related to the number of exercises or coaching sessions were treated as 0 (no exercise or coaching session completed). Other missing values (educational attainment, self-efficacy, reasons for practicing without the app, and participants’ feedback on the app) were not considered in the analyses.

Statistical analyses and visualizations were conducted using R language (version 4.2.2; R Foundation for Statistical Computing) [55] through RStudio (version 2023.06.0+421; Posit, PBC) [56] using *dplyr* [57] for data manipulation and summary statistics; *ggplot2* [58] for box plots and bar plots; *qqplotr* [59] for *Q-Q* plots; *DescTools* [60] for median CIs; and the base R *stats* package to compute the Wilcoxon, Shapiro-Wilks, and Kruskal-Wallis tests.

Ethical Considerations

We submitted the study synopsis to the ethics committee of Zurich, Switzerland, and after review, they stated that the study did not fall under the regulation of the Human Research Act of Switzerland (ethics ID: 2021-01071). The study was conducted according to the Declaration of Helsinki, the Human Research Act, and the Human Research Ordinance. Informed consent was obtained via the app from each participant before enrollment. All data were collected and stored in secure databases and analyzed in a pseudonymized form. Participants did not receive any compensation. Only participants in the intervention group and the nonrandomized third arm received immediate access to the app’s primary features (ie, the relaxation exercises, weekly coaching sessions with Lumy, BCTs, dashboard, reminder notifications, educational video clip, peer support letters, and FAQs), but everyone who downloaded the app had access to a sidebar submenu with useful links (ie, cancer and mental health information leaflets and links to organizations offering support and counseling) and crisis numbers in case urgent help was needed. By using a rule-based conversational agent, we adopted a highly transparent and safe approach compared to artificial intelligence chatbots and had complete control over the content and flow of the coaching sessions [61-63].

Results

Baseline Characteristics

The sample included 77% (77/100) of individuals assigned female at birth and 23% (23/100) of individuals assigned male at birth, and 70% (70/100) self-identified as women, 22% (22/100) self-identified as men, and 8% (8/100) preferred not to disclose their gender. Participants were aged 26 to 79 years (mean 55.6, SD 10.7 years), and 51% (51/100) had a bachelor's degree or higher. The baseline mean distress level (Distress Thermometer [29]) was 5.6 (SD 2.2), with a mean of 6.9 (SD 1.3) in the high-distress (intervention) group versus 3.1 (SD 0.9) in the low-distress (nonrandomized) group. Baseline characteristics between participants in the high-distress (intervention) group (67/100, 67%) and low-distress (nonrandomized) group (33/100, 33%) were generally comparable except that the high-distress group had fewer participants who installed the app because they were "just curious" (5/67, 7% vs 7/33, 21%). Overall, the most common motivations for installing the app were to improve coping strategies (37/100, 37%) and find inner peace (35/100, 35%; Table 1).

Table 1. Descriptive information about the study sample (N=100).

	Total	High-distress group (n=67)	Low-distress group (n=33)
Distress level[a], mean (SD)	5.6 (2.2)	6.9 (1.3)	3.1 (0.9)
Sex assigned at birth, n (%)			
Female	77 (77)	53 (79)	24 (73)
Male	23 (23)	14 (21)	9 (27)
Gender, n (%)			
Woman	70 (70)	48 (72)	22 (67)
Man	22 (22)	13 (19)	9 (27)
Other	8 (8)	6 (9)	2 (6)
Age (years), n (%)			
18-44	12 (12)	8 (12)	4 (12)
45-64	68 (68)	47 (70)	21 (64)
>64	20 (20)	12 (18)	8 (24)
Educational attainment, n (%)			
Nontertiary	48 (48)	34 (51)	14 (42)
Tertiary	51 (51)	32 (48)	19 (58)
Missing	1 (1)	1 (1)	0 (0)
Outcome goal, n (%)			
Coping resources	37 (37)	26 (39)	11 (33)
Inner peace	35 (35)	24 (36)	11 (33)
Just curious	12 (12)	5 (7)	7 (21)
Joy in life	10 (10)	8 (12)	2 (6)
Self-confidence	6 (6)	4 (6)	2 (6)

[a] Distress measured using the Distress Thermometer [29] with a rating scale ranging from 0 (no distress) to 10 (extreme distress).

App Engagement

A visual description of the participants' app use (completed relaxation exercises and coaching sessions) is presented in Multimedia Appendix 5 and Figures 5 and 6, supplemented by the numerical measures in Table 2. During the 10-week study period, 95% (95/100) of the participants used the app at least once after onboarding. These 95 participants completed a total of 4897 relaxation exercises (median 38, IQR 18-73.5) and 714 coaching sessions (median 9, IQR 4-11) over 10 weeks. Of the total number of relaxation exercises, 71.88% (3520/4897) were completed using the CanRelax app 2.0 (95/100, 95% of the participants; median 25.5, IQR 13-55), and 28.12% (1377/4897) were reported as completed without using the app (median 10, IQR 3-19). Among those participants who reported having completed relaxation exercises without using the app, 28% (21/76) specified that they had used different relaxation recordings, 18% (14/76) did not have their smartphones near them, 16% (12/76) knew the exercises by heart, 4% (3/76) preferred to relax without audio recordings, and 34% (26/76) had other reasons for relaxing without using the CanRelax app 2.0.

The proportion of participants who completed at least one relaxation exercise or one coaching session per week ("active app users") dropped from 88% (88/100) in the first week to

62% (62/100) in week 10. A total of 64% (64/100) of the participants complied with the app use suggestions per our adherence definition.

Participants’ perceived self-efficacy toward self-set relaxation goals stayed at a median of 8 (0=very low; 10=very high) throughout the 10-week study period, whereas participants raised their relaxation goals. The level of the self-set goals increased from a median of 3 relaxation exercises per week in the first half of the study period (sessions 1 and 3) to a median of 4 exercises per week in the second half (sessions 5, 7, and 9).

App engagement did not vary across prespecified subgroups (ie, distress level at baseline, sex, educational attainment, and age). Mean rank comparisons showed no substantial difference in the number of completed relaxation exercises or coaching sessions among these subgroups (Table 2).

Of the 100 participants, 52 (52%) provided in-app feedback after the 10-week study period (during session 11; Multimedia Appendix 6). A total of 88% (46/52) of the respondents indicated that they “really enjoyed” or “quite enjoyed” chatting with Lumy, and all respondents rated the overall app experience as “very satisfactory” (41/52, 79%) or “quite satisfactory” (11/52, 21%). The favorite app features of the respondents were relaxation exercises (37/52, 71%) and coaching sessions (12/52, 23%). Elements of the app that respondents felt could be improved included “nothing” (29/52, 56%), “something else” than the answer options provided (7/52, 13%), letters from semifictional peers (5/52, 10%), relaxation exercises (4/52, 8%), and in-app questionnaires related to the RCT (4/52, 8%). Of the 52 completed feedback questionnaires, 41 (79%) contained optional free-text comments from participants contextualizing their selected favorite (41 comments) and least favorite (20 comments) app features. Respondents particularly enjoyed the collection of relaxation exercises (12 mentions), liked the format and voices of the exercises (11 mentions), and found that the exercises helped them relax (8 mentions). For example, one respondent stated that the relaxation exercises “are well constructed, with pleasant voices and short.” However, 20% (8/41) of the respondents would have appreciated a wider selection of exercises to choose from. Another main topic that emerged from the analysis was a positive experience of the interaction with Lumy (9 mentions). The coaching sessions were experienced as friendly, uplifting, and encouraging, as seen in the following example:

> *It is a very friendly chat with a sense of humor, and it always motivates me.*

Another respondent appreciated “the conscious reflection and looking back. The feeling of being accompanied and encouraged.” However, 5% (2/41) of the respondents also felt that the interaction with Lumy sounded too robotic or was not interactive enough (1 mention each). Tables S1 and S2 in Multimedia Appendix 7 provide an overview of all free-text comments.

Figure 5. Comparison of completed relaxation exercises and completed coaching sessions in the high-distress group versus the low-distress group (N=100).

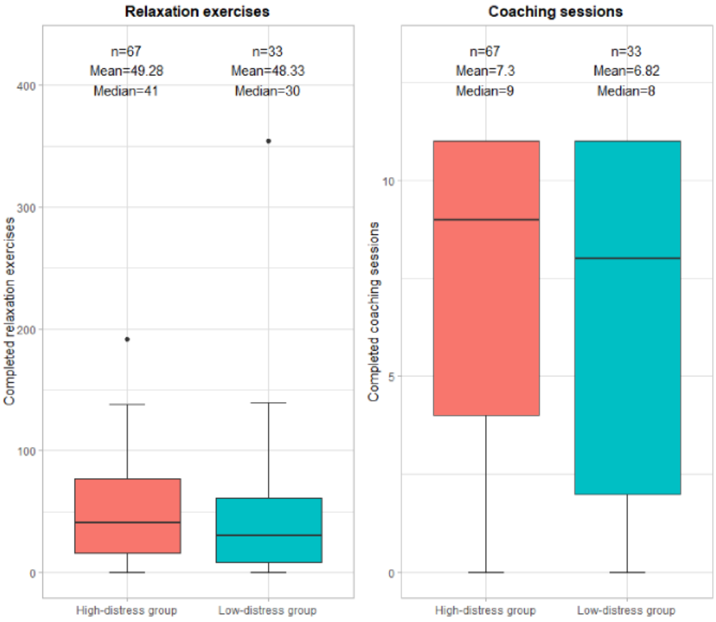


Figure 6. Comparison of completed relaxation exercises and completed coaching sessions in the high-distress group versus the low-distress group for 3 subgroups (N=100).

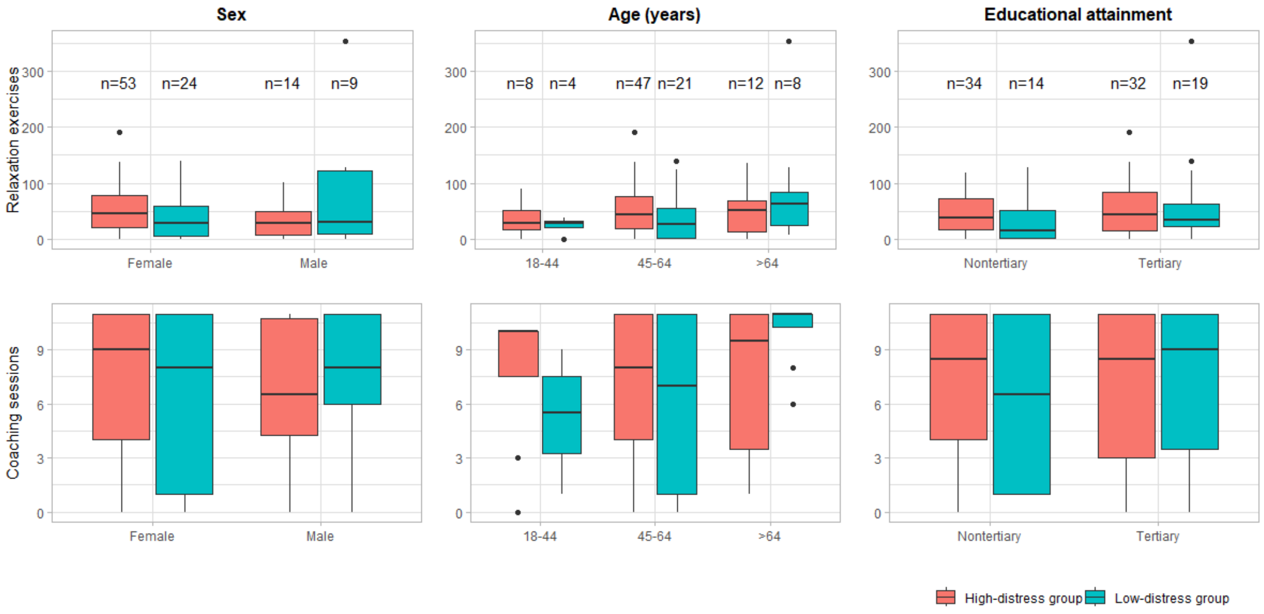


Table 2. Use of the CanRelax app 2.0 in the first 100 study participants with immediate access to the app, stratified by subgroup (N=100).

	Participants, n (%)	Completed relaxation exercises over 10 weeks		Completed coaching sessions over 10 weeks	
		Values, median (IQR)	*P* value[a]	Values, median (IQR)	*P* value[a]
Entire sample	100 (100)	34.5 (14-70.75)	—[b]	8 (4-11)	—
Subgroup					
Distress					
High	67 (67)	41 (15.5-77)	.21	9 (4-11)	.84
Low	33 (33)	30 (8-61)	—	8 (2-11)	—
Sex assigned at birth					
Female	77 (77)	40 (15-70)	.47	9 (3-11)	.64
Male	23 (23)	30 (8.5-64.5)	—	7 (4.5-11)	—
Educational attainment[c]					
Nontertiary	48 (48)	31.5 (12.75-64.75)	.20	8 (2.75-11)	.49
Tertiary	51 (51)	41 (18-78)	—	9 (3-11)	—
Age group (years)					
18-44	11 (11)	27 (12.5-39.5)	.34	9 (3.5-10)	.16
45-64	68 (68)	34.5 (13.25-73.25)	—	8 (3-11)	—
>64	20 (20)	52.5 (19.25-72.25)	—	11 (6.75-11)	—

[a] 2-sided *P* values derived from the Mann-Whitney *U* test (distress, sex, and educational attainment) and Kruskal-Wallis test (age group).

[b] Not applicable.

[c] 1 missing value.

Discussion

Principal Findings

Overall, engagement with the CanRelax app 2.0 declined over the study period but stayed relatively high, with 62% (62/100) of participants actively using the app in week 10. Engagement was unrelated to participant characteristics such as level of distress at baseline, sex assigned at birth, educational attainment, or age. More than one-quarter (1377/4897, 28.12%) of the relaxation exercises were completed without using the app, supporting the need for assessing engagement on a macro level.

Participants' self-efficacy remained stable at a high level. At the same time, participants raised their relaxation goals, which indicates a potential relative increase in self-efficacy. Participants who completed the intervention highly valued the app. Free-text comments suggested that a wider variety of relaxation exercises would further enhance the user experience.

Comparison With Prior Work

Engagement rates with cancer-related digital interventions tend to be higher than in other populations, but high variability in engagement measures and intervention components and lack of a threshold for acceptable engagement make it difficult to compare findings across studies. Reviews of empirical studies using cancer-related digital interventions have reported use rates between 70% and 100% [64,65]. These high use rates contrast with the generally low engagement with mHealth apps reported for individuals with other health conditions [2,10,11,13-15] and suggest that people with cancer might be particularly inclined to improve their health and change certain health behaviors through mHealth apps. Stressful life events such as the diagnosis and treatment of cancer potentially serve as catalysts for behavior change [66,67]. Nonetheless, comparing engagement across studies is difficult as there are no standards regarding the assessment, reporting, and interpretation of engagement with mHealth apps. In a recent review, every primary study stated that their apps achieved good engagement despite large differences in criteria used to assess engagement and a range of reported engagement rates from 35% to 100% [16]. This shows an urgent need for standards for assessing, reporting, and interpreting engagement with mHealth apps [16].

Fully automated mHealth studies with no human support are prone to low engagement rates, but there is great potential for increasing engagement using fully automated social components, behavior change theory, and design principles of successful commercial apps. Most mHealth apps in research settings provide human support, whereas popular commercial apps are typically unguided. Human support is known to positively influence engagement and effectiveness but drastically limits the scalability of mHealth apps [3,18]. Despite this limitation, most mHealth apps in research settings provide human support at varying levels—from high support through guided interventions (ie, involving guidance from a trained professional, eg, through live videoconferencing or web-based workshops) to lower levels of support through study processes (eg, screening visits or telephone surveys conducted by the study team). In the rare studies available on unguided cancer-related mHealth apps with no human support [68-70], engagement rates were <50%. One reason could be that existing researcher-developed apps are not engaging enough and, therefore, need human support to motivate participants [18,71]. This may be less the case for popular commercial apps, which are typically unguided (eg, Headspace and Calm) [18]. Thus, there is great potential for unguided research apps to improve user engagement and the generalizability of research findings to real-life settings if they learn from successful commercial apps. An example of an mHealth study with a low level of human support is the CanRelax 1.0 feasibility study [52]. The CanRelax app 1.0 was a fully automated mHealth app, but study processes such as enrollment were supported by study staff. The authors classified 54% (54/100) of participants as continuous app users in week 10 [52]. In comparison, engagement with the enhanced CanRelax app 2.0 in week 10 improved to 62% (62/100) even though we provided no human support and used stricter definitions of engagement. It is possible that the fully automated social components in the CanRelax app 2.0, such as the weekly coaching sessions with Lumy, compensated for the lack of human support. This aligns with recent research underscoring the potential of conversational agents to positively impact engagement with mHealth apps [3,72-77]. We demonstrated this potential by combining a conversational agent with a theoretical foundation and incorporating key design principles inspired by highly engaging commercial apps (eg, inclusive avatar and visuals).

Existing findings on the impact of participant characteristics on engagement are inconsistent [78]. In our analyses, engagement was not associated with the demographics (sex assigned at birth, educational attainment, and age) or psychological characteristics (level of distress) of the participants. These results contradict the findings of earlier studies that showed higher engagement in female individuals [6,52], individuals with higher educational attainment [6,15], younger [15] or older individuals [6], and individuals with higher baseline distress [15,52]. In the CanRelax app 2.0, the content and design features implemented to increase engagement might have succeeded in reaching those groups of people who needed a little extra encouragement and possibly helped level out differences in engagement among subgroups. Given the inconsistencies in the literature, identifying participant characteristics and other factors that influence engagement is an exciting topic for future studies.

Our findings support the feasibility and value of assessing macrolevel engagement in mHealth behavior change interventions. Although the conceptualization of engagement as a multifaceted construct is widely accepted, macrolevel engagement is rarely assessed in mHealth app studies. We approached this gap by examining engagement on multiple levels and showed considerable engagement with the target behavior (ie, relaxation) beyond app use. First, nearly one-third of all completed relaxation exercises (1377/4897, 28.12%) were practiced without using the CanRelax app 2.0. Relaxation techniques can be practiced in different ways depending on one's experiences, needs, and preferences; for example, beginners could start with guided relaxation via audio recordings (or in-person sessions) and later move on to more silent, self-guided relaxation exercises. In our study, examining only those exercises practiced using the app would have given an incomplete and potentially misleading picture of participants' engagement with relaxation practices. Second, median self-efficacy remained high even as relaxation goals increased, indicating that participants felt encouraged to tackle challenging tasks and were engaged in the behavior change process [24].

Data on macrolevel engagement are necessary to understand how engagement with an mHealth app changes over time and how these engagement patterns relate to the intended health outcomes. Baglione et al [17] found that high baseline distress was associated with initially higher engagement that declined over time, whereas the engagement of the group of participants with lower baseline distress increased over the course of a

7-week intervention, resulting in similar engagement levels in both groups at week 7. Siebenhüner et al [79] examined the associations between distress and adherence (ie, app use) in the CanRelax app 1.0 and showed that a decrease in the level of distress over time (ie, an improvement in health outcomes) was associated with lower adherence. However, the authors did not assess engagement with the target behavior in daily life. Without this information, it remains unclear whether participants with improved distress stopped using the app because they disengaged from the intervention or no longer needed the app's support to continue the new behavior [5]. As lower app use could be associated with higher engagement at the macro level, the suggested "adherence benefit paradox" [79] might not be a paradox after all but could even be considered the goal of a successful mHealth app [2].

Limitations

Our study is subject to common sources of bias that can affect the internal validity and generalizability of the findings. One potential source of bias is the use of self-reported data. To mitigate potential self-reporting bias, we combined self-reported and objectively tracked data in the assessment of engagement. Feedback was only collected from participants who completed the coaching session with Lumy in week 11. As it is possible that only those who enjoyed the app completed this session, feedback might be positively biased. Another potential source of bias is selection bias as our study focused on a group of highly motivated participants. Initial motivation for study participation was needed as participants had no contact with the research team but self-downloaded the app and self-enrolled in the study if they fulfilled the inclusion criteria. Selection bias is also indicated by female individuals being overrepresented in our sample. To improve the generalizability of our study, we used broad recruitment strategies and successfully recruited participants with lower than tertiary education. We also abstained from using research strategies to increase motivation and engagement (eg, compensation for study participation) that would differ from usual real-world app use settings. Another limitation is that we did not consider past engagement with relaxation in our analyses. Participants could have already established a regular relaxation practice before the study; still, engagement with a new app is not necessarily linked to previous experience with relaxation. A third limitation is due to technical issues with the CanRelax app 2.0 during the study, which could have reduced engagement. For example, we did not provide an easy solution to transfer the CanRelax app 2.0 to a new smartphone. Participants with new smartphones had to reach out for technical support and usually had to wait several weeks until they could continue to use the app where they left off. To avoid this problem, individuals must create an account in the future.

Clinical Implications

For a positive impact on health outcomes on a large scale, mHealth apps need to be scalable, engaging to users, and effective. Scalability is a great advantage of fully automated mHealth apps, but these apps tend to suffer from low engagement rates threatening their effectiveness. Our findings show that successful engagement can be achieved with fully automated mHealth apps that are highly tailored, include fully automated social components and BCTs based on theory and evidence, and are developed with design principles used by popular commercial apps. These results provide a valuable context for subsequent outcome evaluations and add to research on optimizing fully automated digital health interventions.

Conclusions

The CanRelax app 2.0 achieved similar engagement to that of other cancer-related mHealth apps even though we used stricter criteria for engagement than other studies and provided no human support. The implemented theory- and evidence-based design principles and fully automated social components, such as a conversational agent that simulated human support, might have compensated for the lack of human involvement and contributed to enhanced engagement at both a micro and a macro level. Our findings underline that engagement is a complex and multifaceted construct and that measures at the macro level are particularly valuable to assess engagement not only with the app itself but also with the larger target behavior, which is, ultimately, the goal of an mHealth app.

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Authors' Contributions

JB, CMW, ME, TK, and SS conceptualized the study. SS and JB conceptualized the intervention. SS created the intervention, designed the conversational flow, wrote the scripts for the chatbot coaching sessions and the letters from semifictional peers, and implemented the app on the MobileCoach platform. JB reviewed and contributed to the intervention content. CMW provided audio recordings of relaxation exercises. FS and PS set up the MobileCoach infrastructure, developed project-specific features, deployed the app, and provided technical support during the study. SS, FS, PS, JB, ME, and TK were involved in app testing. SS drafted the manuscript and conducted the analyses. JB helped interpret the results and contributed to reviewing and finalizing the manuscript. All authors reviewed and contributed to the manuscript and approved the final version.

Conflicts of Interest

ME received institutional research grants from Kaiku Health, reports grants from Bristol Myers Squibb and Roche, and institutional fees as a Scientific Advisory. ME is also a Board Member and Consultant from Roche, outside the submitted work. CMW has active research grants to the university for digital health projects from the DIZH, the Swiss Cancer Research foundation, the German health care Innovation Fund, and Newsenselab GmbH. CMW also received honoraria from Swiss hospitals for scientific presentations on digitalization and AI in medicine and integrative oncology. TK, FS, and PS are developers and promoters of the open-source software platform MobileCoach. TK, FS, and PS are affiliated with the Centre for Digital Health Interventions, a joint initiative of the Institute for Implementation Science in Health Care, University of Zurich; the Department of Management, Technology, and Economics at ETH Zurich; and the Institute of Technology Management and the School of Medicine at the University of St. Gallen. The Centre for Digital Health Interventions is funded in part by CSS, a Swiss health insurer, Mavie Next, an Austrian health insurer, and MTIP, a Swiss digital health investor. TK was also a cofounder of Pathmate Technologies, a university spin-off company that creates and delivers digital clinical pathways. However, neither CSS, Mavie Next, MTIP, nor Pathmate Technologies was involved in this study. JB received honoraria for workshops on digital health. The remaining authors have no conflicts of interest to declare.

Multimedia Appendix 1
CanRelax randomized controlled trial study design and assessments.
[PDF File (Adobe PDF File), 227 KB - cancer_v10i1e52386_app1.pdf]

Multimedia Appendix 2
CanRelax coaching structure.
[PNG File , 22 KB - cancer_v10i1e52386_app2.png]

Multimedia Appendix 3
CanRelax avatar icon.
[PNG File , 11 KB - cancer_v10i1e52386_app3.png]

Multimedia Appendix 4
Behavior change techniques in the CanRelax app 2.0.
[PDF File (Adobe PDF File), 173 KB - cancer_v10i1e52386_app4.pdf]

Multimedia Appendix 5
Active app users over 10 weeks (N=100).
[PNG File , 7 KB - cancer_v10i1e52386_app5.png]

Multimedia Appendix 6
CanRelax in-app feedback.
[PNG File , 22 KB - cancer_v10i1e52386_app6.png]

Multimedia Appendix 7
CanRelax free-text feedback.
[PDF File (Adobe PDF File), 153 KB - cancer_v10i1e52386_app7.pdf]

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Abbreviations

BCT: behavior change technique
FAQ: frequently asked question
HAPA: Health Action Process Approach
MBM: mind-body medicine
mHealth: mobile health
MI: motivational interviewing
RCT: randomized controlled trial
SDT: self-determination theory

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Original Paper

Association of Family-Centered Care With Psychological Distress Among Caregivers of Children With Cancer at a Tertiary-Level Hospital in Ethiopia: Cross-Sectional Study

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Abstract

Background: Psychological distress (PD) is a common mental health problem faced by caregivers of children with cancer. The involvement of families in childcare was found to be associated with lower levels of distress.

Objective: The study aims to determine the associations between family-centered care (FCC) and PD among caregivers of children with cancer receiving treatment at Tikur Anbessa Specialized Hospital (TASH), Ethiopia.

Methods: An institution-based, cross-sectional study was conducted from June to December 2022. Caregivers of children with cancer aged 0-14 years receiving cancer treatment at the pediatric oncology unit completed a face-to-face, interviewer-administered, structured questionnaire during a routine inpatient or outpatient visit. The questionnaire included questions on the characteristics of the child and caregiver, PD (measured by the Kessler Psychological Distress Scale [K10]), FCC (measured by the Measure of Processes of Care [MPOC-20]), and social support (measured by the Oslo-3 Social Support Scale [OSS-3]). Data were collected using the Kobo toolbox and exported to SPSS (version 26; IBM Corp) for cleaning and analysis. A multivariable logistic regression model was used. An odds ratio with a 95% CI was calculated, and a *P* value less than .05 was considered statistically significant.

Results: A total of 384 caregivers of children with cancer participated in the study. The total PD score ranged from 10 to 50, with a mean score of 17.30 (SD 8.96; 95% CI 16.84-18.60). The proportion of caregivers found to have mild, moderate, and severe levels of PD was 43 (11.2%), 35 (9.1%), and 51 (13.3%), respectively. The overall prevalence of mild to severe PD symptoms was 33.6% (95% CI 28.9%-38.3%). A statistically significant negative association was found between FCC and PD (adjusted odds ratio [AOR] 0.68, 95% CI 0.53-0.86). In addition, having no formal education (AOR 2.87, 95% CI 1.28-6.45), having a history of relapse (AOR 3.24, 95% CI 1.17-9.02), beginning cancer treatment at TASH (AOR 2.82, 95% CI 1.4-4.85), beginning treatment within the last 3 months (AOR 3.99, 95% CI 1.73-9.23), and beginning treatment within the last 4 to 18 months (AOR 2.68, 95% CI 1.25-5.76) were significantly associated with higher level of PD.

Conclusions: A total of 1 in 3 caregivers have reported PD. FCC was found to be protective of PD. The finding of this study suggests the need for FCC intervention to improve the mental health condition of caregivers. In addition, the intervention needs to consider the educational status of the caregivers, the time since the cancer diagnosis, and the history of relapse.

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KEYWORDS

child cancer; psychological distress; Ethiopia; parent; caregivers; family

Introduction

A diagnosis of childhood cancer has been described as a life-changing experience for caregivers that causes significant disruptions in a child's and family's life. Caregivers face multiple and inescapable stressors associated with their child's illness, diagnostic procedures, and cancer treatment [1]. Childhood cancer increases the risk of long-term emotional strain [2] and the risk of developing psychosocial distress [3]. Psychological distress (PD) often refers to an undifferentiated combination of symptoms, which is a state of emotional distress characterized by symptoms of depression and anxiety [4]. Distress is defined by the National Comprehensive Cancer Network (NCCN) [5] as follows:

> *an unpleasant experience of a mental, physical, social, or spiritual nature. This affects the way people think, feel, or act and interferes with the ability to cope with cancer, its physical symptoms, and its treatment.*

Caregivers of children with cancer have a higher risk of developing negative emotional states and poor health behaviors [6]. Thus, the prevalence of PD was higher at the time of diagnosis and remained significant during and even after the end of treatment [3,7,8]. It was also found that PD universally affects caregivers of children with cancer. In the United States, 50% of pediatric cancer caregivers are highly distressed and 16% meet the criteria for serious PD [8]. In the United Kingdom, 66% of caregivers of children with cancer have PD [9]. Similarly, 56.0% and 70.5% of caregivers in Lebanon [10] and in Iraq [11] were depressed, respectively. In African studies, PD was reported by 45% and 66.7% of caregivers of children with cancer in Uganda [12] and Tanzania [13], respectively. According to a study conducted in Ethiopia, 72.4% of caregivers of children with cancer had depression [14].

It has also been indicated that parental PD can be affected by various factors. These factors include prognosis and stage of child cancer, child symptom level, treatment status, side effects of chemotherapy, knowledge about treatment modality, treatment cost, employment status, sex of the parent, number of hospital admissions, and family support [8,15-19]. Studies have reported that family-centered care (FCC), which provides holistic care and is planned around the family, is associated with lower PD [20]. Caregivers receiving FCC have been found to have better parental psychosocial health scores, decreased psychological stress, and higher levels of psychological well-being [21-23]. Improved communication and receiving enough information, which are the main components of FCC, are also indicated to have an association with enhanced levels of psychological health in families of children with cancer [24,25].

Although childhood cancer is becoming a significant health burden in Africa [26] and Ethiopia in particular [26], few studies have explicitly examined the level of PD and underlying factors among caregivers of children with cancer. Research on FCC primarily focuses on defining and surveying families and health care providers, with limited exploration of its relationship with family outcomes [20]. To this end, understanding the degree of association between PD and the level of perceived FCC will help to improve the care provided for caregivers of children with cancer. In addition, better insight into factors associated with PD may help to design and implement supportive interventions for caregivers, which reflect their needs in low-income countries. Accordingly, the objective of this study was to describe PD and examine the association between PD and FCC among caregivers of children with cancer receiving treatment at Tikur Anbessa Specialized Hospital (TASH), Ethiopia.

Methods

Study Area and Study Design

This study used a cross-sectional design from June to December 2022. The hospital is situated in Addis Ababa, the capital city of Ethiopia. With more than 800 beds, TASH is the largest tertiary university teaching hospital. The hospital offers the most thorough cancer care with over 120 million people nationwide. Patients with cancer from every region were referred to this hospital. The pediatric oncology unit has 26 beds, along with nurses, residents, hemato-oncologists, and hematopathologists. According to pediatric oncology unit registration, between 500 and 600 new children with cancer get both inpatient and outpatient care each year [27].

Study Participants

Caregivers of children with cancer aged 0-14 years receiving cancer treatment at the TASH pediatric oncology unit were recruited for the study. Due to the restricted number of patients seen during the study period, we did not precalculate the sample size. Instead, we consecutively invited all caregivers who visited the unit during the study period to participate in the study. Accordingly, 393 caregivers of children with cancer were interviewed in this study. A mother or father was selected if they were available with other family members during data collection. If both mothers and fathers were available, the parent who reported spending more time with the child and more frequently visited the health facility was selected.

The inclusion criteria for this study were caregivers or guardians of children with all types of cancer visiting the TASH pediatric oncology unit, having at least 1 previous visit, attending either an inpatient or outpatient department, and at least 1 month had passed since the child's diagnosis. The term "caregiver" or "guardian" refers to the person who decides on most things for the child daily, both inside and outside the medical environment. The study excluded caregivers or guardians of children with known mental health problems before their child's cancer diagnosis. A total of 3 caregivers were excluded because they identified themselves as being in treatment for mental health conditions before knowing their child's cancer diagnosis and 4 caregivers did not provide complete data for the dependent variable.

Data Collection

The study used a face-to-face, interviewer-administered, structured questionnaire (see Multimedia Appendix 1). The questionnaire was prepared in English and independently translated into Amharic by 2 bilingual translators. A third reviewer, who provided feedback at a reconciliation meeting, checked the translated version. After obtaining the agreement, another language checker translated the Amharic version into English. Any inconsistencies were corrected, and a final Amharic translation was used to collect the data. The caregivers were recruited to the interview consecutively as they come to the pediatric oncology unit for regular visits. The participants' responses were instantly entered into a Kobo toolbox data collection tool by the data collector at the time of the interview. The face-to-face interviews were approximately 20 minutes.

Measurements

Overview

The survey included questions regarding caregivers' sociodemographic characteristics, children's health status, parental distress, and caregivers' satisfaction with the treatment received. Information on sociodemographic characteristics was obtained by interviewing caregivers using a standard questionnaire. Data regarding the children's clinical characteristics were obtained from their medical records using a structured data-retrieving checklist with the assistance of an MSc oncology nurse in the pediatric oncology unit.

Kessler Psychological Distress Scale

The Kessler Psychological Distress Scale (K10) is a tool consisting of 10 items originally developed to measure PD [28]. It is made of a 5-point Likert-type scale ranging from 1=none of the time to 5=all of the time. The tool assesses the experience of symptoms of mental distress over the past 30 days. The total score of the tool ranges from 10 to 50. Owing to the lack of a universally accepted method for categorizing K10 scores, various methods were used based on the purpose and context of the study. Considering the absence of a specific threshold in Ethiopia's setting and our aim to screen caregivers of children with cancer for the likelihood of having a mental disorder, we chose the most commonly used grouping for K10 scores to assess PD in primary health care settings. Therefore, the total score was categorized as 10-19, indicating "likely to be well"; 20-24, "likely to have a mild mental disorder"; 25-29, "likely to have a moderate mental disorder"; and above 30, "likely to have a severe mental disorder" [29-32]. Finally, a score less than or equal to 19 was coded as 0 for no mental disorder, and the presence of likelihood of mental disorder for a score greater than or equal to 20 was coded as 1. The K10 scale has been validated and confirmed to effectively assess PD in Ethiopian settings, with Cronbach α of 0.86 and 0.83 reliability [33,34].

Measure of Processes of Care

To evaluate the family-centeredness of care, the Measure of Processes of Care (MPOC-20) was used [35]. MPOC-20 can assess both families' experiences and perceptions of the family-centeredness of services received. The tool is translated and validated in about 14 languages [36]. The MPOC-20 contains 20 items and five scales and they are (1) enabling and partnership (3 items), (2) providing general information (3 items), (3) providing specific information about the child (5 items), (4) coordinated and comprehensive care for the family and child (4 items), and (5) respectful and supportive care (5 items). Patients respond using a 7-point scale that ranges from "not at all" (score=1) to "to a very great extent" (score=7) [35]. MPOC-20 is a widely used tool in different setups to evaluate the level of FCC. For this study, the Cronbach α was found to be 0.92.

Oslo-3 Social Support Scale

The 3 questions of the Oslo-3 Social Support Scale (OSS-3) cover the reported number of close friends, perceived concern, and practical help from others, and the sum score ranges from 3 to 12. Scores 3-7 are considered poor, scores 8-10 as moderate, and scores 11-12 as strong social support [37].

Data Quality Control

The principal investigator guided the data collection process. A total of 2 nurses with MSc in nursing were recruited as supervisors. Six MPH or MSc holders were used as the data collectors. Data collectors and supervisors were not a part of the childcare team. Both supervisors and data collectors received training before data collection. During the training, the need for confidentiality and privacy was emphasized. Different pediatric oncology units at St. Paul Millennium Medical College were used as pretest sites.

Data Processing and Analysis

The data were collected using the Kobo toolbox data collection tool and exported to SPSS (version 26). Missing values and outliers were checked and corrected. Descriptive statistics were calculated, and the data were presented as tables, graphs, and frequencies. Variables such as family size, number of children in the household, child's age, duration in months since the child fell ill, and duration in months since the child was diagnosed with cancer were categorized using the first and third quartiles. The strength of the association between the independent and dependent variables was described using the odds ratio with 95% CI. All variables with P values less than .20 during binary logistic regression were considered candidates for the final model. In addition, we considered the clinical relevance of the variables in the multivariate model. The final fitted multivariable logistic regression model was constructed using the enter method. Variables with P values less than .05 were regarded as having a statistically significant association.

Ethical Considerations

Ethical clearance was obtained from the Addis Ababa University College of Health Science institutional review board (protocol 022/22/SPH). Permission was also obtained from the TASH pediatric oncology unit. Written informed consent for the interviewee was obtained from each study participant. A private place was used for the interview session to keep the respondents' privacy. Participants were assured of their right to withdraw from the interview at any time, and participation in this study or refusal to participate would not affect their ability to access health services or any other services. Names and other personal information, which can violate the confidentiality of the study participants, were not recorded. In addition, no compensation was paid to the interviewed participants.

Results

Sociodemographic Characteristics of Caregivers

A total of 393 caregivers of children with cancer were approached and 384 caregivers provided complete responses (response rate of 97.7%). The caregivers' ages ranged from 18 to 75 years, with a median of 35.17 (IQR 28-40) years; 176 (45.8%) were fathers. From 384 caregivers, the majority of the participants were from urban areas (n=233, 60.7%), attended secondary school (n=135, 35.2%), and were employed (n=232, 60.4%). Most of the families (n=350, 91.1%), were married or living together and 267 (30.5%) had a family size of 5 people or more. A total of 64% (248) of the families had 2 to 4 children. The number of caregivers who stated they could save money was 53 (13.8%). Table 1 provides a detailed overview of the participants.

Table 1. Sociodemographic characteristics of caregivers of children with cancer at the Tikur Anbessa Specialized Hospital pediatric oncology unit from June to December 2022 (n=384).

Variables and category	Values, n (%)
Caregivers' gender	
Mother	158 (41.1)
Father	176 (45.8)
Others[a]	50 (13)
Sex	
Male	205 (53.4)
Female	179 (46.6)
Age of the caregiver or guardian (years)	
≤29	106 (27.6)
30-39	161 (41.9)
≥40	117 (30.5)
Place of residence	
Urban	233 (60.7)
Rural	151 (39.3)
Employment status	
Housewife	90 (23.4)
Currently not employed	62 (16.1)
Currently employed	232 (60.4)
Caregiver or guardian's educational level	
No formal education	62 (16.1)
Primary education (grades 1 to 8)	88 (22.9)
Secondary education (grades 9 to 12)	135 (35.2)
College and above	99 (25.8)
Marital status	
Currently married or cohabiting	350 (91.1)
Not married or not cohabiting	34 (8.9)
Family size	
≤4 family size	117 (30.5)
≥5 family size	267 (69.5)
Number of children	
Single child	56 (14.6)
2-4 children	248 (64.6)
≥5 children	80 (20.8)
Looking after siblings at home	
Yes	288 (75)
No	19 (4.9)
No one is left at home	77 (20.1)
Income and household expenses[b]	
Your household can save money	53 (13.8)
Your household spends what it earns	215 (56)
Your household eats into its assets and savings	68 (17.7)

Variables and category	Values, n (%)
Your household gets into debt	48 (12.5)

[a] Grandparent, brother, sister, uncle, and aunt.

[b] The variable was intended to assess the income and expenses of a household, and it is adapted from the Swiss Household Panel survey questionnaire [38].

Social Support

The OSS-3 was used to evaluate the extent of social support among caregivers of children with cancer, with 381 participants offering comprehensive responses. Among them, 282 (72.5%) indicated poor social support, 98 (25.2%) reported moderate support, and 1 caregiver reported high social support.

Characteristics of Children

Regarding characteristics of children, from the 384 children receiving treatment, the majority (n=227, 59.1%) were male and 78 (20.3%) were older than 10 years. The majority (n=251, 65.4%) of the children were referred to TASH, 357 (93.0%) had no history of relapse, and 325 (84.7%) were receiving treatment. Of 325 children receiving treatment, 247 (69.6%) were getting chemotherapy. Leukemia was the most common cancer type (n=115, 29.6%). From 211 staged cancer cases, 62 (16.1%) were stage IV and 28 (7.3%) were stage III. The median time since the child was ill and diagnosed with cancer was 12 and 7 months, respectively (Table 2).

Table 2. Characteristics of children receiving cancer treatment at the Tikur Anbessa Specialized Hospital pediatric oncology unit from June to December 2022 (n=384).

Variables and category	Values, n (%)
Child's sex	
Male	227 (59.1)
Female	157 (40.9)
Child age (years)	
≤4	153 (39.8)
5-9	153 (39.8)
≥10	78 (20.3)
Place child started treatment	
In this hospital	133 (34.6)
Referred from other hospital	251 (65.4)
History of relapse	
Yes	27 (7)
No	357 (93)
Time in months since the child is ill	
≤6	103 (26.8)
7-25	204 (53.1)
≥26	77 (20.1)
Time in months since your child is diagnosed with cancer	
≤3	104 (27.1)
4-18	191 (49.7)
≥19	89 (23.2)
Child cancer type	
Solid cancer	207 (53.9)
Hematological	177 (46.1)
Type of malignancy	
Leukemia	115 (29.9)
Wilms' tumor	64 (16.7)
Sarcoma	53 (13.8)
Hodgkin's lymphoma	45 (11.7)
Retinoblastoma	32 (8.3)
Central nervous system	30 (7.8)
Non-Hodgkin lymphoma	9 (2.3)
Others	36 (9.4)
Cancer stage	
Not staged	173 (45.2)
Stage I	59 (15.4)
Stage II	62 (16.1)
Stage III	28 (7.3)
Stage IV	62 (16.1)
Treatment status	
On treatment	325 (84.6)

Variables and category	Values, n (%)
Waiting to start treatment	19 (4.9)
Off treatment	40 (10.4)
Type of treatment (n=325)	
Chemotherapy only	247 (76)
Other treatment type	78 (24)

Level of Perceived FCC

The detailed results related to caregivers' perception of the level of FCC were published [38]. Families provided feedback on the MPOC-20, yielding scores ranging from 1.00 to 6.90 and a mean score of 3.71 (SD 1.04). Among the original 5 domains of the MPOC-20, the highest mean score of 4.81 (SD 1.32) was attributed to respectful and supportive care, followed by coordinated and comprehensive care, with a mean score of 4.64 (SD 1.19). The lowest mean scores were recorded for providing specific information (2.33, SD 0.80) and general information (2.70, SD 1.23).

Caregivers' PD

The total K10 score reported by caregivers ranged from 10 to 50. It was skewed to the right with a mean of 17.30 (SD 8.96; 95% CI 16.84-18.60) and a median of 14 (IQR 10-23). Of a total of 384 interviewed caregivers, 43 (11.2%) had mild, 35 (9.1%) had moderate, and 51 (13.3%) of the caregivers had severe PD. The overall prevalence of mild to severe PD symptoms was 33.6% (95% CI 28.9-38.3)

Association of FCC and PD

Logistic regression was used to examine the association of FCC and PD while controlling other variables. During bivariate logistic regression analysis, FCC, place of residence, educational level, level of income and expense, referral from other facilities, history of relapse, time since the child was diagnosed, type of cancer, and treatment status were found to have a significant association with caregivers PD. Variables such as sex of the caregivers, caregiver age, relationship with the child, working status, marital status, child sex, child age, number of children, perceived social support, and family size did not show any association.

The final multiple logistic regression model included 9 variables with *P* values less than .05 from the bivariate logistic regression analysis. The model, as explained between 20.3% (Cox and Snell R^2) and 28.1% (Nagelkerke R^2) of the variance in PD, correctly classified 76.0% of cases. The model fitness test used the Hosmer-Lemeshow statistic, indicating a good model fit (*P*=.46).

After controlling for other variables using multiple logistic regression analysis, FCC was significantly associated with PD. Accordingly, caregivers who reported a unit increase in the level of FCC received were found to reduce PD by 32% (adjusted odds ratio [AOR] 0.68, 95% CI 0.53-0.86). In addition, having no formal education (AOR 2.87, 95% CI 1.28-6.45), having a history of relapse (AOR 3.24, 95% CI 1.17-9.02), starting cancer treatment at TASH (AOR 2.82, 95% CI 1.4-4.85), starting treatment within the last 3 months (AOR 3.99, 95% CI 1.73-9.23), and starting treatment within the last 4 to 18 months (AOR 2.68, 95% CI 1.25-5.76) were significantly associated with higher level of PD (see Table 3).

Table 3. Logistic regression analysis for factors affecting the level of psychological distress among caregivers of children with cancer.

Variables or characteristics	Distressed		Crud OR[a] (95% CI)	Adjusted OR (95% CI)	*P* value
	Yes	No			
Family-centered care (MPOC[b]-20 mean score), mean (SD)	3.45 (1.07)	3.85 (1.01)	0.69 (0.56-0.85)	0.68 (0.53-0.86)	.001
Residential place, n (%)					
Urban	63 (27)	170 (73)	0.47 (0.31-0.73)	0.73 (0.42-1.25)	.25
Rural	66 (43.7)	85 (56.3)	Reference	Reference	
Educational status, n (%)					
No formal education	30 (48.4)	32 (51.6)	3.28 (1.65-6.53)	2.87 (1.28-6.45)	.01
Primary education	37 (42.0)	51 (58.0)	2.54 (1.35-4.79)	1.83 (0.87-3.83)	.10
Secondary education	40 (29.6)	95 (70.4)	1.47 (0.80-2.69)	1.38 (0.71-2.67)	.35
College and above	22 (22.2)	77 (77.8)	Reference	Reference	
Household income and expenses, n (%)					
Household can save money	13 (24.5	40 (75.5)	Reference	Reference	
Household spends what it earns	69 (32.1)	164 (67.9)	1.45 (0.73-2.89)	1.54 (0.70-3.38)	.29
Household eats into its assets and savings	19 (27.9)	49 (72.1)	1.19 (0.53-2.71)	0.70 (0.26-1.87)	.48
Household gets into debt	28 (58.3)	20 (41.7)	4.31 (1.84-10.1)	2.35 (0.88-6.29)	.09
Child cancer type, n (%)					
Solid cancer	81 (39.1)	126 (60.9)	1.73 (1.12-2.67)	1.54 (0.94-2.53)	.09
Hematological	48 (27.1	129 (72.9)	Reference	Reference	
History of relapse, n (%)					
Yes	14 (51.9)	13 (51.9)	2.26 (1.03-4.98)	3.24 (1.17-9.02)	.02
No	115 (32.2)	242 (32.2)	Reference	Reference	
Time since diagnosis (months), n (%)					
Below 3	47 (45.2)	57 (54.8)	3.49 (1.82-6.72)	3.99 (1.73-9.23)	.001
4-18	65 (34.0)	126 (66.0)	2.19 (1.19-4.01)	2.68 (1.25-5.76)	.01
Above 19	17 (19.1)	72 (80.9)	Reference	Reference	
Treatment status, n (%)					
Waiting or off treatment	11 (18.6)	48 (81.4)	0.40 (0.20-0.80)	0.55 (0.25-1.23)	.15
On treatment	118 (36.3)	207 (63.7)	Reference	Reference	
Place of starting treatment, n (%)					
In this hospital	68 (51.1)	65 (48.9)	3.26 (2.09-5.09)	2.82 (1.64-4.85)	<.001
Referred from other hospital	61 (24.3)	190 (75.7)	Reference	Reference	

[a] OR: odds ratio.

[b] MPOC: a measure of process of care.

Discussion

Principal Findings

In this study, the relationships between the perception of FCC and PD in caregivers of children with cancer visiting inpatient and outpatient pediatric oncology units were examined. It is the first study to investigate the level of PD using a locally validated standard tool and investigate its association with FCC. To our knowledge, no study has focused on PD among caregivers of children with cancer receiving treatment in both inpatient and outpatient settings in Ethiopia. The study also evaluated the effect of factors related to caregivers' sociodemographic, child health, and health facility–related factors on PD among caregivers of children with cancer. The findings from this study provide information on the burden of PD and identify the factors contributing to PD among caregivers.

Our findings show that 1 in 3 interviewed caregivers reported mild to severe PD, which indicates that parenting a child with cancer can profoundly affect caregivers' mental health. This finding is higher than the 0.3% mild to severe level of distress reported among the general population scored using the K10 in

Ethiopia [33]. This justifies the need to include screening for PD as a critical element of comprehensive psychosocial care for caregivers of children with cancer [39]. This is supported by previous studies that state mental health screening and care for caregivers help to improve child health by facilitating communication among health care providers and caregivers [40].

The level of mild to severe PD in this study was found to be lower than studies conducted in the United States [8], Lebanon [10], Tanzania [13], and Uganda [12]. This difference in the level of PD may be attributed to sociodemographic differences and differences in the measurement tools used. Notably, in this study, unlike in previous studies, most of the participants were fathers. Since the study was conducted in the leading referral hospitals in Ethiopia, the children came from distant parts of the country. Because of this, primarily fathers bring their sick children to hospitals. Multiple studies have reported that fathers have lower levels of parental distress than mothers [41,42]. Another reason might be due to the fact that this study was conducted in a hospital setting where caregivers consider starting treatment as the main achievement in the cancer care process [43]. In Ethiopia, as caregivers have to wait and go through long bureaucracy and referral systems, starting treatment at TASH may have created a sense of satisfaction and increased hope for a cure. This is supported by previous research, which states that beginning treatment is the main reason for lower stress levels [43].

In this study, caregivers' perceptions of FCC were found to be protective against PD. Our finding is consistent with other studies that reported the association of a higher level of perceived FCC with decreased mental health problems [21,22]. Similarly, previous studies indicated improved psychological health among caregivers who received FCC-based intervention [24,25]. The main components of FCC, such as the provision of specific and general cancer-related information [43,44], enabling caregivers to participate in childcare and decision-making [45,46], having good communication [24,25], and providing coordinated and comprehensive care, were found to decrease caregivers' PD. FCC also reduced parental distress caused by lack of information [43], underscoring the importance of considering the complex nature of caregivers' needs and integrating FCC into pediatric oncology care. FCC can be incorporated into child cancer treatment by offering information and education, preparing families before a child's procedures, enhancing communication between caregivers and the health care team, and providing adequate support and empowerment for caregivers [24,25,49-53].

Our findings show caregivers of children with lower educational levels were more likely to have higher levels of PD than more educated caregivers (college and above), which aligns with previous research [11,16]. Education enables individuals to develop fundamental skills, abilities, and resources for more effective health behaviors, helping them to acquire or create effective means of achieving better health [54,55]. On the contrary, a lower educational level may lead to a higher economic burden, a lower understanding of the information provided to caregivers, and a decreased sense of control over an individual's surroundings [56,57]. In addition, lower education levels might affect caregivers coping mechanisms; more educated people may be better equipped (have better cognitive skills) to deal with the consequences of childhood cancer [4]. This finding indicates the education level of caregivers needs to be considered when preparing and delivering information and care.

The results of this study also indicated caregivers of children with a history of relapse had higher levels of PD. This is similar to previous studies [58,59]. Caregivers of children with cancer have uncertainties associated with the fear of negative consequences such as relapse or death [60]. The relapse of children with cancer could lead to prolonged uncertainty, negative expectations about disease progression, increased fear of losing their child, and causing poor emotional and mental health [61,62]. Facing the trajectories of childhood cancer for the second time might also be associated with feelings of sadness and frustration, which increases the sense of helplessness, vulnerability, and lack of control over the events [58,62]. All these conditions are associated with adverse mental health conditions.

Furthermore, relapse may be considered a sign of treatment failure, complications, or poor disease progression [63]. This perception may also play a role in higher levels of distress. Consequently, the overwhelming distress of relapse has the potential to compromise families' information-processing abilities and further increase their level of PD. Despite this, previous studies have reported that caregivers of children with relapse reported lower levels of distress than the onset of child cancer because of caregivers' ability to learn faster and having prior information about the possibility of relapse [64]. Therefore, establishing a screening mechanism for caregivers of children with relapse, creating good communication, and providing adequate information about the possibility and management of relapse will help to reduce caregivers' PD.

Another child health–related factor that serves as an independent predictor of PD is the duration since diagnosis. Our study revealed caregivers with a shorter period since diagnosis reported higher levels of PD. Similar findings from previous studies show PD is typically higher during the initial diagnosis and gradually decreases over time [2,3,7,8]. This could be attributed to the highly demanding nature of care provided to children with cancer at the time of diagnosis. Caregivers from low-income countries such as Ethiopia have little or no information about what to do when they first hear their child's diagnosis. As time passes, caregivers gain more understanding and develop some of the skills required to care for their sick child [43]. Thus, this study indicates the importance of providing well-designed psychosocial support, focusing on the time of diagnosis. Caregivers who started treatment for the first time in their current hospital were also found to have more PD than those referred from other hospitals. According to a qualitative study [43] conducted in a similar setting, hospital-related factors such as long waiting time for both diagnosis and treatment, shortage of chemotherapy drugs, and high patient load might be the reason why patients who started treatment at TASH had higher levels of PD.

Limitation

This study should be understood in the setting of potential limitations. Because caregivers participated in the study after their child was diagnosed with cancer, the baseline distress level before the diagnosis of their child was not known. To minimize this limitation, caregivers were asked for known mental health conditions and excluded from the study. But still, it was not possible to identify subclinical and undiagnosed cases before a diagnosis of child cancer. Because of the cross-sectional nature of the study design, it is impossible to formulate cause-and-effect relationships among variables. It will be necessary for follow-up studies to include more detailed relationships among variables. Finally, social desirability bias might be introduced since we conducted interview-based surveys.

Conclusions and Recommendation

In this study, the mean K10 was 17.30 (SD 8.96). A total of 1 in 3 caregivers has reported mild to severe levels of PD. Receiving a higher level of FCC was found to be protective for parental PD. In addition, lower educational status, history of relapse, and shorter time since diagnosis and starting treatment at TASH were associated with higher levels of PD. The results suggest that screening for PD following a child's diagnosis may help to identify distressed caregivers early and potentially lead to earlier psychosocial intervention. Furthermore, in developing evidence-based interventions for caregivers of ill children, it is important to understand the potential risk factors for increased parental distress. The risk factors associated with PD found in this study suggest that interventions need to address the needs of lower socioeconomic conditions, caregivers who had children with relapse, and during the early stage of child diagnosis. Furthermore, conducting further studies, including siblings, will help to get more detailed insight into the mental health effects of childhood cancer at the family level.

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Data Availability

All data generated or analyzed during this study are included in this published article.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Structured questionniare.
[DOCX File , 57 KB - cancer_v10i1e54715_app1.docx]

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Abbreviations

AOR: adjusted odds ratio
FCC: family-centered care
K10: Kessler Psychological Distress Scale
MPOC-20: Measure of Processes of Care
NCCN: National Comprehensive Cancer Network
OSS-3: Oslo-3 Social Support Scale
PD: psychological distress
TASH: Tikur Anbessa Specialized Hospital

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Delivering a Group-Based Quality of Life Intervention to Young Adult Cancer Survivors via a Web Platform: Feasibility Trial

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Abstract

Background: Young adult (YA) cancer survivors frequently report unmet health information and peer support needs, as well as poor health-related quality of life (HRQOL). YAs also have expressed a desire that behavioral interventions be convenient. In response to this, our team has developed a 10-week, group-based, supportive care intervention titled TOGETHER to improve YA cancer survivors' HRQOL. TOGETHER is delivered via videoconference and has shown initial feasibility, acceptability, and promise for improving HRQOL among YA survivors.

Objective: In an effort to increase convenience, the goal of this 2-part study was to design and test a website to host the TOGETHER intervention for YA cancer survivors aged 18 - 39 years at the time of participation and aged 15 - 39 years at the time of initial cancer diagnosis.

Methods: In part 1, we leveraged an existing web-based platform and adapted it to meet the needs of TOGETHER. We conducted 3 iterative waves of usability testing with 3 YAs per wave to refine the website. In part 2, we conducted a single-group feasibility trial of TOGETHER using the website. Primary outcomes were feasibility (ie, recruitment, retention, and attendance) and acceptability (ie, satisfaction).

Results: Usability testing participants (n=9) indicated that the TOGETHER website was easy to use (mean 5.9, SD 1.3) and easy to learn (mean 6.5, SD 0.9; possible ranges 1 - 7). Qualitative feedback identified needed revisions to the aesthetics (eg, images), content (eg, session titles), function (eg, clarity of functionality), and structure (eg, expandable sections), which were implemented. In the feasibility trial, participants (n=7) were an average of 25 (SD 4.7) years old and mostly non-Hispanic White (n=4, 57%). Recruitment (58%) and retention (71%) rates and average session attendance (mean 7.1 , SD 4.2) supported feasibility. Participant agreement with positive statements about TOGETHER and average satisfaction ratings (mean 5.06, SD 1.64; possible range: 1 - 7) demonstrated acceptability.

Conclusions: Results supported the usability, feasibility, and acceptability of the TOGETHER program and website. By providing the content digitally, the program effectively addresses YAs' expressed preference for convenience. Future studies are needed to increase TOGETHER's efficiency and explore its efficacy for improving targeted outcomes.

Trial Registration: NCT05597228, October 24, 2022; https://clinicaltrials.gov/study/NCT05597228

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KEYWORDS

cancer survivors; survivorship; clinical trials; psychosocial intervention; usability testing; digital therapeutics; young adults; nonrandomized

Introduction

Young adult (YA) cancer survivors diagnosed between the ages of 15 and 39 years are a rapidly growing population [1]. YAs face unique challenges, such as cancer-related disruptions to reaching normative developmental milestones (eg, education, career, financial independence, emotional and sexual intimacy) [2,3] and biopsychosocial late effects of disease (eg, infertility) that may not be as salient for survivors in other age cohorts [2,4-6]. Perhaps as a result, YAs are at elevated risk for depression, anxiety, and stress [7-9] and frequently report lower levels of health-related quality of life (HRQOL) relative to both older and younger cancer survivors [6,10]. In addition to these challenges, most YA cancer survivors report unmet health information needs, and many report unmet peer support needs, which can further exacerbate low HRQOL [11,12]. Past research among older cancer populations aged>50 years has identified evidence-based approaches, such as interventions grounded in cognitive behavioral therapy, that improve HRQOL [13-16]. However, evidence-based strategies to improve HRQOL that meet the unique needs and preferences of YA cancer survivors are limited.

To address this need, our team developed a supportive care intervention specifically designed to improve YA cancer survivors' HRQOL, called TOGETHER [17]. The TOGETHER content was derived and adapted for YAs from 2 supportive care interventions with established efficacy for improving HRQOL in other cancer survivor populations: Cognitive Behavioral Stress Management [18] and Health Education [19]. In addition to the strong support for their efficacy, these 2 interventions were selected, in part, because they can be remotely delivered via videoconference in a group setting, in accordance with YAs' documented preferences that interventions should be convenient [20-22] and that peer support should be available [22]. Program content was adapted with iterative input from YA cancer survivors via focus groups. In subsequent preliminary testing, 2 intervention groups demonstrated that TOGETHER was feasible and acceptable [17].

Although the first iteration of TOGETHER was well received, it was available only as a static, noninteractive, PDF manual, which diminished the intervention's convenience. In response to this and building on our foundational work, we conducted a 2-part study to design and test a website to host and deliver TOGETHER. In the first part of this study, we leveraged an existing digital platform that has historically been used to deliver similar supportive care interventions to other cancer survivor populations and adapted it to meet the needs of the TOGETHER program. Consistent with a rapid prototyping approach [23], we iteratively refined the platform based on feedback gathered from YA cancer survivors in 3 waves of usability testing. In the second part of the study, we tested the feasibility and acceptability of delivering TOGETHER via the adapted website in a single-arm, single-group feasibility trial. We hypothesized that TOGETHER would be feasible and acceptable based on predetermined benchmarks for recruitment, retention, average session attendance, and average participant satisfaction.

Part 1: Building the TOGETHER Website

Methods

Participants

Participants were YA cancer survivors aged 15 - 39 years at the time of initial cancer diagnosis and aged 18 - 39 years at the time of participation in this study. All participants had completed curative treatment at least 1 month but no more than 5 years before enrollment. Participants were also fluent in English, able to give informed consent, and not currently experiencing a psychiatric or neurological disorder that could impair their participation. YAs were recruited from the University of Arizona Comprehensive Cancer Center and community-based cancer advocacy groups in Tucson, Arizona.

Ethical Considerations

Study procedures were reviewed and approved by the University of Arizona Institutional Review Board (IRB #STUDY00000717). All participants provided written informed consent.

Procedures

To build the initial version of the TOGETHER website, we leveraged an existing digital platform developed by BrightOutcome Inc. [24]. The platform is a customizable, Health Insurance Portability and Accountability Act–compliant, mobile-friendly, password-protected website designed to facilitate remote delivery of course-based supportive care interventions and host live group videoconference sessions. We began by inputting the TOGETHER content into the platform's infrastructure. Subsequently, we held 3 waves of usability testing with 3 participants per wave (n=9 total) based on prior research showing that 9 usability testers are needed to find moderately hard-to-find problems with 75% certainty [25].

Individual usability testing sessions were held in person and each lasted approximately 60 minutes. During these sessions, participants were introduced to a prototype of the TOGETHER website and asked to think aloud while completing a series of prescribed tasks (eg, log in, navigate from the home dashboard to session content). Participants were then asked to provide feedback on the appeal, clarity, comprehensibility, and aesthetic of the website. After each wave of testing, participant feedback was integrated into the website, and testers in the subsequent wave were shown the modified version. We iteratively incorporated stakeholder feedback in this way to maximize user engagement with TOGETHER [26]. Usability testing participants were compensated US $30 for their time.

Measures

Participants completed the 11-item Ease of Use subscale and 4-item Ease of Learning subscale from the Usefulness, Satisfaction, and Ease of Use (USE) questionnaire [27,28]. Items are rated on a 7-point scale ranging from 1 (*Strongly Disagree*) to 7 (*Strongly Agree*) and averaged to yield a total score. Higher scores indicate better usability. Usability testing participants also self-reported demographic and medical information.

Analysis

Audio recordings of the usability testing sessions were transcribed verbatim by a third-party service (GMR Transcription Services, Inc.). Each transcript was reviewed by at least 2 reviewers using an analytic approach similar to Gale and colleagues' [29] rapid qualitative analytic method to identify actionable feedback. Reviewers identified suggested changes to the website and supporting quotes using an analysis template in Microsoft Excel. The audio recordings were revisited as needed for content and wording clarifications. After independent review, coders compared and discussed results to achieve consensus. This process was completed after each round of usability testing, and changes to the website were implemented rapidly in response to participant feedback. In addition, descriptive statistics were used to summarize the demographic and clinical characteristics of study participants and to describe website usability per the USE individual items and subscale scores.

Results

Participant Characteristics

Information about usability testers' demographic and medical characteristics can be found in Table 1. Participants were an average of 27 years old (range 23 - 37) at the time of study participation and predominantly White (n=8, 89%), with two-thirds identifying as Hispanic or Latine (n=6, 67%). Slightly more than half were female, had completed some college or specialized training, and were working full-time (n=5, 56% each). The most common cancer diagnoses reported were breast cancer (n=3, 33%) and leukemia (n=2, 22%), and the average age at diagnosis was 24 (range 19 - 34) years.

Table . Sample characteristics. Unless otherwise specified, all variables represent patient-reported information at the time of study participation. Six participants were included in both the usability testing and feasibility trial samples.

Variable	Statistic	
	Usability testing (n=9)	Feasibility trial (n=7)
Age at study participation in years, mean (range)	27.8 (23-37)	25.1 (18-33)
Age at diagnosis in years, mean (range)	24.7 (19-34)	22.0 (17-32)
Gender, n (%)		
Male	3 (33)	2 (29)
Female	5 (56)	5 (71)
Nonbinary	1 (11)	0 (0)
Race, n (%)		
White	8 (89)	7 (100)
Native American or Alaskan Native	1 (11)	0 (0)
Hispanic or Latine, n (%)	6 (67)	3 (43)
Education, n (%)		
Partial high school	0 (0)	1 (14)
High school graduate	1 (11)	1 (14)
Partial college or specialized training	5 (56)	3 (43)
College or university graduate	3 (33)	2 (29)
Relationship status, n (%)		
Never married	4 (44)	4 (57)
Married or partnered	4 (44)	3 (43)
Divorced	1 (11)	0 (0)
Employment, n (%)[a]		
Working full time	5 (56)	3 (43)
Working part time	0 (0)	2 (29)
Not employed	2 (22)	2 (29)
Student	1 (11)	0 (0)
Missing	1 (11)	0 (0)
Household income, n (%)		
<US $10,000	1 (11)	1 (14)
US $10,000-US $39,999	3 (33)	2 (29)
US $40,000-US $59,999	2 (22)	1 (14)
US $60,000-US $100,000	3 (33)	2 (29)
>US $100,000	0 (0)	1 (14)
Cancer type at diagnosis, n (%)		
Bone and soft tissue	1 (11)	2 (29)
Breast	3 (33)	2 (29)
Colorectal	1 (11)	0 (0)
Leukemia	2 (22)	1 (14)
Lymphoma	1 (11)	1 (14)
Thyroid and endocrine	1 (11)	1 (14)
Stage at diagnosis, n (%)		

Variable	Statistic	
	Usability testing (n=9)	Feasibility trial (n=7)
I	3 (33)	2 (29)
II	0 (0)	0 (0)
III	2 (22)	2 (29)
IV	1 (11)	1 (14)
Unknown or not reported	3 (33)	2 (29)

[a] For employment, participants were instructed to select the response that they felt most closely aligned with their employment status at the time of study participation.

Usability: Quantitative Results

The frequency and means of item-level usability ratings for both USE subscales can be found in Table 2. Mean scores on the Ease of Use subscale of the USE questionnaire (mean 5.94, SD 1.27) and each of the 10 items contained therein (means ranged from 5.22 to 6.33) supported the website's usability. Results for the Ease of Learning subscale demonstrated it was also easy to learn based on both the overall subscale score (mean 6.50, SD 0.89) and the 4 individual item scores (means ranged from 6.44 to 6.56).

Table . Usability ratings.

Item	Mean (SD)	Number of participants that endorsed each response						
		1 (Strongly Disagree)	2	3	4 (Neutral–Neither Agree nor Disagree)	5	6	7 (Strongly Agree)
Ease of use								
Easy	6.00 (1.32)	0	0	1	0	1	3	4
Simple	6.22 (1,30)	0	0	1	0	0	3	5
User-friendly	6.33 (1.00)	0	0	0	1	0	3	5
Fewest steps possible	5.67 (1.50)	0	1	0	0	1	5	2
Flexible	5.78 (1.30)	0	0	1	0	2	3	3
Effortless	6.00 (1.32)	0	0	1	0	1	3	4
Use without instructions	5.67 (1.94)	1	0	0	0	2	2	4
No inconsistencies	5.22 (2.05)	1	0	1	0	2	2	3
Users like	6.22 (1.30)	0	0	1	0	0	3	5
Recover mistakes	6.11 (1.27)	0	0	1	0	0	4	4
Use successfully	6.11 (1.69)	0	1	0	0	1	1	6
Ease of learning								
Learned quickly	6.44 (1.33)	0	0	1	0	0	1	7
Easily remember	6.56 (0.88)	0	0	0	0	2	0	7
Easy to learn to use	6.44 (1.01)	0	0	0	1	0	2	6
Quickly skillful	6.56 (0.73)	0	0	0	0	1	2	6

Usability: Qualitative Results

A screenshot of the TOGETHER website can be found in Multimedia Appendix 1. YA cancer survivors described the website as “clean,” “neat,” “visually pleasing,” “user-friendly,” “straightforward,” “organized,” “intuitive,” and “easy to navigate.” Participants particularly valued that there were multiple ways to access or complete various website functions. For example, participants expressed appreciation that program exercises and home practices could be completed digitally within the website or downloaded as a PDF to be completed offline.

Participants identified several strengths related to the aesthetics, content, function, and structure of the website, as well as recommendations for how to improve the platform. Table 3 lists the modifications made to the website in response to these recommendations. Of note, not all feedback led to immediate changes to the website. For example, some participants requested a progress tracking feature that would enable them to quickly visualize which aspects of the program had already been completed. This change was not feasible immediately following usability testing; however, it has since been implemented in subsequent iterations of the website.

Table . Modifications made to the website in response to usability testing feedback.

Theme	Summary of issues identified by participants	Examples of website modifications
Aesthetics	• Not visually engaging • Images are generic • Text hard to read when insufficiently contrasted with background	• Added bright, colorful, young adult–relevant, session-consistent images throughout • Ensured images reflected broad sociodemographic representation and ages • Avoided business-like images • Added colored text
Content	• Relevance to cancer not obvious • Purpose of both overall program and specific components (eg, interactive exercises) unclear • Acronyms unknown	• Added cancer-specific images throughout • Added more detailed instructions throughout • Spelled out acronyms
Function	• Functionality of some aspects unclear (eg, interactive worksheets, achievements and events, favorites)	• Develop standardized preprogram website orientation for participants to complete prior to being granted an account
Structure	• Difficult to distinguish sections and topics	• Adjusted font colors throughout to identify section headers, instructions, etc • Added descriptive section titles • Presented session text in multiple expandable sections

Part 2: Examining the Feasibility and Acceptability of Delivering TOGETHER Through the Website

Methods

Participants

Eligibility and recruitment for the feasibility trial mirrored that of usability testing, although feasibility trial participants were also required to have access to internet or cellular connectivity with sufficient bandwidth to participate in videoconferences. Participants who completed usability testing were permitted to enroll in the feasibility trial if desired. In such cases, participants provided informed consent for each stage of the study.

Procedures

The feasibility trial was preregistered on ClinicalTrials.gov (NCT05597228) [30] and consisted of a single instance of the 10-week TOGETHER group intervention. After providing informed consent, participants completed a 1-time website orientation videoconference meeting with a member of the research team. Participants were also mailed a physical copy of the TOGETHER participant workbook. The physical copies were provided because YAs who contributed to the development of the intervention content [17] recommended providing both physical and digital copies of intervention materials to program users.

Participants then completed a full administration of the facilitator-led TOGETHER group intervention delivered via the adapted website. All intervention sessions were held on a Health Insurance Portability and Accountability Act–compliant version of Zoom. The link to join each week’s session was visible on the website beginning 36 hours before the session was scheduled to start and remained visible until 2 hours after the session was scheduled to end. Sessions each lasted approximately 2 hours and occurred on the same day of the week at the same time for the duration of the program. Immediately following each session, participants in attendance were sent a unique link to complete a brief electronic survey assessing the acceptability of that session’s content and group dynamics. Participants completed a similar survey postintervention assessing the acceptability of the overall program. Participants completed an individual exit interview with a member of the research team postintervention to provide qualitative feedback on their experience. Participants also completed a battery of patient reported outcome measures at baseline and postintervention. The battery was consistent with the planned assessment protocol for a future, larger-scale trial; however, given the small sample size, we were not powered to detect effects and therefore did not analyze these data. Participants were compensated US $50 for completing the baseline and post-intervention assessment batteries, US $20 for completing the exit interview, and US $5 for each of the 10 weekly surveys completed. In total, feasibility trial participants had the opportunity to earn up to US $170.

TOGETHER Intervention

Details of the TOGETHER intervention have been previously published [17]. Briefly, each TOGETHER session consists of 3 main sections: learn and practice relaxation skills (first 30 min), practice skills derived from cognitive behavioral therapy principles (middle 60 min), and discuss YA-relevant health education topics (remaining 30 min). During each session, a facilitator guides participants through new content and leads interactive activities designed to reinforce the content and skills. Facilitators also create opportunities for participants to discuss their personal experiences and develop group rapport. Between sessions, participants complete home practice assignments to promote mastery of the intervention skills, and each session begins with a review of the prior week's home practice. For this feasibility trial, sessions were facilitated by a predoctoral clinical psychology trainee (TKT) under the supervision of the study Principal Investigator (RSF). Sessions were video- and audio-recorded and reviewed during weekly supervision meetings to ensure intervention fidelity.

Primary Outcomes: Feasibility and Acceptability

Feasibility was measured by calculating study recruitment and retention rates and tracking session attendance [31]. Feasibility was defined as achieving a 50% recruitment rate, a 70% retention rate, and average attendance of ≥ 6 of the 10 sessions. These benchmarks were based on rates observed in past studies of similar behavioral interventions in diverse cancer survivors [19,32,33] and in accordance with our prior investigation of the feasibility of TOGETHER content [17]. Acceptability was measured with study-specific weekly and postintervention surveys our team previously developed to assess the acceptability of the TOGETHER content [17]. Survey items assessed participant satisfaction with multiple aspects of TOGETHER and were rated on a Likert scale ranging from 0 (strongly disagree) to 4 (strongly agree). For this study, a new item was added to the postintervention acceptability survey assessing the acceptability of the study website. The study was considered acceptable if average scores on the weekly and postintervention survey items were ≥2 (ie, neutral or better). Participants also completed the Satisfaction subscale of the USE questionnaire [27,28] postintervention and self-reported demographic and medical information at baseline.

Analysis

Descriptive statistics were used to summarize feasibility and acceptability metrics.

Results

Participant Characteristics

Seven YA cancer survivors enrolled in the single-arm feasibility trial, 6 of whom had also participated in usability testing due to practicality reasons. Information about feasibility trial participants' demographic and medical characteristics can be found in Table 1. On average, feasibility trial participants were 25 years old at the time of participation (range 18 - 33) and were 22 years old at the time of incident cancer diagnosis (range 17 - 32). The majority were female (n=5, 71%), non-Hispanic White (n=4, 57%), and had never been married (n=4, 57%). The most well represented cancer types included bone and soft tissue (n=2, 29%) and breast (n=2, 29%).

Feasibility

All feasibility metrics were met. Of 12 seemingly eligible YA cancer survivors who were approached for participation, 7 (58%) consented and enrolled in the study (Multimedia Appendix 2). All 7 participants attended the first group session, after which 1 withdrew, and 1 was lost to follow-up. Of the remaining 5 participants, all were retained through the postintervention assessment (71% of enrolled). Across all 7 participants, the average attendance was 7.1 of the 10 intervention sessions (SD 4.2); however, among the 5 participants who attended at least 2 sessions, the average attendance was 9.6 of the 10 sessions (SD 0.5).

Acceptability

All acceptability metrics were met. Tables 4 and 5 show the average acceptability ratings for each of the 10 weekly sessions and for the overall program, respectively. Pooled average satisfaction with the individual weekly sessions was ≥3 for all items. Participants agreed to strongly agreed that they liked the sessions, the content was relevant and helpful, they felt confident with the content, and they felt comfortable and respected in the group. Similarly, at postintervention, the means for all items assessing overall program satisfaction were ≥3, with the exception of an item assessing satisfaction with the website. Based on feedback gathered in exit interviews, low ratings for satisfaction with the website were due to a timing feature that prevented participants from viewing data they had entered (eg, responses to home practice prompts) in subsequent weeks even though the data had been saved. This led some participants to express frustration with the website, particularly when reviewing the prior week's home practice assignments at the start of each session. For example, when asked to share additional information about their experience in the program during exit interviews, one participant stated, “everything was great besides the homework assignments not saving” and another specified, “I would have liked using the website even more if it wouldn't have erased the data. Besides that glitch it seemed quite self-explanatory and would've been used more.” This feature has since been fixed.

The Satisfaction subscale of the USE questionnaire supported the acceptability of the program website. The mean score on the overall subscale was 5.06 (SD 1.64), with individual item means ranging from 3.80 to 5.80. The item with the lowest average rating assessed if the website worked as desired, and no items received the lowest possible rating from any participant. When asked to identify the website's most negative aspect(s), multiple participants identified the website not displaying past work properly. Conversely, when asked to identify the website's most positive aspect(s), participants identified the "clean, friendly interface," and described the website as "easy to navigate," and "straight to the point." Some participants also highlighted strengths of the overall program, including the exercises and home practice assignments as well as the value of meeting other YA cancer survivors and learning new tools and skills.

Table . Acceptability of TOGETHER's 10 weekly sessions as delivered through the website. Possible scores range from 0 (strongly disagree) to 4 (strongly agree).

Item	Mean (SD)[a]	Observed range[b]
Overall, I liked this session.	3.30 (0.58)	2.44 - 4.00
The content related to ______ was relevant to me.		
a) Relaxation	3.54 (0.55)	2.67 - 4.00
b) Stress management	3.22 (0.77)	2.00 - 4.00
c) Health topics	3.45 (0.57)	2.56 - 4.00
The content related to ______ was helpful to me.		
a) Relaxation	3.29 (0.57)	2.67 - 4.00
b) Stress management	3.25 (0.71)	2.00 - 4.00
c) Health topics	3.19 (0.81)	2.00 - 4.00
I feel confident with the new information and skills covered in this session.	3.37 (0.45)	3.00 - 4.00
I felt comfortable expressing my experiences and feelings in the group.	3.46 (0.73)	2.00 - 4.00
The other group members respected my experiences and feelings.	3.69 (0.41)	3.00 - 4.00

[a] Means and standard deviations for each item were pooled across the 10 weekly surveys.

[b] Observed range of average values across the 10 weekly surveys.

Table . Acceptability of the overall TOGETHER program as delivered through the website. Possible scores range from 0 (strongly disagree) to 4 (strongly agree).

Item	Mean (SD)	Agreed or strongly agreed (%)
Overall, the content was relevant to me.	3.6 (0.5)	100
Overall, the content was helpful to me.	3.6 (0.9)	80
Overall, I liked the program content related to _____.		
a) Relaxation	3.4 (0.5)	100
b) Stress management	3.6 (0.5)	100
c) Health topics	3.2 (0.8)	80
I liked connecting with other YA[a] cancer survivors in the weekly sessions.	4.0 (0.0)	100
I liked using the study website	2.8 (1.3)	60
I plan to continue using the skills I learned.	3.6 (0.5)	100
I would recommend the program to other YA cancer survivors.	3.8 (0.4)	100
Overall, I am glad I decided to participate.	3.8 (0.4)	100

[a] YA: young adult.

Discussion

Principal Findings

This manuscript describes the usability, feasibility, and acceptability of a website designed to host the TOGETHER group program for YA cancer survivors. We first adapted an existing digital platform to meet the needs of TOGETHER. Then, consistent with best practices for human-centered design [34], we conducted three waves of iterative usability testing to identify and address challenges with the website's functionality, structure, content, and aesthetics as experienced by YA cancer survivors. Finally, we established the preliminary feasibility and acceptability of the TOGETHER program as delivered through the adapted website.

Usability testing identified desired changes to the website. Interestingly, many of these changes were consistent with feedback provided by YA cancer survivors who evaluated the "Roadmap to Parenthood" web-based decision tool for family building after cancer [35]. For example, usability testers of "Roadmap to Parenthood" reported that pages containing large amounts of content were overwhelming. Therefore, the designers divided content into separate pages and adjusted content to only be visible when a header was clicked. Font sizes and colors were also changed to better clarify the division of text. In Part 1 of this study, we made almost identical adjustments to the TOGETHER website. The consistency of these results suggests that individuals developing digital therapeutics for YA cancer survivors may benefit from considering these findings early in the prototype design process. Of note, usability testing for "Roadmap to Parenthood" also yielded findings related to visibility and navigation that did not emerge in the present study. However, an important distinction between TOGETHER and many other digital health interventions [36] is that TOGETHER is designed to be led in real-time by a group facilitator rather than self-guided. Consequently, users can be oriented to the website's functionality prior to using it for the first time and the website does not need to stand alone, which may explain such discrepancies.

Although usability testing demonstrated that the TOGETHER website was easy to use and learn, the single-session nature of the usability testing precluded evaluation of time-based functionality of the website. This led to challenges during the feasibility trial. While the feasibility and acceptability of TOGETHER were generally strong, the website was the least acceptable aspect of the program. This low satisfaction was most likely due to participants being unable to view content they had previously input into the website at each group meeting. Contrary to participant understanding, the data had not been deleted; however, by the time each group meeting occurred, the prior week's data were no longer displayed back for participants to view. This challenge impacted participant experiences of the website. By identifying this challenge at an early stage of testing, we have been able to adjust it prior to future, larger-scale testing of TOGETHER. We will re-evaluate the acceptability of the website following this change, consistent with the cyclic nature of user-centered design [37]. Despite this, the average reported acceptability of the website was still better than the identified threshold of 2.0, thus meeting this benchmark. Moreover, the overall acceptability of the website was comparable to what we found when testing the content as delivered via static, text-only PDF workbooks, further supporting the acceptability.

Implications for Health Care and Research

The TOGETHER intervention is one of the first supportive care interventions for YA cancer survivors that fulfills their expressed desires for convenience (eg, digital delivery) and peer connection. By providing the program digitally, we have further increased its convenience, taking a step toward fulfilling YAs' priorities and increasing dissemination potential. Future research is needed to test the intervention's efficacy for improving HRQOL, to explore approaches for increasing intervention efficiency, and to explore strategies for implementation both within and outside of the healthcare system.

Limitations

Usability testers were not given an opportunity to explore the website independently but rather were directed to complete prescribed tasks and answer specific questions. Although the prescribed tasks reflected what a YA would need to be able to do to engage with the intervention (eg, log in, navigate to session content), it is possible that additional opportunities to enhance usability could have been identified had the usability testers been given an opportunity for non-directed exploration. Of note, feasibility trial participants were given an opportunity to provide non-directed usability feedback during exit interviews. Another limitation is that the sample size for the feasibility trial was small, even when combined with our prior testing of the TOGETHER content. This is particularly true given that, due to practicality, 6 participants were included in both the usability testing sample and the feasibility trial sample, which could have impacted our findings. Further data are needed to confirm the observed results. The small sample size also precluded evaluation of the intervention's effects on theorized outcomes.

Conclusions

Study results support the usability, feasibility, and acceptability of the TOGETHER program and website. The incorporation of YA cancer survivors' feedback into the development of the intervention content and delivery platform is consistent with their expressed desires to be actively engaged in research [21] and likely contributed to the high observed acceptability. Additionally, by enabling digital delivery of TOGETHER, we have directly responded to YAs' expressed priority that interventions be convenient [20-22]. Larger-scale testing is needed to establish the efficacy of TOGETHER and explore alternative study designs to increase efficiency.

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Conflicts of Interest

DY is the President and chief executive officer of BrightOutcome Inc. MHA is a paid consultant for Blue Note Therapeutics. The authors declare there are no other conflicts of interest to disclose.

Multimedia Appendix 1
TOGETHER session 1 screenshot.
[DOCX File, 127 KB - cancer_v10i1e58014_app1.docx]

Multimedia Appendix 2
Participant flow diagram.
[DOCX File, 68 KB - cancer_v10i1e58014_app2.docx]

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Abbreviations

HRQOL: health-related quality of life
USE: Usefulness, Satisfaction, and Ease of Use questionnaire

YA: young adult

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Implementation of Regular Lifestyle Counseling During Long-Term Follow-Up Care of Childhood Cancer Survivors: Monocentric Prospective Study

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Abstract

Background: Many childhood cancer survivors (CCS) develop treatment-related late effects, including an increased risk of obesity and metabolic syndrome. A healthy lifestyle can reduce the risk of associated comorbidities. Therefore, at-risk CCS could benefit from lifestyle counseling during regular long-term follow-up (LTFU).

Objective: We implemented a new form of care to decrease the long-term morbidity among CCS and to gain new insights into the lifestyle of those patients.

Methods: Over a 1-year study period, lifestyle counseling was integrated into LTFU care. Metabolic disorders, including hypercholesterolemia, diabetes mellitus, overweight or underweight, and low activity levels, were assessed as screening parameters for various risk groups. The perspectives of CCS, physicians, and sports scientists were compared to identify those with the highest needs. Each lifestyle counseling included general recommendations for physical activity, as well as an assessment of individual preferences for and barriers to the implementation of a healthy lifestyle. A follow-up appointment after 1 month was performed.

Results: Of the 155 CCS aged 18 to 63 years (n=100, 65% female and n=55, 35% male), 112 (72%) had an indication for lifestyle counseling, identified by physicians, sports scientists, or the CCS themselves. Metabolic disorders affected 45% (n=70) of these CCS, and 46% (n=72) did not meet recommended activity levels. A total of 120 (77%) CCS received lifestyle counseling, including 8 initially uninterested individuals who became open to recommendations. Those with intensive cancer treatment history showed the greatest need. A total of 65 (54%) CCS were advised to change their lifestyle in both areas (diet and exercise) while 51 (43%) CCS received recommendations for only exercise (n=43 CCS, 36%) or diet (n=8 CCS, 7%). A total of 4 (3%) CCS, although interested in counseling, received no advice, as they already met the recommendations. Follow-up revealed high adherence to recommendations and successful integration into daily lives. In total, 97% (n=150) of survivors indicated that the provision of lifestyle counseling during LTFU would be generally beneficial.

Conclusions: Incorporating specialized health care professionals such as sports scientists into survivorship care enhances the multidisciplinary approach of LTFU care. Promoting a healthy lifestyle by offering guideline-based lifestyle counseling is broadly accepted among CCS and may reduce long-term morbidity.

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KEYWORDS

lifestyle counseling; long-term follow-up; childhood cancer survivors; physical activity; metabolic disorders; cancer survivor; treatment-related; risk of obesity; metabolic syndrome; healthy lifestyle; morbidity; patient; hypercholesterolemia; diabetes mellitus; health care professionals

Introduction

Due to improved treatment modalities, the proportion of patients surviving childhood and adolescent cancer has been steadily increasing in recent decades, and 5-year overall survival now exceeds 85% in German childhood cancer survivors (CCS) [1]. Currently, more than 40,000 former patients are included in the long-term follow-up (LTFU) cohort of the German Childhood Cancer Registry [2]. These CCS were diagnosed with cancer at least 5 years ago, so regular oncological follow-up has usually already been completed. During their lifetime, many of these survivors are affected by further health problems and diseases caused by the cancer and its therapy, so-called late effects [3]. These can manifest in different organs of the entire body. Due to hormonal changes and altered body composition that may occur during or after therapy, the risk of obesity and associated diseases such as diabetes mellitus, cardiovascular disease, and hypertension increases [4]. Cardiovascular disease, in turn, is among the most common nonmalignant causes of death in survivors of cancer, with some groups such as Hodgkin lymphoma survivors having a particularly high risk [5,6]. Long-term sequelae may not only manifest in physical form; many CCS develop psychological problems, particularly depression or fatigue syndrome, during or even years after cessation of cancer treatment [7,8]. For these CCS at risk, it is particularly important to develop interventions or treatments that can positively influence their long-term health.

According to Smith et al [9], over 70% of CCS do not meet the lifestyle guidelines of the World Cancer Research Fund. Furthermore, in more than 30% of the adult CCS (median age: 32.7 years, 1598 participants), metabolic syndrome was already prevalent, which is a combination of metabolic parameters associated with increased cardiovascular risk. Consequently, multiple studies evaluated the effect of counseling on CCS' lifestyle and could demonstrate a reduction in comorbidities, as well as a better quality of life due to a healthy lifestyle [10,11]. Furthermore, blood pressure in CCS improved due to lifestyle counseling in previous studies [12]. Therefore, a healthier lifestyle could result in less comorbidities including metabolic syndrome among CCS [10]. A healthy lifestyle in this context includes in general no smoking, the awareness of alcohol consumption, and regular physical activity, as well as a vitamin and nutrition-rich diet [13].

Additionally, previous studies demonstrated that the occurrence of late effects can be positively influenced by regular physical activity, exercise, and a healthy diet [14,15]. Especially avoiding overweight and obesity has a significant impact on the severity of late effects associated with the metabolic syndrome [11]. According to Hammoud et al [16], despite the available guidelines, many cardiometabolic risk factors in CCS remain underdiagnosed or undertreated although CCS have a 4-fold increased risk of cardiac-related mortality compared to the general population. The authors, therefore, recommend further studies that incorporate nutrition, as well as physical activity, taking into account the heterogeneity of late effects and the impact of cancer treatment on the individual's physical abilities. Both the type and intensity of exercise may differ from the type of sport practiced before the disease, but physical activity, in general, has a benefit [15] as it not only improves body composition and reduces the risk of future health conditions, it also often positively affects mental health [17]. Additional factors such as age, gender, and socioeconomic status (that correlate inversely with the risk of obesity) also need to be considered in lifestyle counseling [18-20]. As interest in lifestyle counseling may decrease with increasing time interval from diagnosis and late effects often do not manifest until adulthood, it is especially important to inform and counsel children, adolescents, and young adults about the importance of prevention in terms of a healthy lifestyle [21]. The earlier the education about a healthy lifestyle including physical activity and healthy nutrition starts, the more likely this behavior will be maintained in future life [22]. Therefore, the implementation of regular lifestyle counseling within the framework of LTFU care could be a useful and practical approach to informing CCS about a healthy lifestyle in order to prevent future diseases.

In 2014, an interdisciplinary LTFU clinic for CCS ("LTFU clinic") was established at the University Medical Center Schleswig-Holstein, Campus Luebeck [23]. Among others, we were a consortium partner in the multicenter study CARE for CAYA that took place from 2018 to 2021 and provided specialized lifestyle counseling for high-risk CCS [24]. Based on these experiences, we decided to implement lifestyle counseling as part of standard care for every CCS during their regular visit to our LTFU clinic. It included general, guideline-based recommendations, as well as individualized content based on the survivor's needs. Risk factors for cardiometabolic diseases such as cancer treatment, age, gender, and socioeconomic status were assessed to identify high-risk CCS. Additionally, we performed an analysis to determine how many CCS are in need of lifestyle counseling according to current guidelines [11,13] due to pre-existing metabolic diseases and how they accepted and implemented counseling into their daily life. A subgroup analysis was conducted to identify CCS who may escape standard inclusion criteria for lifestyle counseling. Furthermore, we aimed to develop and establish a lifestyle counseling program considering the physician's, the sports scientist's, and CCS' perspective on who could benefit most from counseling that, due to limited resources, would be mainly limited to at-risk CCS in most settings.

Methods

Study Population

In this study, lifestyle counseling as a routine care offer was implemented within regular LTFU care. All CCS visiting our late effects clinic from February 2022 to the end of January 2023 were offered to participate in lifestyle counseling. They were informed about this offer several weeks before their visit to the LTFU clinic by phone and asked to participate in this study during their stay in the clinic. Survivors who were 18 years or older at initial cancer diagnosis but had undergone cancer treatment in our local department for pediatric oncology, mainly young adults with medulloblastoma, were also transitioned to our late effects clinic and thus analyzed as part of the study group. Risk stratification into three different risk groups, based on survivors' initial cancer diagnosis and treatment, their risk for late effects, and their need for LTFU examinations, was performed according to Gebauer et al [25], with risk group 1 corresponding to a low, group 2 to a medium, and group 3 to a high risk for late effects.

Inclusion Criteria

Inclusion criteria were hypercholesterolemia (total cholesterol ≥5.0 mmol/L), diabetes mellitus (preexisting or hemoglobin A_{1c} [HbA_{1c}] ≥6.5%), BMI ≤18.5 or ≥30 kg/m², not reaching the recommended activity time (<150 minutes moderate or <75 minutes vigorous activity time per week), or the need for counseling expressed by the survivor [11].

These inclusion criteria were based on three different perspectives on who would benefit most from counseling: the perspective of the survivor (expresses the need for counseling), the perspective of the sports scientist (focus on activity level and anthropometric data), and the perspective of the treating physician (focus on metabolic diseases).

Exclusion Criteria

CCS who were not interested in lifestyle counseling or study participation were excluded from this study.

Assessment of Inclusion Criteria

HbA_{1c} was assessed in order to check if CCS were in a diabetic or prediabetic condition (HbA_{1c} level between 5.7% and 6.4%) [26]. For BMI calculation, most CCS were measured wearing clothes, as well as with their prosthesis, if needed. Only one CCS came to the LTFU care without a prosthesis, therefore, we used a formula to correct the BMI for CCS with amputated limbs [27]. Additionally, we calculated the BMI with the Amputee Coalition BMI Calculator Widget.

Ethical Considerations

This study was approved by the ethics committee of the University of Luebeck (registration 18 - 087) and conducted in accordance with the Helsinki Declaration of 1975. Informed consent was obtained from all participants included in the study, with the ability to opt-out. Data were saved anonymously. Patients took part in the study voluntarily and received no compensation other than counseling.

Lifestyle Counseling

Every counseling was performed by the same sports scientist (FR) with several years of experience in counseling of CCS. It was scheduled for 30 minutes and took place in the LTFU clinic right after the regular LTFU visit. The CCS were informed about the appointment before they attended their appointment in the LTFU clinic. Medical and anthropometric data was documented in the clinic's database. Additionally, CCS were asked to answer a set of lifestyle questions (physical activity time, daily activity, and nutritional status) to evaluate to which extent the lifestyle recommendations from the American College of Sports Medicine and the American Cancer Society (ASC) were already implemented [11]. Due to those guidelines, cancer survivors should be physically active for at least 150 minutes per week with moderate intensity or 75 minutes of vigorous-intensity. Physical activity should be performed for at least 10 minutes at a time, and sedentary activities should be avoided or reduced. It is also recommended that adults perform strength exercises at least twice a week for the major muscle groups [11,28]. Every CCS was asked to assess their subjective requirement for the need for nutrition or sports counseling. Sports behavior, as well as nutrition behavior, was assessed by subjective questioning.

During counseling, the sports scientist referred to the recommendations of the ASC and German Nutrition Society, considering the third, updated, and evidence-based ASC nutrition and physical activity guideline for cancer survivors that was published early during the study period in 2022 [11,29]. In addition to pointing out general recommendations, the sports scientist emphasized individual aspects that were not in concordance with the guidelines. Consequently, although every CCS was asked the same set of questions, the content of lifestyle counseling depended on the CCS's individual needs (Multimedia Appendix 1). If CCS already met the recommendations for physical activity and were still interested in the counseling, counseling focused on general lifestyle advices according to the guidelines from Rock et al [11] such as smoking cessation and nutrition counseling.

After 4 weeks, every CCS received a remote follow-up appointment, to check whether they were able to implement the recommendations in their daily life and whether they benefited from the counseling (Multimedia Appendix 1). All statements were answered subjectively.

Statistical Analysis

For descriptive statistics, the median and range were calculated for continuous variables. For categorical variables, the absolute number, as well as the relative number of the respective category, is presented.

Qualitative data were analyzed descriptively. They were only collected for one question in a structured follow-up interview by phone ("effect of lifestyle counseling"). The first author (FR) made field notes during the interview. Afterward, the perceived effect was categorized into three different subcategories (weight loss, quality of life including more joy, balance, and satisfaction, or both). These categories were determined after obtaining an overview of patients' responses. This approach was supervised by JG. Reliability was tested by asking patients about their current weight and comparing this answer to the documented weight in the database.

The programming language R (version 4.2.2; R Core Team) was used for the entire analysis of the data.

Subgroup Analysis

For further analysis, three subgroup analyses were defined to gain a better overview of CCS who may escape standard inclusion criteria for lifestyle counseling. Subgroup 1 was considered to include the CCS who had a need for counseling based only on the criteria of the sports scientist and not from the physician's point of view. Subgroup 2 included CCS who requested lifestyle counseling but did not need it based on the inclusion criteria. Subgroup 3 included CCS who met the inclusion criteria but rejected the offer for counseling. We descriptively compared the subgroups regarding relevant characteristics using the chi-square test or Fisher exact test where appropriate.

Results

Survivors' Characteristics

Overall, lifestyle counseling was offered to 155 CCS (n=100, 65% female and n=55, 35% male), who had a median age of 30 years (IQR 24-39.5) with a range of 18 to 63 years. Most CCS underlying diseases were lymphoma (n=45, 29%), leukemia (n=42, 27%), and brain tumors (34/155, 22%). The median age at first diagnosis was 12 years (IQR 5-16) with a range of 0 to 35 years. In terms of diagnosis and therapy, 18 (12%) CCS were assigned to risk group 1, 42 (27%) CCS to risk group 2, and 95 (61%) CCS to risk group 3. A total of 61% (11/18) of survivors assigned to risk group 1 had an indication for lifestyle counseling and 45% (19/42) of those assigned to risk group 2. In the group with the highest risk for late effects (risk group 3), 72% (68/95) had need for lifestyle counseling. Detailed information on the characteristics of the CCS is shown in Table 1. In addition, 29 (19%) survivors were in a prediabetic condition, of which 10 (6%) survivors were not included in the needs analysis as they did not meet any inclusion criteria. Furthermore, 82 (53%) of all CCS already received previous nutrition or sports counseling, either organized by themselves, during rehabilitation stays, or while being part of the study CARE for CAYA [21].

Table . Characteristics of the study population (n=155).

Characteristics		Survivors (n=155)
Sex, n (%)		
	Female	100 (64.5)
	Male	55 (35.5)
Age at counseling (years)		
	Median (IQR)	30 (24-39.5)
	Range	18-63
Age at cancer diagnosis (years)		
	Median (IQR)	12 (5-16)
	Range	0-35
Primary cancer diagnosis [a] **, n (%)**		
	Lymphomas	45 (29)
	Leukemias	42 (27.1)
	Brain tumors	34 (21.9)
	Sarcomas	19 (12.3)
	Embryonic tumors	7 (4.52)
	Rare tumors	8 (5.2)
Radiation, n (%)		95 (61.3)
Total body or skull irradiation, n (%)		61 (39.4)
Chemotherapy, n (%)		142 (91.6)
Stem cell transplantation, n (%)		25 (16.1)
Operation, n (%)		75 (48.4)
Recurrence or relapse		27 (17.4)
Risk group, n (%)		
	1	18 (11.6)
	2	42 (27.1)
	3	95 (61.3)
Education level [a] **, n(%)**		
	No school degree	2 (1.3)
	Lower secondary education or less (ISCED ≤2)	14 (9)
	Upper secondary+ non-tertiary postsecondary education (ISCED 3 - 4)	48 (30.9)
	Tertiary education (ISCED ≥5)	91 (58.7)
Previous lifestyle counseling, n (%)		82 (52.9)
Desire for lifestyle counseling, n (%)		
	Sports and nutrition	39 (25.2)
	Sports	27 (17.4)
	Nutrition	15 (9.7)
	None	74 (47.7)
Lifestyle counseling performed, n (%)		120 (77.4)
Recommendations, n (%)		
	Sports and nutrition	65 (54.2)
	Sports	43 (35.8)

Characteristics		Survivors (n=155)
	Nutrition	8 (6.7)
	None	4 (3.3)

[a] According to the International Standard Classification of Education (ISCED) [30].

Needs Analysis and Lifestyle Counseling

Lifestyle counseling was provided to 120 survivors (response rate 77.4%) including 112 survivors with a need for counseling from either the physician's, the sports scientist's, or the CCS' perspective (Table 2). Additionally, 8 CCS opted for lifestyle counseling after receiving further study information although they initially did not indicate the need for it. They were open to recommendations and the talk turned into counseling.

For 27 (17%) survivors, there was no need for counseling, while the remaining 8 (5%) survivors did not want counseling even though there was a need from either the physician's or the sports scientist's perspective.

As the inclusion criteria for this study were based on the perspective of the survivor, the sports scientist, and the treating physician on who would benefit most from lifestyle counseling, we analyzed the need for counseling considering these three approaches. The indication for lifestyle counseling based on these different perspectives only matched in 39 (35%) CCS (Figure 1).

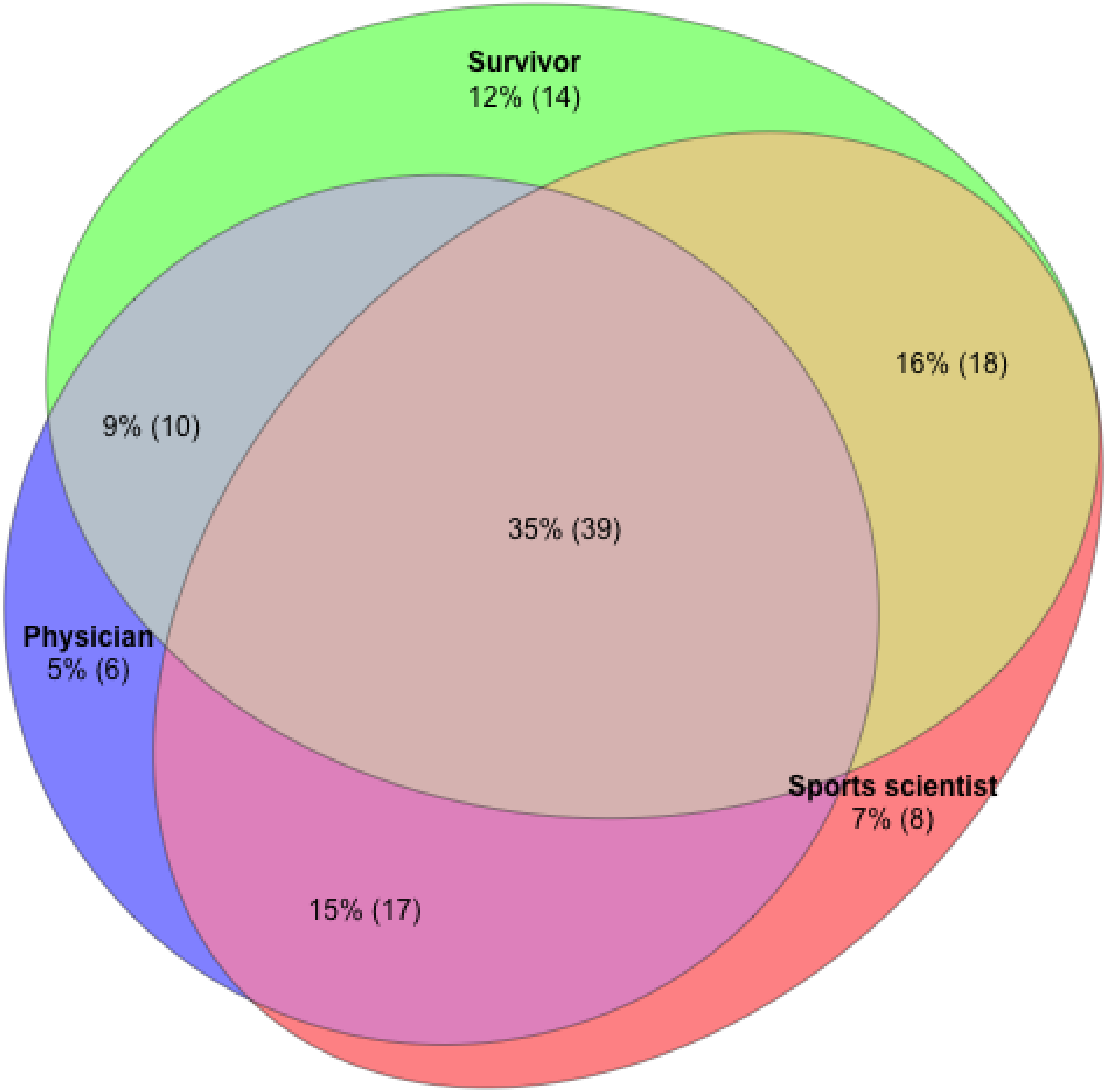
Table . Percentage of survivors (n=155) meeting the different inclusion criteria (activity [<150 min per week], BMI [≤18.5 or ≥30 kg/m^2], diabetes mellitus [preexistent or HbA$_{1c}$ ≥6.5%], hypercholesterolemia [≥5 mmol/L], and desire by patient).

Inclusion criteria	Survivors (n=155), n (%)
Activity	72 (46.5)
BMI	38 (24.5)
Diabetes mellitus	9 (5.8)
Hypercholesterolemia	43 (27.7)
Desire by patient	81 (52.3)

The median duration of the consultation was 25 (IQR 15-30) minutes, with a range of 10 to 60 minutes. Most frequently, CCS (65/120, 54%) were advised to change their lifestyle in both areas (diet and exercise). Furthermore, 51 out of the 120 (43%) CCS received recommendations for only exercise (43/120, 36%) or diet (8/120, 7%). There were 4 out of 120 (3%) CCS who, although interested in counseling, received no advice as they already met the lifestyle recommendations.

Almost all CCS (150/155, 97%) indicated that a general offer of lifestyle counseling would be useful in the context of LTFU.

Figure 1. Overlap in the indication for lifestyle counseling based on the different perspectives of the physician, sports scientist, and childhood cancer survivor.



Follow-Up Interview

For motivational reasons and to check whether CCS were able to implement the recommendations, all CCS with counseling were asked if they wanted a second interview. A total of 16 (14%) CCS did not want, or as they already met the lifestyle recommendations, were not selected for a second interview. In 53 (44%) CCS, it could not be performed due to difficulties with the appointment arrangement outside of the regular LTFU interval. A second interview was performed in 51 (43%) CCS within 1 month. Of these, 49 (96%) CCS reported to have implemented the recommendations of the sports scientist in at least one of the areas, consisting of exercise and diet (Table 3), and 33 (65%) CCS reported to have improved their lifestyle in both areas, although only 21 (41%) CCS received counseling in both areas. In addition, 33 out of 51 (65%) CCS desired further support and counseling. Moreover, 50 CCS attending the follow-up appointment initially indicated that lifestyle counseling should be part of the LTFU care and confirmed this statement in the second consultation. One CCS indicated only in the follow-up appointment that lifestyle counseling would be useful.

Table . Characteristics of CCS[a] who participated in the follow-up interview 1 month after lifestyle counseling.

Assessed at first counseling			Survivors (n=51)
Inclusion criteria (sports scientist), n (%)			36 (71)
Inclusion criteria (physician), n (%)			30 (59)
Desire of counseling (CCS), n (%)			32 (63)
Characteristics at follow-up			
	Subjective benefit, n (%)		
		No	2 (4)
		Yes	47 (92)
		Unclear	2 (4)
	Implementation of the recommendations, n (%)		
		Both	33 (65)
		Sports	8 (16)
		Nutrition	8 (16)
		No	2 (4)
	Duration of the counseling (minutes)		
		Median (IQR)	12 (10-19)
		Range	8 - 40
	Effect perceived, n (%)		38 (75)
		Yes, weight loss	2 (4)
		Yes, quality of life	26 (51)
		Yes, both	8 (16)
		No	15 (29)

[a] CCS: childhood cancer survivors.

Subgroup Analysis

Although the physicians' and sports scientists' inclusion criteria overlapped, 26 (17%) CCS need for counseling were only identified based on the sports scientist's perspective (subgroup 1). A second interview was conducted with 13 of these CCS 1 month later, during which 12 (92%) CCS reported having benefited from counseling.

In addition, 14 (9%) CCS expressed a need for counseling from a personal point of view, although they did not meet the inclusion criteria from the physician's or sports scientist's perspective (subgroup 2). A second interview (recommended for 9 of these CCS) was conducted with 5 CCS, 4 (80%) of whom stated that they had benefited from the counseling.

Furthermore, 31 (20%) CCS did not express a need for counseling, although they met the inclusion criteria (subgroup 3). A total of 23 (74%) CCS agreed to receive lifestyle counseling. One month later, 15 of 16 (94%) participating CCS reported having benefited from counseling. These subgroups are also shown in more detail in Table 4.

Table . Characteristics of childhood cancer survivors in the subgroup analysis, subdivided into three subgroups.

Characteristics		Subgroup 1[a] (n=26), n (%)	Subgroup 2[b] (n=14), n (%)	Subgroup 3[c] (n=31), n (%)	Descriptive *P* value[d]
Sex					.19
	Female	19 (73)	10 (71)	16 (52)	
	Male	7 (27)	4 (29)	15 (48)	
Risk group					.49
	1	3 (12)	3 (21)	2 (7)	
	2	7 (27)	4 (29)	6 (19)	
	3	16 (62)	7 (50)	23 (74)	
Indication for counseling by sports scientist		26 (100)	0 (0)	25 (81)	Not performed
Indication for counseling by physician		0 (0)	0 (0)	23 (74)	Not performed
Desire for counseling		18 (69)	14 (100)	0 (0)	Not performed
Counseling performed		25 (96)	13 (93)	23 (74)	.05
Follow-up appointment[e]					.59
	Performed	13 (50)	5 (36)	16 (52)	
	Not indicated by sports scientist or survivor	2 (8)	5 (36)	9 (29)	
	Not feasible	11 (42)	4 (29)	6 (19)	
Implementation of the recommendations					.35
	Both	7 (27)	3 (21)	9 (29)	
	Sports	4 (15)	0 (0)	4 (13)	
	Nutrition	1 (4)	1 (7)	3 (10)	
	No	1 (4)	1 (7)	0 (0)	
	No follow-up	0 (0)	9 (64)	15 (48)	

[a] Subgroup 1: survivors who have a need for counseling based only on the inclusion criteria of the sports scientist and not from the physician’s point of view.

[b] Subgroup 2: survivors who want lifestyle counseling but do not need it based on the criteria.

[c] Subgroup 3: survivors who need counseling based on the criteria but did not express a desire for counseling.

[d] Descriptive *P*-value from chi-square test (sex, follow-up appointment, implementation of the recommendations) and Fisher exact test (risk group, counseling performed).

[e] For follow-up appointment, we tested performed versus all other categories, and for implementation of the recommendations, we tested implementation of at least one recommendation versus all other categories.

Discussion

Principal Findings

Worldwide, as a result of advances in cancer treatment and diagnostics, the proportion of long-term cancer survivors is rapidly increasing [31]. As many of these survivors develop chronic health conditions later in life, prevention measures gain importance in follow-up care and management of these CCS in order to reduce long-term morbidity and maintain a good health-related quality of life. Regular physical activity can have a major impact on metabolic health and reduce risk factors for metabolic syndrome [11,17,32]. As shown in previous studies, long-term sequelae, like diabetes mellitus and obesity, occur more often in CCS than in the general population and contribute to elevated morbidity and mortality risk. This risk can be diminished by implementing a healthy lifestyle based on regular physical activity and a healthy diet [15,33].

In this study, indications for, as well as the feasibility of, regular lifestyle counseling in an unselected cohort of long-term CCS in a specialized LTFU care setting were prospectively evaluated. In addition, we aimed to identify CCS who could particularly benefit from counseling based on three different perspectives (physician’s, CCS’, and sports scientist’s view).

During the study, over 77% (120 out of 155) of the CCS received lifestyle counseling with a special focus on physical activity and nutrition. About 48% (n=74) of these CCS expressed no need for counseling initially, but were either interested in lifestyle recommendations or had indicators for counseling (based on metabolic risk constellations or reduced physical activity). Consequently, 39 CCS received lifestyle counseling who initially did not state a need for it.

Due to difficulties in contacting, only 51 CCS received a follow-up appointment. Almost all of these CCS (48/51, 94%) indicated that they benefited from lifestyle counseling which is in line with previous studies that highlighted the importance of lifestyle counseling in an unselected CCS cohort as it resulted in higher activity levels after seeing a health practitioner [32]. Considering different perspectives on who would benefit from counseling resulted in a high participation rate and satisfaction with the offer. However, the overlap between the indications for counseling was poor. We classified CCS into three distinct subgroups. Our findings demonstrated that lifestyle counseling can be beneficial for CCS, even if only one perspective recognizes the indication for it. This highlights the relevance of a multidisciplinary approach in LTFU care including sports scientists to support a healthy lifestyle among this cohort [34,35].

Furthermore, our results show that especially CCS with a high risk for late effects (risk group 3 with radiotherapy exposure, according to Gebauer et al [25]) are in higher need of lifestyle counseling. According to Rock et al [36], survivors of pediatric acute lymphoblastic leukemia have an increased risk of becoming overweight throughout their lives. Due to cancer treatment in childhood, like radiotherapy exposure, metabolic late effects such as overweight, obesity, and changes in body composition like an increase in fat mass are common in CCS. They could also be demonstrated in our cohort, with 46.5% (70/155) of the survivors being affected by metabolic disorders [9,37,38]. Cranial radiation often leads to endocrine disorders which in turn may result in overweight or obesity [38,39]. Of note, although the proportion of CCS with an indication for lifestyle counseling was high across all risk groups, CCS with the lowest risk for late effects (risk group 1 according to Gebauer et al [25]) appeared to be affected more often than CCS in risk group 2 (medium risk for late effects). This is most likely due to the small number of CCS in risk group 1 included in this study resulting in a selection bias. This finding should be verified in further studies with more participants representing the different risk groups (based on cancer treatment exposure) in a more balanced way. However, the study findings suggest that lifestyle counseling should be considered more strongly for individuals in higher-risk groups. Consequently, CCS in risk group 3, in particular, should be given serious consideration for regular lifestyle counseling as already proposed by Nathan et al [39].

The fact that almost all CCS (n=150, 97%) considered lifestyle counseling to be beneficial, and those who reported benefits from it in the follow-up appointment (47/51, 92%), support the idea of incorporating lifestyle counseling into regular LTFU care. In addition, 70% (36/51) of CCS receiving a second counseling stated a positive effect on weight or quality of life. These findings are consistent with previous studies that have shown high levels of acceptance and adherence to lifestyle counseling [10,33]. Zhang et al [15,40], suggest that it is crucial to educate CCS about weight management and healthy lifestyle as early as possible, but older CCS may require more lifestyle counseling. Moreover, men may have a greater need for lifestyle counseling (based on the presence of metabolic diseases or a sedentary lifestyle) as demonstrated in this study but often do not perceive this need. Furthermore, the study revealed that CCS with a normal weight who do not meet the inclusion criteria can still derive benefits from counseling. Additionally, there were 29 (19%) CCS with a prediabetic metabolic condition, who could benefit from counseling and should be included in future studies.

Given the constraints of limited resources, it is crucial to deliberate on the inclusion criteria for lifestyle counseling. As demonstrated in this study, factors such as the higher risk for late effects (risk group 3), based on treatment exposure, older age, male gender, and reduced physical activity, as well as established cardiovascular risk factors, such as the presence of obesity, diabetes mellitus, or hypercholesterolemia could serve as potential indicators for lifestyle counseling.

Limitations and Strengths of the Study

Limitations of this study included heterogeneity within the study cohort such as predominance of female gender (n=100, 65%) and risk group 3 (n=95, 61%). This was a result of an unselected inclusion of every CCS receiving regular LTFU care in our specialized clinic, which renders comparison of different risk groups more difficult. A higher proportion of women in LTFU has also been observed in previous studies performed in our cohort, as well as in different LTFU cohorts, and was discussed as a consequence of an increased engagement in preventive health behavior in women compared with men [41,42].

In addition, 53% (n=82) of all CCS already received previous nutrition or sports counseling which may have had an impact on their lifestyle. However, the content of previous counseling was not recorded in a structured way in this study. Furthermore, in 53 (43%) CCS, a follow-up appointment could not be performed due to organizational difficulties. Some measurements were based solely on information provided by the CCS such as nutrition habits and weight loss after counseling and could not be validated clinically. For future research, it would be useful to assess data more objectively and after a longer period of time to better assess the long-term effect on metabolic parameters and activity. A follow-up after 1 month, in this context, is not sufficient to fully capture the impact of lifestyle counseling. However, in the CARE for CAYA study that offered lifestyle counseling to a predefined proportion of CCS, no significant effect of the intervention in a follow-up after 1 year could be demonstrated. As a consequence of these results, for this analysis, we intended to investigate the short-term effect of counseling assuming that the effects might be most pronounced during the first weeks [43].

The small number of CCS experiencing nutritional issues (n=15) may be attributed to the fact that the assessment of nutritional parameters relied solely on subjective questioning. Especially for the evaluation of activity time, it would have been useful to collect either objective data by accelerometry or the moderate and vigorous activity minutes in the follow-up counseling. The assessment of the quality of life did not involve the use of questionnaires; instead, CCS provided subjective responses.

However, to our knowledge, this is the first study to implement regular lifestyle counseling for every CCS in a specialized setting with many years of experience within LTFU care. We collected the data from an unselected cohort in a prospective manner, which allowed us to include all CCS receiving LTFU care and gain an overall understanding of their needs. For further research, it might be useful to analyze CCS after lifestyle counseling over a longer period to see whether they sustained a health-promoting lifestyle. Furthermore, it would be useful for future studies to promote a mobile health intervention for CCS that might increase adherence to adopting a healthier lifestyle [44].

Conclusions

Lifestyle counseling is feasible and considered useful by most CCS. However, due to limited resources, counseling might not be available for every CCS during LTFU. Therefore, it is particularly important to identify CCS at risk for metabolic complications. Although early implementation of lifestyle changes is recommended in order to reduce long-term morbidity, as demonstrated in this study, older CCS, as well as male CCS, were especially in need of counseling. This group should be actively screened for established risk factors such as hypertension, diabetes mellitus, and hypercholesterolemia. Additionally, a more intensive cancer treatment exposure was confirmed as an independent risk factor for poor metabolic outcome and should prompt initiation of counseling. Consequently, as a healthy lifestyle including regular physical activity and a nutrient- and vitamin-rich diet can reduce survivors’ increased risk of developing metabolic diseases, it should be part of regular LTFU care for CCS.

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Data Availability

The datasets generated and analyzed during this study are available from the corresponding author upon reasonable request.

Authors' Contributions

FR, JG, and TL developed the study concept. FR collected the data. LLK and IK analyzed the data and created figures and tables. FR, JG, and LLK were in charge of writing, reviewing, and editing the manuscript. All authors did a critical revision and approval of final version. All authors have read and agreed to the published version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Lifestyle counseling record sheet.
[DOCX File, 24 KB - cancer_v10i1e59614_app1.docx]

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Abbreviations

ASC: American Cancer Society
CCS: childhood cancer survivors
HbA_{1c}: hemoglobin A_{1c}
LTFU: long-term follow-up

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Original Paper

Heart Rate Monitoring Among Breast Cancer Survivors: Quantitative Study of Device Agreement in a Community-Based Exercise Program

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Abstract

Background: Exercise intensity (eg, target heart rate [HR]) is a fundamental component of exercise prescription to elicit health benefits in cancer survivors. Despite the validity of chest-worn monitors, their feasibility in community and unsupervised exercise settings may be challenging. As wearable technology continues to improve, consumer-based wearable sensors may represent an accessible alternative to traditional monitoring, offering additional advantages.

Objective: The purpose of this study was to examine the agreement between the Polar H10 chest monitor and Fitbit Inspire HR for HR measurement in breast cancer survivors enrolled in the intervention arm of a randomized, pilot exercise trial.

Methods: Participants included breast cancer survivors (N=14; aged 38-72 years) randomized to a 12-week aerobic exercise program. This program consisted of three 60-minute, moderate-intensity walking sessions per week, either in small groups or one-on-one, facilitated by a certified exercise physiologist and held at local community fitness centers. As originally designed, the exercise prescription included 36 supervised sessions at a fitness center. However, due to the COVID-19 pandemic, the number of supervised sessions varied depending on whether participants enrolled before or after March 2020. During each exercise session, HR (in beats per minute) was concurrently measured via a Polar H10 chest monitor and a wrist-worn Fitbit Inspire HR at 5 stages: pre-exercise rest; midpoint of warm-up; midpoint of exercise session; midpoint of cool-down; and postexercise recovery. The exercise physiologist recorded the participant's HR from each device at the midpoint of each stage. HR agreement between the Polar H10 and Fitbit Inspire HR was assessed using Lin concordance correlation coefficient (r_c) with a 95% CI. Lin rc ranges from 0 to 1.00, with 0 indicating no concordance and 1.00 indicating perfect concordance. Relative error rates were calculated to examine differences across exercise session stages.

Results: Data were available for 200 supervised sessions across the sample (session per participant: mean 13.33, SD 13.7). By exercise session stage, agreement between the Polar H10 monitor and the Fitbit was highest during pre-exercise seated rest (rc=0.76, 95% CI 0.70-0.81) and postexercise seated recovery (rc=0.89, 95% CI 0.86-0.92), followed by the midpoint of exercise (rc=0.63, 95% CI 0.55-0.70) and cool-down (rc=0.68, 95% CI 0.60-0.74). The agreement was lowest during warm-up (rc=0.39, 95% CI 0.27-0.49). Relative error rates ranged from –3.91% to 3.09% and were greatest during warm-up (relative error rate: mean –3.91, SD 11.92%).

Conclusions: The Fitbit overestimated HR during peak exercise intensity, posing risks for overexercising, which may not be safe for breast cancer survivors' fitness levels. While the Fitbit Inspire HR may be used to estimate exercise HR, precautions are needed when considering participant safety and data interpretation.

Trial Registration: Clinicaltrials.gov NCT03980626; https://clinicaltrials.gov/study/NCT03980626?term=NCT03980626&rank=1

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KEYWORDS

wearable devices; exercise prescription; validity; photoplethysmography; monitoring; wearables; devices; exercise; heart rate; breast cancer; cancer; cancer survivor; community; chest monitor; Fitbit; recovery; safety

Introduction

Wearable sensors have gained traction in both commercial and research sectors [1], with a projected 156 million units to be purchased in 2024 [2]. These devices use microelectronic triaxial accelerometers to measure steps, energy expenditure, sleep, and time spent in different intensities of activity and photoplethysmography above the wrist to measure heart rate (HR). These data, along with options for goal setting, can be used to help individuals self-monitor and increase their daily physical activity (PA) [3]. The ease and utility of these devices have led to their adoption in health promotion research for continuous measurement of health behaviors and as behavior change tools [4].

Traditional research-grade monitors are costly, lack consumer-friendly designs, provide little opportunity for user interaction with the device, often evaluate only 1 dimension of daily activities (eg, HR, motion, or sleep only), and have limited, real-time data transfer capacity [3,5,6]. In contrast, consumer-grade monitors continuously collect and transfer data through Bluetooth and web-based platforms to allow for data collection across months or even years [3]. Additionally, participant data can be easily monitored and accessed via web-based platforms at any point during the data collection period. The increasing number of peer-reviewed publications and National Institutes of Health–funded grant proposals, which include consumer-grade, wrist-worn monitors, emphasizes the utility of these devices in research settings [1,7].

Many of these devices now measure HR, a key component of aerobic exercise prescription. Although electrocardiogram (ECG) is widely accepted as the gold standard for assessing HR during exercise, chest-worn monitors also have well-documented validity for measuring HR [8]. However, like ECG, they may be inconvenient or prohibitive in community-based and unsupervised exercise settings due to necessary receivers and participant discomfort. In contrast, newer devices are increasingly being designed for wear on the forearm or wrist. Commercially available wearable sensors, such as the Fitbit, represent an accessible, multifunctional alternative to HR monitoring in exercise. Appropriate exercise intensity, often expressed as a percentage of HR reserve, is a fundamental dimension of exercise prescription for achieving the health benefits of exercise [9]. For example, cancer survivors begin to reduce fatigue symptoms with a minimum dose of aerobic activity at 45% of their HR reserve, whereas benefits for other symptoms (ie, anxiety, depression, and physical function) begin at a minimum dose of 60% of their HR reserve [10]. To improve dissemination and uptake of exercise prescriptions in clinical or community-based settings, it is critical that survivors have user-friendly methods to independently monitor exercise prescription components.

There is an increasing number of exercise oncology studies that use commercial wearable sensors to intervene in PA behaviors and reduce cancer-related symptom burden, particularly among breast cancer survivors, and evidence indicates that wearable sensors are effective, feasible, and user-friendly for breast cancer survivors in exercise interventions [11-13]. Although these studies have helped bolster the utility of wearable sensors in PA promotion research, they have failed to provide any detail on intensity or HR monitoring during their respective interventions. Many exercise interventions in cancer populations are adopting community-based, hybrid, and unsupervised designs [14]. Therefore, it is integral that researchers understand the capacity, and limitations, of commercially available wearable sensors in providing accurate measurements of HR to monitor participants' safety and compliance with the exercise prescription.

In the general population, the reliability of popular, commercially available activity and HR monitors has been previously examined with varying agreement between commercial products and traditional ECG monitoring [8,15-17]. Unfortunately, many of these data have been collected in controlled settings with predetermined treadmill speeds in young, healthy adult participants. The dearth of literature assessing commercially available, wrist-worn HR monitors in clinical populations during training sessions limits the utility of these devices in less controlled environments. Therefore, the purpose of this study was to examine the agreement between a commercially available, wrist-worn wearable sensor (Fitbit Inspire HR; Fitbit Inc) and a traditional chest-worn monitor (Polar H10; Polar Electro OY) for HR measurement in breast cancer survivors at different stages of exercise in a community-based program. It is hypothesized that HR monitor agreement in this study will be highest at periods of pre- and postexercise rest and lowest during the exercise session when participants were exercising at higher intensities.

Methods

Study Design and Participants

The Study on Physical Activity's Relationship with Cancer and Cognition (SPARCC) was a randomized exercise trial in which 30 women diagnosed with breast cancer were randomized to a 12-week moderate-intensity aerobic exercise program (n=15) or usual care (n=15). Our study includes only those women randomized to the exercise group with valid Fitbit and Polar HR data (n=14), as exercise HR was not collected from women in the usual care control group.

Eligibility criteria for this study included the following: female participants aged 21 years or older; postmenopausal at the time of diagnosis; first, primary diagnosis of breast cancer (stage I-IIIa); within 3-24 months of completing surgery, chemotherapy, or radiation therapy; self-reported an average of <60 minutes of moderate to vigorous PA per week for the previous 6 months; having received physician's clearance to participate in an exercise program; and randomized to the 12-week aerobic exercise program in the SPARCC study. Participants were recruited from a midwestern academic medical center, a private cancer center, and the community (eg, via flyers to community organizations, social media posts, and word of mouth). Interested individuals were scheduled for a phone appointment to confirm eligibility, absence of neurological disorders, and interest in participating in the study. Eligible women were then asked to attend an in-person or Zoom-based orientation session to receive more information about the study, decide if they would like to participate, sign the Institutional Review Board (IRB)–approved informed consent, and schedule baseline testing appointments. After baseline data collection was complete, participants were randomized in a block design to the 12-week aerobic exercise program or usual care. Participants were not instructed to change physical activity behaviors prior to beginning the exercise program.

Ethical Considerations

This study was approved by The University of Nebraska Medical Center IRB and is registered with the National Institutes of Health's ClinicalTrials.gov (NCT03980626). All participants provided written informed consent prior to participation. All data presented herein were deidentified using study identification numbers and stored separately from participants. identifiers. Data were collected and managed using applications hosted by the study institution (ie, Research Electronic Data Capture [REDCap] or Box Enterprise) [18,19]. Participants did not receive payment for their participation in this research but received a Fitbit Inspire HR that was theirs to keep. All participants were offered a 3-month membership to a local fitness center.

Exercise Protocol

Breast cancer survivors randomized to the exercise program engaged in small group or one-on-one, moderate-intensity walking sessions facilitated by a certified exercise physiologist. These sessions were held at local community fitness centers 3 times per week for 1 hour per session. All participants completed a treadmill-based submaximal cardiopulmonary exercise test prior to randomization to establish baseline fitness and safety and inform individualized exercise prescriptions (Table 1).

Table 1. Exercise prescription.

Week	Intensity (rating of perceived exertion), range	Intensity (% heart rate reserve), range	Duration (minutes), range
1	9-11	45-50	15-20
2	9-11	45-50	20-25
3	9-11	45-50	25-30
4	11-13	50-55	25-30
5	11-13	50-55	30-35
6	11-13	50-55	35-45
7	13-15	55-65	35-45
8	13-15	55-65	40-50
9	13-15	55-65	40-50
10	15-17	65-75	40-50
11	15-17	65-75	45-50
12	15-17	65-75	45-50

As originally designed, all 36 exercise sessions were scheduled to be delivered by the exercise physiologist in the supervised, community-based setting. However, due to the COVID-19 pandemic, the exercise program was modified for some participants to include both supervised and unsupervised sessions. Participants who were in the middle of the intervention in March 2020, were transitioned to unsupervised exercise with weekly Zoom-based counseling from their trainer. Participants enrolled after March 2020, engaged in only 4 supervised exercise sessions held once per week in the research team's exercise laboratory in weeks 1-4. All sessions in weeks 7-12 were unsupervised, home-based sessions with weekly Zoom-based exercise counseling. Across the study, 4 breast cancer survivors completed 36 supervised sessions as originally designed, 5 were in the middle of the intervention in March 2020, and 6 were enrolled after March 2020 and received 4 supervised sessions. Depending on the enrollment time (ie, before or after the COVID-19 public health restrictions), participants engaged in an average of 13.33 (SD 13.71) supervised sessions (range: 4-36). Participants who received the original intervention received their fitness center membership during the study. Those enrolled during or after the onset of the COVID-19 pandemic were offered a fitness center membership when it was safe to do so based on local IRB and public health requirements. Only supervised sessions (n=200) were included in our analysis.

The exercise program was progressive in nature such that the volume of exercise increased across weeks from 15-20 minutes of walking in weeks 1-2 to 40-45 minutes in weeks 8-12 and from 40%-55% estimated HR reserve in week 1 to 65%-70% HR reserve in weeks 9-12 (Table 1). All sessions began with a 5-minute light-intensity walking warm-up and ended with an active cool-down including light walking and static stretches (Figure 1). The exercise program was designed to follow American College of Sports Medicine guidelines for exercise in cancer survivors [10].

Figure 1. Exercise session stages for heart rate measurement.

Measures

HR Monitors

All participants received a Fitbit Inspire HR sensor to wear on their nondominant wrist for the duration of the study and a Polar H10 chest strap to wear during supervised exercise. The Fitbit was chosen for this study because it is one of the most popular wrist-worn activity trackers, represents approximately 20% of the commercial wearable sensor market, and has sold 63 million devices worldwide in the last decade [3]. The Fitbit Inspire HR measures HR via optical photoplethysmography, which is processed using proprietary algorithms. Briefly, this is done by shining a light on the skin, assessing the reflected light, using algorithms to determine changes in blood volume based upon reflected light, and calculating HR based on oscillations in blood volume [20,21]. The Polar H10 chest strap monitor was chosen as the comparator device because it has high validity with ECG, the gold standard for measuring exercise HR [8]. Exercise trainers fit participants with the Polar H10 monitors, placed on the distal sternum, at the start of each supervised exercise session and used Polar HR readings to adjust treadmill speed and grade to meet prescribed exercise intensity. HR was measured concurrently using the Fitbit and Polar monitors at 5 stages of the exercise session: pre-exercise seated rest; midpoint of the 5-minute warm-up; midpoint of the moderate-intensity exercise; midpoint of the 5-minute cool-down; and after a 5-minute seated recovery (Figure 1).

Demographic and Clinical Information

Participant demographics (ie, age, race, education, income, employment status, marital status, and comorbid conditions) were self-reported and collected via REDCap hosted by the study institution. Clinical information on breast cancer diagnosis and treatment were obtained via electronic medical records. BMI was calculated from height and weight measured via the Seca 703 scale and stadiometer (Seca Corp) by the study staff at a baseline testing visit.

Data Analysis

HR from the Polar monitor was operationalized as the criterion measure and used to assess absolute and relative paired differences between monitors [8]. Agreement between HR measurements was assessed using Lin concordance correlation coefficient (r_c) with 95% CIs. This test measures the degree to which the paired observations fall on the identity line and defines statistical agreement as $r_c \geq 0.85$ [22]. The agreement was also represented visually across stages using Bland-Altman plots with upper and lower limits set using 95% CIs [23,24]. Absolute paired differences were calculated by subtracting the Fitbit-measured HR from the Polar-measured HR at each stage of the exercise session. Relative paired differences were calculated as relative error rate (RER) across exercise session stages [25,26], as follows:

$$RER = (Polar\ HR\ measurement - Fitbit\ HR\ measurement) \times 100 / Polar\ HR$$

Negative resultant RERs are indicative of an overestimation of HR by the Fitbit, and positive RERs are indicative of an underestimation of HR by the Fitbit, as compared to the Polar monitor. Data were analyzed using SPSS (version 27; IBM Corp) and RStudio (version 1.3.1093; R Core Team).

Results

Participant Characteristics

Participants (mean age 63.1, SD 8.7 years) were White women with a history of early-stage breast cancer; on average, overweight; and physically inactive (Table 2). Additionally, more than 1 quarter of participants had a history of clinically diagnosed anxiety or depression at the time of enrollment. Breast cancer survivors in this study were enrolled approximately 17 months after their diagnosis. Participants' breast cancer treatments included surgery, radiation, and chemotherapy; however, most women in this study did not receive chemotherapy. One participant randomized to the exercise program did not have valid Polar data for supervised sessions and was, therefore, excluded from the analysis (N=14).

Table 2. Participant characteristics.

Characteristics	Values
Demographics	
Age (years), mean (SD)	63.07 (8.66)
Non-Hispanic White, n (%)	13 (93)
Bachelor’s degree, n (%)	8 (57)
Income >US $40,000 per year, n (%)	8 (57)
Employed full-time, n (%)	8 (57)
Married, n (%)	12 (86)
Comorbidities[a], mean (SD)	2.38 (2.10)
β-Blocker medication use, n (%)	0 (0)
Antihypertensive medication use, n (%)	1 (7)
Diagnosed with depression, n (%)	4 (29)
Diagnosed with anxiety, n (%)	4 (29)
BMI (kg/m^2), mean (SD)	29.14 (4.71)
Clinical features	
Cancer stage, n (%)	
I	12 (86)
II	2 (14)
Time since diagnosis (months), mean (SD)	16.57 (7.97)
Chemotherapy, n (%)	3 (21)
Radiation, n (%)	9 (64)
Hormonal therapy, n (%)	9 (64)
Months of hormonal therapy, mean (SD)	13.44 (5.64)

[a] Comorbid conditions include diagnosed arthritis, osteoporosis, asthma, chronic obstructive pulmonary disease, angina, heart failure, previous myocardial infarction, vascular disease, diabetes, tremors, gastrointestinal disease, visual impairment, hearing impairment, degenerative disk disease, anxiety, and depression.

HR Monitor Agreement

Agreement between the Fitbit and Polar HR monitors was highest during seated rest at postexercise (r_c=0.89, 95% CI 0.86-0.92) and pre-exercise (r_c=0.76, 95% CI 0.70-0.81). This was followed by the midpoint of the moderate-intensity exercise session (r_c=0.63, 95% CI 0.55-0.70) and cool-down (r_c=0.68, 95% CI 0.60-0.74). The warm-up was associated with the lowest level of agreement between monitors (0.39, 95% CI 0.27-0.49). RERs ranged from –3.91% to 3.09% and were most pronounced during warm-up (RER: mean –3.91%, SD 11.92%). When inaccurate, the Fitbit overestimated HR during most stages of the exercise session (RER range: –3.91% to –0.52%), except at the midpoint of moderate-intensity exercise, where HR was underestimated (RER 3.09%). RERs and concordance coefficients are provided in Table 3, and Bland-Altman plots are provided in Figure 2.

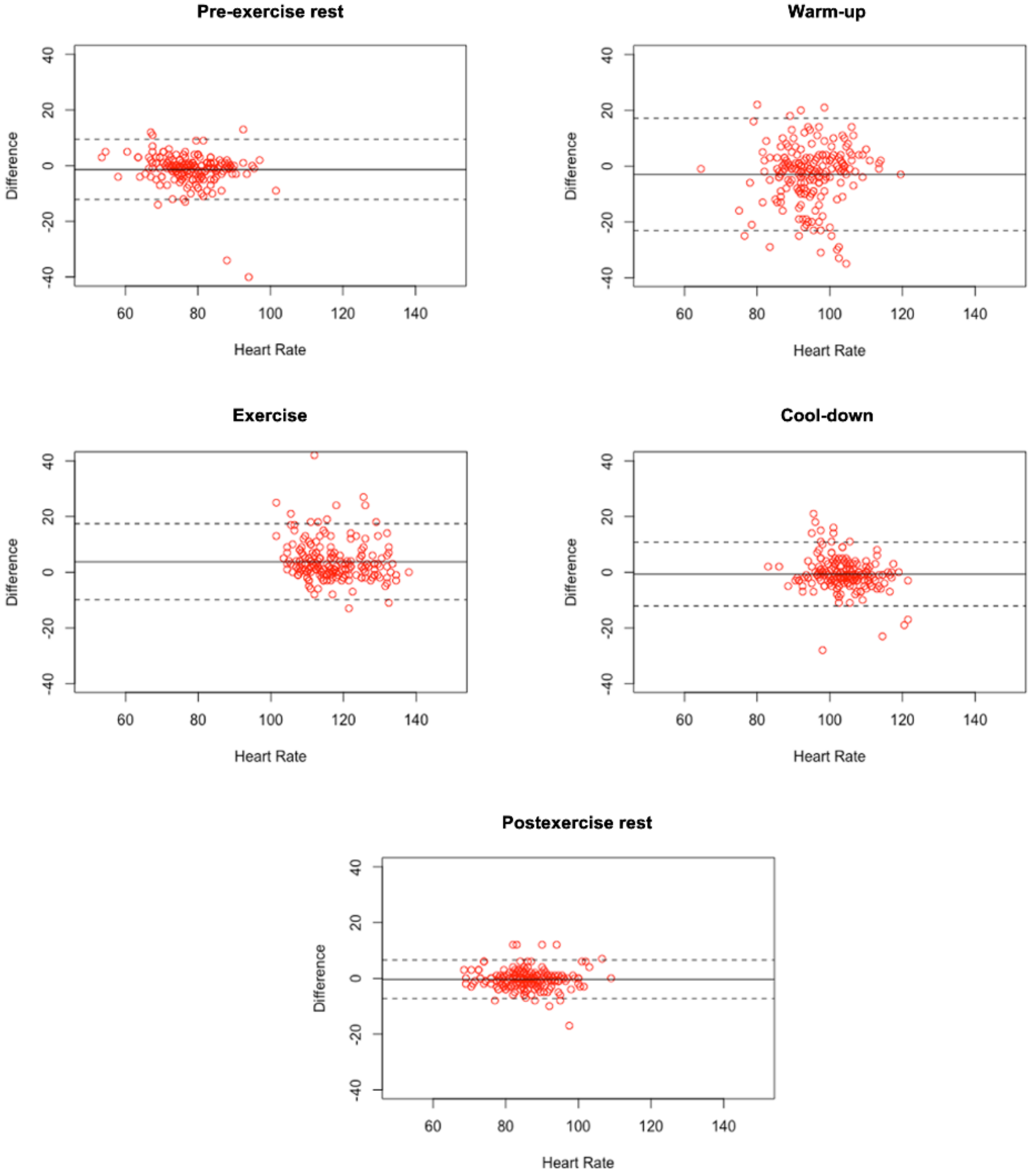
Table 3. Heart rate (beats per minute) monitor differences according to the stage of the exercise.

Activity	Heart rate, mean (SD)		Fitbit differences from Polar H10, mean (SD)		
	Polar H10	Fitbit	Paired difference	Percent difference (RER[a])	Agreement (r_c)[b]
Pre-exercise rest	78.00 (7.68)	78.61 (8.74)	–1.34 (5.53)	–1.84 (7.51)	0.76
Warm-up	94.78 (7.91)	96.26 (9.17)	–2.96 (10.27)	–3.91 (11.92)	0.39
Exercise	117.04 (8.10)	115.15 (9.3)	3.77 (6.98)	3.09 (5.64)	0.63
Cool-down	103.56 (6.68)	104.24 (7.90)	–0.72 (5.83)	–0.77 (5.74)	0.68
Postexercise rest	85.86 (7.42)	85.99 (7.71)	–0.38 (3.53)	–0.52 (4.04)	0.89

[a] Relative error rate.

[b] Lin concordance correlation coefficient.

Figure 2. Bland-Altman plots. Bland-Altman plots depict the average heart rate (Polar H10 and Fitbit) by the relative difference between the two measures for each session by stage in the exercise protocol. Points on the plots indicate individual sessions, solid lines indicate the mean difference across the sample, and dashed lines indicate upper and lower bounds for each stage.



Discussion

Principal Results

This study was the first to examine the agreement between the wrist-worn Fitbit Inspire HR and chest-worn Polar H10 HR monitors in cancer survivors and during an exercise intervention. Major findings from this study indicate that the Fitbit monitor did not produce statistically accurate measures of HR during most exercise stages, especially the warm-up stage; however, agreement during seated rest (pre- and postexercise), midpoint of exercise, and cool-down were associated with moderate agreement between devices. Data also suggest that the Fitbit underestimated HR only during the primary, aerobic portion of the exercise session (ie, the midpoint of the exercise session), which may have serious implications for safety and compliance monitoring in exercise programs. This study extends the current literature on consumer-grade, wrist-worn HR monitors and provides data to inform future studies hoping to use consume-grade sensors to monitor safety, exercise program compliance, and longitudinal behavioral patterns in cancer survivors [8,25,27]. This is particularly important as exercise interventions become less centralized and hybrid and unsupervised approaches increase in prevalence [28-30].

Comparison With Prior Work

The wrist-worn, Fitbit Inspire HR monitor accurately measured HR only during seated rest postexercise compared to the chest-worn Polar H10 monitor. Although pre-exercise seated rest, midpoint of moderate-intensity exercise, and cool-down also exhibited high levels of agreement, they did not reach statistical agreement as defined by Lin concordance correlation coefficient [22]. Results from previous studies have found that Fitbit devices are most accurate in measuring HR during low-intensity activities where the wrist is moving in a repetitive fashion [17]. Nevertheless, in contrast to these previous studies, warm-up represented the period of the poorest agreement. It is also unclear why the Fitbit accurately measured HR during post- but not pre-exercise seated rest; however, both pre-and postexercise seated rest reflected the highest levels of agreement with the Polar monitor, consistent with previous findings [8,16]

Although HR was highest during the midpoint of the exercise session and cool-down, these stages represented higher levels of agreement when compared to the warm-up stage. This may, in part, be due to the slower speeds at which breast cancer survivors were walking in this study, as compared to healthy, young, or middle-aged adults in other studies [8,16,17,31]. While previous research found that lower treadmill speeds showed the highest agreement, overall speeds in those studies ranged from 2 to 9 miles per hour [16,17]. In comparison, breast cancer survivors in this study did not reach speeds greater than 3.5 miles per hour. It is possible that speeds in this study were more similar to light-intensity walking in previous studies, which would align more closely with the results from this study [16,17]. This does not, however, explain the poor agreement during the warm-up and cool-down stages.

Of note, the RER at the midpoint of the exercise session indicates that the Fitbit monitor underestimated HR as compared to the Polar chest strap. Previous studies have reported similar trends in Fitbit data as compared to traditional ECG monitoring [8,16,17,31]. One study found the Fitbit Ionic to be comparable to other wrist-worn monitors and statistically accurate at rest [17], while another found that the Fitbit Blaze provided the least accurate optically measured HR [8]. In contrast to the findings presented here, these studies also found that higher-intensity activity led to decreased accuracy in HR measurement [8,17]. However, differences in Fitbit accuracy at peak exercise intensity between previous studies and data presented in this study may be due to the lower absolute intensity in this study, as both previous studies were conducted among athletes [8,17]. Given the generally lower intensity of exercise prescribed to cancer survivors, participants may not reach an exercise intensity high enough for devices to decrease in accuracy during steady-state exercise. This should, theoretically, reinforce the utility of Fitbits in cancer survivor populations.

Despite this, underestimation of exercise HR may be problematic in programs using Fitbit to monitor intensity during exercise in cancer survivors for several reasons. First, participants may be asked to increase the intensity of a session to achieve the prescribed HR range. If the Fitbit monitor underestimates HR, as it did in this study, participants who reach the prescribed HR as measured by Fitbit may be exercising at an intensity higher than that prescribed, leading to concerns regarding participant safety—particularly if the session is unsupervised. In a previous analysis of exercise prescription adherence in this sample, data indicated that participants only met prescribed intensity during supervised sessions 57.5% of the time when assessed via Fitbit HR, as compared to 92.2% when measured via Polar. However, adherence to the prescribed intensity via Fitbit was 83.2% during unsupervised sessions after the onset of the COVID-19 pandemic [32]. These data, when taken together with the findings of this study, suggest that participants may have been exercising above their prescribed HR range during unsupervised sessions. Although many breast cancer survivors may comfortably exercise at higher intensities, reliance upon consumer-grade wearable sensors only may introduce safety concerns not previously observed in more traditional, controlled exercise trials. Additionally, future studies that use Fitbit to measure the dose of exercise required to effect specific outcomes (eg, cancer-related fatigue and cognitive performance) may underestimate the required intensity of activity to elicit an effect. Although these devices may have utility in exercise oncology, it is critical that researchers and practitioners are aware of limitations that may increase the risk of adverse events or decrease methodological rigor in quantifying compliance with exercise prescriptions.

Limitations

Although this study is one of the first to investigate HR agreement between the Fitbit Inspire HR and Polar H10 chest monitor during community-based exercise in breast cancer survivors, it is not without limitations. First, this study was performed on a small sample of breast cancer survivors. Our sample was primarily comprised of White, educated women with early-stage breast cancer, which may not be representative of the larger breast cancer population. For example, women in this study were also not on any β-Blockers, and only 1 participant reported antihypertensive medication use. Although this improves the internal validity of this study due to the lack of HR suppression, it is likely not representative of the broader breast cancer survivor population in the United States [33]. Future studies would be strengthened by the inclusion of a larger, more diverse sample of breast cancer survivors with more supervised exercise sessions.

Additionally, exercise physiologists were available to help and provide feedback on using the devices during the exercise sessions, making it unclear to what extent user error would influence Fitbit's accuracy in unsupervised exercise settings. Fitbit HR measurements in this study were also compared to Polar chest strap monitors, rather than the gold standard ECG. This may have introduced systematic error in evaluating agreement. Finally, the total number of sessions observed in this study was fewer than originally planned (ie, 200 observed vs 540 planned) due to COVID-19 required adaptations. It is unclear whether additional observations would have changed or stabilized results relative to device agreement.

Conclusions

Overall, Fitbit devices with HR monitoring capabilities may be useful for participant monitoring in exercise oncology studies. Researchers should use caution when using these devices, however, as they likely do not provide accurate HR measurement during critical stages of exercise sessions. This study showed that Fitbit monitors were only statistically accurate during seated rest and likely underestimated HR during steady-state exercise. As a result, Fitbit HR measurements are likely best for estimating exercise intensity rather than evaluating compliance with exercise prescriptions. Because of their ease and potential utility in behavioral PA interventions, future studies should further examine the agreement between wrist-worn wearable sensors and a gold-standard measurement of HR, such as ECG, in a larger, more representative sample of breast cancer survivors. Additionally, studies should analyze agreement by relative HR intensity to determine whether Fitbit may be more appropriate for specific exercise prescriptions.

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Data Availability

The data sets generated during this study are available from the corresponding author on reasonable request.

Authors' Contributions

LLP carried out conceptualization, data curation, formal analysis, investigation, methodology, project administration, and writing of the original draft. JF was in charge of data curation, methodology, and software, as well as reviewing and editing of the manuscript. CP contributed to the formal analysis and visualization as well as reviewing and editing of the manuscript; AMB and ECR carried out the methodology and contributed to the reviewing and editing of the manuscript. ECR also provided resources for the study. DKE was in charge of the conceptualization, funding acquisition, methodology, project administration, resources, and supervision, as well as reviewing and editing of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

ECG: electrocardiogram
HR: heart rate
IRB: Institutional review board
PA: physical activity
REDCap: Research Electronic Data Capture
RER: relative error rate
SPARCC: Study on Physical Activity’s Relationship with Cancer and Cognition

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Original Paper

Do Measures of Real-World Physical Behavior Provide Insights Into the Well-Being and Physical Function of Cancer Survivors? Cross-Sectional Analysis

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Abstract

Background: As the number of cancer survivors increases, maintaining health-related quality of life in cancer survivorship is a priority. This necessitates accurate and reliable methods to assess how cancer survivors are feeling and functioning. Real-world digital measures derived from wearable sensors offer potential for monitoring well-being and physical function in cancer survivorship, but questions surrounding the clinical utility of these measures remain to be answered.

Objective: In this secondary analysis, we used 2 existing data sets to examine how measures of real-world physical behavior, captured with a wearable accelerometer, were related to aerobic fitness and self-reported well-being and physical function in a sample of individuals who had completed cancer treatment.

Methods: Overall, 86 disease-free cancer survivors aged 21-85 years completed self-report assessments of well-being and physical function, as well as a submaximal exercise test that was used to estimate their aerobic fitness, quantified as predicted submaximal oxygen uptake (VO_2). A thigh-worn accelerometer was used to monitor participants’ real-world physical behavior for 7 days. Accelerometry data were used to calculate average values of the following measures of physical behavior: sedentary time, step counts, time in light and moderate to vigorous physical activity, time and weighted median cadence in stepping bouts over 1 minute, and peak 30-second cadence.

Results: Spearman correlation analyses indicated that 6 (86%) of the 7 accelerometry-derived measures of real-world physical behavior were not significantly correlated with Functional Assessment of Cancer Therapy-General total well-being or linked Patient-Reported Outcomes Measurement Information System-Physical Function scores (*P*s≥.08). In contrast, all but one of the physical behavior measures were significantly correlated with submaximal VO_2 (*P*s≤.03). Comparing these associations using likelihood ratio tests, we found that step counts, time in stepping bouts over 1 minute, and time in moderate to vigorous activity were more strongly associated with submaximal VO_2 than with self-reported well-being or physical function (*P*s≤.03). In contrast, cadence in stepping bouts over 1 minute and peak 30-second cadence were not more associated with submaximal VO_2 than with the self-reported measures (*P*s≥.08).

Conclusions: In a sample of disease-free cancer survivors, we found that several measures of real-world physical behavior were more associated with aerobic fitness than with self-reported well-being and physical function. These results highlight the possibility that in individuals who have completed cancer treatment, measures of real-world physical behavior may provide additional information compared with self-reported and performance measures. To advance the appropriate use of digital measures in oncology clinical research, further research evaluating the clinical utility of real-world physical behavior over time in large, representative samples of cancer survivors is warranted.

Trial Registration: ClinicalTrials.gov NCT03781154; https://clinicaltrials.gov/ct2/show/NCT03781154

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KEYWORDS

accelerometer; cancer survivorship; cancer survivors; digital health technology; health-related quality of life; physical behavior; physical function

Introduction

Background

As a result of progress in early cancer detection and the development of effective anticancer therapies, the number of individuals who have survived cancer is increasing. As of 2022, >18 million individuals in the United States were living with a history of cancer [1]. In the future, this number is projected to increase as the aging population grows and cancer screening, treatment, and survivorship care continue to advance [2,3]. Although increases in cancer survivorship are cause for optimism, clinicians and regulators alike are increasingly interested in ensuring that increases in cancer survival rates translate to additional years of good quality life [4,5].

Cancer and its treatments have major impacts on health-related quality of life [6]. These effects persist long into survivorship, with more than one-third of cancer survivors reporting that symptoms persist after treatment ends [7-9]. Across studies, individuals off cancer treatment, henceforth referred to as *cancer survivors*, report reductions in physical performance, fatigue, sleep problems, mood disturbances, and pain as long-term symptoms, even years after being disease free [9-11]. The impacts of cancer and its treatments are also associated with poorer outcomes and survival in the long term. For instance, individuals who experience a greater health burden from cancer symptoms are at an elevated risk of developing chronic comorbidities [12]. Furthermore, among adults with a history of cancer, both depression [13,14] and reduced physical function [15-18] are associated with an increased risk of mortality after controlling for confounding variables. At the same time, there is accumulating evidence that in cancer survivorship, health-promoting behaviors have positive impacts; for instance, exercise interventions have been demonstrated to improve health-related quality of life, objectively assessed physical function, and aerobic fitness in cancer survivors [19-21].

Therefore, understanding and considering the long-term impacts of anticancer therapies on health-related quality of life should be an integral component of assessing risk-benefit profiles during both regulatory and medical decision-making. This necessitates methods to accurately and reliably capture features of health-related quality of life that are important to cancer survivors. Established methods to assess these constructs in oncology clinical research include patient-reported assessments of global and domain-specific well-being, clinician-reported assessments of functional capacity, and performance assessments that capture physical performance capacity [22,23]. Collectively, these assessments have a range of limitations: patient-reported outcome assessments are burdensome and prone to floor and ceiling effects [24], clinician-reported outcome assessments exhibit limited interobserver reliability [25,26], and performance outcome assessments do not reflect many of the day-to-day functional challenges experienced by those with a history of cancer. Together, these limitations raise the question of how to best capture how cancer survivors are feeling and functioning in their real-world environments.

In the midst of a digital transformation in medicine, there is a growing interest in digital health technologies as measurement tools in oncology clinical care and research [27,28]. In particular, wearable sensors such as accelerometers have the potential to address some of the limitations of the established assessments of health-related quality of life in oncology [29]. These technologies can capture aspects of everyday physical behavior remotely (in individuals' lived environment), passively (as individuals go about their daily lives), and continuously (with high granularity) [28,30]. These devices can furthermore capture many domains of physical behavior, including aspects of gait, mobility, posture, physical activity, and sedentary behavior [31-33]. Alongside established outcome assessments, these measures may provide rich insights into the real-world well-being and physical function in cancer survivorship [34-36].

The use of wearable sensors as monitoring tools in oncology clinical research is on the rise [37], but despite their potential for capturing how individuals feel and function in their real-world environments, these tools have not been widely adopted for assessing treatment efficacy or monitoring in cancer clinical research. Furthermore, across trials that have deployed wearable sensors, there is little standardization regarding which outcome measures are included, as well as the definitions of those measures [37]. Together with this lack of standardization, a potential reason for the limited adoption of digital measures derived from wearable sensors is that there is limited clinical validation evidence linking specific digital measures of real-world physical behavior to gold-standard outcome measures commonly used in oncology clinical research (ie, patient-reported, clinician-reported, and performance outcomes) [29].

Objectives

In this secondary analysis, we aimed to gain insight into how various digital measures of real-world physical behavior, captured with wearable sensors, can provide an additional understanding of health-related quality of life following cancer treatment. To do so, we leveraged data from 2 previous studies of individuals who had completed cancer treatment to test whether an array of digital measures of real-world physical behavior, measured with a wearable accelerometer over a 1-week period, were related to self-reported and performance measures of physical function. First, we examined associations between real-world physical behavior and self-reported well-being and physical function. Next, we examined how real-world physical behavior was related to aerobic fitness, captured with a submaximal exercise test performed in the clinic. Finally, we compared these patterns of associations to determine whether real-world physical behavior was more closely related to self-reported well-being and physical function or to aerobic fitness.

Methods

Overview

Data were collected as part of 2 studies. Study 1 was a cross-sectional study conducted at Colorado State University between January 2020 and June 2021 and aimed to examine how reallocating time to physical activity affected body composition and quality of life in individuals who had completed cancer treatment [38,39]. Study 2 was a randomized clinical trial conducted at the University of Colorado Anschutz Medical Campus and Colorado State University and aimed to examine the feasibility and preliminary effects of a videoconference physical activity intervention in individuals who had completed treatment for colorectal cancer [40,41]. For study 2, only data collected at the baseline measurement time point (ie, before the initiation of the intervention) were used. These data were collected between February 2021 and July 2022. For increased statistical power, we combined data from studies 1 and 2.

Ethical Considerations

Study 1

The study protocol was approved by Colorado State University Institutional Review Board (IRB #19-8914H). All participants provided written, informed consent before participation and were compensated US $25 for participation. When providing consent, participants consented to their deidentified data being used for future studies. Data were deidentified before analyses.

Study 2

The study protocol was approved by the University of Colorado Institutional Review Board (IRB #18-2436). Informed consent was obtained from all participants. As a part of this process, participants consented to their deidentified data being used for research purposes beyond the primary study aims. Participants were compensated up to US $75 for participation. Data were deidentified before analyses.

Participants

Study 1

Participants in study 1 were recruited from local and regional cancer centers and the Colorado State University Center for Healthy Aging using flyers, presentations, and email postings. Eligible participants were aged >18 years at the time of their cancer diagnosis and within 60 months of treatment completion at the time of study participation.

Study 2

Participants in study 2 were recruited from the University of Colorado Cancer Center, survivor support organizations, and community outreach using mailed letters, flyers, and social media platforms. Eligible participants (1) were fluent in English, (2) had access to a computer or phone with internet and a camera, (3) stated willingness to comply with all study procedures and be available for the duration of the study, (4) were male or female individuals aged ≥40 years at the time of diagnosis, (5) had histologically confirmed cancer of the colon or rectum (stages II-IV) if treated with curative intent, completed resection or other surgery 3 to 60 months before enrollment, received chemotherapy and/or radiation therapy within the previous year with at least 1 cycle of intended chemotherapy completed (not necessary to have completed all cycles), and had no plans for additional chemotherapy or radiation therapy. Exclusion criteria were evidence of metastatic disease, existing participation in at least 150 minutes per week of at least moderate intensity physical activity, being pregnant or planning to become pregnant, and known contraindications for exercise.

Procedure

We aimed to test relationships between participants' real-world physical behavior, self-reported well-being and physical function, and aerobic fitness; therefore, we focused only on relevant assessments that were included in both studies. These assessments are described in subsequent sections.

Assessments of Self-Reported Well-Being and Physical Function

In the laboratory, participants completed a series of questionnaires in which they reported demographic information and information about their cancer diagnosis and types of treatment completed. They also completed the Functional Assessment of Cancer Therapy-General (FACT-G), a 27-item instrument designed to assess health-related quality of life in individuals with cancer along 4 dimensions: physical, functional, emotional, and social well-being [42]. For FACT-G and its subscales, higher scores indicate better well-being.

Assessment of Aerobic Fitness

Following the questionnaires, participants completed a submaximal exercise test that involved a modified Balke Treadmill Test. The modified Balke Treadmill protocol consisted of a 3-minute warm-up at a treadmill speed of 2.5 mph. Following the warm-up, participants entered stage 1 of the test at 0% grade and 2.5 mph. Every 3 minutes, participants entered a new stage, increasing the treadmill grade by 2.5% until 70% heart rate reserve was reached or until there was a safety indication to stop the exercise test. Heart rate was collected every minute throughout the protocol.

A measure of aerobic fitness, that is, predicted oxygen uptake (VO_2) at 70% heart rate reserve, was then calculated according to the following formula (for women [43]; for men [44]), where *T* denotes the test duration (ie, time to reach 70% heart rate reserve):

$$\text{Predicted submaximal } VO_2 \text{ (mL/kg/min) for women} = 1.38\,(T) + 5.22 \quad \textbf{(1)}$$

$$\text{Predicted submaximal } VO_2 \text{ (mL/kg/min) for men} = 1.44\,(T) + 14.99 \quad \textbf{(2)}$$

Assessment of Real-World Physical Behavior

At the end of the laboratory visit, participants were instructed that during the subsequent 7-day period, their real-world behavior would be monitored continuously using an activPAL3 activity monitor (PAL Technologies Ltd), worn on the thigh [45]. Using an accelerometer to sense limb position and activity, activPAL can discriminate between the activities of lying, sitting, standing, and stepping and therefore allows for the calculation of time spent in various physical activity categories [46-48]. The sensor identifies reciprocal leg movements as steps, and based on the detected steps, measures including cadence and time in stepping bouts of various durations can be calculated [49].

Participants were each given an activPAL and instructed regarding proper use and wear of the device. Each participant was instructed to wear the device on their thigh for 7 days in their real-world environments. A 7-day monitoring period has been demonstrated to provide sufficient accelerometer data for generating reliable estimates of various measures of real-world physical behavior [50-52]. After the remote monitoring period, participants returned their devices to the laboratory. If their appointment to return the device was >7 days after the beginning of the remote monitoring period, participants were permitted to wear the device longer than 7 days to avoid losing it. All available activPAL data were used for analysis.

Analysis

Linkage of PROMIS-Physical Function Scores

To assess self-reported physical function, we first calculated scores on a 5-item subset of the FACT-G physical well-being subscale. The 5 items in the subset were “I have a lack of energy,” “Because of my physical condition, I have trouble meeting the needs of my family,” “I have pain,” “I feel ill,” and “I am forced to spend time in bed.” This 5-item subset excluded 2 items on the FACT-G physical well-being subscale: “I have nausea” and “I am bothered by the side effects of treatment.” These 5-item subset scores were linked to T scores on a custom subset of the Patient-Reported Outcomes Measurement Information System-Physical Function (PROMIS-PF) calibrated item bank, using an established linkage method [53]. PROMIS-PF is a tool for assessing physical function in oncology clinical research [54,55], for which higher T scores indicate better physical function. We used the linkage procedure described by Kaat et al [53] rather than administering the PROMIS-PF assessment directly.

Summarization of Self-Reported and Performance Measures in the Sample

For the purposes of analysis, FACT-G scores, linked PROMIS-PF T scores, and submaximal VO_2 values were treated as continuous variables. Summary statistics were used to summarize the sample in terms of FACT-G total well-being scores, FACT-G physical well-being subscale scores, scores on the 5-item subset of the FACT-G physical well-being subscale used for linkage to PROMIS-PF, linked PROMIS-PF T scores, and submaximal VO_2. Ceiling effects, defined as the percentage of the sample achieving the maximum possible score [56], were calculated for each self-reported measure. The skewness and kurtosis of each self-reported measure’s distribution were also calculated.

Calculation of Measures of Real-World Physical Behavior

Average daily nonwear time, defined as the time in which participants did not wear the activPAL monitor, was calculated for each participant. A valid day was considered as the one in which a participant wore the monitor for at least 10 hours; only participants with at least 4 valid days during the remote monitoring period were included for analysis [57].

The activPAL proprietary software, PALbatch (version 8.11.1.63; PAL Technologies), was used to access summaries of recorded data and whole recording outcomes from the real-world monitoring period. Measures of interest included average daily time spent sedentary (ie, secondary lying, defined as sitting or lying not classified as primary lying); time in light physical activity; time in moderate to vigorous physical activity; and step count. Average daily time in light and moderate to vigorous intensity activity was calculated using established approaches [47]. In addition, we calculated the average daily time that each participant spent in stepping bouts of ≥1 minute in duration. Finally, we extracted 2 measures of cadence: weighted median cadence in stepping bouts of ≥1 minute across all valid days, as well as the number of steps in any 30-second recording period (“peak 30 s cadence”) across all valid days, a measure that is thought to reflect an individual’s best natural effort [58-60]. Summary statistics were used to characterize the sample in terms of the various measures of real-world physical behavior.

Intercorrelations Among Related Measures

As preliminary tests for expected intercorrelations among the self-reported measures and among the measures of real-world physical behavior, we performed Spearman correlation analyses.

Associations With Measures of Real-World Physical Behavior

Pairwise Spearman correlation analyses were then used to test for associations between each measure of real-world physical behavior and (1) the self-reported measures and (2) aerobic fitness. These analyses were repeated in a partial Spearman correlation framework to account for the effects of age, sex, BMI, time since diagnosis, and cancer stage at diagnosis on each association. In addition, to test for differences in physical behavior based on the level of self-reported physical function and well-being, we first performed a tertile split of each self-reported measure and a median split of aerobic fitness. A median split instead of a tertile split was performed for aerobic fitness since fewer participants had values of submaximal VO_2 available compared with the self-reported measures. In cases where scores were equal to a tertile value, they were assigned such that the resulting splits reflecting high, medium, and low scores were approximately equal in size. Then, we used 2-tailed pairwise Welch *t* tests and Mann-Whitney *U* tests to compare the splits in terms of the various measures of real-world physical behavior. Welch *t* tests were used to compare splits in terms of measures that did not exhibit deviations from normality, whereas Mann-Whitney *U* tests were performed to compare splits in terms of measures that exhibited deviations from normality. Deviation from normality was indicated by a statistically significant Shapiro-Walk test result. For each comparison of the splits of self-reported measures, *P* values were adjusted for multiple comparisons using Holm method [61]. For comprehensiveness, we also performed Spearman correlation analyses to test for associations between aerobic fitness and each of the self-reported measures.

Comparison of Associations With Measures of Real-World Physical Behavior

A series of likelihood ratio tests was used to determine if the strength of associations with real-world physical behavior differed between the self-reported measures and aerobic fitness. The following steps were performed for each measure of real-world physical behavior. Here, we describe the process for FACT-G total well-being, but the same process was used for FACT-G physical well-being, FACT-G physical well-being 5-item subset, and linked PROMIS-PF T scores:

1. One multiple linear regression model was fit, with all measures (FACT-G total well-being, submaximal VO_2, age, sex, BMI, time since diagnosis, and cancer stage) regressed onto the measure of real-world physical behavior.
2. A second multiple linear regression model was fit, which was identical to the first, with the exception that the regression coefficients for FACT-G total well-being and submaximal VO_2 were constrained to equality.
3. A likelihood ratio test was performed to compare the fits of the first (unconstrained) and second (constrained) models; a significant test result indicated that constraining the coefficients to equality led to a significantly poorer model fit.

Exploratory Analysis of Associations With Activity Fragmentation

For additional insights into real-world physical behavior, we calculated measures of activity fragmentation, reflecting how participants accumulated their total activity and sedentary time across the days of the remote monitoring period [62]. More fragmented activity patterns have been associated with increased mortality risk, reduced physical function as measured with in-clinic physical performance tests, and fatigability [63,64]. Using a similar approach as mentioned in the *Comparison of Associations With Measures of Real-World Physical Behavior* section, we tested whether the various measures of activity fragmentation were more associated with the self-reported measures or with aerobic fitness (Multimedia Appendix 1 [62,65,66]).

For each analysis comparing regression coefficients, data were restricted to include only those participants with no missing values for the respective measures being compared (ie, the self-reported measure of interest and submaximal VO_2). In addition, for all linear regression analyses, continuous variables were standardized, and binary variables were coded with a sum contrast coding scheme before analysis. All analyses were performed with R (version 4.1.2; The R Foundation).

Results

Overview

For study 1, we screened 101 individuals for participation and enrolled 59 (58.4%) individuals; 2 enrolled participants did not undergo remote monitoring. For study 2, we screened 1149 individuals and enrolled 29 (2.52%; screening details for study 2 are described fully in the study by Leach et al [41]). A total of 86 participants across both studies (study 1: n=57, 66%; study 2: n=29, 34%) completed remote monitoring of physical behavior and were included in the combined data set for analysis. Characteristics of participants included in the combined data set are summarized in Table 1. A comparison of participants in the 2 study samples in terms of demographics, cancer diagnosis, and treatment information is provided in Table S1 in Multimedia Appendix 1. Across studies 1 and 2, the most common cancer types at diagnosis were breast (n=21, 24%), colon (n=20, 23%), and colorectal cancers (n=13, 15%). Detailed information on the distribution of cancer types across the 2 studies is presented in Table S2 in Multimedia Appendix 1.

All participants who underwent remote monitoring had valid activPAL data for least 4 days during the remote monitoring period. Participants had an average of 7.2 (SD 1.4; range 4-13) days of valid data and an average of 35.6 (SD 46.1; range 0-177.8) minutes of nonwear time per day. One participant in study 1 did not complete the FACT-G physical well-being subscale. Due to some in-person assessments being suspended during the COVID-19 pandemic, submaximal VO_2 values were only available for 37% (21/57) of the participants in study 1. Submaximal VO_2 values were available for all but 1 participant (28/29, 97%) in study 2 (due to an equipment malfunction). This yielded a total of 49 participants across both studies with available values for submaximal VO_2.

A summary of the measures of self-reported well-being and physical function, aerobic fitness, and real-world physical behavior is presented in Table 2. Although no ceiling effects were observed for FACT-G total well-being scores, moderate ceiling effects were observed for the FACT-G physical well-being subscale, the FACT-G physical well-being 5-item subset, and linked PROMIS-PF scores, with 19% (16/85), 22% (19/85), and 22% (19/85) of the participants having the maximum score, respectively. Three of the self-reported measures had skewness <–1; distributions of all measures are visualized in Figures S1 and S2 in Multimedia Appendix 1.

As expected, FACT-G total well-being, FACT-G physical well-being, FACT-G physical well-being 5-item subset, and linked PROMIS-PF T scores were significantly correlated (Figure S3 in Multimedia Appendix 1). Similarly, the various measures of real-world physical behavior exhibited mostly expected intercorrelations (Figure S4 in Multimedia Appendix 1).

Table 1. Participant characteristics (n=86).

Characteristics	Values
Age (y), mean (SD; range)	55.4 (12.9); 21-85
Sex, n (%)	
Female	61 (71)
Male	25 (29)
BMI, mean (SD; range)	27.4 (5.2; 18-43)
Education level, n (%)	
12th grade or less	0 (0)
High school graduate or GED	3 (4)
Some college, AA degree, or technical school	21 (24)
College graduate (Bachelor’s)	29 (34)
Graduate degree (masters or doctorate)	32 (37)
Prefer not to answer	1 (1)
Time since diagnosis (mo), mean (SD; range)	32 (25.5; 2-211)
Time since last treatment (mo), mean (SD; range)	21.2 (17.0; 0-60)
Cancer stage at diagnosis, n (%)	
0[a]	4 (5)
I	15 (17)
II	22 (26)
III	29 (34)
IV	9 (11)
Unsure	7 (8)
Cancer treatment	
Had any treatment	86 (100)
Had chemotherapy	65 (76)
Had radiation	42 (49)
Had surgery	76 (88)
Had other	12 (14)
Number of treatment types, n (%)	
1	13 (15)
2	41 (47.7)
3	28 (32.6)
4	4 (4.7)

[a] Stage 0 indicates evidence of abnormal cells in situ.

Table 2. Summary of measures of self-reported well-being and physical function, aerobic fitness, and real-world physical behavior.

Measures	Values, mean (SD; range)
Self-reported well-being and physical function	
FACT-G[a] total well-being (0-108)	87.9 (13.3; 41-107)
FACT-G physical well-being subscale (0-28)	24.4 (3.7; 12-28)
FACT-G physical well-being subscale 5-item subset (0-20)	17.4 (2.6; 9-20)
Linked PROMIS[b]-Physical Function *T*-score (19-61)	51.1 (7.1; 35-61)
Aerobic fitness	
Predicted submaximal VO_2[c] (mL/kg/min)	29.1 (9.9; 10.0-50.0)
Real-world physical behavior	
Daily sedentary time (min)	582.1 (102.8; 295.1-819.4)
Daily step count	6916.3 (2704.5; 1413-17,501)
Daily time in light activity (min)	305.1 (97.2; 103.8-551.3)
Daily time in moderate to vigorous activity (min)	4.0 (6.6; 0.0-58.2)
Daily time in stepping bouts ≥1 min (min)	25.3 (19.7; 0.2-107.7)
Weighted median cadence in stepping bouts ≥1 min (steps/min)	98.7 (12.1; 56.5-126.2)
Peak 30-second cadence (steps/min)	67.2 (8.6; 42.0-86.0)

[a] FACT-G: Functional Assessment of Cancer Therapy-General.

[b] PROMIS: Patient-Reported Outcomes Measurement Information System.

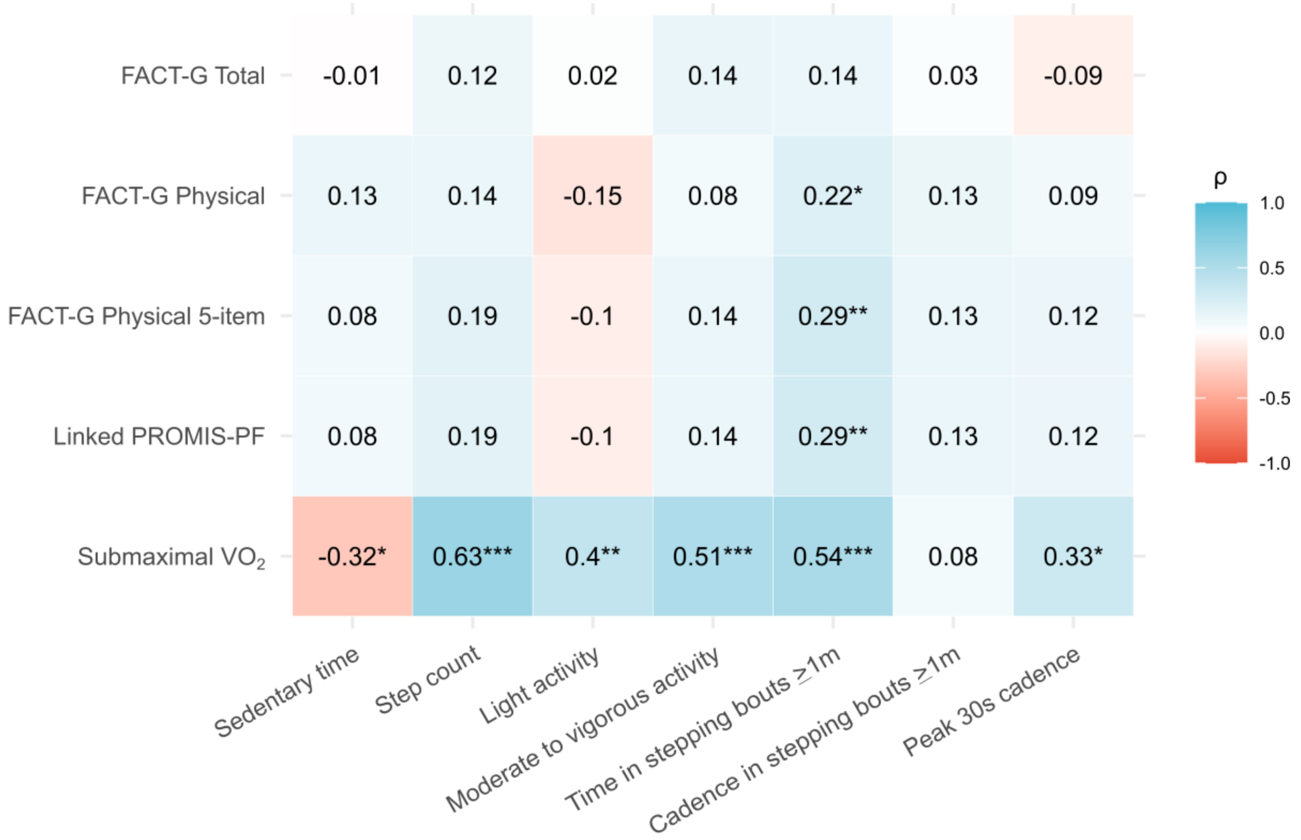
[c] VO_2: submaximal oxygen uptake.

Most Measures of Real-World Physical Behavior Were Not Associated With Self-Reported Well-Being or Physical Function

Spearman correlations with real-world physical behavior are depicted in Figure 1. The various measures of real-world physical behavior were not significantly correlated with FACT-G total well-being (*P*s≥.189; section 5 in Multimedia Appendix 1). Average daily time in stepping bouts ≥1 minute was significantly correlated with FACT-G physical well-being (ρ=0.22; *P*=.046), FACT-G physical well-being 5-item subset (ρ=0.29; *P*=.007), and linked PROMIS-PF T scores (ρ=0.29; *P*=.007), but no other measures of physical behavior were associated with FACT-G physical well-being, FACT-G physical well-being 5-item subset, or linked PROMIS-PF T scores (*P*s≥.08; section 5 in Multimedia Appendix 1). When accounting for the effects of demographics and cancer characteristics on these associations using a partial Spearman correlation framework, the pattern of significance was largely unchanged, except that the correlation between time in stepping bouts ≥1 minute and FACT-G physical well-being was no longer significant (Figure S5 in Multimedia Appendix 1).

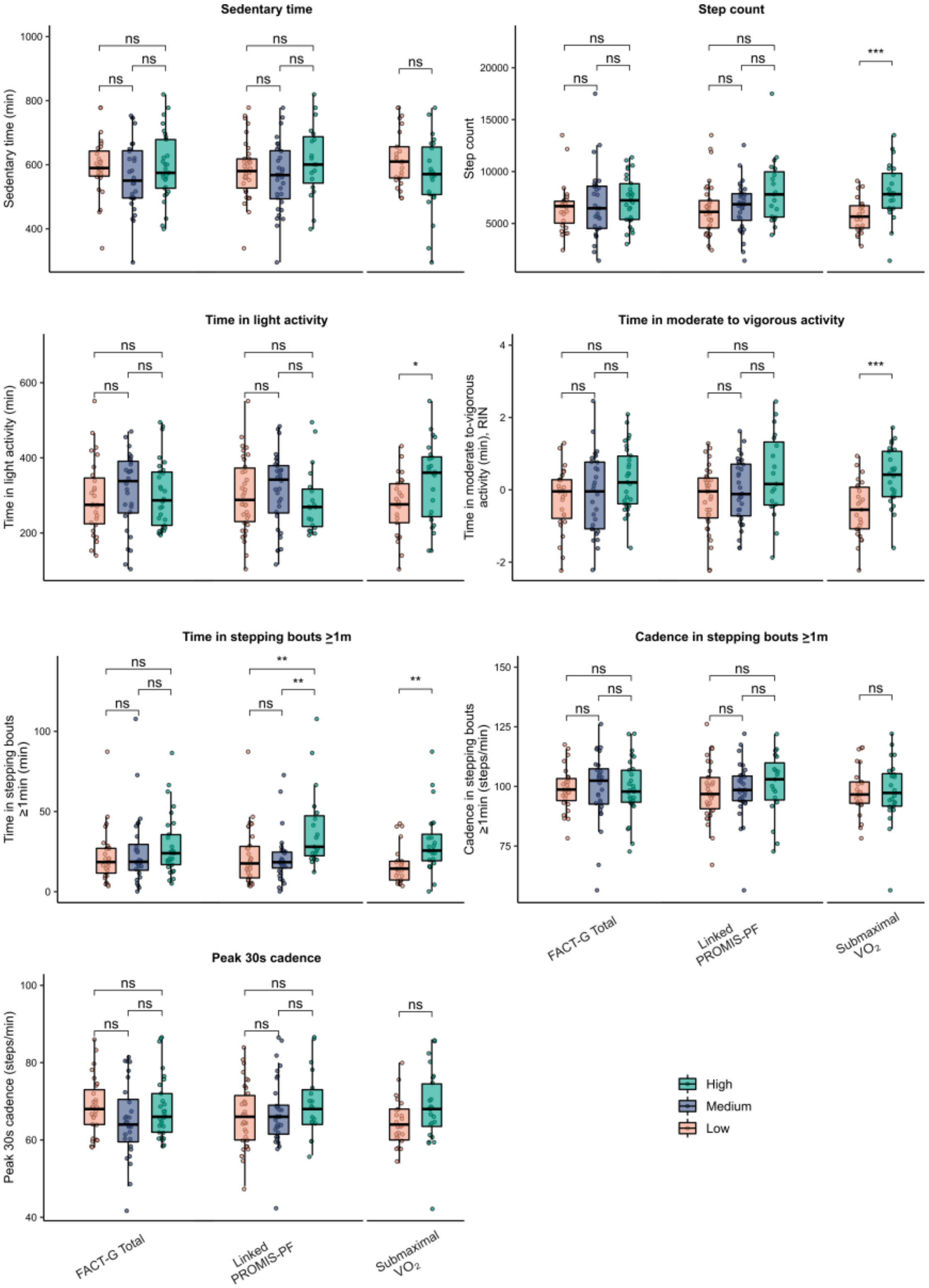
Individuals with high, medium, and low FACT-G total well-being scores did not differ significantly in terms of any of the measures of real-world physical behavior (Figure 2). Similarly, individuals with high, medium, and low levels of FACT-G physical well-being scores, FACT-G physical well-being 5-item subset scores, and linked PROMIS-PF T scores did not differ significantly in terms of sedentary time, step counts, time in moderate to vigorous activity, weighted median cadence, or peak 30-second cadence (Figure 2; Figure S6 in Multimedia Appendix 1). However, we did find that participants with high FACT-G physical well-being 5-item subset and linked PROMIS-PF T scores spent more time in stepping bouts ≥1 minute than those with medium (*W*=121; *P*=.001) and low scores (*W*=155; *P*=.004).

Figure 1. Correlation matrix depicting pairwise Spearman correlations with measures of real-world physical behavior. FACT-G: Functional Assessment of Cancer Therapy-General; PROMIS-PF: Patient-Reported Outcomes Measurement Information System-Physical Function. *P<.05, **P<.01, ***P<.001.



	Sedentary time	Step count	Light activity	Moderate to vigorous activity	Time in stepping bouts ≥1m	Cadence in stepping bouts ≥1m	Peak 30s cadence
FACT-G Total	-0.01	0.12	0.02	0.14	0.14	0.03	-0.09
FACT-G Physical	0.13	0.14	-0.15	0.08	0.22*	0.13	0.09
FACT-G Physical 5-item	0.08	0.19	-0.1	0.14	0.29**	0.13	0.12
Linked PROMIS-PF	0.08	0.19	-0.1	0.14	0.29**	0.13	0.12
Submaximal VO_2	-0.32*	0.63***	0.4**	0.51***	0.54***	0.08	0.33*

Figure 2. Box plots depicting the measures of real-world physical behavior according to tertile splits of self-reported well-being and physical function and a median split of aerobic fitness. FACT-G: Functional Assessment of Cancer Therapy-General; PROMIS-PF: Patient-Reported Outcomes Measurement Information System-Physical Function; submaximal VO_2: submaximal oxygen uptake. Significance labels refer to the results of Welch *t* tests and Mann-Whitney *U* tests. For ease of visualization, time in moderate to vigorous activity was transformed with a reverse inverse normal (RIN) transformation. **P*<.05, ***P*<.01, ****P*<.001.



Real-World Physical Behavior Was Associated With Aerobic Fitness

All but one of the accelerometry-derived measures of real-world physical behavior were significantly correlated with submaximal VO_2 (*P*s≤.03; Figure 1; section 5 in Multimedia Appendix 1). Weighted median cadence in stepping bouts ≥1 minute was the only measure not associated with submaximal VO_2 (ρ=0.08; *P*=.61). After accounting for the effects of demographics and cancer characteristics in a partial Spearman correlation framework (Figure S5 in Multimedia Appendix 1), average daily step count was significantly correlated with submaximal VO_2 (ρ=0.46; *P*=.002), as was time in moderate to vigorous activity (ρ=0.33; *P*=.03).

A median split of submaximal VO_2 (Figure 2) indicated that compared with participants with low submaximal VO_2, participants with high submaximal VO_2 had significantly higher step counts (*W*=130; *P*<.001) and spent significantly more time in light intensity activity ($t_{42.6}$=2.23; *P*=.03), moderate intensity activity (*W*=128; *P*<.001), and stepping bouts ≥1 minute in duration (*W*=144; *P*=.002). Individuals with high and low submaximal VO_2 did not differ significantly in terms of sedentary time (*W*=367; *P*=.19), weighted median cadence ($t_{42.7}$=-0.07; *P*=.95), or peak 30-second cadence (*W*=212; *P*=.08).

Aerobic Fitness Was Not Associated With Self-Reported Well-Being or Physical Function

Spearman correlation analyses indicated that submaximal VO_2 was not significantly correlated with any of the self-reported measures (*P*s≥.21; section 7 in Multimedia Appendix 1). The pattern of significance was unchanged when using a partial correlation approach to account for the effects of demographic and cancer characteristics on these associations (*P*s≥.27; section 7 in Multimedia Appendix 1).

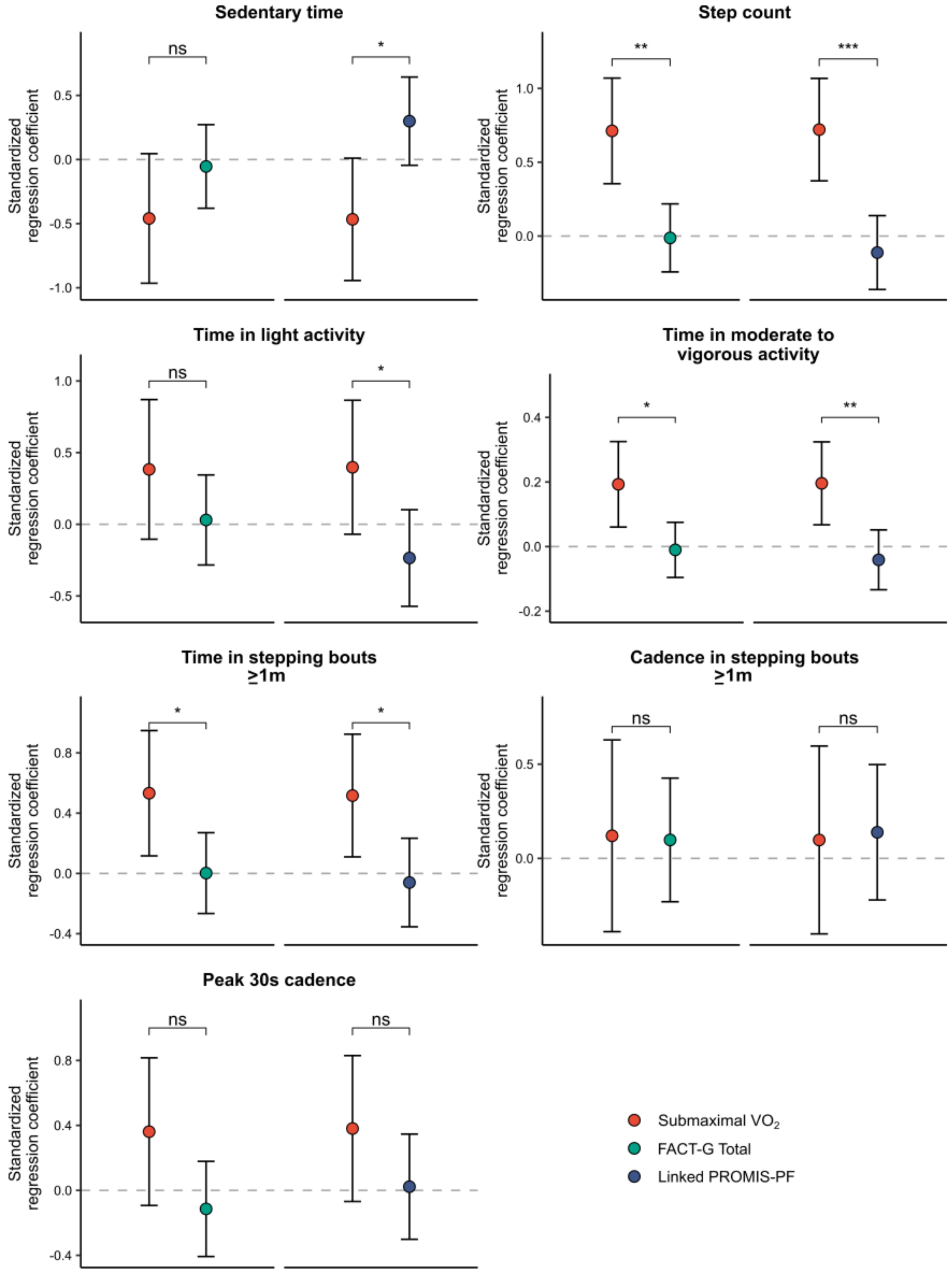
Associations With Real-World Physical Behavior Were Stronger for Aerobic Fitness Than for Self-Reported Well-Being or Physical Function

Having found that the measures of real-world physical behavior were largely uncorrelated with self-reported well-being and physical function but correlated with aerobic fitness, we used likelihood ratio tests to compare these sets of associations (Figure 3; Figure S8 in Multimedia Appendix 1). These analyses indicated that step count was more strongly associated with submaximal VO_2 than with FACT-G total well-being (F_1=12.29; *P*=.001), FACT-G physical well-being (F_1=18.27; *P*<.001), FACT-G physical well-being 5-item subset (F_1=16.32; *P*<.001), and linked PROMIS-PF T scores (F_1=15.72; *P*<.001). Similarly, time in moderate to vigorous activity was more strongly associated with submaximal VO_2 than with FACT-G total well-being scores (F_1=7.05; *P*=.01), FACT-G physical well-being (F_1=8.78; *P*=.005), FACT-G physical well-being 5-item subset (F_1=8.13; *P*=.007), and linked PROMIS-PF T scores (F_1=9.30; *P*=.004). Time in stepping bouts ≥1 minute was also more strongly associated with submaximal VO_2 than with any of the self-reported measures (FACT-G total: F_1=4.87; *P*=.03; FACT-G physical: F_1=8.34; *P*=.006; FACT-G physical 5-item subset: F_1=7.16; *P*=.01; linked PROMIS-PF: F_1=5.48; *P*=.03).

Sedentary time was more negatively associated with submaximal VO_2 than with FACT-G physical well-being (F_1=7.49; *P*=.009), FACT-G physical well-being 5-item subset (F_1=5.36; *P*=.03), and linked PROMIS-PF T scores (F_1=7.02; *P*=.01), but not with FACT-G total well-being scores (F_1=1.93; *P*=.17). Similarly, time in light activity was more positively associated with submaximal VO_2 than with FACT-G physical well-being (F_1=4.86; *P*=.03) and linked PROMIS-PF T scores (F_1=5.01; *P*=.03), but not with FACT-G total well-being scores (F_1=1.57; *P*=.22) or physical well-being 5-item subset scores (F_1=4.01; *P*=.05). For weighted median cadence and peak 30-second cadence, associations with submaximal VO_2 were not significantly different than those with any of the participant-reported measures (*P*s≥.08; section 8 in Multimedia Appendix 1).

A similar pattern of results was observed when examining relationships with measures of activity fragmentation (Multimedia Appendix 1). Specifically, measures indicating a more fragmented activity pattern were correlated with lower submaximal VO_2 but were largely unrelated to measures of self-reported well-being and physical function (Figure S9 in Multimedia Appendix 1); furthermore, multiple measures of activity fragmentation were significantly more associated with aerobic fitness than with the self-reported measures (Figure S10 in Multimedia Appendix 1).

Figure 3. Comparison of associations of real-world physical behavior with (1) self-reported well-being and physical function and (2) aerobic fitness. FACT-G: Functional Assessment of Cancer Therapy-General; PROMIS-PF: Patient-Reported Outcomes Measurement Information System-Physical Function; submaximal VO_2: submaximal oxygen uptake. Significance labels refer to the results of likelihood ratio (F) tests comparing standardized regression coefficients. *P<.05, **P<.01, ***P<.001.



Discussion

Principal Findings

Amid a digital revolution in medicine, the use of digital health technologies as evidence generation tools in oncology clinical trials and routine cancer care is gaining traction [27,67]. Wearable sensors are increasingly being used for assessing the efficacy of anticancer therapies and for posttreatment monitoring [29], but the clinical utility of measures of real-world behavior derived from these devices remains to be fully characterized. In this study, we examined how measures of real-world physical behavior, captured in real-world environments of cancer survivors over a 1-week monitoring period using accelerometry, were related to self-reported and performance outcomes. We found that the volume and patterning of real-world physical behavior were more related to aerobic fitness than to self-reported well-being and physical function.

Previous studies assessing relationships between real-world measures of physical behavior and self-reported well-being and physical function in cancer survivors have reported mixed findings. In a study of prostate cancer survivors, accelerometer-assessed time spent sedentary, time in light activity, and time in moderate to vigorous activity were all associated with global well-being, but only at specific percentiles of well-being [68]. In colon cancer survivors, time spent sedentary was associated with quality of life [69], and among colorectal cancer survivors, time in moderate to vigorous activity was associated with quality of life and physical function [70]. However, one of these studies failed to find a significant association between sedentary time and either quality of life or physical function [70], and in a separate study, neither time in sedentary behavior nor time in moderate to vigorous activity was significantly associated with quality of life in prostate cancer survivors [71]. Our findings are in line with these prior reports of limited relationships with measures of real-world physical behavior and suggest that these measures are more reflective of objective physical capacity than of self-reported well-being and physical function in cancer survivors.

There are several potential explanations for why we did not observe many significant relationships between real-world physical behavior and the self-reported measures. One reason may be that ceiling effects in the self-reported measures limited our ability to detect associations with physical behavior. We observed ceiling effects for FACT-G physical well-being and linked PROMIS-PF T scores, which may be due to selection bias, as well as some participants being far out from diagnosis and treatment at the time of assessment. All participants in studies 1 and 2 had completed treatment, and participants in both the studies had been diagnosed an average of 32 months before data collection. Ceiling effects are a limitation of some participant-reported assessments, including FACT-G, its subscales, and PROMIS-PF short forms [24,54,72,73], with these effects challenging the ability of an assessment to detect changes over time [56]. These effects may be especially relevant when respondents have higher levels of functioning [24,54], which could occur when assessing cancer survivors (1) years out from diagnosis, (2) with cancer types that tend to be detected early, or (3) who experience relatively smaller declines in functioning. As fewer of the real-world physical behavior measures were highly skewed, these measures have the potential to capture aspects of functioning beyond those captured with self-reported measures.

Another reason may be that the real-world measures studied here do not capture the aspects of real-world physical behavior that are most associated with self-reported well-being and physical function. We included a range of measures of real-world physical behavior, with the aim of gaining insights into their differential clinical utility. Step count, time in moderate to vigorous activity, time spent sedentary, time in light activity, and time in stepping bouts ≥1 minute, all demonstrated stronger associations with aerobic fitness than with the self-reported measures, suggesting that these particular measures may offer more insights into individuals' physical capacity than their well-being and perceived physical function. We found that weighted median cadence and peak 30-second cadence were largely unrelated to aerobic fitness, and their associations with aerobic fitness did not differ from those for the participant-reported measures. It is worth noting that we calculated time and weighted median cadence in stepping bouts ≥1 minute in duration (rather than longer-duration stepping bouts), due to many participants not spending time in longer-duration stepping bouts. As most stepping bouts taken in day-to-day behavior tend to be <1 minute in duration [74], time and cadence in longer-duration stepping bouts may be more informative, but studies of larger samples are needed to examine the clinical utility of these measures. At the same time, with participants spending the most time in short-duration stepping bouts, aspects of gait such as gait speed and variability not explored here may be clinically relevant measures of day-to-day functioning and worth further investigation.

Beyond measures reflecting the absolute volume of physical behavior, we found that measures reflecting a more fragmented pattern of daily activity and sedentary time were negatively correlated with aerobic fitness but were mostly unrelated to self-reported well-being and physical function. Fragmented daily physical activity has been associated with poorer physical function as measured in the clinic, as well as higher fatiguability [63,64]. Additional research is needed to understand whether measures reflecting the fragmentation of real-world physical behavior can provide additional insights into real-world physical function, beyond measures reflecting the absolute volume of physical behavior, in cancer survivors. Taken together, it may be that further research is needed to define and validate measurable concepts and features of real-world physical behavior that are more closely related to perceived physical function.

We note several other important limitations. First, this was a cross-sectional analysis; results may differ if examining relationships with change in real-world physical behavior. Testing whether real-world physical behavior is associated with established measures of physical function and well-being over time will be necessary for establishing clinical validity of these measures. In addition, the sample size was small, with only 49 individuals included in the analyses involving aerobic fitness due to some in-person assessments being suspended during the COVID-19 pandemic. Furthermore, participants were mostly White and female, with high levels of educational attainment, limiting the ecological validity of results. In addition, most participants were diagnosed at cancer stage II or lower, with breast, colon, or rectal cancer, so results may not generalize to survivors of more advanced cancers or of other cancer types. Similarly, this analysis was focused on individuals who had completed treatment, which allowed us to consider questions of clinical utility without the confounding effects of disease and treatment on functioning; however, results may not generalize to individuals undergoing active cancer treatment. Further investigation of real-world physical behavior in larger, more representative samples of individuals during and after cancer treatment is warranted.

Another important limitation is that this was a secondary analysis of previously collected data, and so the studies were not designed to test the questions posed in this investigation. Related to this, it is possible that using other self-report and aerobic fitness measures might have yielded different results. Additional work to probe these relationships with other measures may help inform the clinical utility of wearable-derived digital measures in cancer survivorship.

Beyond these limitations, our findings speak to the potential utility of digital measures of real-world physical behavior to contribute to the assessment of functioning in cancer survivorship. That the digital measures did not exhibit many significant relationships with self-reported well-being and physical function suggests that these sets of measures provide different information. Furthermore, real-world physical behavior was significantly associated with submaximal VO_2; if further investigation reveals significant overlap in the clinical utility of these measures, wearable sensors could provide a lower-burden means of capturing information on aerobic fitness. Finally, compared with using any single type of measure, combining participant-reported, performance, and objective real-world measures could provide a more holistic picture of functioning in cancer survivorship [75]. Taking a comprehensive approach to assessing functioning could furthermore increase sensitivity to detect clinical change over time, enabling more efficient discovery of novel anticancer therapeutics or efficacious interventions for cancer survivors. This approach furthermore offers the possibility to better predict clinical outcomes, which could enable earlier disease detection and the personalization of both treatment and survivorship care [76,77]. As they can be captured remotely and passively, digital measures of real-world physical behavior can also enable decentralization of clinical trials, lower patient burden for participation, and facilitate the recruitment of underrepresented populations [78].

Although our findings indicate that digital measures of real-world physical behavior may add value for the measurement of functioning in cancer survivorship, further research is needed to evaluate the relative value and unique contributions of real-world physical behavior and self-reported physical function to the well-being of cancer survivors. Our approach and previous studies have been limited to cross-sectional analyses, but further work assessing how measures of real-world physical behavior relate to established clinical outcomes over time will be important for advancing the appropriate use of digital measures in oncology clinical research [79,80]. There are additional challenges with implementing wearable sensors in clinical populations, including acceptability and feasibility of these devices among participants. In addition, there is a growing regulatory emphasis on patient centricity in the development of clinical outcome assessments, such that digital measures derived from wearable sensors should reflect aspects of health that are meaningful to individuals in the target clinical population of interest [81]. Our findings suggest that digital measures may provide additional insights into physical function beyond those obtained with self-reported assessments, but whether these insights reflect aspects of everyday functioning that are meaningful remains to be determined. Gathering the evidence needed to demonstrate that digital measures are validated, meaningful, and feasible to capture will be important for promoting broad acceptance and proper use of digital measures in oncology clinical research [79,81,82].

Conclusions

Digital health technologies such as wearable sensors are increasingly used in oncology clinical research and offer potential for capturing aspects of real-world functioning in cancer survivors. In this secondary analysis, we investigated the clinical utility of accelerometry-derived measures of real-world physical behavior in a sample of individuals who had completed cancer treatment. We found that several measures of real-world physical behavior were more associated with aerobic fitness, assessed with a submaximal exercise test, than they were with self-reported measures of well-being and physical function. Our findings suggest that in cancer survivors who have completed treatment, measures of real-world physical behavior may be able to complement self-reported measures of well-being and physical function.

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Data Availability

The data sets generated and analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

SLB was responsible for methodology, formal analysis, software, validation, visualization, and writing the original draft. EG contributed to data curation, project administration, and writing—review and editing. SA and DC contributed to writing—review and editing. IC contributed to the methodology and writing—review and editing. KL participated in methodology, data curation,

and writing—review and editing. HL contributed to conceptualization, funding acquisition, supervision, project administration, resources, data curation, methodology, writing—review and editing.

Conflicts of Interest

SLB, SA, KL, and IC are employees of VivoSense, Inc. DC is the president of FACIT.org. IC is on the Editorial Board of Karger Digital Biomarkers and the Scientific Advisory Board for IMI IDEA FAST and has received fees for lectures and consulting on digital health at ETH Zürich and FHNW Muttenz. All the other authors declare no conflicts of interest.

Multimedia Appendix 1
Supplementary methods and results.
[PDF File (Adobe PDF File), 1193 KB - cancer_v10i1e53180_app1.pdf]

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Abbreviations

FACT-G: Functional Assessment of Cancer Therapy-General
PROMIS-PF: Patient-Reported Outcomes Measurement Information System-Physical Function

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Original Paper

Improving Concordance Between Clinicians With Australian Guidelines for Bowel Cancer Prevention Using a Digital Application: Randomized Controlled Crossover Study

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Abstract

Background: Australia's bowel cancer prevention guidelines, following a recent revision, are among the most complex in the world. Detailed decision tables outline screening or surveillance recommendations for 230 case scenarios alongside cessation recommendations for older patients. While these guidelines can help better allocate limited colonoscopy resources, their increasing complexity may limit their adoption and potential benefits. Therefore, tools to support clinicians in navigating these guidelines could be essential for national bowel cancer prevention efforts. Digital applications (DAs) represent a potentially inexpensive and scalable solution but are yet to be tested for this purpose.

Objective: This study aims to assess whether a DA could increase clinician adherence to Australia's new colorectal cancer screening and surveillance guidelines and determine whether improved usability correlates with greater conformance to guidelines.

Methods: As part of a randomized controlled crossover study, we created a clinical vignette quiz to evaluate the efficacy of a DA in comparison with the standard resource (SR) for making screening and surveillance decisions. Briefings were provided to study participants, which were tailored to their level of familiarity with the guidelines. We measured the adherence of clinicians according to their number of guideline-concordant responses to the scenarios in the quiz using either the DA or the SR. The maximum score was 18, with higher scores indicating improved adherence. We also tested the DA's usability using the System Usability Scale.

Results: Of 117 participants, 80 were included in the final analysis. Using the SR, the adherence of participants was rated a median (IQR) score of 10 (7.75-13) out of 18. The participants' adherence improved by 40% (relative risk 1.4, $P<.001$) when using the DA, reaching a median (IQR) score of 14 (12-17) out of 18. The DA was rated highly for usability with a median (IQR) score of 90 (72.5-95) and ranked in the 96th percentile of systems. There was a moderate correlation between the usability of the DA and better adherence ($r_s=0.4$; $P<.001$). No differences between the adherence of specialists and nonspecialists were found, either with the SR (10 vs 9; $P=.47$) or with the DA (13 vs 15; $P=.24$). There was no significant association between participants who were less adherent with the DA (n=17) and their age (*P*=.06), experience with decision support tools (*P*=.51), or academic involvement with a university (*P*=.39).

Conclusions: DAs can significantly improve the adoption of complex Australian bowel cancer prevention guidelines. As screening and surveillance guidelines become increasingly complex and personalized, these tools will be crucial to help clinicians accurately determine the most appropriate recommendations for their patients. Additional research to understand why some practitioners perform worse with DAs is required. Further improvements in application usability may optimize guideline concordance further.

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KEYWORDS

colorectal cancer; guidelines; colorectal cancer screening; digital application; questionnaire; application; cancer prevention; prevention; cancer; bowel cancer; surveillance; clinical vignette quiz; usability; Australia

Introduction

Australia’s National Health and Medical Research Council (NHMRC) screening and surveillance guidelines for colorectal cancer have become substantially more complex with their latest revision [1,2]. This is due to a shift toward personalized recommendations through detailed risk stratification based on an individual’s history of polyps or a family history of cancer. As a result, the guidelines now describe up to 230 different screening or surveillance scenarios, requiring clinicians to navigate through multiple tables to determine an appropriate recommendation. While implementing these changes can considerably improve resource use, this complexity may be a barrier to adherence, limiting the benefits of the guidelines [3,4]. Consequently, there is a need for tools to support clinicians using these guidelines. However, few of these tools have been adequately evaluated.

Several approaches have previously been considered to assist clinicians in determining appropriate bowel cancer prevention guideline recommendations. In the United States, where the complexity of polyp surveillance guidelines is the most similar to those of Australia, researchers have primarily focused on developing methods to assist clinicians in determining the appropriate advice, with a particular emphasis on automating the extraction of clinical information from electronic records to determine guideline-concordant recommendations [5-7]. In clinical practice, this resulted in a small but significant improvement in the rate of guideline-concordant recommendations (84.6% vs 77.4%) [7]. In Australia, print-based educational interventions for screening and surveillance, targeted at patients and clinicians, respectively, have had a minimal impact on improving guideline adherence [8,9]. By contrast, a nurse-led decision-making model has been the most successful intervention, increasing the rate of guideline-concordant recommendations from 83% to 97% [10]. Although successful, these options are associated with substantial costs for setup and maintenance and are not easily scalable beyond individual health services. Furthermore, how they perform when applied to the recently revised Australian guidelines is unclear.

Smartphone- or web-based digital applications (DAs) can be developed cheaply and are readily scalable. However, there are limited studies evaluating their effectiveness in supporting clinician adherence to complex bowel cancer prevention guidelines. Khan et al [11] showed that a DA was able to improve medical students’ knowledge of US colorectal cancer screening guidelines. However, their study was not randomized and did not control for the improvement in scores merely due to repeated exposure to the same clinical questions. In another study, a DA was evaluated by 6 endoscopists assessing a total of 58 colonoscopies [12]. As this was a small pilot study primarily focused on assessing the attitudes of potential users to guide the development of a new DA, it is difficult to draw meaningful conclusions about the potential benefit of the tool in improving guideline concordance.

In Australia, some of the DAs developed in response to the complexity of the latest surveillance guidelines include polyp.guide, polyp.app, and CRCwebapp [13-15]. These 3 tools provide greater ease of use by not requiring users to work through the risk tables manually. To the best of our knowledge, only CRCwebapp has been validated against all 230 possible case scenarios due to its use as a research tool in a previously published study [3]. However, none of these have been evaluated for their ability to improve the rate of guideline concordance among clinicians.

We hypothesized that a DA could improve clinician adherence to Australian screening and surveillance guidelines. To test this, we conducted a randomized controlled crossover study to compare the proportion of guideline-concordant decisions made by clinicians using either the CRCwebapp DA or the standard resource (SR).

Methods

Study Design and Setting

We enrolled practicing Australian clinicians to our online randomized controlled crossover clinical vignette questionnaire between July 1, 2020, and August 1, 2021. Participants were asked to provide guideline-concordant recommendations for 2 sets of clinical vignettes using either the SR or the DA. All participants were provided with an orientation that was tailored according to their experience with the guidelines. The clinical vignettes and order in which the tools were used were randomized. A study portal was used to present the vignettes, and this provided participants with access to both the SR and DA. After completing questions related to the clinical vignettes with both the SR and DA, the System Usability Scale (SUS) questionnaire was administered.

Inclusion Criteria

We included medical, surgical, or specialist nurse practitioners who were actively practicing in Australia during the study period.

Exclusion Criteria

Participants who were not actively involved in making screening or surveillance decisions for colorectal cancer in their clinical work were excluded.

Participant Orientation

We classified participants into 2 groups according to their familiarity with the guidelines. The nonspecialist group comprised primary care practitioners who had limited experience with the terminology and structure of the published guidelines. The specialist group comprised gastroenterologists, colorectal surgeons, and specialist nurse practitioners who were routinely using the current screening and surveillance guidelines in clinical practice. The orientation program was tailored according to the experience of each group, in order to reduce the impact of experience on participant scores and to reduce barriers to participation.

For nonspecialists, the necessary terminology pertaining to screening and surveillance was defined during a web seminar. This included degree of relationship in family history for screening protocols and the individual risk characteristics and classification of lesions for surveillance protocols. The seminar also included a breakdown of every decision table in the SR and the most efficient methods to navigate to each of these. Participants were also introduced to the 4 main pages of the DA and shown how to input data and where the results were presented. In contrast, the specialist orientation did not define the terminology, and the introductions to the SR and the DA were presented as optional videos available before the questionnaire.

Primary Outcome

The primary outcome was the proportion of correct screening and surveillance recommendations issued by participants in response to the clinical vignettes. Each vignette could receive a maximum score of 6, resulting in each participant being graded with a score out of 18 for each of 2 sets of 3 clinical vignettes.

Secondary Outcome

The secondary outcome was the usability of the DA. This was assessed using each participant’s response to the SUS. A score was determined for each participant and normalized in accordance with previously published methods [16].

Clinical Vignette Design

Three pairs of clinical vignettes were developed for the study (alpha and beta, gamma and theta, and delta and omega). Each vignette described the family history, medical comorbidities, and the number and characteristics of conventional adenomas or sessile serrated lesions identified over the preceding 2 colonoscopies. We avoided scenarios commonly highlighted in previous guidelines to reduce the likelihood that participants could answer according to their recollection of these [17]. Each pair of clinical vignettes focused participants on navigating identical sets of tables to balance for difficulty.

For each clinical vignette, participants were asked to determine the age and appropriate screening modality (stool testing or colonoscopy) based on the family history presented, the first and subsequent recommended surveillance intervals, and whether surveillance should be continued when considering the comorbidities of the patient if the age of the patient was >75 years at the time of the intended procedure. Each vignette received a score out of 6. Thus, each participant could receive a maximum score of 18 for each section.

Usability

We adapted the standard SUS questionnaire by changing the term “system” to “application” in order to focus participants on assessing the usability of the DA (Textbox 1). This comprised 10 standardized statements for which users were asked to indicate their level of agreement. Numerical scores provided by participants on a slider scale were translated into Likert scores: 0-20=strongly disagree (1); 21-40=disagree (2); 41-60=neither agree nor disagree (3); 61-80=agree (4); and 81-100=strongly agree (5). A total SUS score was calculated for each participant [18]. The scores were normalized to provide a percentile ranking of the usability of the DA, as described by Sauro and Lewis [16].

Textbox 1. System Usability Scale questionnaire adapted for the use of the digital application.

1. I think that I would like to use this application frequently.
2. I found the application unnecessarily complex.
3. I thought the application was easy to use.
4. I think that I would need the support of a technical person to be able to use this application.
5. I found that the various functions in this application were well integrated.
6. I thought there was too much inconsistency in this application.
7. I would imagine that people would learn to use this application very quickly.
8. I found the application very cumbersome to use.
9. I felt very confident using the application.
10. I needed to learn a lot of things before I could get going with this application.

DA Design

Each NHMRC screening and surveillance recommendation was coded into an Excel (Microsoft Corp) spreadsheet. We eliminated redundant user data entry by determining the minimum number of inputs necessary to calculate each recommendation. For screening decisions, this included 4 fields relating to the number and age of relatives with colorectal cancer and their relation (first or second degree) to the patient. For surveillance intervals, this included the number, type, and characteristics of the lesions found during the initial procedure. Subsequent surveillance intervals required 2 additional inputs: the initial surveillance interval and the type of lesion previously identified. An additional section, incorporating a list of potential patient comorbidities, was used to determine stopping rules.

A graphical user interface was applied using an open-source platform (Open as App), which would allow for the distribution of the DA as either a web page or smartphone app. Each type of calculation (screening, first surveillance, second surveillance, or stopping rules) was identified by a tab on the bottom of the screen. Sliders were used to input data on the number of lesions, and drop-down menus were used to provide details regarding the accompanying risk characteristics. The recommendations for screening, surveillance interval, or cessation of surveillance were provided at the bottom of each respective page. The answers provided by the digital calculator were validated by individually calculating all possible scenarios covered by the updated guidelines before recruitment.

SR for Screening and Surveillance

The SR was the official web publication of the latest guidelines for screening and surveillance for bowel cancer prevention in Australia by the NHMRC [1,2]. In addition to a written summary, it provides details regarding the development of and evidence for each recommendation. Also included are a series of colored risk stratification tables to guide users through screening, initial and follow-up surveillance, and stopping rules. For screening, 90 possible scenarios are defined according to the number of relatives with colorectal cancer as well as how closely they are related to the patient.

For initial surveillance colonoscopy, 37 separate scenarios are described across 3 tables according to the various combinations of “conventional adenomas” or “clinically significant serrated polyps” identified. A total of 140 scenarios are similarly characterized across an additional 9 tables to account for the possible combinations of “conventional adenomas” and “clinically significant serrated polyps” between 2 consecutive procedures. Determining the correct surveillance interval can thus require users to successfully navigate 2 consecutive tables. Lastly, the rules for cessation of surveillance colonoscopy are detailed in a text table that uses a modified Charlson score. Scores are allocated according to age and the presence of comorbidities. Depending on the combination of age and severity of comorbid conditions, the benefit of continuing surveillance for patients may be deemed too low to justify the potential risks of colonoscopy.

Recruitment

Advertising flyers were created and distributed to the 3 local Primary Health Networks, social media (Facebook: Adelaide GP Referral Network, Medical Mums, and Mums To Be), general practitioner education providers (GPEx and GP Synergy), and directly to practice managers located within metropolitan Adelaide. Additional flyers for specialists were distributed to members of the Departments of Gastroenterology and Hepatology and Colorectal Surgery Departments at 4 major teaching hospitals in Adelaide, as well as to private specialist practices. Snowball sampling was used to aid in the recruitment of additional participants. Continuing professional development points and a certificate of completion were awarded as an incentive to improve recruitment.

Data Collection

The questionnaire was programmed using REDCap (Research Electronic Data Capture; Vanderbilt University) tools hosted at the University of Technology, Sydney, and accessed through the Australian Access Federation [19,20]. We collected data including each participant’s age, professional background (general practice, medical specialist or trainee, and surgical specialist or trainee), active affiliation with a university, and experience with tools supporting screening and surveillance guidelines. We scored the answers for each clinical vignette in the order in which they were completed and collected each participant’s responses to the SUS questionnaire regarding their experience with the DA on a digital spreadsheet for analysis according to a previously described methodology [15].

Randomization

Two randomly permuted schedules (primary care and specialist groups) were created for a crossover study with 2 interventions (DA vs SR) with equal allocation over 8 strata (combinations 1-8; Table 1). A total of 14 allocations were generated per stratum with a total of 112 allocations. Participants were randomized to use either the DA or SR as the first aid in a 1:1 ratio. The 2 allocation schedules were programmed into the REDCap software using branching logic tools. The randomization schema was generated using Microsoft Excel (version 16.66.1; Microsoft Corp).

Table 1. Clinical vignette combinations used for randomization.

Combination	Section 1	Section 2
1	Alpha, gamma, and delta	Beta, theta, and omega
2	Alpha, gamma, and omega	Beta, theta, and delta
3	Alpha, theta, and delta	Beta, gamma, and omega
4	Alpha, theta, and omega	Beta, gamma, and delta
5	Beta, gamma, and delta	Alpha, theta, and omega
6	Beta, gamma, and omega	Alpha, theta, and delta
7	Beta, theta, and delta	Alpha, gamma, and omega
8	Beta, theta, and omega	Alpha, gamma, and delta

Statistics

Previously reported rates of adherence to Australian surveillance guidelines have ranged from 50.8% to 83% [4,10]. The impact of a nurse-led intervention improved the rate of guideline concordance by a factor of 1.17 relative to the non–nurse-led group [10]. On the basis of these results, we predicted a mean accuracy score of 60% with the SR and anticipated a 1.17 improvement in the rate of guideline concordance to 70% with the intervention (DA). Using an expected SD of 20%, an α of .05, and a statistical power of 0.8, the minimum necessary sample size required was calculated at 64 participants.

Descriptive statistics were used to characterize the data. A Kolmogorov-Smirnov test was applied to assess for normality of the data before the statistical analysis. A related-samples Wilcoxon signed rank test was used to compare the performances of participants with either the SR or the DA. An independent-samples Mann-Whitney *U* test was used to compare outcomes between specialists and nonspecialists. Spearman ρ was used to assess the relationship between usability and scores from the DA. χ^2 tests of independence were used to compare the allocation of participants between tools and clinical vignettes. The SPSS statistical software (version 22; IBM Corp) was used for all analyses.

Ethical Considerations

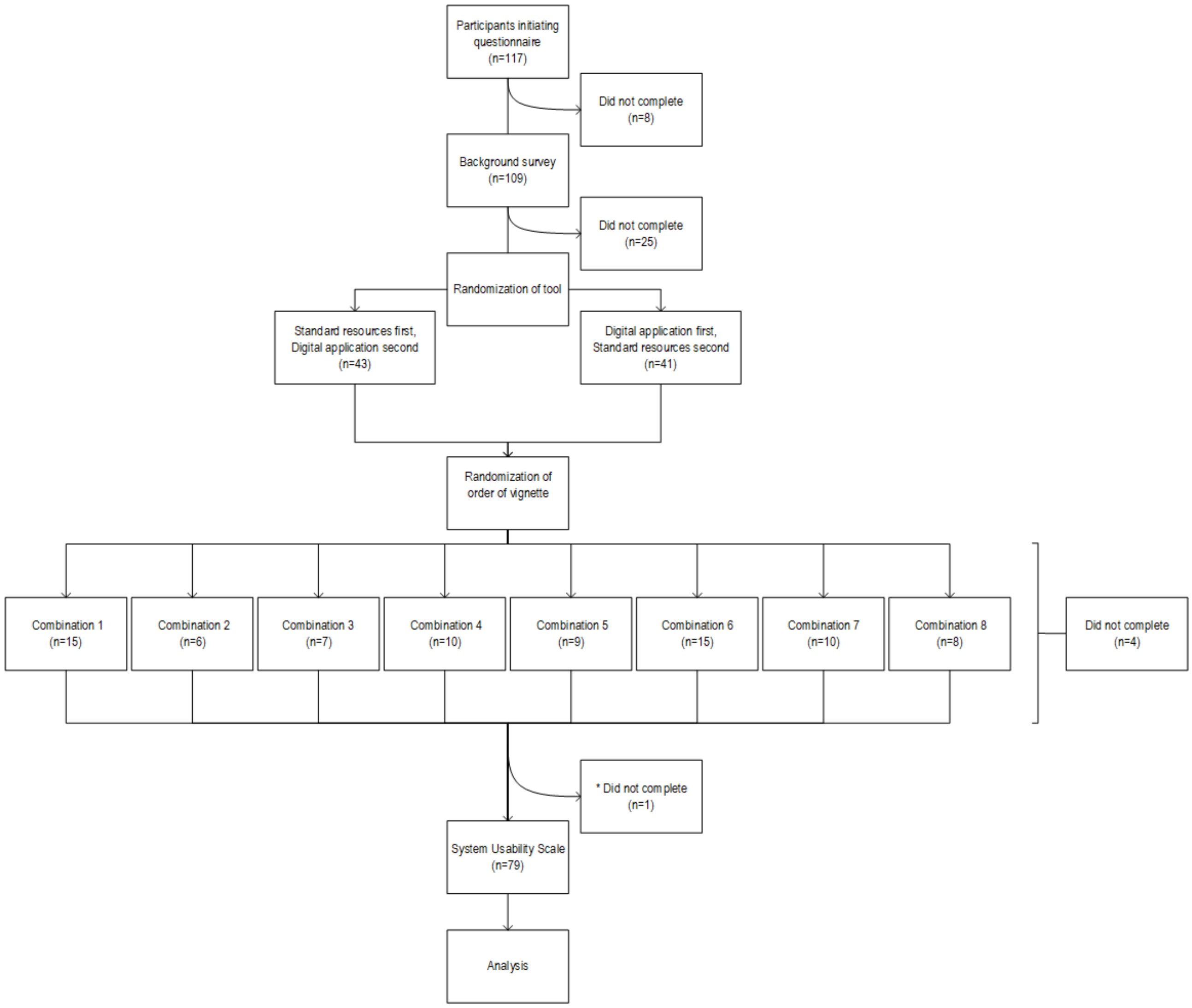
The study protocol was reviewed and approved by the Central Adelaide Local Health Network Human Research Ethics Committee (CALHN Research Office reference 13438). The background, procedures, and aims of the study were provided to prospective participants via a digital participant information sheet before the commencement of the survey. Participants were informed that their consent to participate would be implied via completion and submission of the online questionnaire. All data collected were deidentified. No participants received financial compensation.

Results

Participant Characteristics

In total, 117 participants initiated the questionnaire. The records of 37 participants were excluded from the primary analysis due to survey noncompletion. Of these, no components of the questionnaire were attempted in 8 cases, 25 participants completed the background survey but did not attempt the clinical vignette section, and 4 participants aborted the clinical vignette section before completion (Figure 1). These included 7 primary care doctors, 20 gastroenterologists, 1 surgeon, 1 nurse endoscopist, and 8 participants of unknown vocation. One additional participant aborted the study after completing the vignettes and was included in the primary analysis but not in the evaluation of the usability scores.

Figure 1. Study flowchart. *Included in the primary analysis but excluded from usability evaluation.



The remaining 80 participants, consisting of 43 primary care doctors and 37 specialist doctors (35 gastroenterologists and 2 surgeons), were included in the primary analysis. They had a median age of 38 (IQR 27-71) years. Fewer than half (35/80, 44%) held an affiliation with a university (27/37, 73% of specialists and 8/43, 19% of primary care doctors), and almost two-thirds (51/80, 64%) had previously used tools for screening and surveillance decisions in colorectal cancer (32/37, 87% of specialists and 19/43, 44% of primary care doctors; Table 2). The study flowchart shows how participants were randomized to 1 of 8 sequences of vignettes (Figure 1). Of the 80 included participants, 38 (48%) were assigned to use the DA as the first aid (Figure 2). Alpha, gamma, and delta were the first vignettes in their respective pairs in 48% (38/80), 56% (45/80), and 51% (41/80) of cases (Figure 2).

Figure 2. Allocation of tools and vignettes for the first set of clinical vignettes after randomization. Pearson χ2 tests of independence were used to assess the distribution order of tools (standard resource or digital application) and vignettes (alpha or beta, gamma or theta, and delta or omega) after excluding participants who did not complete the study. The analysis confirmed that the differences in the final allocation of participants at each stage after exclusions were not significant.

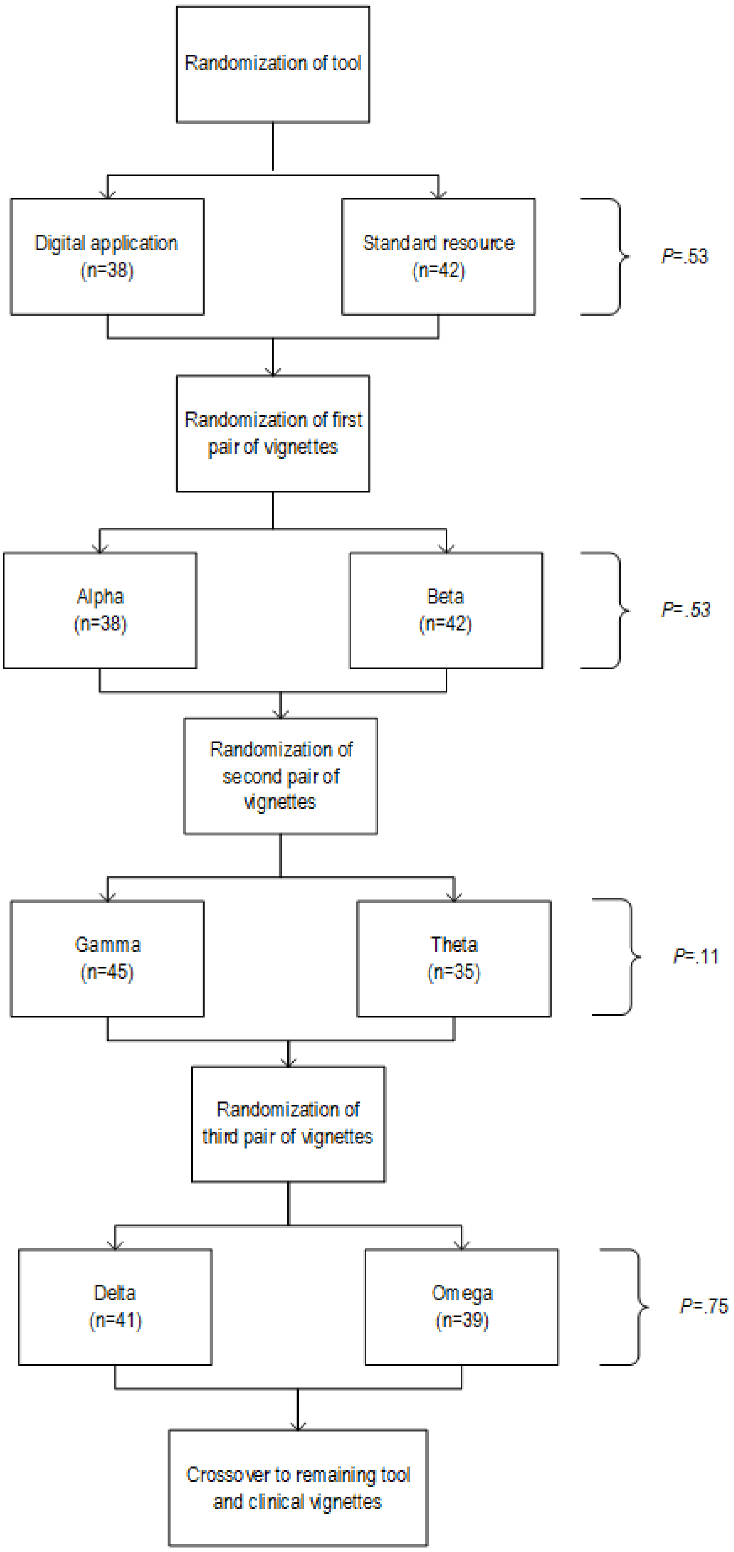


Table 2. Tools to aid decisions in colorectal cancer screening and surveillance (N=80).

Tool	Specialist (n=37), n (%)	Primary care (n=43), n (%)
Wiki.cancer Guideline (NHMRC[a])	20 (54)	11 (26)
Polyp.guide	8 (22)	3 (7)
Digital calculator	6 (16)	1 (2)
Media in endoscopy suite	19 (51)	—[b]
Polyp nurse support	3 (8)	—
Funding codes (Medicare)	2 (5)	—
The Royal Australian College of General Practitioners' Redbook	—	6 (14)
Other	1 (3)	2 (5%)

[a] NHMRC: National Health and Medical Research Council.

[b] Not available.

A Kolmogorov-Smirnov test of normality indicated that the scores of participants using the SR were normally distributed: D(80)=0.075; *P*=.20, while those of the DA were not: D(80)=0.152; *P*<.001. With the SR, the median (IQR) number of guideline concordant answers was 10 (7.75-13) out of 18. The use of the DA improved the number of correct recommendations to a median (IQR) of 14 (12-17) out of 18 (relative risk 1.4, *P*<.001; Figures 3 and 4). Lower performance with the DA compared with SR (n=17) was not associated with previous experience with screening and surveillance decision tools (*P*=.51), affiliation with a university (*P*=.39), or age (*P*=.06).

Figure 3. Comparison of spread of clinical vignette scores with either the standard resource (SR) or the digital application (DA). The participant scores when using the SR showed a normal distribution. A rightward shift in the distribution of the scores was observed with the use of the DA.

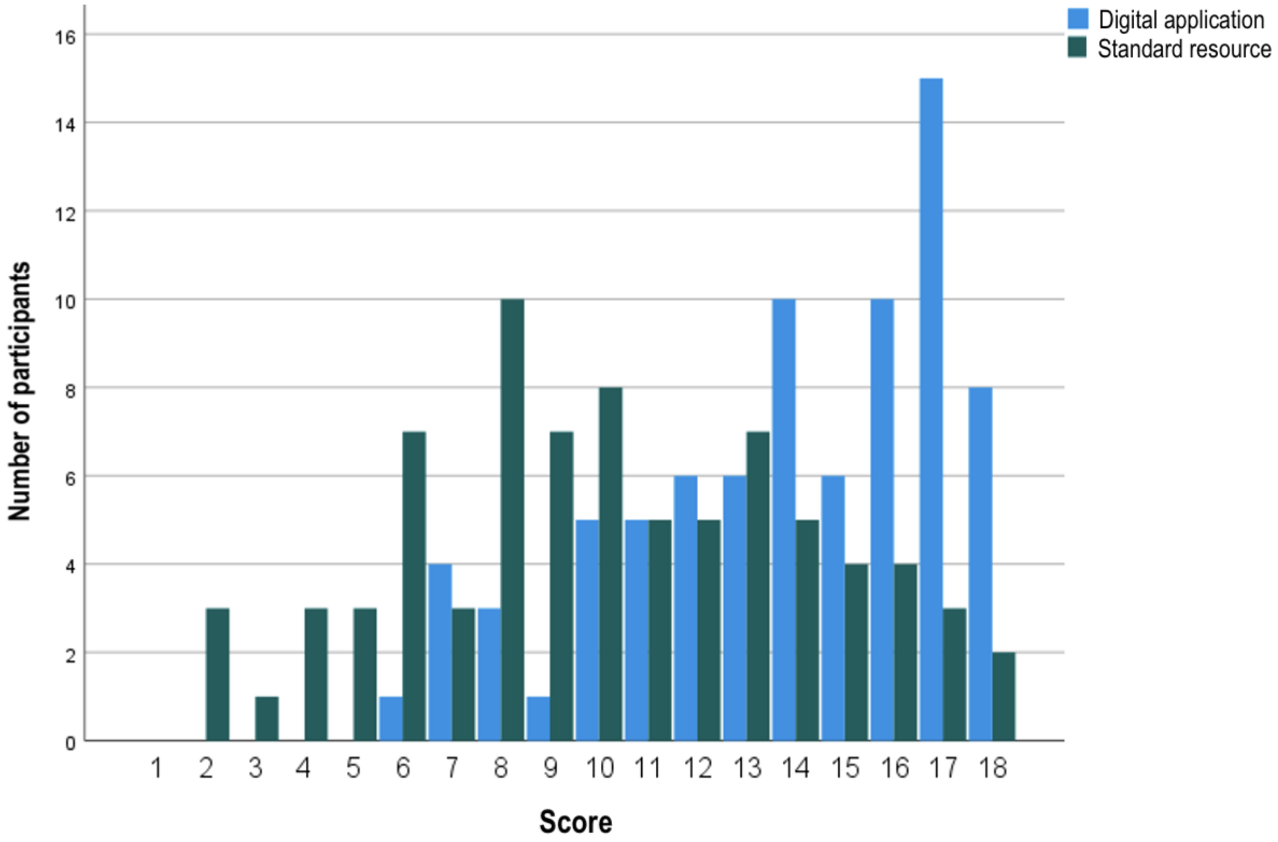
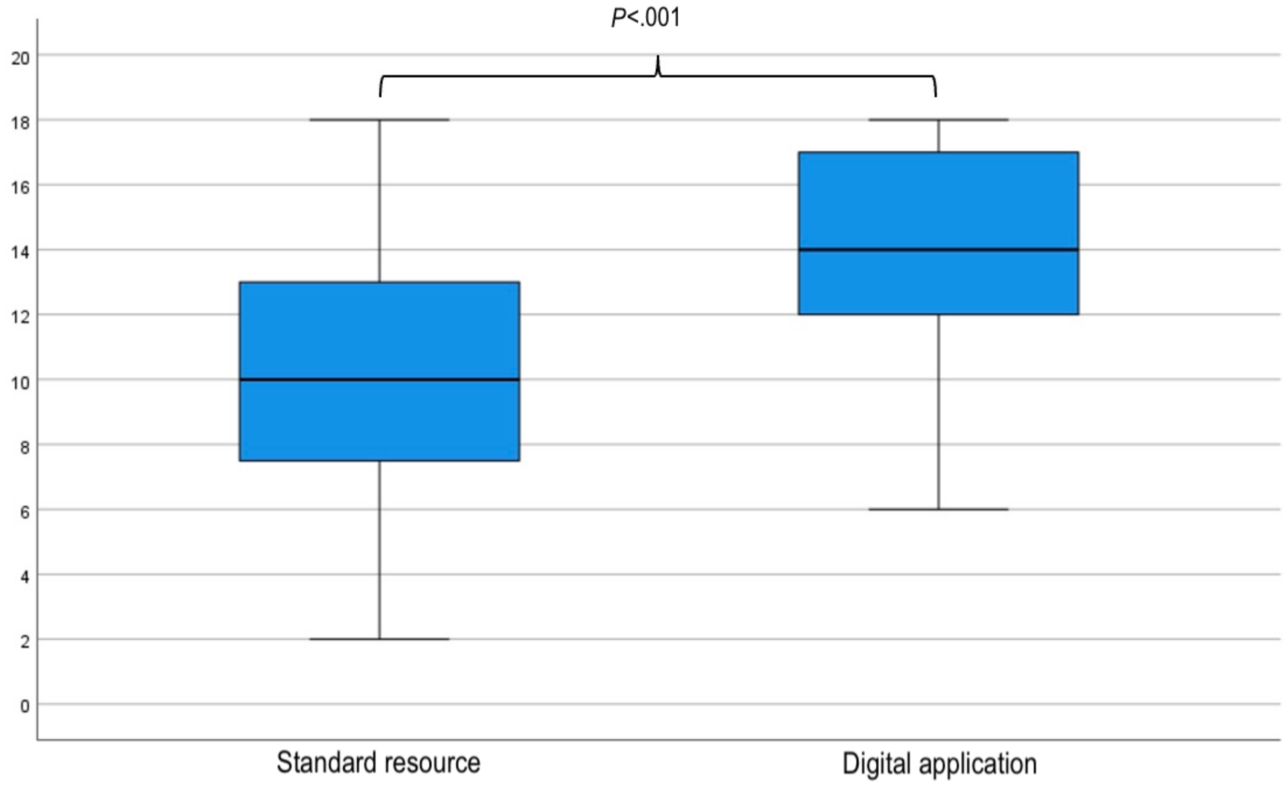


Figure 4. Box and whisker plot of clinical vignette scores with either the standard resource or the digital application.



The median (IQR) SUS score for the DA was 90 (72.5-95), which equated to a top 4 percentile ranking among tested applications (Table 3). A moderate correlation between usability grade and DA results was observed using Spearman ρ correlation coefficient (r_s=0.4; *P*<.001; n=79).

Table 3. System Usability Scale (SUS) grades and percentiles for participants using the digital application (n=79).

Grade	SUS	Participants, n (%)	Percentile
A	>78.8	51 (65)	85-100
B	72.6-78.8	7 (9)	65-84
C	62.7-72.5	11 (14)	35-64
D	51.7-62.6	6 (8)	15-34
F	0-51.7	4 (5)	0-15

Sensitivity Analysis

After excluding those who did not complete the study, differences in the randomization of participants regarding order of use of the tools (SR vs DA) and clinical vignettes (alpha vs beta, gamma vs theta, and delta vs gamma) were not significant (Figure 2). Additionally, there was no difference (*P*=.55) between the median number of guideline concordant recommendations according to whether the clinical vignettes were posed to participants: first (12, IQR 8.75-15) or second (13, IQR 9-16; Figure 5). Similarly, no difference was observed between the performance of specialists and primary care doctors, either with the SR (10 vs 9; *P*=.47) or with the DA (13 vs 15, *P*=.24; Figures 6 and 7).

Figure 5. Box and whisker plot of clinical vignette scores according to the order they were answered (first or second). A related-samples Wilcoxon signed rank test was used to compare the results achieved in the first and second set of questions indicating no significant difference (*P*=.55). Thus, increasing familiarity with the format of the questionnaire did not improve the scores achieved by participants.

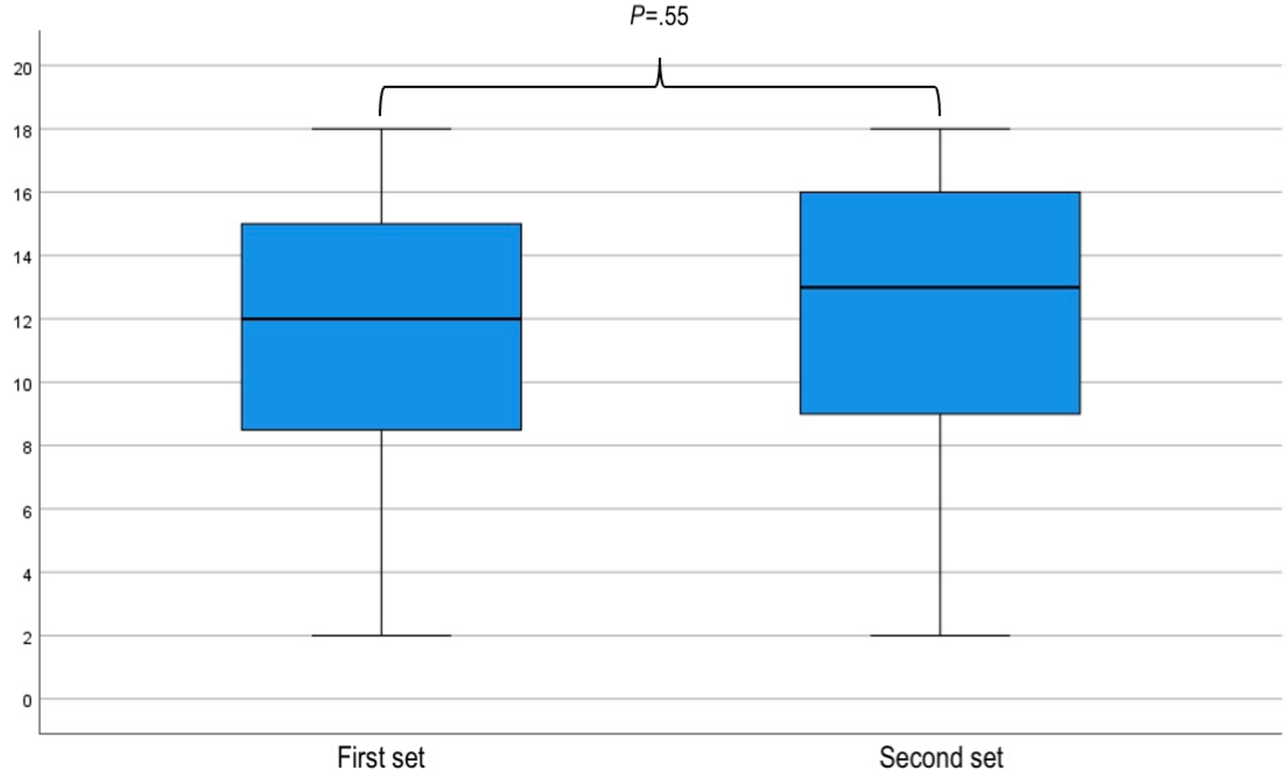


Figure 6. Box and whisker plot of clinical vignette scores according to the vocational training of the participants (specialist or primary care) using the standard resource (SR). An independent-samples Mann-Whitney U test was used to compare the results of specialists with primary care doctors using the SR. There was no significant difference (*P*=.47) in the performance of participants based on their previous training in either specialist or primary care.

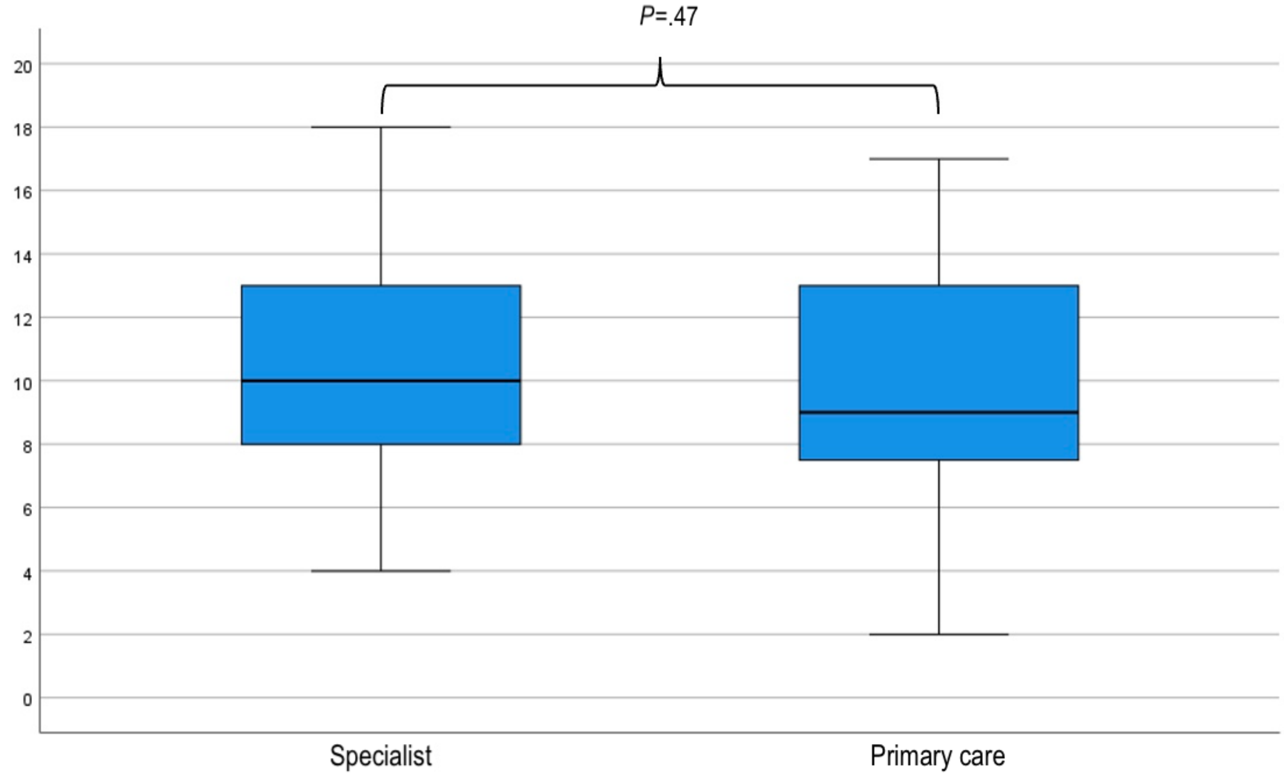
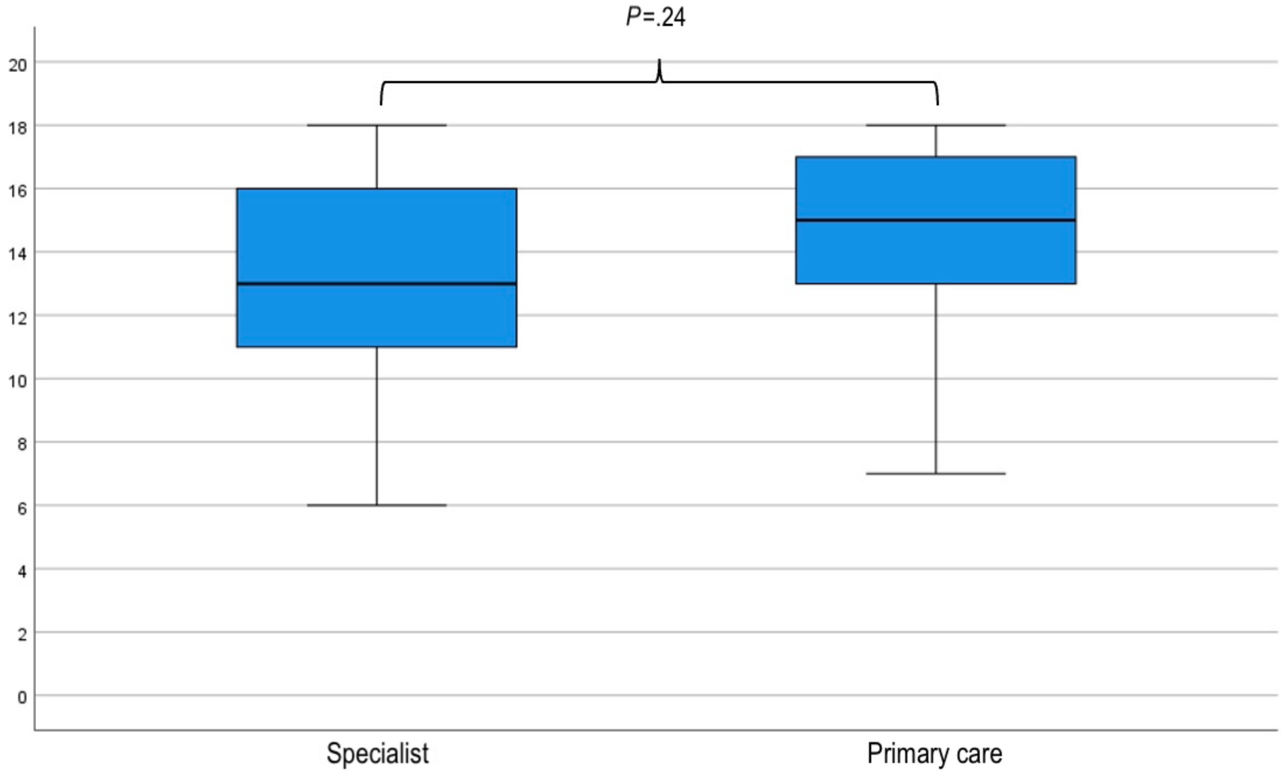


Figure 7. Box and whisker plot of clinical vignette scores according to the vocational training of the participants (specialist or primary care) using the digital application (DA). An independent-samples Mann-Whitney U test was used to compare the results of specialists with primary care doctors using the DA. There was no significant difference (*P*=.24) in the performance of participants based on their previous training in either specialist or primary care.



Discussion

Principal Findings

The findings of this study showed that the adherence of clinicians with Australia's current screening and surveillance guidelines in their current form is limited. This was significantly improved when clinicians used a DA to assist their navigation of these complex guidelines. These findings were independent of the clinicians' level of specialization, age, university affiliation, or experience with the use of other decision support tools. However, greater adherence was associated with better DA usability ratings, highlighting the importance of this attribute as a potential target to further bolster clinician guideline adherence.

Australia's screening and surveillance guidelines are among the most complex worldwide. With the increasing trend toward personalized health care and our growing knowledge of colorectal cancer risk factors, guidelines are likely to continue increasing in complexity. For clinicians, navigating these guidelines in busy practices can be challenging. Even under the controlled conditions of our testing environment, participants could only provide appropriate recommendations in slightly over half of the questions when evaluating the scenarios only with the SR. These findings are consistent with another recent report that assessed the concordance of surveillance recommendations with current guidelines [4]. Because the adherence to previous relatively more straightforward guidelines was already known to be suboptimal, it could be anticipated that rates of adherence may be even lower as their complexity increases. This could undermine their potential benefits in the care of patients and the allocation of limited colonoscopy resources in Australia.

DAs can play an important role in supporting the implementation of Australia's complex bowel cancer prevention guidelines. Not only do they improve the ability of clinicians to provide guideline-concordant recommendations, as demonstrated by our study, but they can be developed at a relatively low cost and are scalable to a national level. Furthermore, they can be updated with future revisions of the guidelines, ensuring that clinicians can continue to make decisions that are in keeping with the latest evidence.

Despite their clear advantages, the role of DAs in supporting complex guideline adoption has received little attention in the literature. To date, only 2 studies have evaluated DAs in assisting medical personnel with the application of bowel cancer screening and surveillance guidelines. However, these were assessed in relation to US guidelines and are limited by their small size and lack of a randomized controlled methodology. To our knowledge, our study is the first to evaluate a DA using a rigorous randomized controlled crossover design.

Participants provided discordant recommendations in 22% of clinical decisions despite assistance from the DA. However, as the DA used in this study had been validated across all the possible scenarios provided by the guidelines, we considered other factors that may have contributed to this. Our results showed that poor performance with the DA relative to the SR was not associated with participant age, academic experience, or prior experience with similar tools. One area that may have contributed was DA usability. Although the DA scored very well in the SUS, ranking at or above the 96th percentile of tested systems, there was still a relatively large spread of scores (median 90, IQR 72.5-95) and a moderate correlation between SUS scores and participant performance. This suggests that improvements directed at improving usability for those who scored the DA less well could bolster the adherence rate of clinicians with guidelines; however, the magnitude of overall improvement may be small. Therefore, additional research to gather the opinions of participants who found the interface difficult to use and quantify the degree of progress achieved by addressing these is required.

Human error is another potential factor contributing to the rate of discordant answers. Despite simplifying the process of determining guideline-concordant recommendations, the DA still requires individuals to extract relevant and appropriate data from sometimes complex patient histories. Although human error remains an inevitable component of any interface requiring human input, natural language processing software, which has been used in prior US-based studies, could provide a valuable adjunct to a mobile app [5,6]. This would retain the scalability and portability of the DA but would require additional research, development, and testing before it could be implemented. Such a tool could provide a better balance of the advantages of the tools tested thus far.

Strengths

Our study design accounted for the possibility that participants could improve their performance in the clinical vignettes simply due to increasing experience with the questionnaire, by randomizing the order of use of the 2 aids (SR or DA). Furthermore, although the clinical vignettes were designed in pairs that were balanced for difficulty, the order in which each pair was presented to the participant was randomized to limit the risk of bias. The vignettes also focused on clinical scenarios with updated and distinct recommendations within the guidelines, requiring participants to determine the correct answer solely through navigation of the SR or DA.

Another strength of our study was the ability to cater for participants with varying levels of familiarity with guidelines. Our participants included specialists, who are accustomed to using colorectal cancer screening and surveillance guidelines in their everyday practice, and nonspecialists, whose breadth of clinical practice typically limits their experience with specialty guidelines. As these differences may have impacted participant vignette questionnaire scores, particularly those encountered without the DA, we tailored the introductory briefings to provide nonspecialists with additional information in the structured seminars. When the 2 groups were compared, no significant differences between them were observed, either with the SR or with the DA. Although this indicated that the potential effect of experience had been controlled for during our study, it is not possible to say whether this resulted from our differential approach to participant briefing, as this was not an outcome that was measured during our study.

Additionally, we were able to control successfully for potential confounders by randomizing both the order of the questions and the tools used by participants during the vignettes. This was used to address the possibility that participant scores may have improved over time and that the clinical vignettes may not have been completely balanced in their difficulty. Our sensitivity analysis showed that the distribution of questions and tools remained balanced, even after exclusion of participants, and that increasing participant experience with the questionnaire did not result in higher scores.

Limitations

While the vignettes intentionally challenged participants to navigate the breadth of the decision tables, only a limited number of scenarios are typically encountered in clinical practice. More than 95% of patients will be classified in the lowest risk category for screening based on family history, while most colonoscopies in Australia will detect few or no significant lesions [1]. Thus, participant performance in this study may not be indicative of real-world application. However, adherence rates to current surveillance guidelines, which have been reported at 50.8%, closely resemble the scores obtained using the SR in our study [4]. Clarification of the real-world efficacy of the DA will require further studies, for example, through prospective randomized nested case-controlled studies involving both primary and specialist group practices.

Our study was also prone to sampling bias. Despite efforts to circulate advertising material for the study via social media, education providers, and hospitals, only 117 participants visited the questionnaire website, and the recruitment rate was slow. The diversity of our sample group was also affected, with surgeons outnumbered by gastroenterologists in the specialist group (2-35). Due to our specific subject matter, it is possible that our participants held favorable views toward technology that may not be representative of the greater community of medical professionals. Although these challenges are not uncommon among studies recruiting clinical personnel as participants, the generalizability of our findings may be limited [21].

Finally, as both resources were readily available for public access at the time of the study, it was not possible to restrict participants to using the tools in the prerandomized order specified. Our intention-to-treat analysis may therefore have underestimated the potential differences in the scores obtained by users in the trial.

Conclusions

Australia's bowel cancer screening and surveillance guidelines have become increasingly complex, posing a challenge for clinicians trying to make appropriate recommendations. Currently, the available options to assist them are costly and need more scalability. DAs represent an inexpensive and scalable solution that enhances guideline concordance among clinicians. Further development and assessment of these tools could improve screening and surveillance outcomes and optimize resource use in an era of increasingly complex and personalized care.

Acknowledgments

We would like to acknowledge the participants who kindly donated their time for this study, without which it would not have been possible.

Data Availability

The data sets generated during and/or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

TO was responsible for study conceptualization, data curation, formal analysis, investigation, methodology, project administration, programming of the online questionnaire and digital application, and writing and review of the manuscript. OS was involved in the formal analysis and review and editing of the manuscript. PB and GI were involved in the conceptualization of the study. CR and ET were involved in the conceptualization, supervision, and review and editing of the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
CONSORT checklist.
[PDF File (Adobe PDF File), 70 KB - cancer_v10i1e46625_app1.pdf]

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Abbreviations

DA: digital application
NHMRC: National Health and Medical Research Council
REDCap: Research Electronic Data Capture
SR: standard resource
SUS: System Usability Scale

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Review

Implementation of Health IT for Cancer Screening in US Primary Care: Scoping Review

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Abstract

Background: A substantial percentage of the US population is not up to date on guideline-recommended cancer screenings. Identifying interventions that effectively improve screening rates would enhance the delivery of such screening. Interventions involving health IT (HIT) show promise, but much remains unknown about how HIT is optimized to support cancer screening in primary care.

Objective: This scoping review aims to identify (1) HIT-based interventions that effectively support guideline concordance in breast, cervical, and colorectal cancer screening provision and follow-up in the primary care setting and (2) barriers or facilitators to the implementation of effective HIT in this setting.

Methods: Following scoping review guidelines, we searched MEDLINE, CINAHL Plus, Web of Science, and IEEE Xplore databases for US-based studies from 2015 to 2021 that featured HIT targeting breast, colorectal, and cervical cancer screening in primary care. Studies were dual screened using a review criteria checklist. Data extraction was guided by the following implementation science frameworks: the Reach, Effectiveness, Adoption, Implementation, and Maintenance framework; the Expert Recommendations for Implementing Change taxonomy; and implementation strategy reporting domains. It was also guided by the Integrated Technology Implementation Model that incorporates theories of both implementation science and technology adoption. Reporting was guided by PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews).

Results: A total of 101 studies met the inclusion criteria. Most studies (85/101, 84.2%) involved electronic health record–based HIT interventions. The most common HIT function was clinical decision support, primarily used for panel management or at the point of care. Most studies related to HIT targeting colorectal cancer screening (83/101, 82.2%), followed by studies related to breast cancer screening (28/101, 27.7%), and cervical cancer screening (19/101, 18.8%). Improvements in cancer screening were associated with HIT-based interventions in most studies (36/54, 67% of colorectal cancer–relevant studies; 9/14, 64% of breast cancer–relevant studies; and 7/10, 70% of cervical cancer–relevant studies). Most studies (79/101, 78.2%) reported on the reach of certain interventions, while 17.8% (18/101) of the included studies reported on the adoption or maintenance. Reported barriers and facilitators to HIT adoption primarily related to inner context factors of primary care settings (eg, staffing and organizational policies that support or hinder HIT adoption). Implementation strategies for HIT adoption were reported in 23.8% (24/101) of the included studies.

Conclusions: There are substantial evidence gaps regarding the effectiveness of HIT-based interventions, especially those targeting guideline-concordant breast and colorectal cancer screening in primary care. Even less is known about how to enhance the adoption of technologies that have been proven effective in supporting breast, colorectal, or cervical cancer screening. Research is needed to ensure that the potential benefits of effective HIT-based interventions equitably reach diverse primary care populations.

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KEYWORDS

cancer prevention; health information technology; implementation; implementation strategies; scoping review

Introduction

Background

For common cancer types such as cervical, colorectal, and breast cancer, routine screening provided in primary care settings can save lives [1]. Although evidence-based national guidelines exist for the provision of such screenings [1-4], patient receipt of guideline-concordant cancer screening is suboptimal nationally and varies substantially across clinical settings [5,6]. This is driven by multiple factors, including provider-level barriers such as the challenge of staying current on changing cancer screening guidelines [6] and the cognitive overload that providers can face when managing the needs of patients with complex conditions [7-11]. Patient-level barriers include lack of knowledge of screening recommendations [6], loss to follow-up [12], fear about screening procedures or outcomes, and financial and logistical challenges [13].

Understanding which interventions effectively address these challenges—and the barriers and facilitators to implementing such interventions—is needed to enhance the delivery of guideline-concordant cancer screening in primary care. The Community Preventive Services Task Force summary of evidence-based interventions for addressing barriers to guideline-concordant cancer screening [14] identifies health IT (HIT)–based interventions as showing particular promise [15-17]. Prior systematic reviews found that HIT-based interventions such as patient reminders and provider feedback tools can be effective in supporting cancer prevention care [15,17,18]. Such interventions can enhance provider-patient communication about cancer screening [19-22]. These interventions can also help care teams identify patients due for screening with automated reminders embedded in the electronic health record (EHR) that can appear either at the point of care [23] and during panel or population management [24].

Yet HIT-based interventions targeting numerous health outcomes are underused in primary care settings [23,25]. One recent systematic review involving 55 studies showed that clinical decision support tools were adopted in <35% of eligible encounters [26]. The adoption of such interventions is impeded by multilevel barriers, such as the challenges inherent to integrating new tools into clinical workflows [27], and lack of training in how to use such tools [28,29]. There is a need to understand best practices for enhancing the adoption of effective HIT-based interventions targeting cancer prevention, including how barriers to the adoption of such interventions can best be addressed in primary care [17,18,30,31].

Objectives

In 2020, the National Cancer Institute’s Consortium for Cancer Implementation Science (CCIS) “Technology in Implementation Science Action Group” identified a need for the scoping review presented here. This review aims to describe the specific knowledge gaps in this evidence base, that is, what is known and unknown about the implementation of effective HIT for cancer screening in primary care. Specifically, it aims to identify (1) HIT-based interventions that effectively support guideline concordance in breast, cervical, and colorectal cancer screening provision and follow-up in the primary care setting and (2) barriers or facilitators to the implementation of effective HIT in this setting. To refine the scope of this review, we focused on common cancer screenings that are in the purview of primary care: breast, colorectal, and cervical cancer screening. We note that earlier systematic reviews [15,17,18] assessed the effectiveness of HIT-based interventions at improving cancer screening rates in primary care, but the most recent included data up to June 2014 [15]. This review first summarizes related evidence accrued since 2014 and then assesses current knowledge on the adoption of such interventions. To our knowledge, this is the first scoping review to assess the implementation of HIT in cancer screening.

Methods

Overview

This scoping review was conducted by a multidisciplinary team of researchers from the CCIS with expertise in implementation science, health informatics, health services research, and cancer control. We followed the 6-stage scoping review methodology described by Arksey and O'Malley [32], with consideration of later modifications to this approach made by Levac et al [33]. This review was reported in accordance with the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) [34].

Ethical Considerations

Ethics approval from the George Mason University Institutional Review Board was not required for this review.

Research Questions

This scoping review was designed to answer two overarching questions: (1) What is known about how HIT-based interventions are used to enhance guideline concordance of cancer screening in primary care settings? (2) What is known about the barriers or facilitators to the implementation and dissemination of these interventions?

Identifying Relevant Studies

With assistance from a health sciences librarian, the first author (COJ) conducted a 3-step search process to identify relevant US-based peer-reviewed and gray literature studies. First, the following bibliographic databases were systematically searched: MEDLINE, CINAHL Plus, Web of Science, and IEEE Xplore. These databases were searched using a combination of search strings that included relevant controlled vocabulary (eg, Medical Subject Heading) and keywords with Boolean operators. The search terms were selected based on a review of the existing literature and refined based on the input of the coauthors. To ensure that the search yielded relevant studies, variations of the search strategy were pilot-tested by 3 authors (COJ, RG, and RX) and refined before the final search was conducted. Our final search strategy for bibliographic databases is provided in Multimedia Appendix 1.

Second, this search was supplemented by a review of gray literature (eg, study protocols, unpublished empirical trials, dissertations, reports, and government publications) to consider studies that might not be indexed in bibliographic databases. This search primarily consisted of targeted website searching of cancer, HIT, public health organizations, and funding agencies recommended by the authors (COJ, RG, KHC). Our final gray literature search strategy is provided in Multimedia Appendix 2. Additional gray literature databases (CQ Press Library, Policy File Index, Find Policy, and Harvard Kennedy School Think Tank Search), recommended by the health sciences librarian, were explored but did not yield useful results. Finally, we identified relevant studies with a snowball search technique, whereby the reference lists of sources selected for full-text review were also examined for additional studies to include in the final review sample.

Study Selection

Eligibility Criteria

Studies on HIT and cancer screening before January 2015 are covered in prior publications [15,17,18]. Our search was designed to build on that work, so it was limited to studies published from 2015 to 2021 (the time at which we started the review process). Studies were considered eligible for inclusion if they (1) were US-based, reported in the English language, and published between January 2015 and June 2021; (2) reported on activities conducted in the primary care setting; (3) focused on evidence-based cancer screening; (4) involved the use of HIT to support this screening; (5) were related to specific workflow steps involved in conducting cancer screening in primary care (identifying patients due for screening at the point of care or in panel management, obtaining results of past screenings through data exchange, or providing appropriate follow-up care); and (6) targeted screening for breast, colorectal, or cervical cancer. A checklist of these criteria was created to guide the selection of relevant studies and then pilot-tested in a subsample of articles (n=60) and refined (COJ, RG, and RX) to ensure that its criteria could be applied consistently. The checklist was supported by a glossary of key terms to ensure shared understanding across reviewers of potential studies. The final checklist and glossary are provided in Multimedia Appendices 3 and 4, respectively. All study designs were eligible for inclusion as long as the study included some description of how HIT was used to support breast, colorectal, and cervical cancer screening in primary care settings. If a study was an evidence review (eg, systematic review or narrative review), only studies included in the final sample of the review and published between January 2015 and June 2021 were assessed for potential inclusion. If multiple publications described a single intervention but described different approaches for using HIT, all applicable studies were assessed for inclusion.

Dual Screening Review

Results of the search strategies described above were imported and managed in Zotero [35]. The first author (COJ) removed duplicate studies. Then, reviewers in eight 2-person teams were assigned studies to dual screen [36] (team 1: COJ and RG; team 2: AH and HA; team 3: LD and RX; team 4: KR and JMF; team 5: KHC and EB; team 6: KAR and JC; team 7: MMK and ATR; and team 8: MIF and DJA). Dual screening was performed in 2 steps. First, study titles and abstracts were dual screened by each review team using the inclusion and exclusion checklist to assess eligibility. Second, studies included for full-text dual screening were assessed by the same review teams for final inclusion in the scoping review. Any discrepancies that emerged within a review team were reconciled by consensus. The first and senior authors (COJ and RG) provided final decisions for any studies that could not be reconciled by a review team.

Data Charting

A data charting form was developed using Qualtrics, a web-based survey software, to systematically extract information from studies selected for inclusion in the review analyses. The form was initially pilot-tested on 2 articles and refined (COJ, RG, and HA). Next, the review teams extracted information from their assigned studies. Extracted data elements included study citation, publication year, publication type, study design, study setting, sample composition by race or ethnicity, and cancer screening focus (breast, colorectal, and cervical cancer). Extracted characteristics of the relevant HIT tools involved in a given study included type, users, functions, purpose (intervention or implementation strategy supporting an intervention), and supported cancer screening activities. Data elements were extracted in multiple choice or free-text form, depending on the type of data. Multiple implementation frameworks [37-40] were used to guide data extraction. A check of at least 50% (49/101 studies) of extracted studies suggested that data charting quality was high and the agreement rate between the initial reviewers and the reviewers that conducted the quality check was >90%.

Multiple implementation frameworks [37-40] were used to guide data extraction. Specifically, the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework [37] guided the extraction of dissemination and implementation outcomes: target end users (clinical staff and patients) of HIT (Reach), HIT impact on cancer screening in primary care (Effectiveness), the rate of HIT adoption (Adoption), the extent to which a given HIT-based intervention was implemented (Implementation), and the extent to which sustainability of HIT adoption was measured (Maintenance). Assessment of the evidence on barriers and facilitators of HIT adoption was guided by the Integrated Technology Implementation Model (ITIM), which includes 12 inner and outer context concepts known to be central to the implementation and adoption of technology in health care settings, and is based on the Consolidated Framework for Implementation Research, adapted to HIT-based interventions [38]. Although technology frameworks have been used to investigate the usability and acceptance of HIT-based interventions [41-43], to our knowledge, the ITIM is the only model that incorporates theories of both implementation science and technology adoption. The Expert Recommendations for Implementing Change (ERIC) compilation [39] guided the categorization of discrete implementation strategies identified in the studies. The implementation strategies reporting the framework by Proctor et al [40] guided the extraction and analysis of implementation strategies used to support the HIT adoption.

Collating, Summarizing, and Reporting Results

Descriptive data were compiled and interpreted using Stata/MP (version 15.1; StataCorp LLC) to quantify the frequencies of extracted data in discrete fields. Free text data charted in Qualtrics were exported to Excel (Microsoft Corp) for qualitative content analysis [44,45]. Authors (COJ, JC, RX, and RG) reviewed and categorized free text for HIT characteristics, RE-AIM domains, implementation barriers, facilitators, and core elements of implementation strategies (eg, actor and target of action). Most analyses used an iterative process, which involved initial coding and identification of themes (ie, categories) by 2 reviewers, resolving discrepancies and refining categories through team discussion, and recoding the text using finalized categories. Multimedia Appendix 5 provides details about these procedures.

Consultation

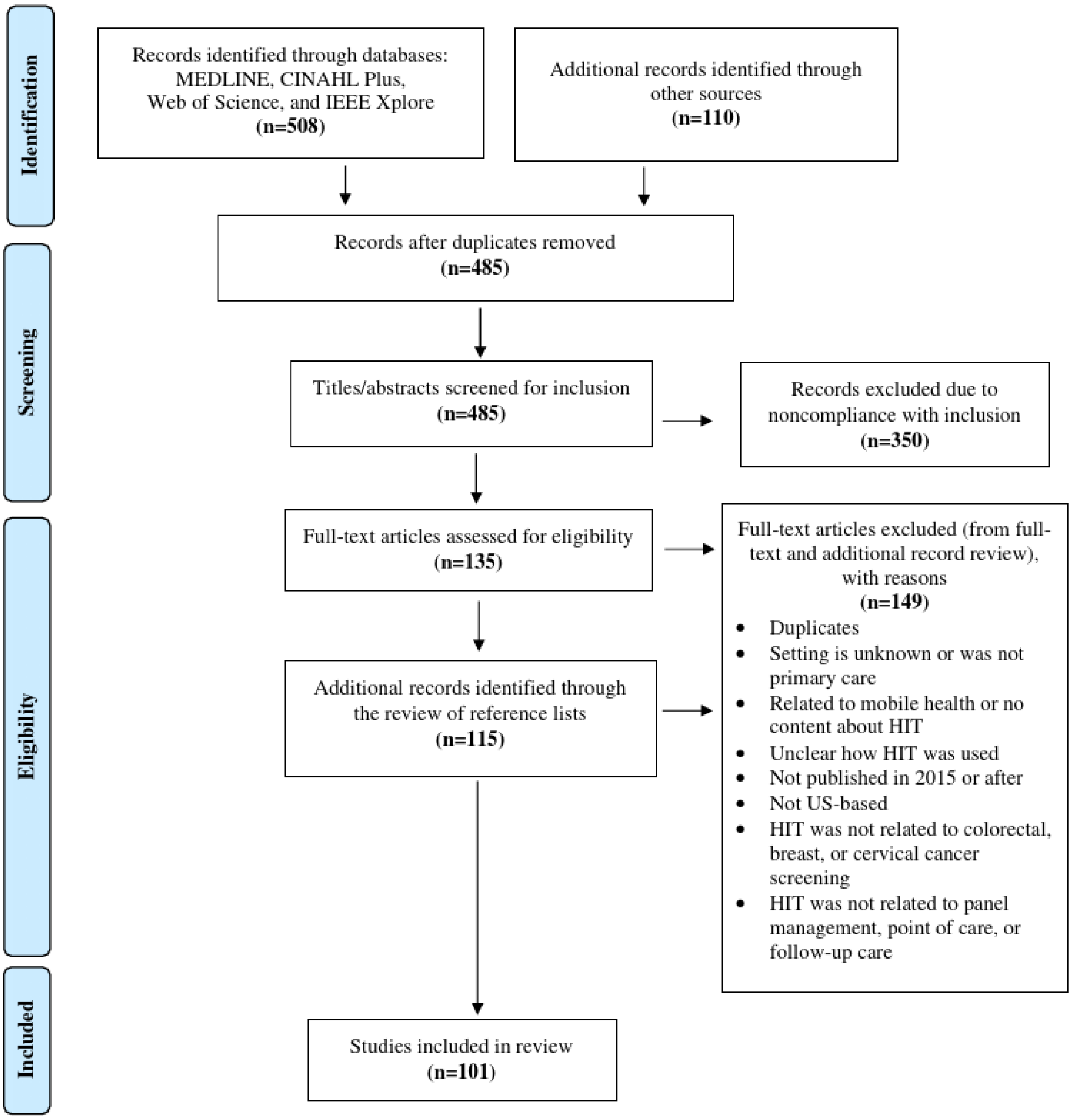
Authors (RG, JC, RX, HA, and AH) were consulted at each stage of the scoping review to provide input on the search, data abstraction, and interpretation of the results. We also consulted with implementation science experts about the conceptual frameworks selected for this study.

Results

Literature Search

The search yielded an initial total of 618 studies (Figure 1). After removing duplicates, 485 titles and abstracts were assessed for inclusion. Among these, 350 studies were excluded as not meeting the inclusion criteria. Full-text review was conducted on 135 records that met the inclusion criteria. A snowball search yielded an additional 115 studies that were assessed for eligibility. A final total of 101 studies met the inclusion criteria. Multimedia Appendix 6 provides a complete list of these studies.

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram. HIT: health IT.



Characteristics of the Included Studies

Included studies were published between January 2015 and June 2021 (Table 1). Most studies were peer-reviewed (92/101, 91.1%). Study design was mostly nonexperimental (descriptive: 18/101, 17.8% or observational: 15/101, 14.9%) in comparison to experimental (randomized controlled trials: 29/101, 28.7%), quasi-experimental (pre-post design: 21/101, 20.8%; nonrandomized controlled trials: 5/101, 5%; or other quasi-experimental studies: 3/101, 3%), and other studies (10/101, 9.9%). Most studies covered HIT targeting colorectal cancer screening (83/101, 82.2%), followed by breast cancer screening (28/101, 27.7%) and cervical cancer screening (19/101, 18.8%); these sum up >101 as some addressed more >1 type of cancer screening.

Table 1. Characteristics of the included studies (N=101).

Characteristics	Colorectal cancer (n=83), n (%)[a]	Breast cancer (n=28), n (%)	Cervical cancer (n=19), n (%)	Total, (N=101), n (%)
Publication year[b]				
2015	13 (15.7)	4 (14.3)	1 (5.3)	15 (14.9)
2016	15 (18.1)	6 (21.4)	3 (15.8)	18 (17.8)
2017	15 (18.1)	5 (17.9)	4 (21.1)	21 (20.8)
2018	16 (19.3)	2 (7.1)	3 (15.8)	18 (17.8)
2019	10 (12)	5 (17.9)	4 (21.1)	13 (12.9)
2020	9 (10.8)	5 (17.9)	3 (15.8)	11 (10.9)
2021	5 (6)	1 (3.6)	1 (5.3)	5 (5)
Publication type				
Peer-reviewed article	78 (94)	26 (92.9)	16 (84.2)	92 (91.1)
Report	1 (1.2)	2 (7.1)	2 (10.5)	4 (4)
Study protocol	3 (3.6)	—[c]	—	3 (3)
Other	1 (1.2)	—	1 (5.3)	2 (2)
Study design				
Nonexperimental				
Descriptive	15 (18.1)	5 (17.9)	4 (21.1)	18 (17.8)
Observational	11 (13.3)	9 (32.1)	4 (21.1)	15 (14.9)
Experimental				
RCT[d]	24 (28.9)	7 (25)	5 (26.3)	29 (28.7)
Quasi-experimental				
Pre-post study design	17 (20.5)	5 (17.9)	2 (10.5)	21 (20.8)
Non-RCT	3 (3.6)	1 (3.6)	3 (15.8)	5 (5)
Other quasi-experimental	3 (3.6)	—	—	3 (3.0)
Other study designs	10 (12)	1 (3.6)	1 (5.3)	10 (9.9)

[a] Percentages were calculated based on column totals.

[b] Publication year represents studies published from January 2015 to June 2021.

[c] Not available.

[d] RCT: randomized controlled trial.

Characteristics of the primary care settings where the research in the included studies was conducted are shown in Table 2. Approximately half of the included studies (52/101, 51.5%) reported on practice location. Most studies involving colorectal (22/83, 27%) or breast (6/28, 21%) cancer screening were conducted in urban areas, and most studies on cervical cancer screening (5/19, 26%) were conducted in rural areas. Studies on colorectal cancer screening were primarily conducted in federally qualified health centers (20/83, 24%); most of those on breast and cervical cancer screening were conducted in academic-based clinics (9/28, 32% and 5/19, 26%, respectively). More than half (59/101, 58.4%) of the included studies (colorectal: 47/83, 57%; breast cancer: 17/28, 61%; and cervical: 8/19, 42%) reported information on racial or ethnic minoritized participants (patients from racial or ethnic minority groups). Of these 59 studies, 34 (58%) reported that ≤50% of study participants were members of racial or ethnic minority populations.

Table 2. Primary care practice characteristics of the included studies (N=101).

Characteristics	Colorectal cancer (n=83), n (%)[a]	Breast cancer (n=28), n (%)	Cervical cancer (n=19), n (%)	Total, (N=101), n (%)
Practice location				
Urban	22 (26.5)	6 (21.4)	2 (10.5)	26 (25.7)
Rural	11 (13.3)	5 (17.9)	5 (26.3)	15 (14.9)
Combination of urban and rural	11 (13.3)	2 (7.1)	3 (15.8)	11 (10.9)
Not reported	39 (47)	15 (53.6)	9 (47.4)	49 (48.5)
Practice type				
Academic-based clinic	17 (20.5)	9 (32.1)	5 (26.3)	22 (21.8)
Federally Qualified Health Centers	20 (24.1)	1 (3.6)	3 (15.8)	21 (20.8)
Freestanding or other	18 (21.7)	4 (14.3)	3 (15.8)	21 (20.8)
Hospital-based clinic	10 (12)	2 (7.1)	1 (5.3)	12 (11.9)
Not reported	18 (21.7)	12 (42.9)	7 (36.8)	25 (24.8)
Sample percentage of racial or ethnic minority groups				
≤50%	25 (30.1)	13 (46.4)	6 (31.6)	34 (33.7)
>50%	22 (26.5)	4 (14.3)	2 (10.5)	25 (24.8)
Not reported	36 (43.4)	11 (39.3)	11 (57.9)	42 (41.6)

[a] Percentages were calculated based on column totals.

Characteristics of the HIT Interventions

Our definitions of HIT tool types and functions and the types of cancer screening activities they supported are provided in Multimedia Appendix 4. Of the 101 included studies, 66 (65.3%) reported on interventions involving 1 HIT tool and 35 (34.7%) reported on interventions involving >1 HIT tool (Table 3). In these studies, the HIT tool was either the intervention of focus, one component of a multicomponent intervention that also included non-HIT elements, or was used as an implementation strategy to support the intervention of focus.

Most of the included studies (85/101, 84.2%) involved EHR-based HIT tools (Table 3). Web-based (18/101, 17.8%) and other types of HIT tools (19/101, 18.8%) were less common. The HIT *function* most commonly involved in included studies was clinical decision support (CDS) across all cancer screening types (Table 3). CDS tools for panel management were most common in studies involving colorectal cancer screening (50/83, 60%). CDS at the point of care was commonly used in studies on breast (16/28, 57%) and cervical cancer screening (12/19, 63%). Other commonly studied HIT functions included risk identification (colorectal: 13/83, 16% and cervical: 6/19, 32%), patient decision aids (colorectal: 13/83, 16% and breast: 9/28, 32%), and tools for tracking patient adherence to recommended care (colorectal: 27/83, 33% and cervical: 6/19, 32%).

The *cancer screening activities* were primarily related to identifying patients for screening in panel management (colorectal: 50/83, 60%; breast: 8/28, 29%; and cervical: 7/19, 37%) and at the point of care (colorectal: 39/83, 47%; breast: 15/28, 54%; and cervical: 12/19, 63%). Other commonly supported cancer screening activities included follow-up care for referral (colorectal: 36/83, 43%; breast: 7/28, 25%; and cervical: 7/19, 37%) and for positive or abnormal screening results (colorectal: 12/83, 15% and cervical: 5/19, 26%; Table 3).

Table 3. Characteristics of the health IT (HIT) sources and functions used to promote cancer screening in primary care, as represented in the included studies (N=101).

Characteristics	Colorectal cancer (n=83), n (%)[a]	Breast cancer (n=28), n (%)	Cervical cancer (n=19), n (%)	Total (N=101), n (%)
Using single or multiple HIT tools				
Single HIT tools	53 (63.9)	22 (78.6)	14 (73.7)	66 (65.3)
Multiple HIT tools	30 (36.1)	6 (21.4)	5 (26.3)	35 (34.7)
HIT sources				
EHR[b] based	74 (89.2)	20 (71.4)	18 (94.7)	85 (84.2)
Web based	11 (13.3)	9 (32.1)	3 (15.8)	18 (17.8)
Other or unclear	15 (18.1)	3 (10.7)	3 (15.8)	19 (18.8)
HIT functions				
CDS[c] panel management or outreach	50 (60.2)	7 (25)	9 (47.4)	57 (56.4)
CDS point of care	41 (49.4)	16 (57.1)	12 (63.2)	48 (47.5)
Risk identification	13 (15.7)	5 (17.9)	6 (31.6)	18 (17.8)
Patient decision aid	13 (15.7)	9 (32.1)	2 (10.5)	18 (17.8)
Provider assessment and feedback	11 (13.3)	1 (3.6)	1 (5.3)	12 (11.9)
Tracking patient adherence	27 (32.5)	4 (14.3)	6 (31.6)	30 (29.7)
Other	3 (3.6)	—[d]	—	3 (3.0)
Cancer screening activities supported by HIT				
Panel management	50 (60.2)	8 (28.9)	7 (36.8)	56 (55.4)
Point of care	39 (47)	15 (53.6)	12 (63.2)	45 (44.6)
Follow-up (referral)	36 (43.4)	7 (25.0)	7 (36.8)	41 (40.6)
Follow-up (abnormal or positive result)	12 (14.5)	2 (7.1)	5 (26.3)	17 (16.8)
Acquire previous results	7 (8.4)	2 (7.1)	4 (21.1)	10 (9.9)
Other	21 (25.3)	11 (39.3)	5 (26.3)	24 (23.8)

[a] Percentages were calculated based on column totals. Some studies featured >1 HIT source, function, and cancer screening activity. As a result, these categories are not mutually exclusive and will not necessarily sum to 100%. Refer to Multimedia Appendix 4 for definitions of the terms used in this table.

[b] EHR: electronic health record.

[c] CDS: clinical decision support.

[d] Not available.

Reporting on RE-AIM Outcomes

Overview

A summary of reporting on RE-AIM outcomes is provided in Table 4.

Table 4. Reporting on Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) outcomes for health IT (HIT) targeting cancer screening in primary care.

RE-AIM domains	Data charted	Cancer screening type		
		Colorectal cancer	Breast cancer	Cervical cancer
Reach	Was the number of targeted staff or patients for HIT-based intervention reported	High[a]	High	High
Effectiveness	Did the HIT tools show positive results in the cancer screening intervention	High	Moderate	High
Adoption	Rate of HIT adoption	Low	Moderate	Low
Implementation	Barriers, facilitators, and implementation strategies used related to HIT	Moderate	Low	Low
Maintenance	Was the sustainment of HIT adoption measured	Low	Low	Low

[a] Low: <25% of the included studies for each cancer screening type category, moderate: 25% to 50% of the included studies for each cancer screening type category, and high: >50% of the included studies for each cancer screening type category. Percentages were calculated with respect to the included studies for each cancer screening type category.

Effectiveness

Of the 101 included studies, 24 (23.8%) reported on the effectiveness of HIT targeting breast (14/28, 50% of breast cancer–relevant studies) and cervical cancer screening (10/19, 53% of cervical cancer–relevant studies; Multimedia Appendix 7 includes a table with these results). Of the 101 included studies, 54 (53.5%) reported the effectiveness of HIT targeting colorectal cancer screening (54/83, 65% of colorectal cancer–relevant studies). Among studies reporting on effectiveness, most-reported positive outcomes (improved screening rate) associated with the use of HIT (36/54, 67% of colorectal cancer–relevant studies; 9/14, 64% of breast cancer–relevant studies; and 7/10, 70% of cervical cancer–relevant studies). This evidence mostly represented CDS used during panel management (22/83, 27% of colorectal cancer–relevant studies) or at the point of care (5/28, 18% of breast cancer–relevant studies and 5/19, 26% of cervical cancer–relevant studies; Multimedia Appendix 7).

Reach, Adoption, and Maintenance

Among the 101 included studies, 79 (78.2%) reported on the reach of HIT-based interventions. Most of the studies focused on reach involved HIT for colorectal cancer screening (63/83, 76% of colorectal cancer–relevant studies studies). The reach of HIT-based interventions targeting breast cancer screening was reported in 82% (23/28) of the breast cancer–relevant studies and in 74% (14/19) of the studies targeting cervical cancer screening. Overall, 15.8% (16/101) of the studies reported on HIT adoption (colorectal: 10/83, 12%; breast: 9/28, 32%; and cervical: 1/19, 5%), and 2% (2/101) of the studies reported on maintenance of HIT-based interventions. Of those that reported on adoption, there was mostly a low rate of adoption (≤50%) across all cancer screening types (Multimedia Appendix 8 includes a table with these results).

Implementation

The proportion of studies reporting on the implementation of the HIT ranged from 25% to 50% for those related to colorectal cancer screening (Table 4). It was reported in <25% of the studies related to HIT targeting breast and cervical cancer screening. Implementation barriers, facilitators, and strategies related to HIT adoption across all cancer screening types are described further in the next 2 sections.

Implementation Barriers and Facilitators of HIT Adoption

A total of 34 studies reported on barriers and 37 studies reported on facilitators to implementing the HIT-based interventions of focus in primary care (Table 5). The most-reported barriers and facilitators were related to the ITIM constructs inner context (barriers: 17/34, 50% and facilitators: 14/37, 38%), nature of the innovation (barriers: 15/34, 44% and facilitators: 17/37, 46%), and outer context (barriers: 11/34, 32% and facilitators: 9/37, 24%). Inner context barriers included limited staff time to use the HIT and adoption competing with other clinic priorities. Inner context facilitators included having dedicated staff assigned to operate and manage a given HIT tool, and organizational policies supporting HIT adoption. Barriers related to the nature of the innovation included inaccurate cancer screening data reported by the HIT intervention and the burden of HIT development and maintenance. Facilitators related to the nature of the innovation included that HIT automation and customization features reduced staff resources and time needed in providing care. Outer context barriers included challenges involved with working with an EHR vendor to activate and update the tool and challenges with accessing screening results conducted outside the clinics. Outer context facilitators included Medicaid expansion including cancer screening as an incentivized metric and the clinic being a Federally Qualified Health Center, which necessitated responsiveness to such metrics. A table with more examples of barriers and facilitators is provided in Multimedia Appendix 9.

Table 5. Reporting on the barriers and facilitators of health IT adoption aligned with the Integrated Technology Implementation Model (ITIM).

ITIM constructs	Barriers (n=34), n (%)[a]	Facilitators (n=37), n (%)
Adoption or adopters	2 (6)	1 (3)
Communication	6 (18)	5 (14)
Economic environment	5 (15)	6 (16)
Facilitators (boundary spanner)	—[b]	4 (11)
Implementation	3 (9)	9 (24)
Inner context	17 (50)	14 (38)
Interfacing systems	5 (15)	2 (5)
Leadership	2 (6)	2 (5)
Nature of the innovation	15 (44)	17 (46)
Outer context	11 (32)	9 (24)
Users (adopters)	9 (26)	4 (11)
Workflow	9 (26)	11 (30)

[a] Percentages were calculated with respect to the total studies that reported barriers or facilitators. Some studies featured both barriers and facilitators to health IT adoption for cancer screening in primary care. As a result, these categories are not mutually exclusive and will not necessarily sum to 100%.

[b] Not available.

Implementation Strategies to Support HIT Adoption

Implementation strategies targeting HIT adoption were reported in 24% (24/101) of the included studies. Those reported were mapped to 22 implementation strategies from the ERIC compilation [39] (Multimedia Appendix 10). Of the studies reporting implementation strategies, >50% used ≥2 strategies and >50% reported strategies promoting HIT use for colorectal cancer screening. Common strategies to promote HIT use among all cancer screening types included central technical assistance, conducting small tests of change, and educational meetings. A table with more examples is available in Multimedia Appendix 10. Reported evidence mapped to the domains formulated by Proctor et al [40] (Table 6) and were mostly focused on describing implementation strategies to support HIT adoption for colorectal cancer screening (22/83, 27% of colorectal cancer–relevant studies) in comparison to breast (6/28, 21% of breast cancer–relevant studies) and cervical cancer screening (4/19, 21% of cervical cancer–relevant studies). Overall, less than half of the included studies, for each cancer screening type, reported evidence in accordance with each implementation strategy domain.

Table 6. Reporting on the implementation strategies used to support health IT adoption.

Implementation strategy domains by Proctor et al [40]	Data charted	Cancer screening type		
		Colorectal cancer	Breast cancer	Cervical cancer
Actor	Who delivers the strategy	Moderate[a]	Low	Low
Action	Procedures to conduct the strategy	Moderate	Low	Low
Target of action	Intent of action	Low	Low	Low
Temporality	When does the strategy happen	Low	Low	Low
Dose	Frequency or intensity	Low	Low	Low
Implementation outcomes affected	What will the strategy change	Low	Low	Low
Justification	Purpose of the strategy	Moderate	Low	Low

[a] Low: <25% of the included studies for each cancer screening type category, moderate: 25% to 50% of the included studies for each cancer screening type category, and high: >50% of the included studies for each cancer screening type category.

Discussion

Principal Findings

This scoping review summarizes the state of the science about the implementation of HIT-based interventions targeting breast, cervical, or colorectal cancer screening in primary care. Previous reviews identified the positive impact of HIT-based interventions throughout the cancer care continuum, including cancer screening [15,17,18]. This review adds to prior evidence by bringing an implementation science perspective; this is needed because the impact of HIT-based interventions is limited by the extent to which such interventions are effectively integrated into practice. This scoping review provides updated evidence up to 2021. This is not a systematic review; our goal was to identify knowledge gaps. Results indicate that key knowledge gaps related to the implementation of HIT in cancer screening in primary care include (1) the effectiveness of HIT targeting *breast and cervical* cancer screening, (2) HIT *adoption* in diverse primary care settings, (3) the *implementation strategies* that support the adoption of HIT, and (4) equitable reach or adoption of HIT. Addressing these evidence gaps may be critical to supporting the implementation of high-quality primary care [46].

Knowledge Gap 1: Limited Evidence on the Effectiveness of HIT Targeting Breast and Cervical Cancer Screening

This review emphasizes the need to improve the evidence on HIT effectiveness, especially HIT targeting breast and cervical cancer screening uptake, in diverse primary care settings. Effectiveness outcomes included, but were not limited to, improvements in cancer screening initiation by the patient or provider and patient completion of cancer screening. Although the use of HIT-based interventions was associated with improved screening outcomes for all 3 cancer types, there were far fewer studies of HIT effectiveness for breast and cervical cancer screening (a combined total of 24 studies) in comparison to the 54 studies involving colorectal cancer screening. Furthermore, most studies related to HIT targeting breast or cervical cancer prevention were conducted in academic medical centers and were not readily generalizable to other primary care settings. This limited evidence is concerning as both are common cancers, and evidence-based guidelines for such screenings are not met in many patient populations.

In addition, the lack of reporting on HIT effectiveness was especially common in studies in which HIT was part of a multicomponent intervention [14]; thus, even if the effectiveness of the overall intervention was reported, the impact of the HIT element of the intervention was not clear. More research is needed to establish the effectiveness of HIT targeting cancer screening in diverse primary care settings, including trials of the individual and combined effect of HIT within multicomponent interventions. The need for an improved understanding of the effectiveness of HIT is especially salient given that national programs (eg, Promoting Interoperability Program, formerly Meaningful Use) promote the use of HIT in health care settings [47] as a means to improve health outcomes.

Knowledge Gap 2: Limited Evidence of the Reach, Adoption, and Maintenance of Effective HIT Targeting Cancer Screening

The limited reporting on the reach, adoption, and maintenance of such interventions aligns with the known lack of reporting on these implementation outcomes in analyses of other interventions [48]; the need to improve such reporting is well known in implementation science. When HIT adoption is not reported, it is difficult to assess an intervention's population-level impact. In particular, if a limited number of potential users adopt an intervention, even when there is good reach and it is highly effective, population-level impacts may be low. Where adoption was reported, its rates were generally low (≤50%), underscoring the need for further research on improving the uptake of effective HIT [49]. When implementation barriers and facilitators to HIT adoption were reported, most related to inner context, outer context, and the nature of the innovation (including a given HIT tool's function). Future research should assess which combination of these contextual factors is associated with the adoption of HIT with varied functions when used in different workflow steps (ie, panel management, point of care, and follow-up care). To further understand how contextual factors impact care teams' adoption of HIT for cancer screening, there is also a need for more widespread reporting on practice type, which was rarely noted in the studies included here. Similarly, few studies reported on the sustainment of tool adoption. This evidence gap is seen throughout the implementation science literature [50]; improved knowledge of how to sustain the use of effective interventions is critical to maximizing their impact. Knowledge gap 3 describes the need for evidence on *how to improve* the adoption and maintenance of HIT-based interventions targeting cancer screening in primary care. We also posit that the lack of evidence on such interventions' *reach* is relevant to how such interventions support *equity* in cancer screening, as discussed in knowledge gap 4.

Knowledge Gap 3: Limited Evidence on Implementation Strategies That Support the Adoption of HIT Targeting Cancer Screening in Primary Care

A total of 24 studies (<25% of the included studies) reported on strategies used to support the adoption of HIT-based interventions, and few of these assessed the effectiveness of the strategies. This is complicated by the fact that in some cases a given HIT tool was considered the intervention or an intervention component, and in others, it was considered an implementation strategy for supporting the adoption of a clinical intervention. In the implementation science literature, the boundaries between clinical intervention and implementation intervention and between implementation intervention and implementation strategies are not always clear, adding complexity to this reporting.

Research is needed on how to support the adoption of HIT-based interventions targeting cancer screening using implementation strategies, how to use HIT as an implementation strategy, and what types of support strategies are used even in reports on HIT-based interventions' impact. Reporting must strive to clearly differentiate between these approaches; the need for better reporting on implementation strategies is well known [51-53]. Although such reporting can be resource intensive, methods are emerging to facilitate it [40,54].

Research is also needed to specify how effectively different implementation strategies support the adoption of different HIT-based interventions in different care settings. Known barriers and facilitators to HIT adoption, in general, may also be impactful for HIT targeting cancer screening. For example, evidence indicates that barriers to HIT use include inadequate training for care teams on using EHR functions to their full potential [55-58]. Thus, effective implementation strategies for HIT targeting cancer prevention may involve training.

Knowledge Gap 4: Limited Evidence on the Reach and Equitable Implementation of HIT for Cancer Screening in Primary Care

The equitable reach of HIT tools for cancer screening is poorly described. A few studies specifically focused on racial or ethnic minority groups; many were conducted in federally qualified health centers, which often serve racial or ethnic minority groups. Relevant data were reported in just 58.4% (59/101) of the studies included here. However, where such data were reported, eligible patients reached by the HIT interventions had a lower percentage of non-White patients than would be expected for the populations served, suggesting inequities in reach or underreporting. This is concerning, as racial disparities in cancer screening persist [59-61], and previous research found that interventions targeting breast or cervical cancer screening are less likely to target patients considered most at risk, for example, those in socioeconomically and racial or ethnic minoritized groups [5]. Findings from this scoping review underscore the need to understand potential drivers of these inequities (eg, design flaws in algorithms used to identify eligible patients and clinician bias in applying the HIT tool) and solutions to mitigate these inequities. One step toward addressing this inequity must involve improved reporting on how HIT is used in diverse patient populations. The well-documented need to improve reporting of race or ethnicity in health care [62] likely exacerbates the lack of reporting on the comparative reach of the tools included in this review among different groups. Another step toward equitable reach of HIT is understanding and addressing barriers to the inclusion of racial or ethnic minoritized patients in research on HIT adoption and impact. Future research on HIT adoption for cancer screening should explore strategies that support documentation, recruitment, and retention of racial or ethnic minoritized patients [63].

Limitations

HIT-based interventions might be used to improve outcomes at each step of the cancer control continuum, such as risk assessment, prevention, detection, diagnosis, treatment, survivorship, and end-of-life care [15]. This review was limited to cancer screening. Furthermore, although breast, colorectal, and cervical cancer are highly prevalent cancers whose detection is in the purview of primary care, no other cancers recommended for screening in primary care (eg, lung cancer) were included; future research could assess whether the gaps identified in this study are seen for a broader set of cancers. This review was limited to US studies; therefore, the relevance of the findings is limited to the context of HIT policies and infrastructure as applicable to US primary care settings. Another potential limitation is that urban or rural status was defined based on what each study reported, and they may have used different methods for making this characterization.

In addition, the overlapping quality of some HIT characteristic categories (tool types and functions) made it difficult to execute related data charting. Similarly, content analysis of HIT functions was complicated when implementation strategies overlapped or when studies did not specify which cancers were targeted by the strategies. Our definition of effectiveness did not capture screening outcomes related to each clinical workflow (eg, an intervention using CDS for panel management showed improvements in colorectal cancer screening but did not clarify how improvements impacted screening initiation, completion, or follow-up care). Finally, we followed the PRISMA-ScR guidelines [34] to examine a broad array of literature to include studies that are heterogeneous in design and quality [64]. Although our search strategy followed an iterative process, it is possible that some relevant existing articles were not captured; we sought to mitigate this using a snowball search.

Conclusions

In what is, to our knowledge, the first scoping review of the implementation of HIT-based interventions for cancer screening in primary care settings, we identified critical knowledge gaps. Little is known about the effectiveness of HIT-based interventions specifically targeting guideline-concordant breast and cervical cancer screening. Clarity is needed on the individual and combined effectiveness of HIT when integrated into a multicomponent intervention targeting cancer screening. Even less is known about how to enhance the adoption of cancer-targeted HIT in primary care. The potential for inequities in the reach of HIT for cancer screening remains underexplored. Research is necessary on implementation strategies to promote equitable access, ensuring that the potential benefits of HIT for population health are realized across diverse patient populations.

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Authors' Contributions

COJ and RG conceptualized the research questions. COJ conceptualized and led the data collection methods and analysis. COJ conducted a 3-step search process to identify relevant US-based peer-reviewed and gray literature studies. To ensure that the search yielded relevant studies, variations of the search strategy were pilot-tested by 3 authors (COJ, RG, and RX) and refined before the final search was conducted. COJ and RG conceptualized the eligibility criteria, and COJ, RG, and RX participated in the pilot-testing of the eligibility criteria before study selection. All authors conducted dual screening and applied the eligibility criteria for study selection. COJ and RG developed the data charting form, and COJ, RG, and HA participated in pilot-testing the data charting form before data charting. All authors conducted data charting of the final sample of studies selected for inclusion. COJ, JC, RX, and RG synthesized the data and performed quality checks on the reported results. COJ led the manuscript development. All coauthors had the opportunity to read, edit, and approve the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Database search strategy.
[DOCX File , 34 KB - cancer_v10i1e49002_app1.docx]

Multimedia Appendix 2
Gray literature search strategy.
[DOCX File , 35 KB - cancer_v10i1e49002_app2.docx]

Multimedia Appendix 3
Inclusion and exclusion criteria checklist.
[DOCX File , 34 KB - cancer_v10i1e49002_app3.docx]

Multimedia Appendix 4
Glossary of key terms.
[DOCX File , 38 KB - cancer_v10i1e49002_app4.docx]

Multimedia Appendix 5
Stage 5 procedures for qualitative content analysis.
[DOCX File , 33 KB - cancer_v10i1e49002_app5.docx]

Multimedia Appendix 6
References to the included studies (N=101).
[DOCX File , 55 KB - cancer_v10i1e49002_app6.docx]

Multimedia Appendix 7
Reporting status of health IT (HIT) effectiveness by cancer screening activities and HIT functions as represented in the included studies.
[DOCX File , 41 KB - cancer_v10i1e49002_app7.docx]

Multimedia Appendix 8
Reporting of health IT adoption as represented in the included studies.
[DOCX File , 35 KB - cancer_v10i1e49002_app8.docx]

Multimedia Appendix 9
Barriers and facilitators (with examples) of health IT adoption aligned with the Integrated Technology Implementation Model.
[DOCX File , 39 KB - cancer_v10i1e49002_app9.docx]

Multimedia Appendix 10
Expert Recommendations for Implementing Change implementation strategies used to support health IT adoption (n=24 studies).
[DOCX File , 46 KB - cancer_v10i1e49002_app10.docx]

Multimedia Appendix 11
PRISMA-ScR checklist.
[PDF File (Adobe PDF File), 81 KB - cancer_v10i1e49002_app11.pdf]

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Abbreviations

CCIS: Consortium for Cancer Implementation Science
CDS: clinical decision support
EHR: electronic health record

ERIC: Expert Recommendations for Implementing Change
HIT: health IT
ITIM: Integrated Technology Implementation Model
PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews
RE-AIM: Reach, Effectiveness, Adoption, Implementation, and Maintenance

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Original Paper

Pediatric Cancer Communication on Twitter: Natural Language Processing and Qualitative Content Analysis

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Abstract

Background: During the COVID-19 pandemic, Twitter (recently rebranded as “X”) was the most widely used social media platform with over 2 million cancer-related tweets. The increasing use of social media among patients and family members, providers, and organizations has allowed for novel methods of studying cancer communication.

Objective: This study aimed to examine pediatric cancer–related tweets to capture the experiences of patients and survivors of cancer, their caregivers, medical providers, and other stakeholders. We assessed the public sentiment and content of tweets related to pediatric cancer over a time period representative of the COVID-19 pandemic.

Methods: All English-language tweets related to pediatric cancer posted from December 11, 2019, to May 7, 2022, globally, were obtained using the Twitter application programming interface. Sentiment analyses were computed based on Bing, AFINN, and NRC lexicons. We conducted a supplemental nonlexicon-based sentiment analysis with ChatGPT (version 3.0) to validate our findings with a random subset of 150 tweets. We conducted a qualitative content analysis to manually code the content of a random subset of 800 tweets.

Results: A total of 161,135 unique tweets related to pediatric cancer were identified. Sentiment analyses showed that there were more positive words than negative words. Via the Bing lexicon, the most common positive words were support, love, amazing, heaven, and happy, and the most common negative words were grief, risk, hard, abuse, and miss. Via the NRC lexicon, most tweets were categorized under sentiment types of positive, trust, and joy. Overall positive sentiment was consistent across lexicons and confirmed with supplemental ChatGPT (version 3.0) analysis. Percent agreement between raters for qualitative coding was 91%, and the top 10 codes were awareness, personal experiences, research, caregiver experiences, patient experiences, policy and the law, treatment, end of life, pharmaceuticals and drugs, and survivorship. Qualitative content analysis showed that Twitter users commonly used the social media platform to promote public awareness of pediatric cancer and to share personal experiences with pediatric cancer from the perspective of patients or survivors and their caregivers. Twitter was frequently used for health knowledge dissemination of research findings and federal policies that support treatment and affordable medical care.

Conclusions: Twitter may serve as an effective means for researchers to examine pediatric cancer communication and public sentiment around the globe. Despite the public mental health crisis during the COVID-19 pandemic, overall sentiments of pediatric cancer–related tweets were positive. Content of pediatric cancer tweets focused on health and treatment information, social support, and raising awareness of pediatric cancer.

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KEYWORDS

cancer; COVID-19; Twitter; communication; child health; caregivers; social media; tweet; tweets; sentiment; oncology; cancers; pediatric; pediatrics; child; children' youth; experience; experiences; attitude; attitudes; opinion; opinions; perception; perceptions; perspective; perspectives

Introduction

Social media platforms are widely used to exchange information and share resources. One such platform is Twitter (recently rebranded as "X"), a microblogging site with approximately 400 million global users. Social media platforms such as Twitter have been used by patients with health conditions, their caregivers, and other family members to connect with individuals in similar situations and learn from patients, researchers, and organizations worldwide. Patients with cancer, survivors of cancer, and their family members commonly use Twitter as a resource for treatment information and social support. Twitter users consist of a variety of cancer stakeholders including cancer centers, pharmaceutical companies, nonprofit organizations, medical providers, patients, and patients' family and friends [1]. Individuals and organizations also use Twitter and other social media platforms to increase awareness and reach of cancer-related messages [2]. The increasing use of social media among patients, providers, and organizations has allowed for novel ways of studying cancer communication [3].

The global COVID-19 pandemic led to major changes in lifestyle, social distancing, and isolation that uniquely affected patients with cancer, caregivers, and other stakeholders. They were negatively impacted by overly taxed health care infrastructure and medical systems, restricted access to medical care, and a mental health crisis. Research on cancer during the pandemic spanned a range of topics including the global impact of COVID-19 on cancer care management [4,5]. Cancer survivors' stressors during the pandemic included anxiety about in-person appointments, fear of cancer recurrence, medical care delays, uncertainty about future medical care, untreated symptoms, and mental health concerns [6]. Caregivers of patients with pediatric cancer experienced changes to their child's medical care, financial disruptions, and emotional stress related to COVID-19 [7]. The COVID-19 pandemic was also associated with an increased risk of depression and loneliness in people living with cancer [8].

Twitter has been the most frequently used social media platform for public health surveillance since 2006, and there were over 2 million cancer-related tweets during the pandemic [9,10]. Previous studies have examined changes in public sentiment and the increasing use of Twitter during the pandemic [11,12]. For example, an analysis of Twitter showed that patients with cancer expressed significant negative sentiment during the COVID-19 pandemic [9]. Recent studies have examined the content of cancer-related tweets for different types of cancer diagnoses including lung, breast, and prostate cancer [13-15]. We only identified 2 studies thus far that have examined the pediatric cancer experience on Twitter. The first was a cross-sectional study examining the use of Twitter to discuss childhood cancer during Childhood Cancer Awareness Month [16]. The second used Twitter data to conduct a lexicon-based sentiment analysis of patients with pediatric cancer using the hashtag #ChildhoodCancer and found generally positive sentiment scores [17].

Lexicon-based sentiment analytic approaches determine positive and negative sentiments based on individual words [18]. Recent behavioral health studies have used lexicon-based approaches to analyze short text messages on social media platforms such as Twitter [19-23]. In addition to determining the positive or negative sentiment of words, the "NRC" lexicon assigns a sentiment type using the following additional emotion categories: anger, anticipation, disgust, fear, joy, sadness, surprise, and trust [18]. Such analyses provide population-level insights into patterns of health information sharing and support-seeking on social media, and can inform the dissemination of time-critical information and resources during challenging times such as the COVID-19 pandemic. Additionally, the launch of Open AI's chatbot, ChatGPT, provides a novel tool for nonlexicon-based sentiment analysis via text-based chat inquiries. Emerging research suggests that ChatGPT demonstrates superior performance in sentiment analysis of free-text responses [24].

In this study, we examined cancer-related tweets for pediatric cancer globally to capture the experiences of patients and survivors of cancer, their caregivers, medical providers, and other stakeholders. The objectives of our analysis using a Twitter data set over a time period representative of the impact of the COVID-19 pandemic were two-fold: (1) to quantitatively analyze the public sentiment of tweets related to pediatric cancer via lexicon-based and nonlexicon-based sentiment analytic approaches; and (2) to qualitatively examine the topics relevant to cancer diagnosis, treatment, and survivorship covered with hashtags commonly associated with pediatric cancer via a directed content analysis.

Methods

Ethical Considerations

This study did not require institutional review board approval because we used publicly available social media data that do not involve human subjects and do not fall within the scope of Human Subjects Research. Seattle Children's Hospital's Institutional Review Board uses the US Department of Health and Human Services (DHHS) definition of Human Subjects Research. Human Subjects Research under DHHS regulations is defined as the investigator obtaining information through intervention or interaction with living individuals; or obtaining, using, studying, analyzing, or generating identifiable private information. Our research is Nonhuman Subjects research according to the Seattle Children's HRP-101 Human Research Protection Program Plan, P. 3, which uses the DHHS definition of Human Subjects Research [25,26]. The publicly available social media data reported in this paper have been anonymized and contains no IDs, user names, or nonparaphrased tweets.

Data Collection

In this study, we examined pediatric cancer–related communication on Twitter encompassing a representative timeframe ranging from before to after the COVID-19 pandemic. We obtained a total of 182,628 publicly available global tweets from December 11, 2019, to May 7, 2022, using the Twitter application programming interface. An example of the query and timeline information using "#teenagecancer" is available in Multimedia Appendix 1. For this study, we restricted our collection to English-only tweets. We identified a list of hashtags commonly associated with pediatric cancer: #childhoodcancer, #childhoodcancerawareness, #childhoodcancerday, #internationalchildhoodcancerday, #kidsgetcancertoo, #pediatriccancer, #pediatriconcology, #teenagecancer. These 8 keywords were selected because they were representative of hashtags frequently used for pediatric cancer. The prepandemic period was designated as December 2019 to February 2020. The pandemic time period was designated as March 2020 to June 2020. Lockdown and mandatory stay-at-home orders were issued in 42 US states and territories across the United States between March and May 2020 during the height of the pandemic [27]. The postpandemic time period was designated as July 2020 to May 2022 after mandatory stay-at-home orders were lifted in all states across the United States. Removing duplicates resulted in a total of 161,135 tweets from 40,289 unique users. All unique tweets were used for lexicon-based sentiment analysis. Among the 161,135 tweets from 40,289 unique accounts, we then randomly sampled a subset of 800 tweets and analyzed them using a directed content approach. Of the subset of tweets, 300 were randomly sampled and proportionately stratified by pandemic period (prepandemic, during the pandemic, and postpandemic).

Sentiment Analysis

Overview

"Sentiment analysis" or "opinion mining" is a natural language processing technique used to analyze and extract insights from text data, enabling the identification and understanding of the sentiment, emotions, and subjective opinions expressed within the text, which can be valuable for various applications such as market research, customer feedback analysis, and social media monitoring. We used lexicon-based approaches to conduct analyses using the full data set of tweets. Nonlexicon-based approaches can be used to evaluate whether the results may align with lexicon-based analysis. Thus, we used ChatGPT to conduct supplemental analyses on a randomly selected subsample of tweets.

Lexicon-Based Approaches

All data preprocessing, cleaning, and analyses were performed in R (version 4.2.2; R Foundation for Statistical Computing). We used "saotd" for preprocessing and initial analyses [28]. Nonlanguage elements such as symbols, weblinks, punctuation, emojis, and stop words, such as "the" and "of," were removed. Sentiment scores were first computed based on the Bing lexicon, and we presented the most common positive and negative words within the data set. Additional analyses were conducted using the "syuzhet" package. We computed sentiments based on "Bing," "AFINN," and "NRC" lexicons. The "Bing" lexicon was developed by Liu [29] and categorizes 6788 English words into positive and negative categories. The "NRC" lexicon includes 6468 English words and classifies words as positive or negative sentiments and includes emotional categories of anger, anticipation, disgust, fear, joy, sadness, surprise, and trust [30]. The "AFINN" lexicon includes 2476 English words that were labeled with a value between –5 (negative sentiment) and +5 (positive sentiment) [31]. We used the "get_sentiment" function in the "syuzhet" package to calculate sentiment scores. Final sentiment scores were generated for each of the lexicons. All positive sentiment scores for "Bing," "AFINN," and "NRC" lexicons were recoded to 1 and all negative sentiment scores were recoded to –1. Weekly average scores were calculated to reflect the average sentiment of tweets in a given week. We used the "plot_ly" function in the "plotly" package to visualize changes in weekly sentiment over time.

Supplemental Nonlexicon-Based Approach

ChatGPT (version 3.0) is a next-generation artificial intelligence–based chatbot optimized for using natural language processing to generate responses to user input [32]. We asked ChatGPT (version 3.0) to analyze the overall sentiments of a subset of 150 randomly sampled tweets, with 50 tweets each from our pre-, during-, and postpandemic data sets. We entered, "Can you provide the overall sentiments of the following tweets?" into the query box. ChatGPT responded: "I'd be happy to help you analyze the overall sentiments of the tweets you've provided" along with its conclusions on sentiment. We analyzed the sentiment of 50 tweets per data set which was below the maximum size data set allowed for the free version of ChatGPT.

Qualitative Coding

We explored the background literature related to cancer and other health conditions to identify a codebook based on directed content analysis for our project [13,33-36]. We identified Sutton et al [13] for lung cancer messages as the codebook that was most relevant and related to our sample of pediatric cancer tweets. We conducted a directed content analysis [37] using codes and coding definitions from Sutton et al's codebook. Further, 2 of the authors (NL and AO) coded tweets in sets of 10 to iteratively refine and adapt the Sutton et al codebook and definitions to correspond to pediatric cancer-related tweets. We expanded the preliminary codebook to include the emergence of 7 new coding categories that did not exist in the original codebook. We also added a not enough information coding category for tweets that were ambiguous and could not be coded. Furthermore, 2 of the authors (NL and AO) met weekly to discuss and address codebook discrepancies, and further refine the codebook. The entire authorship team met to discuss codebook development and refinement until it was stable and finalized. The same 2 coders (NL and AO) used the final codebook of content of tweets (adapted from Sutton et al [13]; Textbox 1) to independently double-code all 800 of the randomly sampled tweets.

Textbox 1. Final version of qualitative codebook of content of tweets.

Research

- Text that describes research on cancer at any point in the continuum, including study results, study in progress, conference presentations, journal publications, research gaps, news publications describing recent findings, and researcher profiles. Any media source, for example, internet blogs, WebMD, or consumer-focused articles apply.

Awareness

- Text that promotes awareness of cancer (eg, fundraising and prevalence), discusses potential symptoms and signs of cancer, activism, philanthropy, inequities, books, or memoirs about the cancer experience, or makes general references to cancer.

Policy and the law

- Text about insurance, benefits, legal issues, public policy, and government funding. Code policy and the law only if the tweet does not contain additional content that would lead you to double-code as awareness or another code.

Pharmaceuticals and drugs

- Text that mentions a generic or brand name drug or a pharmaceutical firm.

Prevention and risk information

- Text that describes cancer risk, behaviors that increase risk (eg, smoking and environmental causes), and behaviors that reduce risk or prevent cancer (eg, healthy diet and smoking cessation).

Early detection

- Text that describes screening tests (eg, low-dose computed tomography), warning signs, early symptoms, and family history.

Diagnosis

- Text that contains information about a diagnosis, such as tests (eg, imaging, tests, and biopsy) and results (eg, malignant or benign).

Treatment

- Text that describes attempts to medically remove or alter cancer or cancer symptoms (eg, chemotherapy and surgery), discusses treatment of symptoms, references individuals receiving treatment (eg, “fighting cancer”), or information about potential treatments.

Survivorship

- Text that describes life after cancer treatment, including remission, and long-term effects of treatment.

Mental health

- Text that describes the impact of the cancer journey on mental health, mental health treatment or resources, and mental health support.

End of life

- Text that discusses cancer-related deaths and legacy. Supportive messages, remembrances, and condolences regarding a patient who died. Parents tweeting about their own children who died of cancer.

Personal experiences

- Text that mentions a personal experience with cancer, including messages about the self and others who have experienced cancer or are worried about cancer. Includes publicized memoirs. If unclear identity of the tweet author (eg, patient, caregiver, and provider), only code personal experiences.

Patient experiences

- Text from individuals with pediatric cancer diagnosis regarding self-experiences. Double-code with personal experiences.

Caregiver experiences

- Text from caregiver of pediatric cancer regarding personal experiences. Double-code with personal experiences.

Health status

- Text that describes current health status, illness progression, and related effects (eg, worries, concerns, and hope).

Social support

- Supportive messages to a patient or caregiver in their illness journey. Encouraging messages from survivors of cancer to other survivors.

Provider experiences

- Supportive messages and appreciation for specific providers who care for patients with cancer or providers in general. Clinicians discussing their experiences providing care. Double-code with personal experiences.

Not enough information

- Not enough information in the tweet to code content.

Interrater reliability was calculated as the percent agreement between raters before consensus meetings. Consensus conversations occurred weekly and we referenced the codebook to resolve any discrepancies. The qualitative data were analyzed using DeDoose (Sociocultural Research Consultants, LLC) software for code frequency counts and code co-occurrences. Data visualization of codes was represented by a word cloud generated in DeDoose.

Research Team

Authors' backgrounds included health services research (NL, XZ, AO, HW, and KB), digital health research (NL, XZ, and AO), analytics (XZ), implementation science (NL), clinical psychology (NL, XZ, and AO), pediatric psychology (NL and XZ), bioethics (KB), qualitative research (NL, XZ, and KB), and psychosocial oncology research (NL, AO, HW, and KB).

Results

Sentiment Analyses

Cancer was the most commonly mentioned word, as it was included in all hashtags that were used to collect the tweets. Excluding "cancer," "Bing" lexicon-based sentiment analyses revealed that there were more positive words than negative words in the extracted tweets (Figure 1). The "Bing" lexicon was based on the largest lexicon among our 3 lexicons and was able to analyze the largest number of tweets. The 5 most commonly observed positive words in the "Bing" lexicon and our data set were "support," "love," "amazing," "heaven," and "happy." The 5 most commonly observed negative words in the "Bing" lexicon and our data set were "grief," "risk," "hard," "abuse," and "miss." Analyses from the "NRC" lexicon showed that most tweets were categorized under the sentiment types of "positive" (N=138,752), "trust" (N=101,036), and "anticipation" (N=100,635). Figure 2A-C displays weekly sentiment scores over a time period representative of the impact of the COVID-19 pandemic for the "Bing," "AFINN," and "NRC" lexicons. The sentiment was overall positive. These findings were consistent across lexicons. Based on responses from ChatGPT (version 3.0), the randomly selected subsamples from the pre-, during-, and postpandemic periods demonstrated overall positive sentiment (Textbox 2). Although ChatGPT (version 3.0) analysis was exploratory, findings were consistent with our lexicon-based analyses.

Figure 1. Most common positive and negative words using the Bing lexicon.

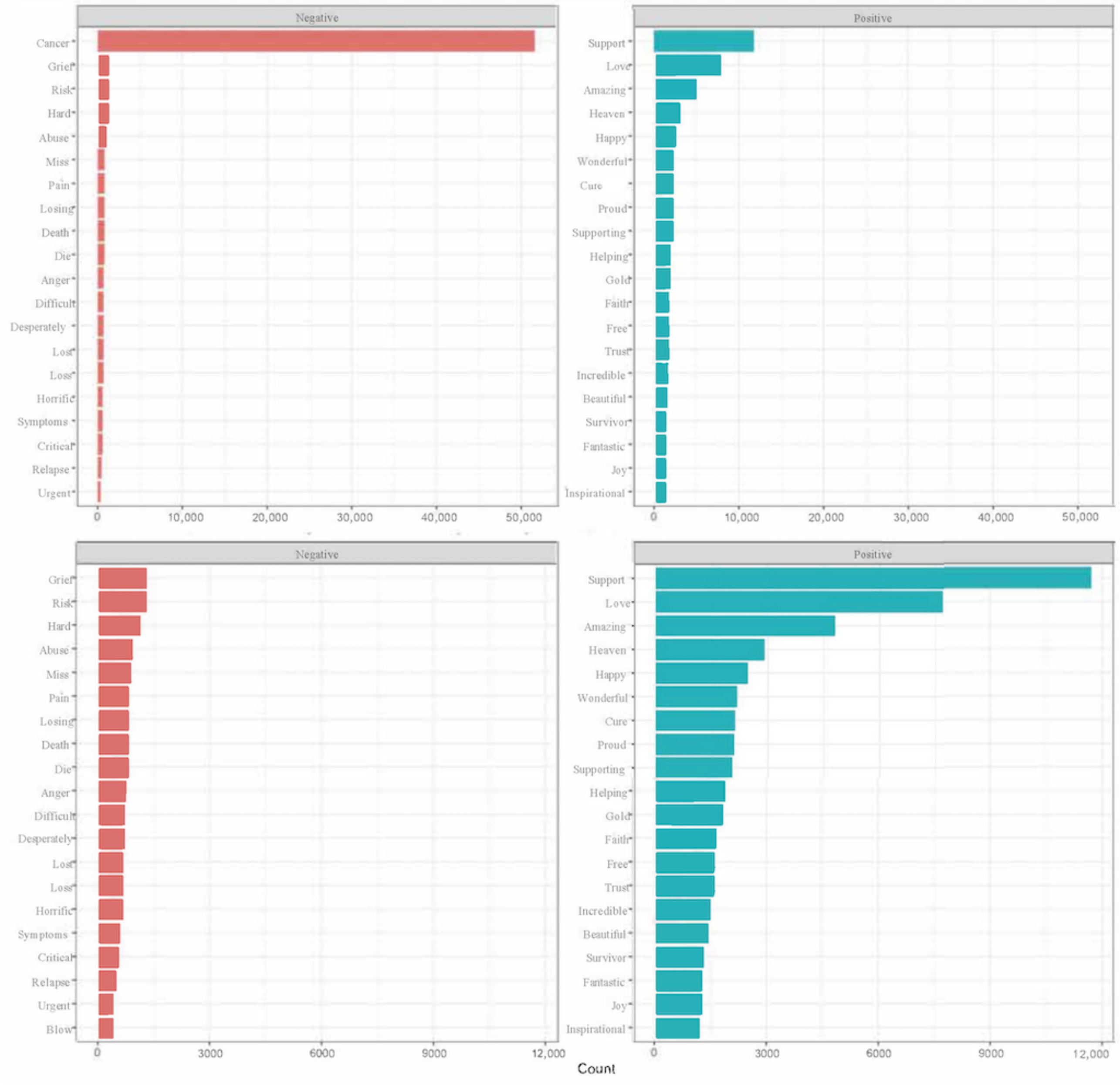
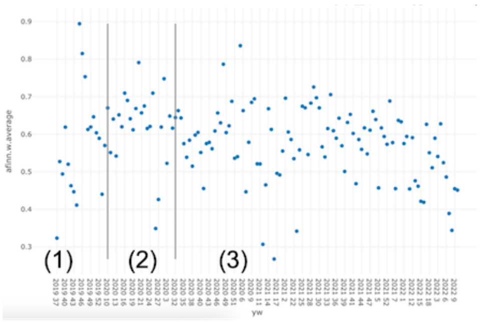
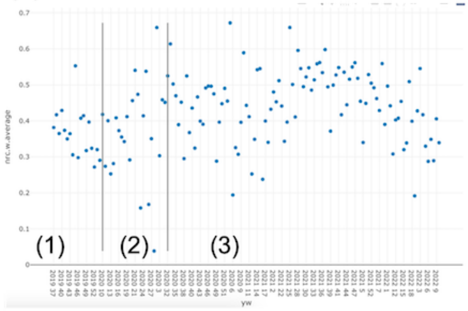


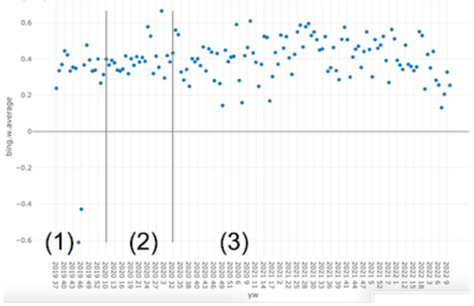
Figure 2. Weekly sentiment using different lexicons from December 11, 2019, to May 7, 2022, a time period representative of the impact of the COVID-19 pandemic. (1) Pre–COVID-19 pandemic, (2) during–COVID-19 pandemic, and (3) post–COVID-19 pandemic.



(A) AFINN



(B) NRC



(C) Bing

Textbox 2. Overall sentiments provided by ChatGPT in supplemental analysis.

Pre–COVID-19 pandemic

- The overall sentiments in the provided texts are predominantly positive or neutral. The texts largely revolve around messages of support, encouragement, and raising awareness for childhood cancer, which are inherently positive causes. There is an emphasis on helping and supporting children with cancer and celebrating their milestones. Overall, the texts convey sentiments of empathy and goodwill toward individuals affected by childhood cancer, making the overall sentiment positive and empathetic.

During–COVID-19 pandemic

- Overall, the sentiment in most of these tweets is positive or neutral, as they primarily involve raising awareness, requesting support, or expressing gratitude for contributions to childhood cancer causes.

Post–COVID-19 pandemic

- Overall, this collection of tweets has a predominantly positive and neutral sentiment with some mixed and concerned sentiments. The positivity in these tweets largely stems from support for childhood cancer-related causes and achievements in the field.

Qualitative Coding

Percent agreement between coders was high (91%) before consensus meetings. Consensus meetings resolved all coding discrepancies. The top 5 codes were awareness (N=449), personal experiences (N=166), research (N=60), caregiver experiences (N=54), patient experiences (N=53), policy and the law (N=52), treatment (N=21), end of life (N=21), pharmaceuticals and drugs (N=17), and survivorship (N=15). Data visualization of code applications in a word cloud using DeDoose software is presented in Multimedia Appendix 2.

Twitter users predominantly used the social media platform to promote public awareness of pediatric cancer. In addition, Twitter users frequently use the social media platform to share personal experiences with cancer. Many accounts were from the firsthand perspectives of caregivers of patients with pediatric cancer in active treatment, bereaved parents, and from patients or survivors of cancer themselves. Twitter was frequently used for health knowledge dissemination of research findings (topics included cancer prevention and risk information, early detection, diagnosis, treatment, and survivorship). Twitter was also frequently used to call attention to and lobby for government programs and federal policies that support pediatric cancer treatment and affordable medical care. Example tweets for the top 10 codes are presented in Textbox 3.

DeDoose software displays the frequency of co-occurring codes using a heat map. Most frequently co-occurring codes are in red, moderately frequent co-occurring codes are in green, and less frequently co-occurring codes are in blue. The code co-occurrence chart of the top 10 codes is presented in Figure 3. Overwhelmingly, awareness and personal experiences were the most frequently cocoded (110 times). Moderately frequent co-occurring codes were caregiver experiences and personal experiences (cocoded 54 times), personal experiences and patient experiences (cocoded 53 times), awareness and patient experiences (cocoded 36 times), and awareness and caregiver experiences (cocoded 34 times).

Textbox 3. Example of paraphrased and deidentified tweets for Top 10 coding categories.

Awareness

- GOLD is the symbolic color for #ChildhoodCancerAwareness. Wearing GOLD to show your support for our children! From head-to-toe, we want to see how gold you can be for Spirit Day! Tag us in your photos
- We are grateful for the impact on the #pediatriccancer world! Every donation makes a difference.

Personal experiences

- Please help get [this] story out there. #CancerSucks #ChildhoodCancerAwareness. she needs our help!!! RT and donate if you can. Thank you! *Awareness
- FAMily Update» [Child's name] is back in the hospital. The medical team has ordered a 24 hour [inpatient stay]. #FAM #FightingAllMonsters #ChildhoodCancer *Caregiver Experiences; Health Status

Research

- Brain and spinal cord tumors are the 2nd most common cancers in children. In honor of #ChildhoodCancerAwareness month, here's a look at recent #Umich discoveries to help treat brain cancer in kids. *Awareness; Treatment
- With more than 10,000 experts worldwide and nearly 100 active clinical trials across the spectrum of childhood cancers, COG is committed to ending #childhoodcancer as we know it. #ChildhoodCancerAwareness #ChildhoodCancerAwarenessMonth *Treatment

Caregiver experiences

- I'm involved with many amazing groups for bereaved parents (like myself) and many other #ChildhoodCancer groups. I'd love to see you join us. *End of Life; Personal Experiences
- I am blessed to be the [caregiver] of one of the toughest kids in the world. Love you. #InternationalChildhoodCancerDay #teensvscancer *Personal Experiences

Patient experiences

- [Child's name] has [medical event] which landed him in the ER. Shout out your loudest prayers and coolest thoughts for [child's name] so he can return home #FAM #FightingAllMonsters #ChildhoodCancer *Personal Experiences; Social Support
- Agree friends get nervous of saying wrong thing so tend to say nothing I was lucky had a couple of mates there throughout. *Personal Experiences; Social Support
- [Child's name] finishes his radiotherapy tomorrow!! He put a smile on everyone's face with his [resilience/playfulness]! *Personal Experiences; Health Status

Policy and the law

- Please do not allow the Creating Hope Reauthorization Act S.4010 to die on YOUR watch! It has produced 28 drugs for rare pediatric diseases, My [child] received 1. *Pharmaceuticals & Drugs; Personal Experiences; Caregiver Experiences
- Please join Congressman Peter Welch VT-0 as a cosponsor of HR 6556 Gabriella Miller Kids First Research Act 2.0. No taxpayer funds required to help #ChildhoodCancer & rare diseases #GMKF2
- We need non-toxic therapies developed for #ChildhoodCancer which is not the same as adults. In the last 10 years, kid's cancers received only 4% of the budgeted govt research. Will you help? *Awareness

End of life

- This time of year can be especially difficult for those who are grieving, esp. for parents who have lost a child. This is my [personal experience]. Here is some advice to help us get through. Please RT. #ChildhoodCancer #Grief #Grieving *Mental Health; Personal Experiences; Caregiver Experiences
- Nothing will ever be so awful as [child's death]. I am very grateful to the NHS and @TeenageCancer for their efforts but they just couldn't save him. *Personal Experiences; Caregiver Experiences
- Missing [child's name] today. Please lend some support to this petition to fund research into childhood cancers #ChildhoodCancer #BrainTumourCharity *Awareness; Personal Experiences

Treatment

- A novel #CARTcelltherapy has shown promising early results in #children with #neuroblastoma, a rare form of ChildhoodCancer. #CancerImmunotherapy *Pharmaceuticals & Drugs
- Clear guidance for stem cell transplant patients, those who have had abdominal radiotherapy, and those who have had total body irradiation as part of transplant #coronavirus #COVID19 #childhoodcancer

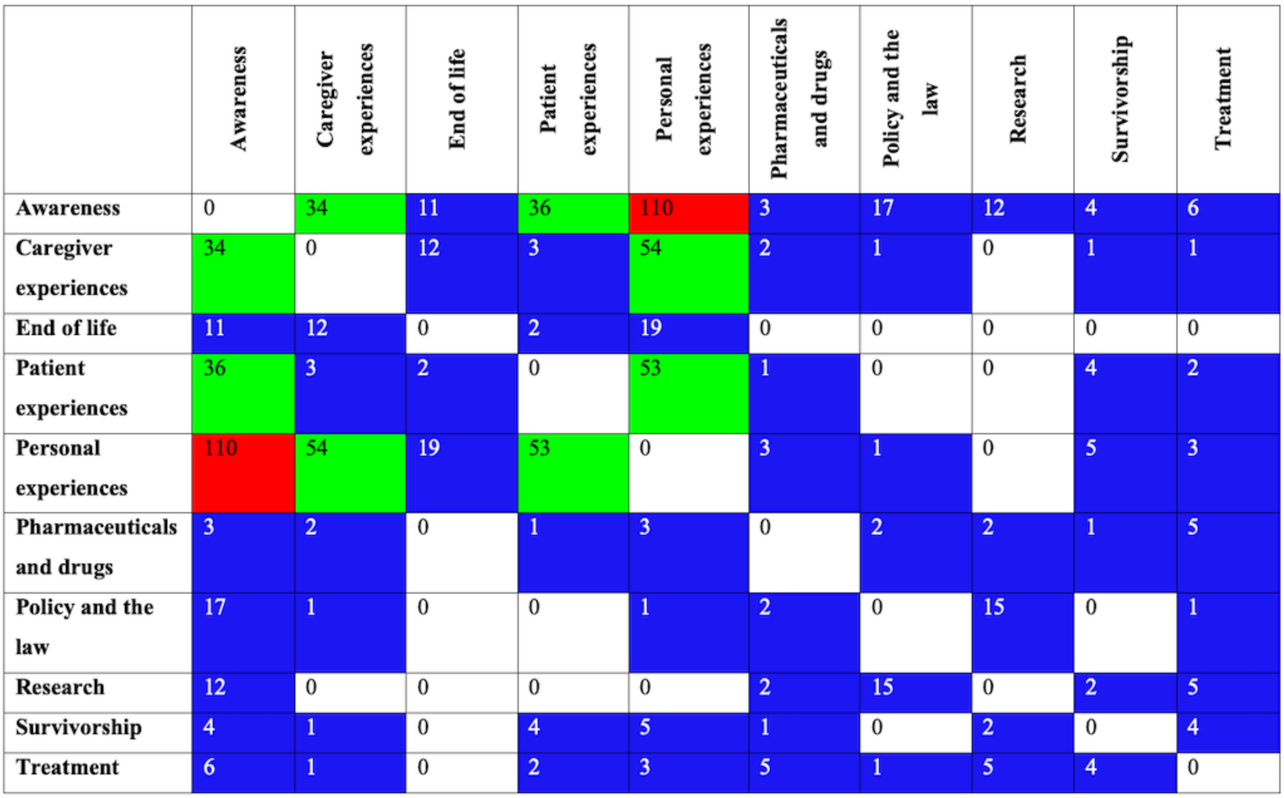
Pharmaceuticals and drugs

- A NFCR partner working to advance new therapies for #childhoodcancer, @OncoHeroesBio, recently announced that the @US_FDA has granted Orphan Drug Designation and Rare Pediatric Disease Designation to one of its drugs. #Together4ACure
- Check out the article: "Leaving no child behind in the fight against cancer" A very good explanation on the current issues we face in #ChildhoodCancer drug development, as well as recommendations to solve the current issues! @SIOPEurope
- #ACCELERATEcure (virtual) Annual Conference 2021 - REGISTRATION open next week! Looking forward to welcoming you to discover latest developments worldwide in #ChildhoodCancer drug development! Join us *Research

Survivorship

- The list of potential side effects of #ChildhoodCancer treatments includes future fertility problems, visual loss, dental complications. With the right testing these side effects can be guarded against #ChildhoodCancerAwarenessMonth #Pharmacogenomics *Awareness; Treatment
- Substantial progress has been made against the most common types of pediatric cancers and overall survival rates are up, but more hard work remains so more children with cancer not only survive but thrive. #GoldTogether #ChildhoodCancer *Treatment

Figure 3. Code co-occurrence chart of top 10 coding categories generated by DeDoose.



	Awareness	Caregiver experiences	End of life	Patient experiences	Personal experiences	Pharmaceuticals and drugs	Policy and the law	Research	Survivorship	Treatment
Awareness	0	34	11	36	110	3	17	12	4	6
Caregiver experiences	34	0	12	3	54	2	1	0	1	1
End of life	11	12	0	2	19	0	0	0	0	0
Patient experiences	36	3	2	0	53	1	0	0	4	2
Personal experiences	110	54	19	53	0	3	1	0	5	3
Pharmaceuticals and drugs	3	2	0	1	3	0	2	2	1	5
Policy and the law	17	1	0	0	1	2	0	15	0	1
Research	12	0	0	0	0	2	15	0	2	5
Survivorship	4	1	0	4	5	1	0	2	0	4
Treatment	6	1	0	2	3	5	1	5	4	0

Discussion

Principal Results

The purpose of this study was to examine the communication content of pediatric cancer–related tweets and the public sentiment of pediatric cancer tweets. The sentiment of tweets on pediatric cancer was overall positive, revealing the supportive, hopeful, and inspirational messages relayed by patients, caregivers, and other relevant stakeholders. Our findings were consistent with the only other study to examine the public sentiment of pediatric cancer–related tweets [17]. Despite previous research showing predominantly negative sentiments globally during the COVID-19 pandemic [38], our study describes a positive sentiment of pediatric cancer–related tweets during the COVID-19 pandemic. We found that pediatric cancer–related tweets predominantly focused on raising awareness about pediatric cancer and disseminating health knowledge. We found that both patients with pediatric cancer or survivors and their caregivers frequently used Twitter to provide updates on their health status, for social support, and to share messages of hope.

We only identified 2 studies thus far that have examined the pediatric cancer experience on Twitter. The current study expanded on the growing body of literature on social media use in patients with cancer, and early research on pediatric cancer-related use of Twitter. Previous research studies have discussed the importance of including caregiver experiences in addition to those of the patient for individual and family-based well-being and adaptive coping [39-41]. Our findings were consistent with previous studies that have shown that cancer-related tweets center on health communication and social support [36]. Similar to previous studies, there was a diverse array of Twitter users, representing perspectives from patients, family members, oncology providers, and health care, pharmaceutical, nonprofit, and other organizations [2,36,42,43]. Additional studies may use combined sentiment analysis and qualitative approaches to better understand pediatric cancer communication and support resources on Twitter and other popular social media platforms. The current and future studies can help inform the development of novel patient- and caregiver-based social media interventions to improve health knowledge, change health behaviors, and improve health outcomes.

Limitations

Our study has several limitations. First, our analysis included only tweets in the English language which limits generalizability to populations that do not speak English as a primary language. Second, we analyzed tweets that contained prespecified keywords (ie, hashtags) and may have missed other pediatric cancer–related tweets during the specified study period. Third, we only examined social media use on Twitter which may differ from usage on other popular social media platforms. Fourth, we were unable to identify the account type (organization vs individual, patient or caregiver vs researcher) and extract sociodemographic information of users; this information may have further informed our research findings and the conclusions drawn. Fifth, our qualitative content analysis of Twitter only included a random sample of tweets from the full data set which may not be representative of all pediatric cancer–related tweets during the specified timeframe of our analysis. Sixth, our lexicon-based approaches have inherent limitations. Despite using multiple sentiment lexicons in our analyses, such approaches analyze sentiment based on individual words. We did not expand contractions and apply stemming in our analyses as they were not available in “saotd,” the statistical package we used for data preprocessing. The lack of expanding contractions and applying stemming may have reduced the number of analyzable words and tweets. Twitter users commonly use contractions, abbreviations, slang, and sarcasm. Thus, we conducted supplemental analyses using ChatGPT (version 3.0), a next-generation artificial intelligence optimized for natural language processing, to validate our findings. Although exploratory, these findings were consistent with lexicon-based approaches. Research should further investigate the use of other recent innovative nonlexicon-based approaches that analyze entire sentences, such as embedding-based approaches or transformer-based approaches to analyze tweets related to pediatric cancer. Seventh, our data were global tweets but our specified “pre-,” “during-,” and “post-” pandemic time periods were based on United States lockdowns and timelines. We acknowledge that pandemic timelines differ within the United States and certainly globally. Nonetheless, we think it is important to include all tweets regardless of geographic location for representativeness of experiences due to the pandemic being a global crisis.

Conclusions

Acute, ongoing, and evolving pediatric medical traumatic stress impacts the child in the context of their family, which emphasizes the importance of incorporating the perspectives and experiences of caregivers and other family members [44,45]. Social media use by patients with pediatric cancer, their families, and their medical providers has been well-described [46]. Uses and benefits include opportunities for social support, building collaborative networks, dissemination of health-related information, and treatment recommendations [46]. Researchers have increasingly turned to sentiment and content analyses of Twitter to capture real-time experiences of patients with a range of health conditions and other relevant stakeholders. Such research has included analyses of tweets about various cancer diagnoses.

Twitter, as a popular social media platform, may serve as an effective means for researchers to examine pediatric cancer communication and public sentiment around the world. This study used both quantitative and qualitative methods to examine the pediatric cancer experience on Twitter. Despite the global mental health crisis during the COVID-19 pandemic, we found overall positive sentiment of pediatric cancer–related tweets over a time period representative of the COVID-19 pandemic. The content of pediatric cancer tweets was posted by a range of users and centered on the delivery of health and treatment information, seeking and providing social support, and the amplification of awareness of pediatric cancer. Twitter may serve as a powerful platform for rapid communication with survivors of pediatric cancer and their caregivers, and facilitate the widespread dissemination of patient- and caregiver-targeted behavioral health interventions to improve well-being and quality of life. This would be well-matched to pediatric cancer survivors’ and their caregivers’ current preferences in social media use.

Acknowledgments

NL was supported by the National Cancer Institute of the National Institutes of Health (K08CA263474). The opinions herein represent those of the authors and not necessarily the funders.

Data Availability

The publicly available data underlying this paper were accessed from Twitter. The derived data generated in this research will be shared on reasonable request to the corresponding author.

Authors' Contributions

Conceptualization was done by NL, XZ, AO, and KB. Data were curated by NL, XZ, AO, and HW. Formal analysis was handled by NL, XZ, and KB. Investigation was done by NL, XZ, AO, HW, and KB. Methodology was handled by NL, XZ, and KB.

Project administration and supervision were by NL. Visualization was done by XZ and HW. Writing of the original draft was by NL and XZ. Review and editing of the writing was by NL, XZ, AO, HW, and KB.

Conflicts of Interest

XZ has received consulting payments from FirstThen Inc for work unrelated to this paper. The other authors declare no conflict of interest.

Multimedia Appendix 1
An example of the query and timeline information using the hashtag #teenagecancer.
[DOCX File , 100 KB - cancer_v10i1e52061_app1.docx]

Multimedia Appendix 2
Data visualization of code applications in a word cloud using DeDoose software.
[PNG File , 244 KB - cancer_v10i1e52061_app2.png]

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Abbreviations

DHHS: Department of Health and Human Services

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Original Paper

Influence of Breast Cancer Awareness Month on Public Interest of Breast Cancer in High-Income Countries Between 2012 and 2022: Google Trends Analysis

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Abstract

Background: Breast cancer is the most common cancer among women worldwide. High-income countries have a greater incidence and mortality rate of breast cancer than low-income countries. As a result, raising awareness about breast cancer is crucial in increasing the chances of early detection and treatment. Social media has evolved into an essential tool for Breast Cancer Awareness Month campaigns, allowing people to share their breast cancer stories and experiences while also providing a venue for education and support.

Objective: The aim of this study was to assess the level of public interest in searches linked to breast cancer among a sample of high-income nations with a sizable internet user base from 2012 to 2022. We also sought to compare the proportional search volume for breast cancer during Breast Cancer Awareness Month with that during other months of the year.

Methods: Google Trends was used to retrieve data on internet user search behaviors in the context of breast cancer from 2012 to 2022. Seven countries were evaluated in this study: Australia, Canada, Ireland, New Zealand, the United Kingdom, Saudi Arabia, and the United States, in addition to global data. Breast cancer relative search volume trends were analyzed annually, monthly, and weekly from 2012 to 2022. The annual percent change (APC) was calculated for each country and worldwide. Monthly and weekly data were used to identify potential trends.

Results: A fluctuating pattern in APC rates was observed, with a notable increase in 2018 and a significant decrease in 2020, particularly in Saudi Arabia. Monthly analysis revealed a consistent peak in search volume during October (Breast Cancer Awareness Month) each year. Weekly trends over a 20-year period indicated significant decreases in Australia, Canada, New Zealand, and the United States, while increases were noted in Ireland. Heatmap analysis further highlighted a consistent elevation in median search volume during October across all countries.

Conclusions: These findings underscore the impact of Breast Cancer Awareness Month and suggest potential influences of governmental COVID-19 pandemic control measures in 2020 on internet search behavior.

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KEYWORDS

Google Trends; breast cancer; pandemic; awareness; public interest; cancer; cancer awareness; women; mortality rate; detection; treatment; social media; tool; education; support; internet users

Introduction

Breast cancer is the most common cancer among women globally, accounting for 25% of all cancer cases with an estimated 2.3 million new cases diagnosed each year [1]. In Saudi Arabia alone, there was a 5-fold increase in breast cancer incidence over 17 years [2]. Breast cancer is also the most common cancer type in the United States, with over 280,000 new cases and 43,600 deaths in 2020 [3]. The incidence of breast cancer varies among different countries and regions. High-income countries have relatively high incidence and mortality rates of breast cancer compared to low-income countries, with approximately 1 in 8 women being diagnosed with breast cancer during their lifetime [4]. A recent study on 148 countries showed that breast cancer mortality rates were lower in countries where universal health coverage for breast cancer was high [5] and the mortality rate was high in low-income countries [6]. Specifically, the number of women diagnosed with breast cancer in high-income countries is twice that in middle- and low-income countries [4]. This is partly due to better access to screening and health care, leading to earlier detection and treatment of the disease. In addition, lifestyle factors such as diet, physical activity, and alcohol consumption contribute to the incidence of breast cancer [7]. Therefore, breast cancer awareness is crucial in high-income countries given the high incidence rate, which can offer education and consequently potential for early detection and treatment [7].

A recent study in the United States showed a significant increase in public interest in breast cancer during the month of October, which is marketed as Breast Cancer Awareness Month (BCAM), from 2012 to 2021, reaching peaks in weekly relative search volume (RSV) [3]. This trend was even greater in 2020 at the beginning of the COVID-19 pandemic. Early detection of breast cancer through regular screening and self-examination can significantly improve the chances of successful treatment and survival. In particular, raising public awareness for breast cancer can decrease the breast cancer mortality rate by 20% [8]. Increased awareness of breast cancer symptoms and risk factors can also help women to identify any potential issues early on and seek appropriate medical advice [9].

BCAM is an annual campaign that takes place in October to raise awareness of breast cancer and encourage early detection and treatment. The campaign aims to educate women about the importance of self-examination, clinical examination, and mammography screening [10]. High-income countries have been at the forefront of BCAM campaigns, with various activities such as walks, runs, and fundraisers to support breast cancer research and treatment [11]. In addition, social media has become an essential tool for BCAM campaigns, allowing people to share their stories and experiences with breast cancer and providing a platform for education and support [12]. High-income countries with high rates of internet use have an advantage in using social media for breast cancer awareness campaigns, reaching a wider audience and providing more significant opportunities for engagement and participation [13]. As mentioned above, the RSV was found to be higher during BCAM, especially with respect to breast cancer donations and related events [3].

High-income countries have high rates of individuals using the internet, with an average of 89% to 95% of the population using the internet in 2021 [14]. This has implications for breast cancer awareness, education, and prevention. The internet provides access to a vast amount of information on breast cancer, including risk factors, symptoms, screening, and treatment options. In addition, social media platforms such as Facebook and Twitter provide opportunities for breast cancer awareness campaigns to reach a wider audience and engage with the public [15]. Therefore, it is essential to evaluate the public interest in breast cancer awareness using widely usable online searching websites such as Google, particularly among high-income countries with high breast cancer incidence rates [16].

Google Trends can provide valuable insights into how people are searching for and engaging with information related to breast cancer. Google Trends enables tracking and analyzing search patterns and interest in specific topics over time, providing a useful tool for researchers and health care professionals to monitor public interest and awareness [17]. This information can be used to inform targeted awareness campaigns and public health interventions, as well as to evaluate the effectiveness of existing campaigns. This type of research can also help to identify opportunities for increased awareness and education, as well as to assess the potential impact of media coverage on the public perception of breast cancer. However, there have been very few studies on the effectiveness of BCAM to improve public awareness for breast cancer [3]. Therefore, the primary aim of this study was to evaluate the public interest of breast cancer–related searches among selected high-income countries with a large number of internet users between 2012 to 2022. We further aimed to compare the breast cancer RSV during BCAM with that during other months of the year.

Methods

Sample and Data

We used the web-based tool Google Trends [18] to assess the level of interest in specific search queries. Our methodology adhered to the Google Trends Methodology Framework in Infodemiology and Infoveillance [19,20]. Notably, Google Trends does not disclose exact RSV figures; rather, it presents the relative number of searches within a defined region and time frame for a given query based on a scale from 0 to 100. A score of 100 signifies the zenith of query popularity, while 0 denotes minimal search activity [21]. Data from Google Trends were compiled between January 2012 and December 2022. The following 7 countries were assessed in this study: Australia, Canada, Ireland, New Zealand, the United Kingdom, Saudi Arabia, and the United States, in addition to worldwide data. The rationale for the selection of these countries was to gain a global perspective based on the trends occurring in high-income countries in which Google and YouTube are commonly used search engines [22]. Additionally, the high percentage of individuals using the internet in these high-income countries (90%-97% of the total population) facilitates analyzing the distinct trend line due to the large volume of internet and Google users in these countries [22].

Variables

The Google Trends tool [18] was used on November 29, 2022, to retrieve data on internet user search activities in the context of breast cancer. Saudi Arabia Google Trends indicators were retrieved from January 2012 to December 2022 onward using the search terms “breast cancer” and the Arabic translation “ ”. We used both English and Arabic languages as key term search indicators. Using weekly data, yearly average Google Trends indicators were calculated for 2012 to 2022, which were used to describe the annual trend in the data.

Ethical Considerations

We used publicly available data through Google Trends [18]. The study was approved by the Institutional Review Board of King Abdullah International Medical Research Center (SP24 J/009/03) with a waiver for informed consent as the study intended to analyze unidentified public data retrospectively. Notably, none of the queries in the Google database for this study can be associated with a particular individual. The database does not retain information about the identity, IP address, or specific physical location of any user. All research methods were performed following relevant guidelines and regulations.

Statistical Analysis

To assess the comprehensive temporal patterns of the breast cancer RSV throughout the study period, we performed analyses on an annual, monthly, and weekly basis. Initially, we calculated the annual percent change (APC) with the 95% CI to examine the characteristics of the trend in breast cancer RSV over the specific study period for each country and worldwide, spanning 2012 to 2022. Subsequently, monthly and weekly data on breast cancer RSVs were used to discern the potential trends in terms of direction and magnitude. Considering the anticipated seasonal trend and the nonnormal distribution of the data, we used the seasonal Mann-Kendall test for the trend analysis. As outlined by Hirsch et al [23], Gilbert [24], and Helsel et al [25], the seasonal Mann-Kendall test serves the purpose of examining a monotonic trend in a variable when the data collected over time are anticipated to represent consistent changes (either upward or downward) during one or more seasons, such as months. A monotonic upward trend indicates that the variable consistently increases over time, whereas a monotonic downward trend indicates a consistent decrease over time, with the trend not necessarily being linear. The identification of seasonality suggests that the data display distinct distributions during different seasons, such as months throughout the year [26-28].

The seasonal Mann-Kendall test statistic S_i is calculated as:

where n is the number of data points included in the analysis; x_i and x_j are the breast cancer monthly RSVs in the ith and jth month, respectively ($j>i$); and $sgn(x_j–x_i)$. This function takes on the value 1, 0, or –1 according to the sign of $(x_i–x_j)$ as follows:

The variance is computed as:

where g_i is the number of tied groups for the ith month and t_{ip} is the number of data points in the pth group for the jth month; n is the number of months included in the analysis. A tied group is a set of sample data having the same value. As n>10, the standard normal test statistic Z_S was computed using the following formula:

A positive value of Z_{Sk} indicates that the data tend to increase over time, whereas a negative value indicates a decreasing trend over time [23-25].

The final step was to compare the RSV during BCAM to that of other months in the year over the study period. Toward this end, we reorganized the data by month of the year to compare between-group differences in month variables. The month variables followed neither a reliably normal nor log-normal distribution; thus, the Kruskal-Wallis test and pairwise multiple-comparisons test were used to compare the distributions of breast cancer RSVs between October (BCAM) and each other month of the year. A 2-sided P value <.05 was the threshold for statistical significance. All analyses were carried out in SAS 9.4.

Results

Trends in the APC for Breast Cancer RSVs

As shown in Table 1, from 2012 to 2022, there was substantial fluctuation in the APC for breast cancer RSVs across all countries and worldwide. In 2018, there was a significant increase in the percentage change in all countries, with the highest increase in the United Kingdom (65.9%, 95% CI 63.49%-68.32%), followed by Australia (60.58%, 95% CI 57.21%-63.94%). In 2020, there was a significant downturn in APC rates of breast cancer searches in all countries, with the highest decrease found in Saudi Arabia of –35.23% (95% CI –37.93% to –32.52%).

Figure 1 displays the monthly breast cancer RSVs from 2012 to 2022, exhibiting a consistent uptrend peak wave in the month of October (BCAM) in each year of the study period for all included countries and worldwide.

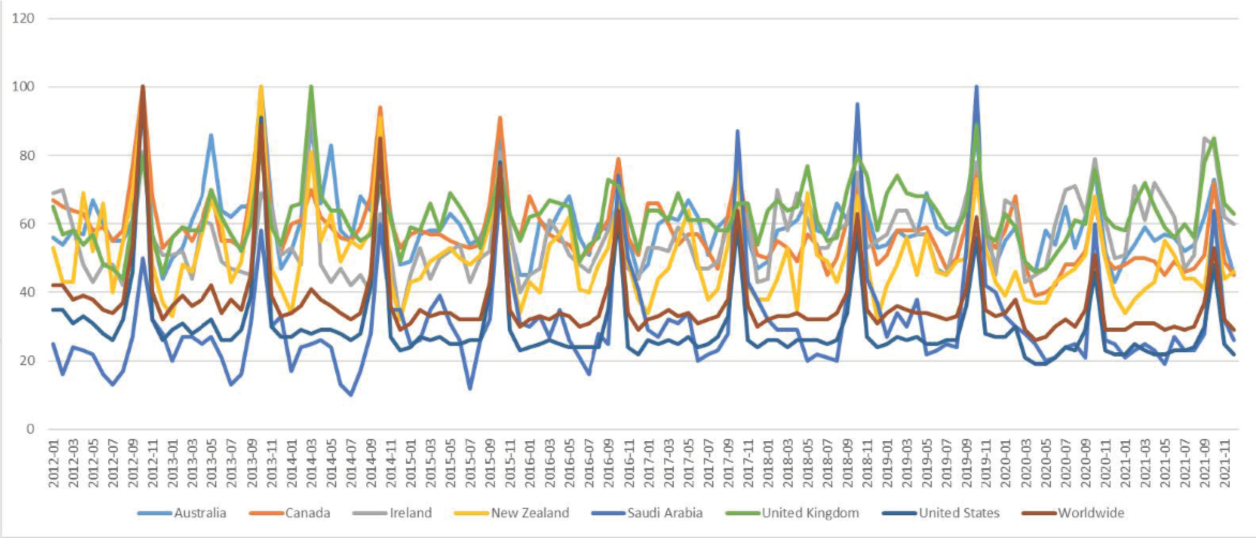
Table 1. Annual percentage change rates (95% CIs) of breast cancer relative search volume (2012 to 2022).[a]

Year	Australia	Canada	Ireland	New Zealand	Saudi Arabia	United Kingdom	United States	Worldwide
2012	30.00 (55.53 to 62.26)	6.98 (4.22 to 9.74)	19.28 (16.34 to 22.21)	16.19 (14.07 to 18.31)	1.68 (–1.02 to 4.38)	5.49 (3.07 to 7.9)	12.95 (10.84 to 15.06)	7.34 (4.72 to 9.95)
2013	8.51 (5.14 to 11.87)	–5.77 (–8.53 to –3.01)	–4.54 (–7.47 to –1.6)	–2.43 (–4.54 to –0.31)	10.68 (7.97 to 13.38)	7.43 (5.01 to 9.84)	–8.84 (–10.95 to –6.73)	–5.36 (–7.97 to –2.74)
2014	0.5 (–2.86 to 3.86)	1.84 (–0.92 to 4.6)	–4.57 (–7.5 to –1.63)	1.05 (–1.06 to 3.16)	–4.47 (–7.17 to –1.76)	6.67 (4.2 to 9.08)	–4.75 (–6.8 to –2.64)	–5.00 (–7.61 to –2.38)
2015	–12.03 (–15.39 to –8.66)	–5.27 (–8.03 to –2.51	1.75 (1.18 to 4.68)	–9.02 (11.13 to –6.9)	21.7 (18.99 to 24.41)	–4.69 (–7.1 to –2.27)	–6.13 (–8.24 to –4.02)	–7.15 (–9.76 to –4.53)
2016	–0.72 (–4.08 to 2.64)	–2.72 (–5.48 to 0.03)	–0.15 (–3.08 to 2.78)	–3.05 (–5.16 to –0.93)	1.24 (–1.46 to 3.94)	–0.4 (–2.81 to 2.01)	–10.9 (–13.01 to –8.79)	–4.92 (–7.53 to –2.3)
2017	1.13 (–2.23 to 4.49)	1.13 (–1.63 to 3.89)	3.12 (0.18 to 6.05)	–1.9 (–4.01 to 0.21)	1.94 (–0.76 to 4.64)	0.26 (–2.15 to 2.67)	2.59 (0.48 to 4.7)	0.92 (–7.53 to –2.3)
2018	60.58 (57.21 to 63.94)	54.41 (51.65 to 57.17)	59.08 (56.14 to 62.01)	48.58 (46.46 to 50.69)	34.75 (32.04 to 37.45)	65.91 (63.49 to 68.32)	29 (26.89 to 31.11)	35.91 (33.29 to 38.52)
2019	2.48 (–0.88 to 5.84)	–8.58 (–11.34 to –5.82)	9.44 (6.51 to 12.3)	0.51 (–1.61 to 2.62)	0.72 (–1.98 to 3.42)	6.07 (3.6 to 8.48)	__[b]	—
2020	–8.21 (–11.57 to –4.84)	–12.02 (–14.78 to –9.26)	2.63 (–0.3 to 5.56)	–12.40 (–14.51to –10.28)	–35.23 (–37.93 to –32.52)	–15.4 (–17.81 to –12.98)	–16.46 (–18.57 to –14.35)	–13.32 (–15.93 to –10.7)
2021	0.16 (–3.21 to 3.52)	–1.00 (–3.76 to 1.76)	6.61 (3.67–9.54)	0.35 (–1.76 to 2.46)	–1.19 (–3.89 to 1.51)	12.25 (9.83 to 14.66)	1.63 (–0.48 to 3.74)	0.25 (–2.3 to 2.86)
2022	5.23 (1.86 to 8.59)	7.26 (4.5 to 10.02)	–9.54 (–12.47 to –6.61)	6.62 (4.5 to 8.73)	20.69 (17.98 to 23.39)	–0.37 (–2.78 to 2.04)	8.91 (6.8 to 11.02)	31.76 (29.14 to 34.37)

[a] Search results were normalized to the time and location of a query by the following process: each data point was divided by the total searches of the geography and time range it represents to compare relative popularity. Otherwise, places with the highest relative search volume would always be ranked the highest. The resulting numbers were then scaled on a range of 0 to 100 based on a topic's proportion to all searches on all topics.

[b] No changes.

Figure 1. Monthly trends in breast cancer relative search volume.



Weekly Breast Cancer RSV From 2012 to 2022

Table 2 and Figure 2 illustrate the long-term weekly trend over 20 years. Using the Mann-Kendall trend test, 4 countries (Australia, Canada, New Zealand, and the United States) showed a statistically significant decrease in the weekly breast cancer RSV. The highest decrease was in Canada. By contrast, 2 countries showed a statistically significant increase in weekly breast cancer RSV, with the highest increase found in Ireland.

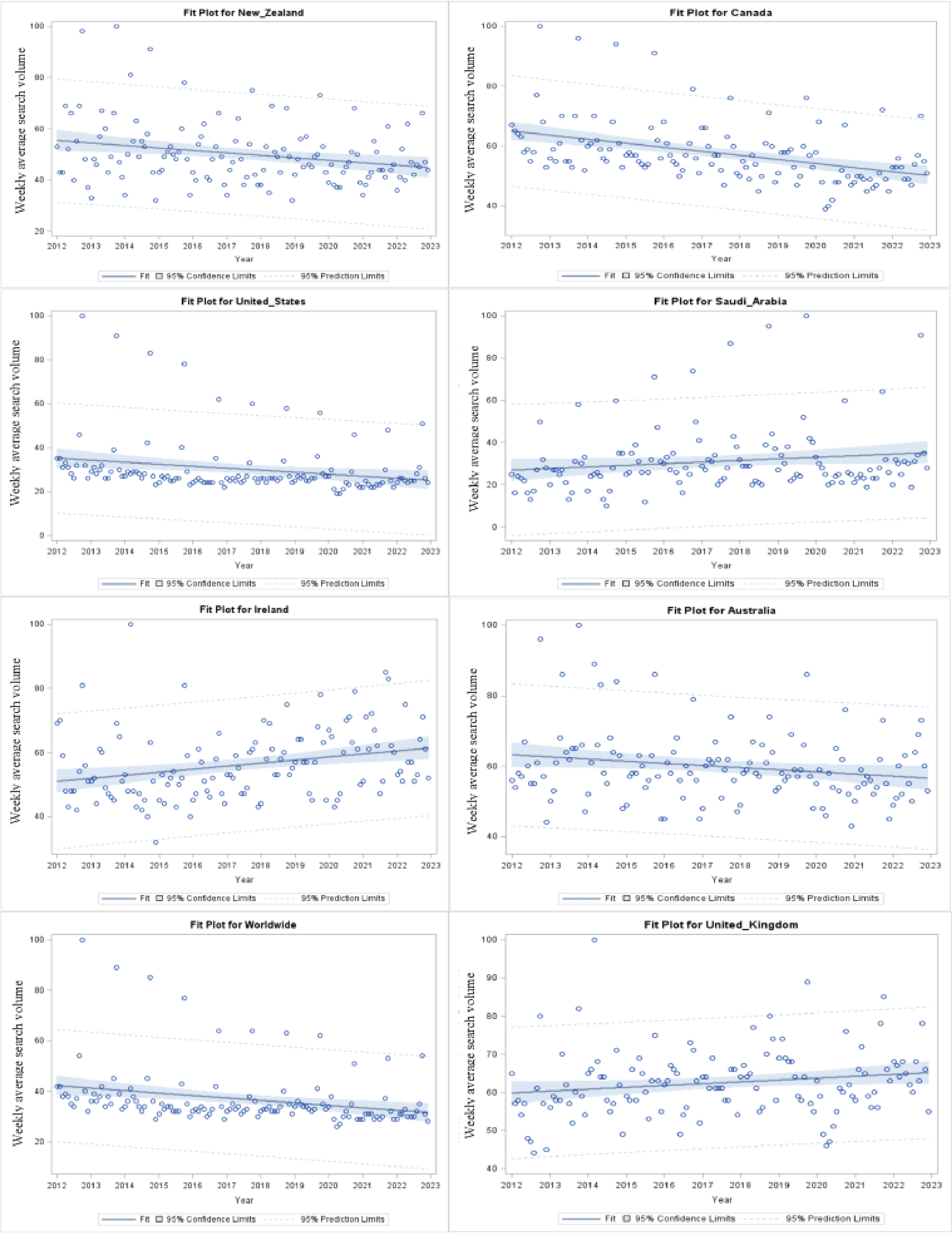
Table 2. Mann-Kendall trend analysis for weekly breast cancer relative search volume from 2012 to 2022.

Country	S[a] (95% CI)	Mann-Kendall time trend[b]	*P* value
Australia	–0.18 (–0.34 to –0.018)	Decrease	.05
Canada	–0.42 (–0.55 to –0.27)	Decrease	<.001
Ireland	0.27 (0.11 to 0.42)	Increase	<.001
New Zealand	–0.24 (0.11 to 0.42)	Decrease	.004
Saudi Arabia	0.15 –-0.01 to 0.31)	Increase	.07
United Kingdom	0.17 (0.006 to 0.33)	Increase	.01
United States	–0.22 (–0.38 to –0.05)	Decrease	<.001
Worldwide	–0.27 (–0.42 to –0.11)	Decrease	<.001

[a] Seasonal Mann-Kendall coefficient.

[b] The Mann-Kendall trend test was applied to determine the magnitude and significance of the time trends. The estimated slope indicates the number of weekly new searches during the study period.

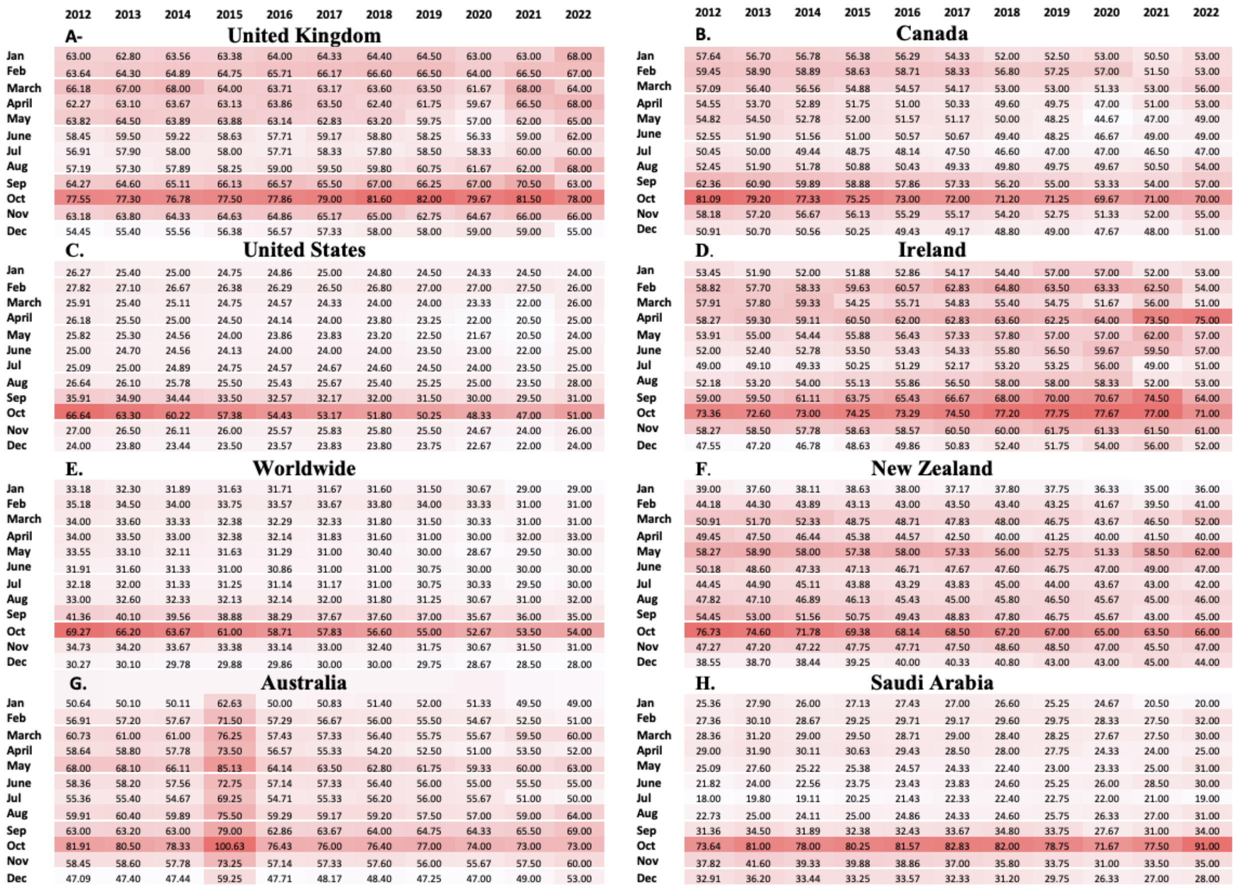
Figure 2. Weekly breast cancer relative search volume from 2012 to 2022. The estimated slope indicates the direction of the number of weekly new searches during the study period. The statistical significance of the magnitude and time trends calculated by the Mann-Kendall trend test are as follows: (A) *P*=.004, (B) *P*<.001, (C) *P*<.001, (D) *P*=.07, (E) *P*<.001, (F) *P*=.05, (G) *P*<.001, (H) *P*=.01.



Comparison of the Breast Cancer Median RSV Between Months

As illustrated in the heatmaps in Figure 3, there was a clear and consistent elevation in the median breast cancer RSV during the month of October every year across all included countries. The Kruskal-Wallis test, accompanied by pairwise multiple comparisons, confirmed that October exhibited a significantly higher median compared to every other month throughout the year.

Figure 3. Heatmaps for median breast cancer relative search volume from 2012 to 2022 by month. The statistical significance in the trends for each country was confirmed at *P*<.001, as determined by a Kruskal-Wallis test with pairwise multiple comparisons between October and all other months. A darker color in the heatmap indicates a larger median value.



A- United Kingdom

	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Jan	63.00	62.80	63.56	63.38	64.00	64.33	64.40	64.50	63.00	63.00	68.00
Feb	63.64	64.30	64.89	64.75	65.71	66.17	66.60	66.50	64.00	66.50	67.00
March	66.18	67.00	68.00	64.00	63.71	63.17	63.60	63.50	61.67	68.00	64.00
April	62.27	63.10	63.67	63.13	63.86	63.50	62.40	61.75	59.67	66.50	68.00
May	63.82	64.50	63.89	63.88	63.14	62.83	63.20	59.75	57.00	62.00	65.00
June	58.45	59.50	59.22	58.63	57.71	59.17	58.80	58.25	56.33	59.00	62.00
Jul	56.91	57.90	58.00	58.00	57.71	58.33	57.80	58.50	58.33	60.00	60.00
Aug	57.19	57.30	57.89	58.25	59.00	59.50	59.80	60.75	61.67	62.00	68.00
Sep	64.27	64.60	65.11	66.13	66.57	65.50	67.00	66.25	67.00	70.50	63.00
Oct	77.55	77.30	76.78	77.50	77.86	79.00	81.60	82.00	79.67	81.50	78.00
Nov	63.18	63.80	64.33	64.63	64.86	65.17	65.00	62.75	64.67	66.00	66.00
Dec	54.45	55.40	55.56	56.38	56.57	57.33	58.00	58.00	59.00	59.00	55.00

B. Canada

	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Jan	57.64	56.70	56.78	56.38	56.29	54.33	52.00	52.50	53.00	50.50	53.00
Feb	59.45	58.90	58.89	58.63	58.71	58.33	56.80	57.25	57.00	51.50	53.00
March	57.09	56.40	56.56	54.88	54.57	54.17	53.00	53.00	51.33	53.00	56.00
April	54.55	53.70	52.89	51.75	51.00	50.33	49.60	49.75	47.00	51.00	53.00
May	54.82	54.50	52.78	52.00	51.57	51.17	50.00	48.25	44.67	47.00	49.00
June	52.55	51.90	51.56	51.00	50.57	50.67	49.40	48.25	46.67	49.00	49.00
Jul	50.45	50.00	49.44	48.75	48.14	47.50	46.60	47.00	47.00	46.50	47.00
Aug	52.45	51.90	51.78	50.88	50.43	49.33	49.80	49.75	49.67	50.50	54.00
Sep	62.36	60.90	59.89	58.88	57.86	57.33	56.20	55.00	53.33	54.00	57.00
Oct	81.09	79.20	77.33	75.25	73.00	72.00	71.20	71.25	69.67	71.00	70.00
Nov	58.18	57.20	56.67	56.13	55.29	55.17	54.20	52.75	51.33	52.00	55.00
Dec	50.91	50.70	50.56	50.25	49.43	49.17	48.80	49.00	47.67	48.00	51.00

C. United States

	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Jan	26.27	25.40	25.00	24.75	24.86	25.00	24.80	24.50	24.33	24.50	24.00
Feb	27.82	27.10	26.67	26.38	26.29	26.50	26.80	27.00	27.00	27.50	26.00
March	25.91	25.40	25.11	24.75	24.57	24.33	24.00	24.00	23.33	22.00	26.00
April	26.18	25.50	25.00	24.50	24.14	24.00	23.80	23.25	22.00	20.50	25.00
May	25.82	25.30	24.56	24.00	23.86	23.83	23.20	22.50	21.67	20.50	24.00
June	25.00	24.70	24.56	24.13	24.00	24.00	24.00	23.50	23.00	22.00	25.00
Jul	25.09	25.00	24.89	24.75	24.57	24.67	24.60	24.50	24.00	23.50	25.00
Aug	26.64	26.10	25.78	25.50	25.43	25.67	25.40	25.25	25.00	23.50	28.00
Sep	35.91	34.90	34.44	33.50	32.57	32.17	32.00	31.50	30.00	29.50	31.00
Oct	66.64	63.30	60.22	57.38	54.43	53.17	51.80	50.25	48.33	47.00	51.00
Nov	27.00	26.50	26.11	26.00	25.57	25.83	25.80	25.50	24.67	24.00	26.00
Dec	24.00	23.80	23.44	23.50	23.57	23.83	23.80	23.75	22.67	22.00	24.00

D. Ireland

	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Jan	53.45	51.90	52.00	51.88	52.86	54.17	54.40	57.00	57.00	52.00	53.00
Feb	58.82	57.70	58.33	59.63	60.57	62.83	64.80	63.50	63.33	62.50	54.00
March	57.91	57.80	59.33	54.25	55.71	54.83	55.40	54.75	51.67	56.00	51.00
April	58.27	59.30	59.11	60.50	62.00	62.83	63.60	62.25	64.00	73.50	75.00
May	53.91	55.00	54.44	55.88	56.43	57.33	57.80	57.00	57.00	62.00	57.00
June	52.00	52.40	52.78	53.50	53.43	54.33	55.80	56.50	59.67	59.50	57.00
Jul	49.00	49.10	49.33	50.25	51.29	52.17	53.20	53.25	56.00	49.00	51.00
Aug	52.18	53.20	54.00	55.13	55.86	56.50	58.00	58.00	58.33	52.00	53.00
Sep	59.00	59.50	61.11	63.75	65.43	66.67	68.00	70.00	70.67	74.50	64.00
Oct	73.36	72.60	73.00	74.25	73.29	74.50	77.20	77.75	77.67	77.00	71.00
Nov	58.27	58.50	57.78	58.63	58.57	60.50	60.00	61.75	61.33	61.50	61.00
Dec	47.55	47.20	46.78	48.63	49.86	50.83	52.40	51.75	54.00	56.00	52.00

E. Worldwide

	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Jan	33.18	32.30	31.89	31.63	31.71	31.67	31.60	31.50	30.67	29.00	29.00
Feb	35.18	34.50	34.00	33.75	33.57	33.67	33.80	34.00	33.33	31.00	31.00
March	34.00	33.60	33.33	32.38	32.29	32.33	31.80	31.50	30.33	31.00	31.00
April	34.00	33.50	33.00	32.38	32.14	31.83	31.60	31.00	30.00	32.00	33.00
May	33.55	33.10	32.11	31.63	31.29	31.00	30.40	30.00	28.67	29.50	30.00
June	31.91	31.60	31.33	31.00	30.86	31.00	31.00	30.75	30.00	30.00	30.00
Jul	32.18	32.00	31.33	31.25	31.14	31.17	31.00	30.75	30.33	29.50	30.00
Aug	33.00	32.60	32.33	32.13	32.14	32.00	31.80	31.25	30.67	31.00	32.00
Sep	41.36	40.10	39.56	38.88	38.29	37.67	37.60	37.00	35.67	36.00	35.00
Oct	69.27	66.20	63.67	61.00	58.71	57.83	56.60	55.00	52.67	53.50	54.00
Nov	34.73	34.20	33.67	33.38	33.14	33.00	32.40	31.75	30.67	31.50	31.00
Dec	30.27	30.10	29.78	29.88	29.86	30.00	30.00	29.75	28.67	28.50	28.00

F. New Zealand

	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Jan	39.00	37.60	38.11	38.63	38.00	37.17	37.80	37.75	36.33	35.00	36.00
Feb	44.18	44.30	43.89	43.13	43.00	43.50	43.40	43.25	41.67	39.50	41.00
March	50.91	51.70	52.33	48.75	48.71	47.83	48.00	46.75	43.67	46.50	52.00
April	49.45	47.50	46.44	45.38	44.57	42.50	40.00	41.25	40.00	41.50	40.00
May	58.27	58.90	58.00	57.38	58.00	57.33	56.00	52.75	51.33	58.50	62.00
June	50.18	48.60	47.33	47.13	46.71	47.67	47.60	46.75	47.00	49.00	47.00
Jul	44.45	44.90	45.11	43.88	43.29	43.83	45.00	44.00	43.67	43.00	42.00
Aug	47.82	47.10	46.89	46.13	45.43	45.00	45.80	46.50	45.67	45.00	46.00
Sep	54.45	53.00	51.56	50.75	49.43	48.83	47.80	46.75	45.67	43.00	45.00
Oct	76.73	74.60	71.78	69.38	68.14	68.50	67.20	67.00	65.00	63.50	66.00
Nov	47.27	47.20	47.22	47.75	47.71	47.50	48.60	48.50	47.00	45.50	47.00
Dec	38.55	38.70	38.44	39.25	40.00	40.33	40.80	43.00	43.00	45.00	44.00

G. Australia

	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Jan	50.64	50.10	50.11	62.63	50.00	50.83	51.40	52.00	51.33	49.50	49.00
Feb	56.91	57.20	57.67	71.50	57.29	56.67	56.00	55.50	54.67	52.50	51.00
March	60.73	61.00	61.00	76.25	57.43	57.33	56.40	55.75	55.67	59.50	60.00
April	58.64	58.80	57.78	73.50	56.57	55.33	54.20	52.50	51.00	53.50	52.00
May	68.00	68.10	66.11	85.13	64.14	63.50	62.80	61.75	59.33	60.00	63.00
June	58.36	58.20	57.56	72.75	57.14	57.33	56.40	56.00	55.00	55.50	55.00
Jul	55.36	55.40	54.67	69.25	54.71	55.33	56.20	56.00	55.67	51.00	50.00
Aug	59.91	60.40	59.89	75.50	59.29	59.17	59.20	57.50	57.00	59.00	64.00
Sep	63.00	63.20	63.00	79.00	62.86	63.67	64.00	64.75	64.33	65.50	69.00
Oct	81.91	80.50	78.33	100.63	76.43	76.00	76.40	77.00	74.00	73.00	73.00
Nov	58.45	58.60	57.78	73.25	57.14	57.33	57.60	56.00	55.67	57.50	60.00
Dec	47.09	47.40	47.44	59.25	47.71	48.17	48.40	47.25	47.00	49.00	53.00

H. Saudi Arabia

	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Jan	25.36	27.90	26.00	27.13	27.43	27.00	26.60	25.25	24.67	20.50	20.00
Feb	27.36	30.10	28.67	29.25	29.71	29.17	29.60	29.75	28.33	27.50	32.00
March	28.36	31.20	29.00	29.50	28.71	29.00	28.40	28.25	27.67	27.50	30.00
April	29.00	31.90	30.11	30.63	29.43	28.50	28.00	27.75	24.33	24.00	25.00
May	25.09	27.60	25.22	25.38	24.57	24.33	22.40	23.00	23.33	25.00	31.00
June	21.82	24.00	22.56	23.75	23.43	23.83	24.60	25.25	26.00	28.50	30.00
Jul	18.00	19.80	19.11	20.25	21.43	22.33	22.40	22.75	22.00	21.00	19.00
Aug	22.73	25.00	24.11	25.00	24.86	24.33	24.60	25.75	26.33	27.00	31.00
Sep	31.36	34.50	31.89	32.38	32.43	33.67	34.80	33.75	27.67	31.00	34.00
Oct	73.64	81.00	78.00	80.25	81.57	82.83	82.00	78.75	71.67	77.50	91.00
Nov	37.82	41.60	39.33	39.88	38.86	37.00	35.80	33.75	31.00	33.50	35.00
Dec	32.91	36.20	33.44	33.25	33.57	32.33	31.20	29.75	26.33	27.00	28.00

Discussion

Principal Findings

This study demonstrated that the APCs in the breast cancer RSV on Google from 2012 to 2022 exhibited substantial fluctuations across all selected countries, with a significant drop in 2020, particularly in Saudi Arabia. Despite these changes, a constant upward peak wave in breast cancer relative searches was observed in October.

The significant fluctuations in APCs internationally and across each selected country were possibly affected by substantial global events such as the COVID-19 pandemic, which may have shifted user preferences [29]. The drop in 2020, particularly in Saudi Arabia, can be assigned to the various policy steps implemented by governments to combat the pandemic; Saudi Arabia's rigorous policies likely deflected public interest away from breast cancer searches [30].

Internet searches for health-related topics have proven to be a very effective approach to spread knowledge of all health issues, particularly breast cancer [31].

Using Google Trends allows us to better understand the impact of BCAM on RSV, especially the trends in infoveillance, a branch of infodemiology based on observations of information-seeking behavior [32]. This will provide insight for the better management of BCAM. Previous Google Trends research demonstrated an increase in public interest and engagement in breast, colon, and oral cancer awareness campaigns, as seen by the evolving search volumes [32-34]. However, past studies have shown that BCAM regularly boosts the breast cancer RSV when compared to cancer awareness efforts for men's cancers such as prostate cancer and testicular cancer [33,35]. In general, compared to men, women tend to seek more health-related information using electronically available tools [36-40].

Breast cancer is the most common cancer in women worldwide, including both high- and low-income countries [41]. However, based on an infographic published by the World Health Organization in 2019, breast cancer was shown to be twice as frequently diagnosed in women in high-income countries than in low- and middle-income countries [42]. Consistently, Coccia [43] demonstrated that wealthier countries have a higher incidence of breast cancer, which could be due to more efficient mammography screening [44,45]. Previous studies indicate that a lack of availability and accessibility to mammography services may account for a portion of cases going undetected, which would explain the lower incidence of breast cancer reported in some less-developed nations [45-47]. Screening and early diagnosis of breast cancer have proven to be efficient means to initiate appropriate treatment and achieve a cure for patients with cancer [48]. Therefore, we used Google Trends to track the number of searches for breast cancer in 7 high-income nations and globally between 2012 and 2022. We anticipated that the breast cancer–related RSV would be more common in high-income countries owing to the higher literacy and internet availability. Another reason could be the large public events and celebrities commissioned to increase awareness [35]. Funds allocated for BCAM marketing and the use of the pink ribbon campaign impacts the public interest in breast cancer [3]. For instance, the United States has seen higher rates of breast cancer during BCAM [45], indicating the significant impact these events have on promoting awareness, early detection, and prevention of advanced-stage disease.

The analysis of the long-term weekly trend in the breast cancer RSV from 2012 to 2022 reveals fascinating insights regarding search behaviors across countries. We discovered significant variances in search volume patterns among the studied countries. Specifically, a significant decrease in Australia, Canada, New Zealand, and the United States and a significant increase in Ireland and the United Kingdom over the 20-year period warrants further investigation into potential contributing factors such as changes in public awareness, access to health care, impact of landmark academic publications, or shifts in search engine algorithms [49,50]. Kastora et al [51] argued that analyzing geotemporal oscillations in Twitter and Google Trends for breast cancer hashtags might provide early insights into information diffusion and user involvement. These findings highlight the dynamic nature of breast cancer–related internet search activity, as well as the need for monitoring and interpreting patterns over time. More study is needed to determine the underlying causes of these observed changes and their possible implications for public health initiatives and awareness efforts. Furthermore, comparative analyses across geographies and socioeconomic circumstances may offer useful insights into the worldwide landscape of breast cancer awareness and information-seeking behaviors.

A previous study demonstrated that BCAM stimulated online searches for breast cancer [33]. Our results also confirm the importance and effectiveness of BCAM campaigns in October, as we found a correlation between the breast cancer RSV and BCAM across high-income countries and globally based on the striking seasonal increased tendency during the month of October. This implies that the awareness initiatives during this month consistently generate interest and engagement worldwide. This finding also emphasizes the importance of infoveillance to evaluate the outcome of health campaigns in general and for breast cancer in particular.

Moreover, our study revealed that over the last 10 years, the volume of searches for breast cancer varied among high-income nations that have universal health care coverage, with a significant and descending trend in the number of weekly breast cancer–related searches in Australia, Canada, New Zealand, the United States, and globally. By contrast, Ireland and the United Kingdom showed a significantly increased search volume. Despite the positive impact of BCAM in spreading awareness for breast cancer, other factors are playing a role in wealthier nations to contribute to a high breast cancer incidence, such as delayed childbearing age, obesity, smoking, hormone replacement therapy, and a higher rate of screening [44,52-54].

Limitations

This study has several limitations that warrant consideration. First, as an ecological study, there is a risk of ecological fallacy, where trends in the specific regions we targeted might not have represented true subnational or other national trends. Second, the absence of demographic and other potential confounding factors in our analysis leaves room for the possibility of confounding bias. These unaccounted variables could influence public interest and their corresponding Google search behavior, potentially affecting the study outcomes. Third, it is acknowledged that the population seeking health information on breast cancer online may differ from the offline population. For example, not everyone searching for information on breast cancer may be connected online or use search engines, and the number of individuals connected to the internet has fluctuated over the study period (2012-2022). Therefore, this study does not precisely map the online behavior of all individuals searching for breast cancer information in the selected countries.

Conclusion

In conclusion, the variations in the APC in the breast cancer RSV can largely be attributed to major global events such as the COVID-19 pandemic, which have the potential to shift user interest. The decrease in the APC in 2020 may be associated with variances in governmental policy measures aimed at controlling the pandemic. The uncertainty surrounding the pandemic and its impact on businesses and consumer behavior could have also contributed to the decrease in the APC. The consistent and significant peak in the breast cancer RSV during October across all countries and globally throughout the study period suggests a notable impact of BCAM on the level of public interest, as reflected by the RSV of Google Trends users. We advocate increasing the number of BCAM initiatives and spreading them throughout the year and in multiple countries to generate more awareness and reach a larger population in the countries with a downward trend. Increasing the funding toward marketing for breast cancer education will improve public awareness. This will in turn improve the screening rate and help more people eradicate the disease in its early stages.

Acknowledgments

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Data Availability

The data sets generated during and/or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

MR and RA conceptualized the study. DA and MR were responsible for the methodology and software. RA, MR, and SA contributed to data curation. MR and MA wrote the original draft of the manuscript. MR and RA performed the visualization and investigation. MR and AS supervised the study. MR, RA, TA, and SA were responsible for software and validation. MR, RA, and SA reviewed and edited the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

APC: annual percent change
BCAM: Breast Cancer Awareness Month
RSV: relative search volume

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Original Paper

Health Information Seeking on the Internet Among Patients With and Without Cancer in a Region Affected by the 2011 Fukushima Triple Disaster: Cross-Sectional Study

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Abstract

Background: Health information seeking via the internet among patients with cancer in disaster-affected areas is underresearched.

Objective: This study aims not only to assess the extent and means of web-based health information seeking among patients with cancer living in the disaster-affected area of the 2011 Fukushima triple disaster but also to compare these patterns with those without cancer, identifying distinct and shared factors influencing their web-based health information behaviors.

Methods: We surveyed 404 patients (263 with and 141 without cancer) from the surgery department outpatient office at Minamisoma Municipal General Hospital, from October 2016 to January 2017. The survey included self-administered questions on internet and digital device use. Descriptive analyses were performed to examine the use patterns of digital devices and the internet and their impact on health information seeking across different age groups of patients with and without cancer. Multivariable logistic regression was used to examine factors associated with web-based health information seeking, stratifying by cancer diagnosis.

Results: The proportion of participants who sought health information on the internet was comparable between patients with cancer and patients without cancer (19% vs 17.4%; *P*=.71). Digital device use varied significantly with age, with peak smartphone use occurring among the youngest cohorts for both groups. Multivariable logistic regression revealed that patients with cancer using smartphones or tablets daily were significantly more likely to gather web-based health information (odds ratio [OR] for smartphones 3.73, 95% CI 1.58-8.80; OR for tablets 5.08, 95% CI 1.27-20.35). Trust in institutional websites also significantly influenced web-based health information gathering among patients with cancer (OR 2.87, 95% CI 1.13-7.25). Conversely, among patients without cancer, unemployment was associated with a lower likelihood of seeking web-based health information (OR 0.26, 95% CI 0.08-0.85), whereas trust in both institutional and personal websites significantly increased this likelihood (OR for institutional websites 6.76, 95% CI 2.19-20.88; OR for personal websites 6.97, 95% CI 1.49-32.58).

Conclusions: This study reveals that a small proportion of both patients with cancer and patients without cancer engage in health information seeking via the internet, influenced by age, digital device use, and trust in institutional websites. Given the growing prevalence of digital literacy, strategies to enhance accessible and reliable web-based health information should be developed, particularly for patients with cancer in postdisaster settings. Future efforts should focus on tailored health communication strategies that address the unique needs of these populations.

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KEYWORDS

health information; patients with cancer; disaster; Japan; internet; patient with cancer; cancer; internet health; mobile phone

Introduction

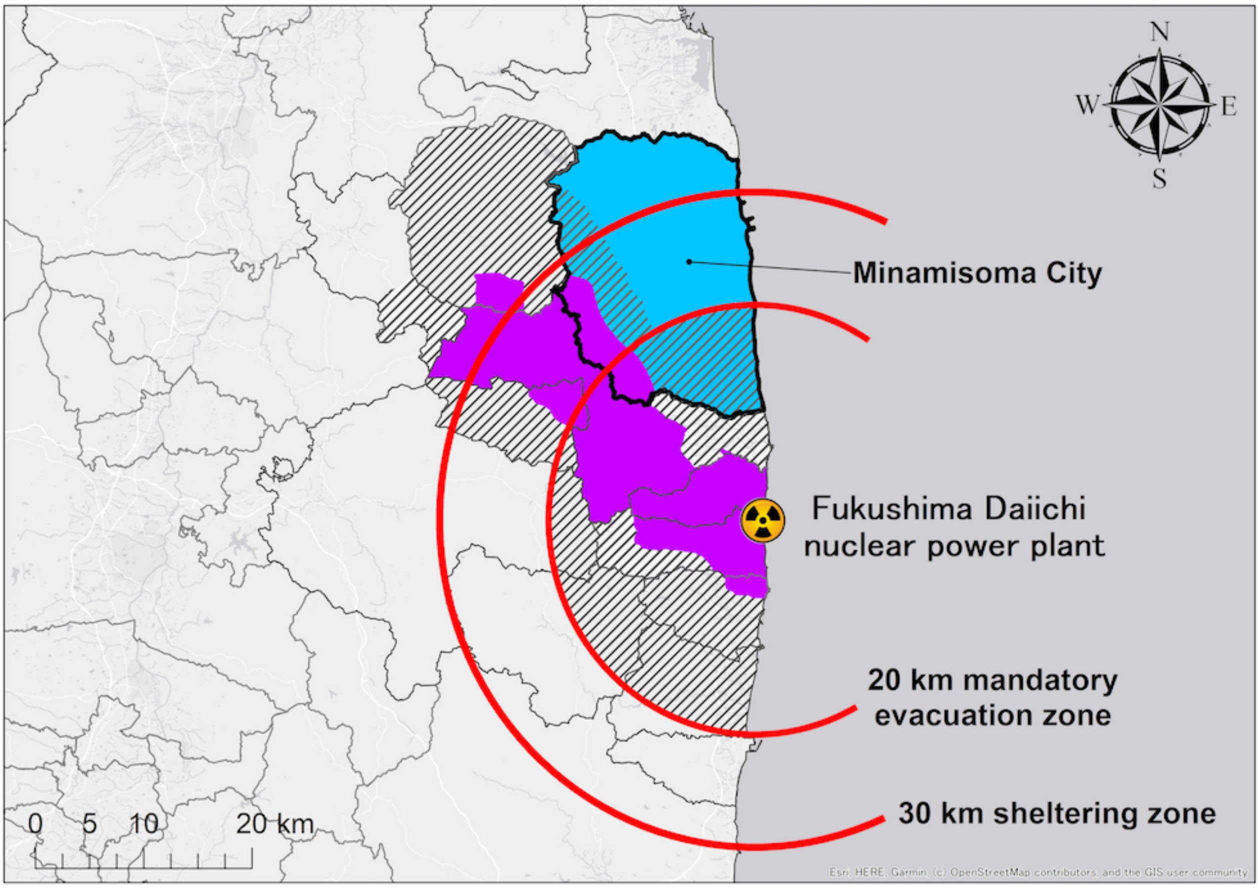
Individuals diagnosed with cancer require a wealth of health information to effectively manage their daily lives and the course of their treatment [1]. Seeking such information has been shown to yield a magnitude of beneficial health effects within this patient group [2,3]. Nonmedical information sources, especially those available via the internet, have become increasingly significant to these individuals in recent years [4]. In the United States, there has been a notable rise in patients with cancer seeking web-based health information, with the percentage increasing from 10% in 2005 to 62% in 2018 [5,6]. However, the frequency of internet use among this patient group varies widely based on several sociodemographic factors including age, gender, educational level, and socioeconomic status [4,7-9].

Not only do individual characteristics impact the extent of health information seeking via the internet but external circumstances also play a vital role [10]. Crises and disasters serve as a particularly relevant context to explore this phenomenon due to the expansive range and magnitude of health information needs they instigate among patients with cancer, as evidenced during events such as the 2011 Japan triple disaster and the recent COVID-19 pandemic [11-15]. Furthermore, there is emerging evidence indicating the internet's efficacy and growing popularity as a medium for transmitting health information to patients with cancer [16,17]. In summary, the internet is a highly convenient and useful tool to access health information among patients with cancer. Medical institution staff often face overwhelming responses from the sick and injured, making the internet a valuable resource. However, the accuracy and reliability of web-based health information have been subject to debate, especially in the acute phase [10,16,18]. It is worth noting that there is a lack of empirical studies investigating health information seeking specifically through the internet for patients with cancer, especially in non–COVID-19 contexts [19].

In this sense, the 2011 Japan triple disaster provides an unprecedented case study for examining the use of internet-based health information in disaster settings. On March 11, 2011, a significant earthquake triggered a tsunami, which in turn precipitated a nuclear accident at the Fukushima Daiichi nuclear power plant (FDNPP; Figure 1 [20]). The ensuing fallout significantly impacted the nearby city of Minamisoma, situated between 14 and 38 km north of the FDNPP [21]. In the aftermath of the accident, sections of Minamisoma City were designed as mandatory evacuation and sheltering zones by the central government. This order, the first issued on March 12, 2011, and later revised [22], precipitated a rapid depopulation and an acceleration in the aging of the city's population [21,23]. Irrespective of radiation exposure as a secondary consequence of the disaster, including evacuations, an increase in various secondary health issues, such as the increased prevalence of chronic diseases including diabetes and delays in hospital visits, has been observed among the residents [24].

Simultaneously, the disaster had a noticeable impact on the societal structures of Minamisoma, weakening the community and familial support systems. This change was particularly pronounced in the context of health care, where the residents found themselves increasingly isolated and underserved [14]. Notably, the triple disaster also led to a reduction in the number of medical facilities within the city [25]. In light of these circumstances, the internet has emerged as a vital lifeline for residents, particularly for those diagnosed with cancer. The accessibility and convenience of web-based health information platforms have potentially increased their relevance in this health-challenged community.

Figure 1. The geographical location of Minamisoma City and the FDNPP, with the transition of evacuation zones over time. Minamisoma City is located 14-38 km to the north of the FDNPP. Following the earthquake and subsequent tsunami on March 11, 2011, an initial hydrogen explosion occurred at reactor 1 of the nuclear power plant on March 12, 2011, and the areas within 20 and 30 km radius of the power plant were designated as mandatory evacuation and sheltering zones, respectively. The evacuation zone was expanded (in border, red) on April 22, 2011, and again at later dates, lifting orders from certain places (in border) with the progress of restoration work; however, the order remained in effect primarily in areas with severe contamination near the power plant (in red), as of June 1, 2019. Minamisoma Municipal General Hospital (triangle) is located 23 km north of the power plant, which is within the sheltering zone. Permission for the use of this image has been granted by ESRI Japan Corporation. This figure was reproduced from our previous open-access study under the CC BY-NC license [25]. FDNPP: Fukushima Daiichi nuclear power plant.



Our initial investigation not only evaluated the scope of health information exposure (HIE) among the local patients with cancer at Minamisoma Municipal General Hospital (MMGH) but also included a comparative analysis with patients without cancer to assess differences in HIE between the two groups in the aftermath of the disaster. We found that most participants were regularly exposed to health information [20]. However, our study did not specifically explore HIE facilitated through the internet. We posit that using the residual data from our previous study could provide insight into additional queries in this follow-up study. First, foundational data on the internet use for health information seeking, an active and major form of HIE, such as frequency and the devices used to gain internet access, is vital for understanding the role of the internet in health information seeking. Second, identifying factors associated with health information seeking through the internet is a crucial investigative area for elucidating the demographics accessible and those inaccessible via the internet in postdisaster settings. Our particular interest is the impact of age on digital device use and internet access in these settings, given existing reports indicating a decrease in digital device use among older individuals in nondisaster settings [26].

The primary objectives of this study were to assess the extent and distinctive characteristics of health information seeking through the internet among the patients with cancer at MMGH, located in the area affected by the 2011 Fukushima triple disaster with a particular focus on the presence or absence of cohabitants. This is because it is plausible that family members living with the patient may have learned how to use the internet and have developed the habit of gathering health information on the internet. We also examined the factors associated with health information seeking through the internet. We believe that the findings will aid health care professionals, media, and government entities in tailoring health information delivery to patients with cancer in the aftermath of disasters.

Methods

Settings and Participants

The study setting was a surgery department outpatient office at MMGH (Figure 1 [20]), which is located 23 km to the north of the FDNPP. MMGH is the central hospital of this and treats most of the patients with cancer in these areas. Details of the disaster experience, the subsequent recovery process, and the care of patients at MMGH and its surgical department can be obtained in our previously published papers [20,27].

Following a previous study [28], this study included all 404 adult patients (18 years old or older) among the total of 493 patients who visited this surgical department outpatient office and agreed to participate in the study from October 17, 2016, to January 31, 2017, with more details on the survey period and the characteristics of patients with cancer and patients without cancer are also available in our previously published paper [20]. The cohort consisted of 263 patients with cancer (median age 67 years; male 30%, n=79) and 141 patients without cancer (median age 63 years; male 46.1%, n=65) who agreed to participate in the study, providing a basis for a comparative analysis of health information seeking via the internet [20]. Individuals without consent or younger than 18 years of age were excluded from this study. As previously reported, to represent the population of 2 million people in Fukushima Prefecture with a 5% margin of error and a 95% CI, a sample size of 384 individuals is required [29]. The number of patients who participated in this study exceeded that amount. Given that the overall study project primarily sought to provide a comprehensive overview of HIE among both patients with and those without cancer in areas affected by disaster, we did not establish inclusion or exclusion criteria predicated on clinical variables among the patient with cancer cohort, encompassing disease stage or the nature of active treatments [20]. The logistic regression analysis was stratified by the presence or absence of cancer.

Survey

We created the survey items by revising previous literature in accordance with the local and postdisaster context of cancer care in Minamisoma City [28,30,31]. Patients who visited the MMGH surgical outpatient department during the study period were included in the study. The survey comprised 3 sections: the first section covered items for health information gathering, internet use, and digital device use; the second section covered items for health status and attitudes toward health care; and the third section covered items for sociodemographic and disaster-related characteristics. In this study, we primarily focused on the answers to items for internet use, digital device use, and sociodemographic and disaster-related characteristics. The detailed survey complication process and outpatient operations were both described in our previous study [20].

Variables

Primary Diagnosis and Sociodemographic Factors

When collecting the survey, participants' primary disease was extracted from their medical records and classified as cancer (eg, breast cancer or gastric cancer) or noncancer (eg, trauma and inguinal hernia). Those who were assigned as patients with cancer had already been diagnosed at the time of recruitment into this study.

Use of the Internet and Digital Devices

Frequency of internet use was assessed with the item "How often do you use the internet?" (everyday, once every few days, once per week, once per month, or never). Further, among those who used the internet at least once per month, we evaluated the purposes by which they use the internet, with the item "For what purposes do you use the internet?" The patients responded whether they used the internet for general information seeking, health information seeking, social networking services, emailing, internet banking, and other purposes, using the 2-point scale (yes or no). Similarly, we assessed the daily use of digital devices with the item "Do you use the following digital devices every day?" for cellular phones (other than smartphones), smartphones, tablet devices, and personal computers. The variables are listed in the results table.

Health Information Seeking Using the Internet

We used the items "How often do you use the internet?" (everyday, once every few days, once per week, once per month, or never) and "For what purposes do you use the internet?" to assess the health information seeking using the internet. We combined the responses to these items and created a variable addressing the participants who use the internet at least once per month for health information seeking, "Health information seeking using the internet," with a 2-point scale (yes or no).

Cohabitant Status

With regard to cohabitant status, we considered a partner, children, family members other than a partner and children, and any type of family member. Those who answered that they lived with these people before or after the earthquake were classified as "Living together with at least one family member either pre- or postdisaster."

Data Analysis

We performed 3 analyses. First, we made descriptive analyses for variables relating to the internet and digital devices both among patients with cancer and patients without cancer, namely the proportion of those who relied on each source of information, frequency of internet use, and the purposes of the internet use among the patients with cancer who seek information on the internet. Further, we evaluated a proportion of the patients who sought health information using the internet. We used the Mann-Whitney *U* test for continuous variables and the Fisher exact test or chi-square test for categorical variables, as appropriate, comparing patients with cancer and patients without cancer.

Second, to clarify whether there were any age effects on daily digital device use and health information–seeking behavior on the internet among patients with cancer, we calculated the proportion of those who were engaged in these behaviors, both patients with cancer and patients without cancer. The patients were then categorized according to their age with a 10-year age unit (49 years or younger, 50-59 years, 60-69 years, 70-79 years, and 80 years or older).

Third, to clarify the characteristics of patients with cancer who seek health information using the internet, we constructed a logistic regression model for the binary variable "Health information seeking using the internet." As covariates, we considered all sociodemographic and health-related factors, and daily use of digital devices, using the backward stepwise variable selection method (inclusion criteria *P*=.05). The primary interest of this analysis was to detect any association between the exposure to health information and cohabitant status, and covariates other than cohabitant status were also examined in an exploratory manner. The covariates with a small number of participants were regrouped as necessary. We constructed the same model for patients without cancer for comparison. We estimated the variation inflation factor for the variables used in the final model to assess multi-collinearity, using the Stata command "Collin" [32].

As we aimed to examine whether a diagnosis of cancer influences health information seeking via the internet, "Health information seeking using the internet" was set as the primary outcome, with the remaining factors being the independent variables. All analyses were performed using Stata/IC 15.0 (StataCorp LLC).

Ethical Considerations

This study received ethical approval from the MMGH ethics committee (approval 30-10) and Fukushima Medical University (approval 3064). Hospital staff trained for the study briefly explained it to patients who consented to participate and distributed the materials. They were notified that their data would be anonymized and used for academic purposes, and they were also informed that they could withdraw their consent at any time before the paper was submitted to journals. As such, participants in the original study consented to the use of their data obtained in the survey; thus, for this secondary analysis, which used the same data set as the original study, the original informed consent and Institutional Review Board approval sufficiently covered the use of anonymized data without requiring additional consent. No financial compensation was provided to participants, and the study adhered to stringent privacy and confidentiality measures to protect participant information.

Results

Table 1 shows the participants' reliance and use of the internet and digital devices. There was a significant difference in the frequency of internet use between patients with cancer and patients without cancer (*P*=.05); 39.9% (n=99) of the patients with cancer and 52.2% (n=72) of the patients without cancer used the internet at least once per month, respectively. In patients with cancer, the most popular purpose of internet use was seeking general information (n=85, 86%), followed by seeking health information (n=47, 47%) and emailing (n=33, 33%). In contrast, in patients without cancer, the most popular purpose was seeking general information (n=61, 85%), followed by the use of social networking services (n=30, 42%) and seeking health information (n=24, 33%). With regard to use of the digital devices, the proportion of patients who use smartphones on a daily basis was significantly smaller in patients with cancer than in patients without cancer (n=58, 22.1% vs n=61, 43.3%; *P*<.001). A proportion of the participants who sought health information on the internet did not differ between patients with cancer and patients without cancer (n=47, 19% vs n=24, 17.4%; *P*=.71).

Table 2 shows the proportions of the patients with daily digital device use and regular health information seeking on the internet in patients with cancer and those without cancer, with classifications of the patients by 10-year age unit. Among patients with cancer, daily cell phone use peaked at ages 70-79 years (n=39, 53%), while patients without cancer had the highest rates of use at ages 60-69 years (n=25, 66%). In addition, the percentage of tablet use peaked among patients with cancer aged 50-59 years (n=4, 9%), whereas the patients without cancer had the highest percentage of use among those aged 49 years or younger (n=6, 14%). The percentage of patients with cancer who gather health information on the internet peaked at age 49 years or younger (n=13, 46%), while among patients without cancer, the percentage of those who gather health information on the internet peaked at age 50-59 years (n=7, 33%). Personal computer use was highest among patients with cancer at age 49 years or younger (n=13, 46%), whereas it was highest among patients without cancer at age 50-59 years (n=8, 38%). The age groups with the highest percentage of each of the above devices were different for patients with cancer and patients without cancer, but for smartphone use, the highest percentage of both was 49 years old or younger (patients with cancer: n=23, 82%; patients without cancer: n=36, 86%).

Table 1. Participants' reliance and use on the internet and digital devices.

	Patients without cancer (n=141)	Patients with cancer (n=263)	*P* value
Reliance on newsletter, n (%)			.07
Yes	0 (0)	6 (2.3)	
No	141 (100)	257 (97.7)	
Reliance on personal websites, n (%)			.06
Yes	10 (7.1)	8 (3)	
No	131 (92.9)	255 (97)	
Reliance on institutional websites, n (%)			.23
Yes	25 (17.7)	35 (13.3)	
No	116 (82.3)	228 (86.7)	
Reliance on social networking services, n (%)			.37
Yes	4 (2.8)	4 (1.5)	
No	137 (97.2)	259 (98.5)	
Frequency of the internet use[a], n (%)			.05
Everyday	49 (35.5)	53 (21.4)	
Once per 2 or 3 days	12 (8.7)	24 (9.7)	
Once per week	7 (5.1)	12 (4.8)	
Once per month	4 (2.9)	10 (4)	
None	66 (47.8)	149 (60.1)	
Purposes of internet use (among those who regularly use the internet)[b], n (%)			
Seeking of general information	61 (84.7)	85 (85.9)	.84
Seeking of health information	24 (33.3)	47 (47.5)	.06
Use of social networking service	30 (41.7)	25 (25.3)	.02
Emailing	22 (30.6)	33 (33.3)	.70
Internet banking	7 (9.7)	4 (4)	.14
Other purposes	4 (5.6)	4 (4)	.64
Daily use of digital devices			
Cellular phones (other than smartphones)	57 (40.4)	116 (44.1)	.48
Smartphones	61 (43.3)	58 (22.1)	<.001
Tablet devices	11 (7.8)	13 (4.9)	.25
Personal computers	28 (19.9)	40 (15.2)	.23
Health information seeking using the internet[a]			.71
Yes	24 (17.4)	47 (19)	
No	114 (82.6)	201 (81)	

[a] Information missing for 3 patients without and 15 patients with cancer.

[b] Patients without cancer n=72, and patients with cancer n=99.

Table 2. Proportions of the patients with daily digital device use and regular health information seeking on the internet in patients with cancer and patients without cancer, with classifications of 10-year age unit.

	Cellular phone	Smartphone	Tablet device	Personal computer	Health information collection on the internet
Patients with cancer (age in years), n (%)					
49 or younger (n=28)	4 (14)	23 (82)	2 (7)	13 (46)	13 (46)
50-59 (n=45)	20 (44)	17 (38)	4 (9)	17 (38)	16 (36)
60-69 (n=79)	42 (53)	13 (16)	5 (6)	5 (6)	12 (15)
70-79 (n=73)	39 (53)	3 (4)	2 (3)	5 (7)	5 (8)
80-89 (n=38)	11 (29)	2 (5)	0 (0)	0 (0)	1 (3)
Patients without cancer, (age in years) n (%)					
49 or younger (n=42)	7 (17)	36 (86)	6 (14)	11 (26)	8 (19)
50-59 (n=21)	5 (24)	16 (76)	1 (5)	8 (38)	7 (33)
60-69 (n=38)	25 (66)	7 (18)	4 (10)	7 (18)	8 (23)
70-79 (n=18)	10 (56)	0 (0)	0 (0)	1 (6)	0 (0)
80-89 (n=22)	10 (45)	2 (9)	0 (0.0)	1 (5)	1 (5)

Table 3 shows the findings of the multivariable logistic regression analyses for health information seeking using the internet among patients with cancer and patients without cancer. With regard to family cohabitation, patients with cancer who lived together with at least one family member either pre- or postdisaster tended to seek health information using the internet though a difference was not statistically significant (odds ratio [OR] 0.33, 95% CI 0.09-1.17). However, this was not the case for patients without cancer (OR 0.47, 95% CI 0.10-2.17). With regards to other covariates, patients with cancer who used smartphones (OR 3.73, 95% CI 1.58-8.80) or tablet devices (OR 5.08, 95% CI 1.27-20.35) on a daily basis were significantly more likely to seek health information using the internet. This was also true for patients with cancer who trusted institutional websites (OR 2.87, 95% CI 1.13-7.25). Furthermore, this was also the case for patients with cancer who generally seek information (OR 6.30, 95% CI 2.44-16.29). On the other hand, among patients without cancer, those with no occupation were less likely to seek health information using the internet (OR 0.26, 95% CI 0.08-0.85). In addition, patients without cancer who trusted institutional websites (OR 6.76, 95% CI 2.19-20.88) and personal websites (OR 6.97, 95% CI 1.49-32.58) were more likely to seek health information using the internet.

Table 3. Multivariable logistic regression models for health information seeking using the internet among patients with and those without cancera.

Covariates	Patients without cancer (n=136)[b]		Patients with cancer (n=243)[c]	
	OR[d] (95% CI)	*P* value	OR (95% CI)	*P* value
Living together with at least one family members either pre- or post-disaster		.33		.09
No	Reference		Reference	
Yes	0.47 (0.10-2.17)		0.33 (0.09-1.17)	
Employment status		.03		
Employed	Reference			
Not employed	0.26 (0.08-0.85)			
Daily use of smartphones				.003
No			Reference	
Yes			3.73 (1.58-8.80)	
Daily use of tablet devices				.02
No			Reference	
Yes			5.08 (1.27-20.35)	
Reliance on institutional websites		.001		.03
No	Reference		Reference	
Yes	6.76 (2.19-20.88)		2.87 (1.13-7.25)	
Reliance on personal websites		.01		
No	Reference			
Yes	6.97 (1.49-32.58)			
General information seeking using the internet				<.001
No			Reference	
Yes			6.30 (2.44-16.29)	

[a] Only the variables which were kept in the final models for the patients with cancer and patients without cancer are presented in the table.

[b] Variation inflation factor of the variables included in the final model ranged from 1.06 to 1.10 and was judged to be sufficiently low.

[c] Variation inflation factor of the variables included in the final model ranged from 1.01 to 1.60 and was judged to be sufficiently low.

[d] OR: odds ratio.

Discussion

Principal Findings

Our study assessing both patients with cancer and patients without cancer in the area affected by the Fukushima triple disaster revealed that fewer than 20% of patients with cancer sourced health information using the internet. It should be noted that the proportion was similar among the patients without cancer, with no statistically significant difference detected. Residing with at least one family member before and after the disaster was associated with the internet use for health information seeking among patients with cancer in a clinically meaningful way, though the difference itself was not statistically significant. On the other hand, daily use of smartphones and tablet devices, reliance on newsletters and institutional websites, and general information seeking were positively associated with this behavior. Additionally, younger individuals seeking web-based health information were more reliant on internet-based sources than older individuals.

Studies conducted in the United States between 2007 and 2013 indicated that approximately 60% of patients with cancer search for web-based health information under normal circumstances, a finding that was echoed in a study carried out in Singapore from 2015 to 2016 [5,9,33]. However, in this study, we observed a notably lower percentage of patients with cancer using the internet to gather health information. Several explanations are possible for this discrepancy. First, the median age of the patients with cancer in this study was approximately 67, around 10 years older than in the previous studies. Previous studies have identified older age as a barrier to gathering web-based health information [4,7,9]. It is possible that this is also influencing this study, however, in our multiple variable analysis, this factor did not show a statistically significant effect. This indicates that the age of the participants does not completely explain the lower internet use. Hence, it is likely that our patients are not as active in using the internet for information gathering as patients in previous studies. Second, only a small proportion of our patients with cancer used digital devices suitable for internet use, including smartphones (n=58, 22.1%), tablets (n=13, 4.9%), and personal computers (n=40, 15.2%). Given the significant association between daily digital device use and web-based health information seeking, the limited use of these devices likely contributed to the reduced internet use for health information seeking. Third, our study was conducted in a remote area. Minamisoma City was originally remote before the disaster and its remoteness was exacerbated afterward [25]. Studies have indicated that remoteness predicts less frequent internet use for health information seeking [10], suggesting that the city's environment may have affected our findings.

We also found that patients with cancer living with family members tended to seek health information on the internet. Although this association was not statistically significant, we considered this difference as clinically meaningful. Our original hypothesis was that the patients' coliving family members may have helped the patients learn how to use the internet and gain the custom of seeking health information on the internet, and thus, the obtained findings were basically consistent with what we hypothesized. This could be interpreted as patients having extra support in learning how to use the internet from their family members. However, given that there was no significant association between the presence of family members and health information seeking via internet use, the finding does not rule out the possibility that patients with cancer may have gained necessary health information directly from their cohabiting family members simultaneously. Indeed, family members are reported to be key providers of health information for patients with cancer [34], and more likely to seek web-based health-related information, which behavior can even predict family health outcomes [35].

In addition, our results suggested a correlation between patients' information-gathering habits and their use of digital devices, such as smartphones and tablets, as well as their reliance on institutional websites and newsletters. This connection likely stems from the convenience and accessibility of digital devices. With a smartphone or tablet, information is readily available at any time and place, making them crucial tools for staying informed about one's health condition. Additionally, the prevalence of these habits indicates a certain level of digital literacy among the patient population, signifying that these patients can navigate web-based resources to gather pertinent information about their condition. The reliance on newsletters and institutional websites also suggests a preference for curated, reputable, and possibly personalized sources of health-related information. The combination of these factors implies that these habits not only allow patients with cancer to stay informed but also provide them with the tools to take an active role in managing their condition.

There were strong age effects on daily digital device use and web-based health information seeking among patients with cancer. In this study, younger patients showed higher engagement in these behaviors, reflecting potentially enhanced access to digital devices and web-based health information. As such, therefore, as reported in another study [36], it is expected that health information seeking via the internet will become more common among patients with cancer in the future, regardless of whether it is during a disaster or a nondisaster situation.

These circumstances urge the relevant stakeholders, including health care professionals, policy makers, and media outlets, to establish proper strategies to deliver necessary health information on the internet including and beyond the aftermath of the 2011 Fukushima triple disaster. Especially, the delivery of information should not be a one-way process but rather requires tailoring and optimization that consider patients' unique needs, preferences, and digital device use patterns. Moreover, recognizing and implementing these measures not just in crisis situations but also under normal circumstances could serve as a vital approach to enhancing the quality of health care services.

Limitations

There are several limitations to this study. First, the study assessed data from only a single institution and focused exclusively on patients with breast cancer. This may have introduced a gender bias or cultural background influences, potentially affecting the results. Furthermore, the study was not conducted in the context of comparing conditions before and after the disaster, nor did it evaluate the types of health information that patients with cancer sought on the internet. To gain a comprehensive understanding of the information needs of patients with breast cancer, further research, including qualitative studies, is necessary. Moreover, given that this survey was conducted during 2016-2017, its results might not fully capture the impact of recent advancements in information acquisition such as social media and artificial intelligence chatbots. Although these limitations constrain the generalizability of the findings, it is important to note that the majority of patients with cancer are older people and may not be familiar with these new methods of information gathering [37-39], which is particularly relevant in the context of global aging [40]. Therefore, although the robustness of these insights may have limitations, they are deemed potentially valuable for improving strategies to provide health information in environments affected by disasters, especially in regions with advancing aging populations.

Conclusions

In this study, we assessed the prevalence and other characteristics of health information seeking among patients with cancer affected by the 2011 Fukushima triple disaster. We primarily found that only limited patients with cancer sought health information on the internet. In addition, factors, such as treatment status, use of digital devices, reliance on institutional websites and newspapers, and living with family, were identified as significant determinants influencing internet use for health information gathering among patients with cancer compared to patients without cancer. Given that both daily digital device use and health information seeking on the internet were more prevalent in the younger population, their prevalence would increase in the future. Considering these patterns and the likelihood of increased internet use for health information in the future, health care professionals, policy makers, and media outlets should think about specific strategies to deliver necessary health information to patients with cancer in postdisaster settings. Therefore, we believe that health care professionals, policy makers, and media outlets should conceive of specific strategies to deliver necessary health information to patients with cancer in postdisaster settings. The present findings should be used to tailor the health information delivery among patients with cancer in disaster settings beyond and including the aftermath of the 2011 Fukushima triple disaster.

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Data Availability

The data sets generated during or analyzed during this study are available from the corresponding author upon reasonable request.

Authors' Contributions

YK conducted the analysis and wrote the initial manuscript. AO contributed to patient care, helped conceive and design the study, and managed data collection, cleaning, and analysis. MM contributed to the conception and design of the study. TS contributed to patient care and the study’s conception and design and managed data collection. SN, DB, and HS each contributed to the conception and design of the study. M Tsubokura contributed to the study’s conception and design and provided financial support. KY and YN similarly contributed to the conception and design of the study. M Tsukada and HO contributed to patient care, helped in the conception and design of the study, and managed data collection. All authors critically revised the study and approved the final manuscript.

Conflicts of Interest

AO receives personal fees from Medial Network Systems, MNES Inc, outside the submitted work.

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Abbreviations

FDNPP: Fukushima Daiichi nuclear power plant
HIE: health information exposure
MMGH: Minamisoma Municipal General Hospital
OR: odds ratio

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Original Paper

Digital Smoking Cessation Intervention for Cancer Survivors: Analysis of Predictors and Moderators of Engagement and Outcome Alongside a Randomized Controlled Trial

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Abstract

Background: Recent studies have shown positive, though small, clinical effects of digital smoking cessation (SC) interventions for cancer survivors. However, research on associations among participant characteristics, intervention engagement, and outcomes is limited.

Objective: This study aimed to explore the predictors and moderators of engagement and outcome of MyCourse-Quit Smoking (in Dutch: “MijnKoers-Stoppen met Roken”), a digital minimally guided intervention for cancer survivors.

Methods: A secondary analysis of data from the randomized controlled trial was performed. The number of cigarettes smoked in the past 7 days at 6-month follow-up was the primary outcome measure. We analyzed interactions among participant characteristics (11 variables), intervention engagement (3 variables), and outcome using robust linear (mixed) modeling.

Results: In total, 165 participants were included in this study. Female participants accessed the intervention less often than male participants (B=–11.12; *P*=.004). A higher Alcohol Use Disorders Identification Test score at baseline was associated with a significantly higher number of logins (B=1.10; *P*<.001) and diary registrations (B=1.29; *P*<.001). A higher Fagerström Test for Nicotine Dependence score at baseline in the intervention group was associated with a significantly larger reduction in tobacco use after 6 months (B=–9.86; *P*=.002). No other associations and no moderating effects were found.

Conclusions: Overall, a limited number of associations was found between participant characteristics, engagement, and outcome, except for gender, problematic alcohol use, and nicotine dependence. Future studies are needed to shed light on how this knowledge can be used to improve the effects of digital SC programs for cancer survivors.

Trial Registration: Netherlands Trial register NTR6011/NL5434; https://onderzoekmetmensen.nl/nl/trial/22832

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KEYWORDS

smoking cessation; cancer survivors; engagement; digital intervention; eHealth; smoking; intervention; randomized controlled trial; predictor; RCT; smoking; smoker; addict; cessation; quit; cancer; oncology

Introduction

Background

In the past decade, digital interventions have commonly been used to target addictive behaviors, including smoking cessation (SC). Several systematic reviews have shown that these SC interventions can be effective, albeit with generally small effect sizes [1-4]. For example, the Cochrane review by Taylor et al [4] showed that the use of web-based SC interventions resulted in significantly higher rates of smoking abstinence compared to nonactive control groups, 6 months after randomization (risk ratio=1.15). Cancer survivors are a growing population who can benefit considerably from SC. Yet, the prevalence of people who smoke is about the same as in the general population, and research on effective digital SC interventions for cancer survivors is scarce [3]. Accordingly, not much is known about active ingredients or engagement factors of SC interventions targeting cancer survivors [5], despite engagement being an important moderator of the effect of digital SC interventions [6]. It is therefore important to look more closely into the predictors and moderators of engagement and outcome among this target group.

Although the primary effects of digital SC interventions are moderately positive on average, there is room for improvement. One possible explanation for the modest effects of digital SC interventions is the generally low adherence rates. Taylor et al [4] found that 18 out of 34 web-based SC studies had more than 50% attrition at follow-up. Analyzing whether the uptake of specific intervention components is related to better intervention outcomes increases the understanding of primary intervention effects [7]. Some studies on addictive behaviors investigated the relationship between intervention engagement and outcome [8-10]. A study by Perski et al [8] found that participants who completed more (varied) exercises had 64% higher odds of SC compared to participants who almost exclusively set an SC goal. Siemer et al [10], examining adherence to a blended SC intervention, revealed a dose-response relationship between the number of executed activities and smoking abstinence. Another study by Ramos et al [9] also found that intervention engagement, in terms of number of logins, forum visits, and number of participation badges, was a strong predictor of successful SC. Not all studies have shown that intervention engagement predicts intervention effectiveness, even contradictory effects are found. For example, Smith et al [11] showed that engagement with particular components of a digital SC intervention can be counterproductive when the content does not fit the participants’ needs.

Behavior change programs targeting SC notoriously encounter challenges when trying to reach target groups with the highest smoking rates (eg, groups with lower socioeconomic status [12] and groups with low literacy [13]). In addition, it could be useful for the improvement of intervention content and implementation to identify which characteristics predict engagement. This will help to improve the content and design of the intervention for the right target group [7,14]. Several studies have related digital SC intervention use to participant characteristics [8,15-17]. These studies showed that digital SC interventions were used longer or more frequently by older participants [8,15] and women [16]. Participants who had lower education, smoked more heavily, and had depressive symptoms were found to be less engaged with the digital SC intervention [17].

There is some evidence on the effects of digital SC interventions for cancer survivors. For example, a meta-analytic study by Mujcic et al [3] showed that digital and nondigital distance-based SC interventions for cancer survivors led to significantly reduced smoking rates compared to baseline (risk difference=0.29). However, research on the predictors and moderators of engagement and outcome of digital SC studies for cancer survivors is limited, while cancer survivors are a growing and diverse population [18]. A pilot study by Bricker et al [18] of an application on SC for cancer survivors showed greater acceptability, use, and effectiveness when compared to the national SC app for the general population.

This Study

In this study, we aim to investigate the predictors and moderators of engagement and outcome of a minimally guided digital intervention for cancer survivors called MyCourse-Quit Smoking (in Dutch “MijnKoers-Stoppen met Roken”) in a secondary analysis. The main effects study did not find a differential effect on SC between intervention and control at 6 months. In both groups, around a quarter abstained from smoking, and the number of cigarettes smoked was cut back by half [19]. With this secondary analysis, we aim to answer the following research questions: (1) Are participant characteristics related to intervention engagement at 6-month follow-up? (2) Is intervention engagement associated with tobacco use at 6-month follow-up? (3) Are participant characteristics related to tobacco use at 6-month follow-up?

Methods

Design

For this paper, an exploratory secondary data analysis was carried out using data from a randomized controlled trial on the MyCourse-Quit Smoking digital intervention. The data used for this study were collected between November 2016 and September 2019.

Ethical Considerations

Ethics approval for the trial was acquired from an accredited medical research and ethics committee in The Netherlands (Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. NL55921.101.16). Participants provided digital informed consent before inclusion in the trial [20]. Data were deidentified before processing or analysis. Identifying data were stored separately from research data. For each completed follow-up assessment, they were reimbursed €25 (approximately US $30).

Procedure

A web-based screening questionnaire on the study website determined whether people were able to participate in the study. Eligible participants received an informed consent form via mail and had 30 days to sign the form. In the meantime, participants had the possibility to contact the research team or an independent physician for more information. After signing the informed consent form, they were asked to fill out a baseline questionnaire and were allocated to either the MyCourse group or the control group. Individuals in the control group were provided access to a noninteractive web-based informational brochure regarding the hazards associated with smoking and strategies for SC. The informational content encompassed both general SC information and content tailored to the unique needs of cancer survivors. Follow-up measurements were conducted at 3, 6, and 12 months after randomization. The study was conducted completely over the web, but after continued nonresponse, participants received a reminder by telephone. A more extensive description of the randomized controlled trial study procedures can be found elsewhere [20].

Participants

For the study, 165 adults who were diagnosed with any form of cancer in the past 10 years were recruited. Other eligibility criteria included having a PC or laptop in addition to an internet connection at home, having smoked 5 or more cigarettes per day in the past 7 days, having the intention and ability to participate in the 12-month study, and having the intention to quit smoking cigarettes. People who were pregnant; had insufficient mastery of the Dutch language; or self-reported suicidal ideation, dementia, severe depression, severe alcohol dependence, or acute psychosis were not eligible to participate in the study.

MyCourse Intervention

MyCourse-Quit Smoking is a digital minimally guided intervention that provides support for SC among cancer survivors. The intervention is based on empirically evaluated therapeutic approaches for SC in the general population: cognitive behavioral therapy [21], motivational interviewing [22], and acceptance and commitment therapy [23]. The intervention can be accessed via PC, tablet, and smartphone. At first login, participants receive instructions to set up a quit plan and gain access to 13 different exercises, information about smoking, quitting, and cancer, a web-based diary to track their tobacco use, and a peer support platform [20]. Exercises focused on different topics including previous experiences, high-risk situations, self-control measures, reinforcement, relapse prevention, and acceptance and commitment therapy. For the complete structure of the intervention, see Figure 3 in the protocol paper [20]. After the first login, all parts of the intervention could be accessed, and participants were free to choose how often and which parts of the intervention they wanted to use. Participants were only advised to use the intervention daily for 4 weeks.

Measures

The primary outcome measure in this study was the number of cigarettes smoked in the past 7 days at 6-month follow-up. Intervention engagement was measured using 3 indicators: the number of logins into the MyCourse-Quit Smoking intervention, the number of self-monitoring registrations of smoking urges and smoked cigarettes, and the number of completed intervention exercises. The following participant characteristics were extracted from the participant records: gender, age, educational level (higher or lower, where the minimum for the higher educational level was an academic university or university of applied sciences degree), and living situation (alone or together). We specifically looked at the presence of lung cancer and breast cancer (yes or no) among the participants in the analyses because lung cancer has a direct relationship with smoking and breast cancer was the most common type of cancer in the sample. In addition, patients with cancer at other sites were included in the analyses. Furthermore, the number of cancer sites (1 or >1) distinguished participants who reported that they had received multiple cancer diagnoses. The severity of nicotine dependence was measured by the 6-item Fagerström Test for Nicotine Dependence (FTND) [24]. Problematic alcohol use was measured using the Alcohol Use Disorders Identification Test (AUDIT) [25], a 10-item questionnaire on alcohol consumption patterns and problems experienced due to alcohol consumption. The AUDIT score was included as a variable because research has shown that people with a high risk of problematic alcohol use have a harder time quitting smoking and may benefit from different types of SC treatment [26,27]. The EQ-5D was used to measure the quality of life [28]. Comorbid anxiety, depression, and somatic symptoms were indicated using the Brief Symptom Inventory-18 questionnaire [29].

Statistical Analysis

Imputation of Missing Data

Missing data for primary (ie, cigarettes smoked in the past 7 days) and secondary (ie, participant characteristics) outcome measures were multiple imputed (number of imputations=50) based on the intention-to-treat principle using the predictive mean matching method from the mice package in R (R Foundation for Statistical Computing) [29]. At the 6-month follow-up, the nonresponse rate (ie, participants who did not complete the 6-month questionnaire) was 27.7% (23/83) in the intervention group and 25.6% (21/82) in the control group. Data on intervention usage were not imputed. For the analyses containing engagement measures, participants who did not log in once were excluded.

Regression Analyses

Data were analyzed using R [30]. Bonferroni correction was applied in all analyses. The association between intervention engagement and participant characteristics within the intervention group was analyzed with a robust linear regression using the MASS package [31]. Whether participant characteristics and intervention engagement predicted intervention outcome within the intervention group was analyzed using robust linear mixed modeling (RLMM) with a random intercept using the robustlmm package [32]. RLMM is an effective analytical approach to account for outliers or skewed data [32]. The moderation analyses to investigate whether the study condition moderated the effect between participant characteristics and outcome were performed using RLMM with a random intercept and study condition × participant characteristics as the interaction term. This analysis is performed to assess whether the study condition (ie, being in the intervention group compared to the control group) moderates the association between participant characteristics and outcome. Model estimates, 95% CIs, and *P* values are reported. All base case analyses followed the intention-to-treat principle and used multiple imputed data sets. Sensitivity analyses were performed using observed data only.

Results

Sample Characteristics

Participant characteristics are shown in Table 1. The majority of participants were female (136/165, 82.4%), the mean age was 54.2 (SD 11.2) years, 29.1% (48/165) were living alone, and 41.2% (68/165) had completed higher education. On average, participants had smoked for 34.5 (SD 12.0) years and smoked 100 (SD 51.2) cigarettes per week. The main clinical effects of the MyCourse intervention and the results of the cost-effectiveness analysis can be found elsewhere [19].

Table 1. Baseline characteristics.

Characteristics	MyCourse (n=83)[a]	Control (n=82)	Total (N=165)[a]
Sex, n (%)			
Female	70 (84.3)	66 (80.5)	136 (82.4)
Male	13 (15.7)	16 (19.5)	29 (17.6)
Age (years), mean (SD)	55.0 (12.1)	53.3 (10.3)	54.2 (11.2)
Higher education, n (%)			
Yes	25 (30.1)	19 (23.2)	44 (26.7)
No	49 (59.0)	48 (58.5)	97 (58.8)
Living situation, n (%)			
Living alone	22 (26.5)	26 (31.7)	48 (29.1)
Living together	61 (73.5)	56 (68.3)	117 (70.9)
Smoking behavior , mean (SD)			
Years smoked	34.4 (11.8)	34.6 (12.2)	34.5 (12)
Number of cigarettes in past 7 days	101.8 (54.3)	98.2 (48.2)	100 (51.2)
FTND[b]	4.9 (2.4)	4.9 (2.3)	4.9 (2.4)
Drinking behavior			
Drank alcohol in last month, n (%)	55 (66.3)	55 (67.1)	110 (66.7)
Number of drinks in past 7 days, mean (SD)	6.9 (13.1)	5.6 (8.7)	6.2 (11.2)
AUDIT[c], mean score (SD)	3.7 (5.1)	3.6 (4.2)	3.6 (4.7)
Cancer diagnosis, [d] n (%)			
Breast	42 (42.9)	33 (34)	75 (38.5)
Lung	14 (14.3)	9 (9.3)	23 (11.8)
Uterine	7 (7.1)	12 (12.4)	19 (9.7)
Head and neck	10 (10.2)	8 (8.2)	18 (9.2)
Colon	5 (5.1)	5 (5.2)	10 (5.1)
Other (including bladder, lymphatic, melanoma, skin, kidney, prostate)	20 (20.4)	30 (30.9)	50 (25.6)
Cancer sites, n (%)			
1	69 (83.1)	68 (82.9)	137 (83)
2 or 3	14 (16.9)	14 (17.1)	28 (17)

Participant Characteristics and Intervention Engagement

Of all 83 participants of the intervention group, 56 people logged into the MyCourse portal at least once and thus were included in the analysis. When comparing the 56 people who logged in at least once with the 27 people who did not log in once at all baseline characteristics mentioned in Table 1, only the number of patients with uterine cancer differed significantly between the 2 groups (*P*<.05), with 5 patients with uterine cancer who did not log in once and 2 patients with uterine cancer that logged in at least once. In total, 82 participants in the control group were not included in the analysis. Among the 56 MyCourse users, the average number of logins was 21 (SD 41.0; median

5.5, IQR 3-18.5), the average amount of self-monitoring registrations was 31 (SD 53.9; median 5, IQR 2-22), and the average amount of completed exercises was 6.5 (SD 5.1; median 4, IQR 2-12). As shown in Table 2, female participants showed a significantly lower number of logins in the MyCourse-Quit Smoking intervention than male participants (*P*=.004). The relationship between sex and other indicators of intervention engagement was nonsignificant. Furthermore, a higher AUDIT score at baseline was associated with a significantly higher number of logins (*P*<.001) and diary registrations (*P*<.001) but not with the number of completed exercises (*P*=.05).

Table 2. The association between baseline participant characteristics and intervention engagement (N=56).

	Logins		Diary entries		Exercises	
	B (95% CI)	*P* values[a]	B (95% CI)	*P* values[a]	B (95% CI)	*P* values[a]
Age (years)	0.25 (–0.10 to 0.60)	.16	0.40 (–0.16 to 0.96)	.16	0.08 (–0.06 to 0.22)	.28
Sex						
Male (n=8)	Reference	Reference	Reference	Reference	Reference	Reference
Female (n=48)	–11.12 (–18.70 to –3.55)	*.004*[b]	–11.85 (–24.25 to 0.54)	.06	–2.24 (–6.43 to 1.94)	.29
Higher education						
No (n=40)	Reference	Reference	Reference	Reference	Reference	Reference
Yes (n=16)	3.08 (–4.10 to 10.26)	.40	4.43 (–4.71 to 13.57)	.34	1.71 (–1.24 to 4.67)	.26
Living situation						
Alone (n=11)	Reference	Reference	Reference	Reference	Reference	Reference
Together (n=45)	0.32 (–7.46 to 8.11)	.94	0.72 (–10.64 to 12.08)	.90	–0.43 (–3.90 to 3.04)	.81
FTND[c]	–0.15 (–1.51 to 1.22)	.83	–0.33 (–2.32 to 1.66)	.75	0.15 (–0.46 to 0.75)	.64
EQ-5D	–4.88 (–21.59 to 11.84)	.57	–9.43 (–33.30 to 14.44)	.44	–4.25 (–11.37 to 2.87)	.24
BSI-18[d]	–3.57 (–8.36 to 1.23)	.15	–5.07 (–11.46 to 1.32)	.12	–1.30 (–3.48 to 0.87)	.24
AUDIT[e]	1.10 (0.60 to 1.61)	*<.001*[f]	1.29 (0.62 to 1.95)	*<.001*	0.25 (0.00 to 0.50)	.05
Diagnosis of lung cancer						
No (n=47)	Reference	Reference	Reference	Reference	Reference	Reference
Yes (n=9)	–2.19 (–10.48 to 6.09)	.60	–3.01 (–15.04 to 9.02)	.62	1.30 (–2.36 to 4.96)	.49
Diagnosis of breast cancer						
No (n=25)	Reference	Reference	Reference	Reference	Reference	Reference
Yes (n=31)	3.70 (–2.59 to 9.99)	.25	5.94 (–1.87 to 13.74)	.14	1.65 (–1.07 to 4.37)	.24
Cancer sites						
1 (n=47)	Reference	Reference	Reference	Reference	Reference	Reference
2 or 3 (n=9)	–2.75 (–11.29 to 5.79)	.53	–3.88 (–17.73 to 9.98)	.58	0.64 (–3.04 to 4.31)	.73

[a] A Bonferroni correction was applied based on 11 tests resulting in an α of .0045.

[b] Female participants showed a significantly lower number of logins in the MyCourse-Quit Smoking intervention than male participants.

[c] FTND: Fagerström Test for Nicotine Dependence.

[d] BSI-18: Brief Symptom Inventory-18.

[e] AUDIT: Alcohol Use Disorders Identification Test.

[f] A higher AUDIT score at baseline was associated with a significantly higher number of logins and diary registrations but not with the number of completed exercises.

Intervention Engagement, Participant Characteristics, and Smoking Behavior

Table 3 shows the outcomes of the analysis on the association between intervention engagement and smoking behavior among the 56 participants who logged in to the MyCourse portal at least once. No significant effects were found between intervention engagement and smoking behavior. Table 3 also shows the association between several participant characteristics and smoking behavior among the 83 participants of the intervention group. The results show that a higher FTND score at baseline is associated with a significantly greater reduction of the 7-day sum of smoked cigarettes after 6 months in the intervention group (*P*=.002). None of the other participant characteristics or measures of engagement predicted smoking behavior at 6 months.

Table 3. The relationship between participant characteristics and intervention engagement with smoking behavior.

Characteristics	Effect on 7-day tobacco use at 6-month follow-up	
	B (95% CI)	*P* values[a]
Age (years) (n=83)	0.70 (–0.89 to 2.29)	.39
Sex		
Male (n=13)	Reference	Reference
Female (n=70)	–5.71 (–51.07 to 39.65)	.81
Higher education		
No (n=58)	Reference	Reference
Yes (n=25)	–2.16 (–37.12 to 32.80)	.90
Living situation		
Alone (n=22)	Reference	Reference
Together (n=61)	–1.04 (–38.13 to 36.05)	.96
FTND[b] (n=83)	–9.86 (–15.95 to –3.76)	*.002* [c]
EQ-5D (n=83)	17.28 (–64.19 to 98.74)	.68
BSI-18[d] (n=83)	1.25 (–27.43 to 29.94)	.93
AUDIT[e] (n=83)	2.38 (–0.76 to 5.53)	.14
Diagnosis of lung cancer		
No (n=69)	Reference	Reference
Yes (n=14)	19.84 (–10.95 to 50.62)	.21
Diagnosis of breast cancer		
No (n=41)	Reference	Reference
Yes (n=42)	11.77 (–32.27 to 55.81)	.60
Cancer sites		
1 (n=69)	Reference	Reference
2 or 3 (n=14)	53.77 (13.70 to 93.83)	.009
Number of logins (n=56)	–0.13 (–0.55 to 0.30)	.56
Number of diary entries (n=56)	–0.02 (–0.35 to 0.30)	.88
Number of exercises (n=56)	0.19 (–3.31 to 3.69)	.92

[a] A Bonferroni correction was applied based on 14 tests resulting in an α of .004.

[b] FTND: Fagerström Test for Nicotine Dependence.

[c] A higher FTND score at baseline is associated with a significantly greater reduction of the 7-day sum of smoked cigarettes after 6 months in the intervention group.

[d] BSI-18: Brief Symptom Inventory-18.

[e] AUDIT: Alcohol Use Disorders Identification Test.

Moderation Analysis

Table 4 reports the outcomes of the moderation analysis on the interaction effect of participant characteristics and study condition on the number of cigarettes smoked in the past 7 days among the 165 participants at 6-month follow-up. No significant effects were found in this analysis.

Table 4. Moderation analysis of study condition on the relationship between participant characteristics and smoking behavior.

Characteristic	Participant characteristic × randomized controlled trial condition 7-day tobacco use at 6-month follow-up (N=165)	
	B (95% CI)	*P* values[a]
Age (years)	1.229 (–1.06 to 3.52)	.29
Sex		
Male (n=29)	Reference	Reference
Female (n=136)	–11.7 (–73.76 to 50.36)	.71
Higher education		
No (n=121)	Reference	Reference
Yes (n=44)	–25.21 (–77.18 to 26.76)	.34
Living situation		
Alone (n=48)	Reference	Reference
Together (n=117)	7.989 (–43.59 to 59.57)	.76
FTND[b]	–3.624 (–12.20 to 4.95)	.41
EQ-5D	45.117 (–75.26 to 165.49)	.46
BSI-18[c]	–12.024 (–55.66 to 31.61)	.59
AUDIT[d]	4.155 (–1.04 to 9.35)	.12
Diagnosis of lung cancer		
No (n=142)	Reference	Reference
Yes (n=23)	42.98 (–24.59 to 110.55)	.21
Diagnosis of breast cancer		
No (n=90)	Reference	Reference
Yes (n=75)	9.25 (–36.89 to 55.39)	.69
Cancer sites		
1 (n=137)	Reference	Reference
2 or 3 (n=28)	81.71 (22.50 to 140.91)	.007

[a] A Bonferroni correction was applied based on 11 tests resulting in an α of .0045.

[b] FTND: Fagerström Test for Nicotine Dependence.

[c] BSI-18: Brief Symptom Inventory-18.

[d] AUDIT: Alcohol Use Disorders Identification Test.

Sensitivity Analysis

The association between sex and the number of logins on the nonimputed data did not reach significance after the Bonferroni correction (*P*=.006). The association between the FTND and 7-day cigarette smoking at 6-month follow-up in the nonimputed data did not reach significance after Bonferroni correction (*P*=.10). In the moderation analysis, after Bonferroni correction on the nonimputed data, the interaction effect of the number of cancer sites and study condition on smoking behavior reached significance (*P*=.002). For all other analyses, the results did not change significantly. Detailed results of the sensitivity analyses can be found in Multimedia Appendix 1.

Discussion

Principal Findings

In this study, we evaluated hypothesized predictors and moderators of intervention engagement and smoking behavior in MyCourse-Quit Smoking, a digital SC intervention for cancer survivors. With regard to the relationship between participant characteristics and intervention engagement, it was found that female participants logged on significantly less often than male participants. This effect should nevertheless be interpreted with caution since the number of male participants in the sample was low (n=8). Moreover, previous research shows that female participants are generally more engaged in digital SC interventions than male participants [16,33-37]. A significant positive association between the baseline AUDIT score and intervention engagement was found; a higher AUDIT score at baseline was related to a higher number of logins and diary registrations in the MyCourse intervention. There was no effect of the baseline AUDIT score on the number of completed exercises. Previous studies showed that participants with a higher risk of alcohol dependence had a harder time to quit smoking, and therefore needed more support from the intervention, as demonstrated in several previous studies [26,27]. Toll et al [27] showed that people who drink more heavily were less likely to quit smoking, but problematic alcohol use was not measured. Sells et al [26] pointed out that people with a high risk of problematic alcohol use may need more intensive intervention in order to quit smoking, whereas people with a high risk of problematic alcohol use were defined with an AUDIT score higher than 7. However, in this study, we did not find an effect of the AUDIT score on smoking behavior. Furthermore, participants of the MyCourse-Quit Smoking trial had generally low AUDIT scores (mean 3.6, SD 4.7), and few participants with a score higher than 7 (21/165).

Regarding the association between participant characteristics and smoking behavior, we found that participants of the MyCourse intervention who had higher nicotine dependence scores at baseline showed a greater reduction in the number of smoked cigarettes in the past 7 days at the 6-month follow-up. This negative association between nicotine dependence at baseline and tobacco use at follow-up is a reasonable finding because it is likely that less addicted participants at baseline already smoke fewer cigarettes than highly addicted participants, and therefore, a smaller reduction of cigarettes at 6 months is possible. This finding does not indicate whether heavier nicotine dependence predicts SC, as participants can greatly reduce the number of smoked cigarettes but not enough to completely quit smoking. Previous research shows that, in general, less severe nicotine dependence is associated with a higher SC rate [38,39].

The analyses on the association between intervention engagement (ie, the number of logins, self-monitoring registrations, and exercises) and the outcome did not yield any significant effects. This study showed the overall prevailing pattern of the majority of participants quitting the use of the intervention in the first few days and a smaller group that uses the intervention for a longer period [40]. However, other studies on digital SC interventions have shown a dose-response relationship between intervention engagement and outcome [9,10,41], with higher engagement predicting greater SC rates, although this is sometimes limited to certain engagement measures [34] or with low quality of the evidence due to low follow-up rates [9]. For example, Heminger et al [34] did not find a significant association between program dose and SC, but the use of specific intervention elements (eg, making a pledge toward a smoke-free life and tracking saved money and health benefits gained after quitting) was associated with SC. For future research, it is therefore important to properly define engagement, differentiate between indicators of engagement, and use empirically effective intervention techniques in order to enhance engagement [6].

The moderation analysis did not yield any significant effects. This indicates that being in the intervention group, compared to the control group, does not amplify the effect between any of the participant's characteristics and tobacco use, and hence no specific participant characteristic renders participants more or less likely to be successful when participating in the MyCourse intervention.

Limitations

The initial study was 80% powered to detect a relative risk of 2.1 in SC [20], while this explored different outcome variables, potential moderator effects herein, and made comparisons other than between treatment arms. Hence, the initial sample size calculation might not be applicable. Post hoc power analyses were omitted, as these would merely reflect the already obtained *P* value [42]. While the applied Bonferroni correction accounted for multiple comparisons, it might be overly strict in our case [43]. Furthermore, the tendency to overfit data might also be a problem for linear mixed modeling analyses. The study had missing data, which might have caused bias in the results. On the other hand, as a strength of this study, multiple imputation was applied to compensate for the missing values, and the sensitivity analysis did not reveal any substantial differences in the analyses without imputation. Another limitation is the sample size of the analyses for the first research question, especially for the subgroup analyses of sex and living situation. Since some of the categories of these variables had small group sizes, the outcomes of the analyses should be interpreted with caution.

Clinical Implications

The MyCourse intervention is presumably more engaging for people who smoke and people with moderate to high alcohol dependence. Furthermore, this study did not identify any specific subgroups where the MyCourse-Quit Smoking intervention might be particularly effective or ineffective.

Conclusions

This study aimed to provide more insight into predictors and moderators of engagement and outcome for a digital SC intervention targeting cancer survivors. Overall, a limited number of associations was found between participant characteristics, engagement, and smoking behavior. Female participants accessed the intervention less often than male participants, and participants with higher AUDIT scores accessed the intervention more often and had more diary registrations than participants with lower AUDIT scores. Greater nicotine dependence at baseline was associated with a greater reduction in number of cigarettes at 6 months. Future studies in a larger sample and with a preregistered analysis plan are needed to corroborate these findings and shed light on how this knowledge can be used to improve the effects of digital SC programs.

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Authors' Contributions

AM, MvL, BB, RE, and MB contributed to the conception and data collection of the original research. RA, AM, WdH, and MB conceived the research questions and design for this study. ML, BB, and RE commented on or rewrote the design and research questions. RA and WdH performed the statistical analyses. RA wrote the first draft of the manuscript. AM, WdH, MvL, BB, RE, and MB commented on the draft and rewrote sections of the draft. All authors approved the final version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Sensitivity analysis of all performed analyses.
[DOCX File , 38 KB - cancer_v10i1e46303_app1.docx]

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Abbreviations

AUDIT: Alcohol Use Disorders Identification Test
FTND: Fagerström Test for Nicotine Dependence
RLMM: robust linear mixed modeling
SC: smoking cessation

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Original Paper

A Theory and Evidence-Informed e-Cycling Intervention for Individuals Diagnosed With Cancer: Development Study

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Abstract

Background: Physical activity engagement following a cancer diagnosis is positively associated with survival, reduced risk of disease recurrence, and reduced cancer-specific and all-cause mortality. However, rates of physical activity engagement are low among individuals diagnosed with and being treated for breast cancer or prostate cancer.

Objective: The purpose of this study was to describe the systematic process of developing an e-cycling intervention aimed at increasing physical activity among individuals living with prostate cancer or breast cancer and outline the key components to be implemented.

Methods: The Medical Research Council guidance for developing complex interventions and the Behaviour Change Wheel were used to guide intervention development. Information was gathered from the literature and through discussions with end users to understand factors influencing e-cycling. These factors were mapped onto the Theoretical Domains Framework to identify potential mechanisms of action. Behavior change techniques were selected from theory and evidence to develop intervention content. Interested parties, including cycling instructors, end users, and behavior change experts, reviewed and refined the intervention.

Results: Anticipated barriers and facilitators to e-cycling engagement were mapped onto 11 of the 14 domains of the Theoretical Domains Framework. A total of 23 behavior change techniques were selected to target these domains over 4 one-to-one e-cycling sessions delivered by trained cycling instructors in the community. Cycling instructors were provided a 3-hour classroom training session on delivering the intervention and a 3-hour practical session with feedback. The outcome of this work is a theory and evidence-informed intervention aimed at promoting e-cycling behavior among individuals being treated for breast cancer or prostate cancer, which is currently being implemented and evaluated.

Conclusions: Transparent intervention development and reporting of content is important for comprehensively examining intervention implementation. The implementation of this intervention package is currently being evaluated in a pilot randomized controlled trial. If the intervention is found to be effective and the content and delivery are acceptable, this intervention will form a basis for the development of e-cycling interventions in other survivors of cancer.

Trial Registration: ISRCTN Registry ISRCTN39112034 https://www.isrctn.com/ISRCTN39112034; and IRSCTN Registry ISRCTN42852156; https://www.isrctn.com/ISRCTN42852156

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KEYWORDS

prostate cancer; breast cancer; electrically assisted cycling; physical activity promotion; behavior change techniques; BCTs; Behaviour Change Wheel; Medical Research Council; Theoretical Domains Framework; TDF; physical activity; e-cycling intervention; e-cycling; cancer; risk of disease; all-cause mortality; behavioral health; instructor; instructors; cancer survivor; patient with cancer; healthy lifestyle; intervention; physical fitness; exercise

Introduction

Globally, cancer is one of the leading causes of mortality [1]. Specifically in the United Kingdom, prostate cancer and breast cancer are the most common male and female cancers, respectively [2]. Physical activity engagement following a cancer diagnosis is positively associated with survival, reduced risk of disease recurrence, and reduced cancer-specific and all-cause mortality [3-10]. Furthermore, physical activity engagement during cancer treatment positively impacts quality of life and is associated with reduced fatigue, a common side effect of treatment [11-14]. Despite these positive benefits, rates of physical activity engagement are low among individuals diagnosed and being treated for breast cancer and prostate cancer [15-17], with rates decreasing following diagnosis and during treatment [18,19]. The extent to which individuals diagnosed with cancer are willing to engage in physical activity varies greatly due to differences in the type of treatment, the time scale of treatment, and the number and severity of mental and physical side effects resulting from treatment including fatigue and depression [7,20]. In addition, lack of equipment or facilities as well as lack of time, motivation, and confidence are common barriers to physical activity engagement in this population [21-25]. The lack of clinical guidance on appropriate physical activity to undertake and a limited clinical emphasis on the importance of engaging in physical activity during this time are also barriers to engagement [26].

There is a need for novel interventions to encourage the initiation and maintenance of physical activity in this population. Electrically assisted bicycles (e-bikes; also known as pedelecs) have been highlighted as a potential means through which to increase physical activity, particularly among inactive and older individuals [27,28]. Despite the electrical assistance, e-cycling engagement provides physical activity of at least a moderate intensity [29,30] with the potential to positively impact physical and mental health outcomes [27]. Furthermore, e-cycling has been reported to be an enjoyable activity, an affect response that is considered important for the long-term sustainability of physical activity behavior [31]. To date, the use of e-bikes to increase physical activity in individuals being treated for cancer has yet to be explored.

Developing effective interventions and associated implementation strategies requires an understanding of the target behavior and the factors that influence engagement in that behavior [32]. Specifically, the intervention design and selection of active ingredients with the potential to bring about behavior change should be guided by theory and the context in which the intervention is to be delivered [33,34]. To date, the majority of e-cycling interventions have involved the provision of an e-bike; however, no additional behavior change mechanisms have been reported [35-37]. While the provision of an e-bike provides the opportunity to ride, it may not be sufficient to encourage sustained behavior change [32]. The inclusion of theory-driven behavioral support can help increase the effectiveness of physical activity interventions [38] and engagement with e-cycling in a real-world setting [39]. A recent e-cycling intervention delivered to individuals with type 2 diabetes (T2D; PEDAL2) incorporated behavioral counseling components and demonstrated the potential to improve cardiorespiratory fitness and mental and physical quality of life [40]. The development of the PEDAL2 behavioral counseling was guided by qualitative interview findings in the same population following an e-bike loan [41,42]. While informative, these interviews were designed to assess individuals’ ability to manage their diabetes rather than factors associated with e-cycling engagement [42]. Building on this, qualitative interviews with PEDAL2 participants were conducted after the intervention to ascertain specific barriers and facilitators to e-cycling engagement, and an associated conceptual model was developed [43]. This conceptual model provides a starting point from which to design future e-cycling interventions in other clinical populations. In addition to using this conceptual understanding, the end users of an intervention should be involved in the design of an intervention and implementation strategies to determine factors specific to the population in which the behavior change is targeted [44].

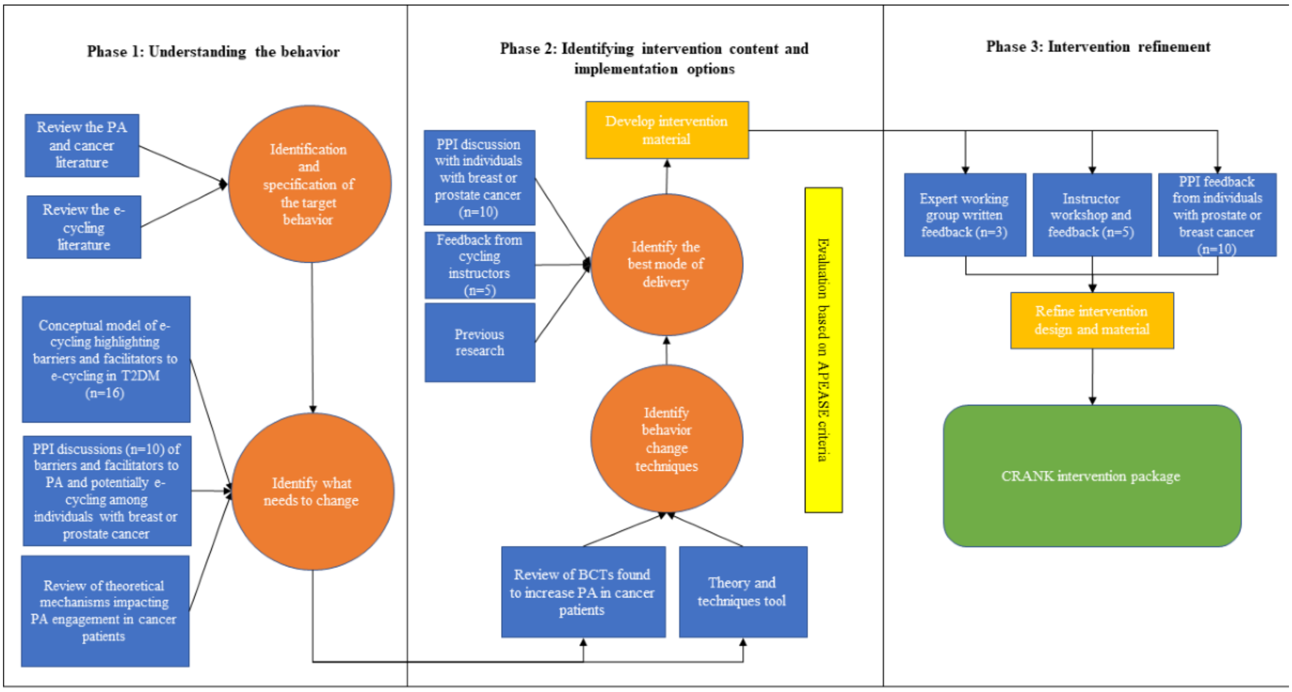
The aim of this study was to develop and refine a theory and evidence-based intervention and associated implementation strategies to promote e-cycling engagement in individuals with prostate cancer or breast cancer (the intervention was named CRANK). The development of the CRANK intervention was guided by formalized intervention development approaches, specifically the Medical Research Council (MRC) guidance for developing and evaluating complex interventions [34] and the Behaviour Change Wheel (BCW) [32], drawing upon the Theoretical Domains Framework (TDF) [45] and stakeholder input [33].

Methods

Design

The MRC guidance emphasizes the incorporation of both theory and best available evidence to develop complex interventions [34], while the BCW provides a systematic process through which to develop such interventions by completing a series of activities in stages [32]. This research was guided by stage 1 (understand the behavior) and stage 3 (identify content and implementation options) of the BCW. Stage 2 (identify intervention options) was not conducted, as an appropriate behavior change strategy was identified in phase 1 (stage 1 of the BCW guidance), which was directly mapped to behavior change techniques (BCTs) in phase 2 (stage 3 of the BCW guidance). In phase 3, the intervention and implementation strategies were refined through engagement with patient and public involvement (PPI) group members, cycling instructors, and experts in the field of behavior change. Figure 1 [40,43,46] outlines the process of intervention development. PEDAL2 interviews were conducted between August 2019 and November 2020, and the findings from these interviews and the development of the conceptual framework are reported elsewhere [43]. Intervention development, including PPI discussions with individuals living with breast or prostate cancer, expert review and feedback, and instructor workshops and feedback, took place between September 2021 and March 2022. Patient partners with breast cancer (n=4) were recruited through an existing patient and partner group established for a wider research program, while patient partners with prostate cancer (n=6) were recruited through a local prostate cancer charity. Instructors (n=5) were recruited through Life Cycle, the community organization involved in delivering an e-cycling intervention to another clinical population (PEDAL2) [40].

Figure 1. Outline of the CRANK intervention development. APEASE: Acceptability, Practicability, Effectiveness, Affordability, Side-Effects, and Equity; BCT: behavior change technique; PA: physical activity; PPI: patient and public involvement; T2DM: type 2 diabetes mellitus [40,43,50].



Phase 1: Understanding the Behavior

Define the Problem in Behavioral Terms and Select the Target Behavior

Step 1 focused on the specific problem that the intervention was aiming to address: low levels of physical activity in individuals being treated for breast cancer or prostate cancer. The social and environmental contexts in which the behavior occurs and the individual factors that affect physical activity engagement were considered to identify the major barriers and facilitators to increasing physical activity in this population. Following this, the potential ways in which physical activity could be increased in this population by overcoming some of the identified barriers and facilitators to engagement were considered, and this formed the basis from which this e-cycling intervention was conceived and was based on reviews of the literature and previous work conducted by the authors in a different clinical population.

Specify the Target Behavior

Upon selection of the target behavior, we specified who needed to perform the behavior, what needed to be done differently to achieve the change, where and when they needed to do it, and how often and with whom.

Identify What Needs to Change

To identify what needs to change in the individual or the environment to bring about the desired change in behavior (ie, engagement in e-cycling), we drew from multiple sources of information, as suggested by the MRC guidance to ensure that theory and research evidence identified are relevant to this context [34]. First, a conceptual model identifying barriers and facilitators to e-cycling, guided by the Capability, Opportunity, Motivation-Behavior (COM-B) model, among individuals with T2D was used to identify the factors that impact e-cycling in clinical populations [43]. Given that e-cycling has yet to be explored among individuals living with cancer, this conceptual model provided a good position from which to begin CRANK intervention development. Second, PPI group discussions took place to gain insight into the factors that may specifically impact e-cycling among individuals living with cancer. In total, 2 web-based discussion groups, 1 each for individuals being treated for prostate and breast cancer, were facilitated and lasted approximately 120 minutes. The groups discussed potential factors that could impact cycling in this population, specifically e-cycling. By the end of the discussion, the group had identified several factors that they felt would impact e-cycling engagement and identified the most important factors based on consensus decisions. Third, the literature was reviewed to identify interventions that were deemed to be successful at increasing physical activity engagement in individuals with cancer (specifically prostate cancer and breast cancer). The theoretical underpinnings of these interventions were identified to advance our understanding of the likely mechanisms of change.

Information obtained from these 3 sources was mapped onto the constructs of the TDF, which is an expansion of the COM-B model, to identify the key constructs that need to change to encourage engagement in e-cycling behavior. The TDF is comprised of 14 theoretical domains that summarize the theoretical constructs from 33 theories of behavior change [45]. In line with the MRC guidance, a program theory was developed to present the hypothesized theoretical underpinning of the intervention.

Phase 2: Identifying Behavioral Content and Implementation Options

Identify Behavior Change Techniques

Having hypothesized the theoretical components required to achieve change in the target behavior, intervention content was developed by the selection of BCTs. The 93-item behavior change technique taxonomy (BCTTv1) [47] was used to provide detailed definitions of BCTs. BCTs were chosen from (1) an examination of systematic reviews that have identified specific BCTs that have been shown to be effective at promoting physical activity behavior in adults living with cancer, with a focus on breast cancer and prostate cancer [48,49] and (2) using the theory and techniques' web-based tool to identify specific BCTs linking the proposed mechanisms of action identified using the TDF that should be targeted in this intervention [46]. The use of these BCTs in this intervention was considered with regard to acceptability, practicality, effectiveness, cost-effectiveness, affordability, side effects, safety, and equity (APEASE [Acceptability, Practicability, Effectiveness, Affordability, Side-Effects, and Equity] criteria [32]).

Identify the Best Mode of Delivery

The mode of delivery including the provider, intensity, and duration was based on previous feasibility findings from participants and instructors of PEDAL2 reported by Bourne et al [40] and from feedback from the CRANK PPI group (n=10) and cycling instructors (n=5). Feedback was elicited through web-based open group discussions. The modes of intervention implementation were considered using the APEASE criteria to assess suitability within the constraints and resources of the trial. Intervention materials were created alongside training manuals for cycle instructors.

Phase 3: Intervention Feedback and Refinement

The intervention was refined following feedback from CRANK PPI members (n=10), instructors (n=5), and the expert group (n=3). Specifically, the intervention material was sent to PPI members initially for review. After review of these documents, group members met on the web, with 3 group discussions for each of the 3 groups, where feedback on the intervention content and delivery method was provided to the research team. All discussions were recorded in order for the researcher to listen back to the discussion, and notes were taken throughout the discussions. These discussions lasted up to 120 minutes. For instructors, the intervention material was sent for review prior to a 2-hour web-based meeting. At this meeting, the research team presented the intervention material, and instructors were asked to provide feedback on both the instructor training and participant intervention material. Any disagreements within the groups were discussed in the session until a consensus was reached regarding the required intervention changes. The intervention was sent to members of the CRANK trial steering committee with expertise in behavior change. These individuals provided written feedback on the intervention content. The information from CRANK PPI members, instructors, and the trial steering committee was collated and reviewed by 2 researchers, and consensus decisions were made on appropriate changes to be made based on the APEASE criteria.

Ethical Considerations

The National Health Service Health Research Authority Southwest/Central Bristol Research Ethics Committee provided ethics approval to conduct qualitative interviews among individuals living with T2D as part of PEDAL2 (reference 18/SW/0164). While ethical practice was upheld, formal ethical approval was not obtained for these PPI activities, as advised by the National Institute for Health Research. PPI contributors were involved in the design, implementation, and management of the research process itself. Patient partners were informed of what engagement in the PPI activities would entail prior to agreeing to participate. Ethics approval for the pilot randomized controlled trials to evaluate the intervention (named CRANK) was granted by the National Health Service Health Research Authority Dulwich Research Ethics Committee (REC: 22/LO/0036; CRANK-P) and the Nottingham Research Ethics Committee (REC: 22/EM/0010; CRANK-B), and the protocol for this study is reported by Bourne et al [50].

Results

Define the Problem and Select the Target Behavior

Justification for this research is provided in the Introduction section and summarized here for completeness. Individuals living with cancer are less physically active than their healthy counterparts [15,17,51,52]. Specifically, it has been estimated that adherence to the physical activity guidelines among individuals living with cancer ranges from 10% to 47% [15,16,52-56]. Engagement in regular physical activity can help recovery from cancer, reduce the side effects associated with treatment, and reduce the chances of recurrence [3,5,10,11,57]. Several physical activity interventions have been developed for individuals living with and recovering from cancer, with varied success [58-61]. Common barriers to engagement in regular physical activity for individuals with cancer include cancer-related physical symptoms (eg, fatigue), lack of equipment or facilities, lack of knowledge of what to do or support or advice on how to engage in physical activity, lack of motivation and time, and low confidence [21-25].

e-Cycling has been identified as an activity that may overcome some of the identified barriers to engaging in physical activity and promote long-term adherence [28]. The potential of e-cycling to increase physical activity in individuals being treated for or recovering from cancer has not been explored but warrants further investigation. As such, the target behavior of this intervention was to increase physical activity specifically through e-cycling in individuals being treated for breast cancer or prostate cancer.

Specify the Target Behavior

The aim was to increase individual's weekly physical activity through engagement in e-cycling. No specific weekly e-cycling targets were imposed by the research team, as we wanted participants to have autonomy over their e-cycling goals. The e-cycling behavior will need to be performed by individuals aged 18 years or older with a diagnosis of prostate cancer or breast cancer on a regular basis, whenever possible with the mantra that every move counts. e-Cycling can be conducted for any purpose (ie, exercise, travel, social, and leisure) in an outdoor setting. e-Cycling can be performed alone or with others.

Identify What Needs to Change

Drawing on the conceptual model developed from PEDAL2 and incorporating information from PPI discussions with patients being treated for breast cancer or prostate cancer, the intervention team identified key mechanisms of action to target in the intervention to bring about engagement in e-cycling (Tables 1-3).

Table 1. Behavioral analysis identifying what needs to change to encourage e-cycling within the capability component of COM-B[a] model, associated behavior change techniques, and how this will be incorporated into the CRANK intervention.

COM-B component and TDF[b] domains	What is needed for change?	Behavior change techniques	Description of how this will be incorporated into the intervention-implementation strategy
Physical capability			
Skills	• Must feel physically capable to e-cycle, despite potential physical limitations	• 4.1 Instruction on how to perform the behavior • 6.1 Demonstration of the behavior • 8.1 Behavioral practice or rehearsal • 8.7 Graded tasks	• Provide instruction on how to ride the bike and instructor to demonstrate the behavior. • Prompt individuals to practice riding during training sessions and at home, starting with riding in quiet locations with minimal surrounding risk and building up to busier locations.
Psychological capability			
Knowledge	• Must have the knowledge of how to perform the activity using the correct and safe technique • Knowledge of how to ride safely in traffic or through awareness of cycle paths	• 4.1 Instruction on how to perform the behavior • 2.2 Feedback on behavior	• Advise the individual on how to ride correctly and how to ride safely in traffic. • Provide information on where to ride (eg, where the nearest cycle paths are located and how to ride a specific journey without traffic). • Provide feedback on e-cycling behavior regarding safety and route chosen.
Memory, attention, and decision processes	• e-Cycling must be perceived as not complicated in order to compete with the car	• 7.1 Prompts or cues • 8.4 Habit reversal • 11.3 Conserving mental resources	• Individuals encouraged to gather and organize all e-cycling equipment ahead of riding in one obvious location to reduce mental resources and prompt the behavior. • Individuals encouraged to e-cycle for a journey that would normally be made by the car.
Behavioral regulation	• Engaging in physical activity is difficult, setting e-cycling targets and monitoring their behavior helps promote engagement	• 1.1. Goal setting (behavioral) • 1.4 Action planning • 2.3 Self-monitoring of behavior	• Individuals prompted to set their own goals, which they feel are achievable taking fitness levels, readiness to change, and lifestyle into account (goals will be SMART[c]). • Individuals prompted to develop specific planning on how they will achieve each goal set (eg, when and where they will e-bike). • Individuals encouraged to monitor their activity using a paper logbook or GPS watch.

[a] COM-B: Capability, Opportunity, Motivation-Behavior.

[b] TDF: Theoretical Domains Framework.

[c] SMART: Specific, Measurable, Achievable, Relevant, and Time-Bound.

Table 2. Behavioral analysis identifying what needs to change to encourage e-cycling within the opportunity component of COM-B[a] model, associated behavior change techniques, and how this will be incorporated into the CRANK intervention.

COM-B component and TDF[b] domains	What is needed for change?	Behavior change techniques	Description of how this will be incorporated into the intervention-implementation strategy
Physical opportunity			
Environmental context and resources	• Provision of maintenance service will encourage activity engagement • Perceived access to safe cycling and parking infrastructure • Provision of suitable equipment (e-bike itself and accessories)	• 3.2 Social support (practical) • 1.2 Problem-solving • 12.5 Adding objects to the environment	• Individuals will be provided with the details of an e-bike maintenance service that can be contacted in case of emergency. • Individuals will be encouraged to identify common barriers to e-cycling (eg, weather and access to infrastructure) and plan ways to overcome these problems. • Instructor to offer practical solutions based on experience and what other individuals have reported. • Individuals to be properly fitted with an e-bike, and adjustments to be made by the instructor to ensure the bicycle is comfortable. • Individuals to be provided with basic accessories (bicycle lock, helmet, lights, and pannier). • Individuals to be provided with maps of cycle routes to outline safe riding routes.
Social opportunity			
Social support	• Support from friends and family regarding e-cycling engagement • Watching others engage in the activity and having the opportunity to engage with others while riding and with a similar condition will promote engagement	• 3.1 Social support (emotional) • 3.2 Social support (practical)	• Individuals encouraged to seek verbal support from friends and family if they are struggling with the behavior. • Individuals will be invited to attend group riding sessions. • Individuals encouraged to seek practical support from friends and family if they are struggling to engage in the behavior (eg, going on a bike ride with a friend). • Instructor to offer verbal and practical support during loan period with riding catch-ups.

[a] COM-B: Capability, Opportunity, Motivation-Behavior.

[b] TDF: Theoretical Domains Framework.

Table 3. Behavioral analysis identifying what needs to change to encourage e-cycling within the motivation component of COM-B[a] model, associated behavior change techniques, and how this will be incorporated into the CRANK intervention.

COM-B component and TDF[b] domains	What is needed for change?	Behavior change techniques	Description of how this will be incorporated into the intervention-implementation strategy
Reflective motivation			
Belief about capabilities	• Confidence to engage in e-cycling • Confidence to e-cycle in traffic and on roads	• 8.1 Behavioral practice or rehearsal • 8.7 Graded tasks • 15.1 Verbal persuasion about capability • 15.3 Focus on past success	• Individuals encouraged to practice riding, particularly in areas where they are comfortable to build confidence. • Individuals encouraged to build up to riding in areas in which there is traffic. • Instructor to encourage individuals and tell them they are capable of engaging in e-cycling during all sessions. • Individuals asked to review their logbooks or e-cycling behavior. • Instructor to focus on successful e-cycling experiences to provide motivation and encouragement.
Belief about consequences	• Hold beliefs that engaging in e-cycling will positively impact various facets of physical and mental health • Hold beliefs that e-cycling will enable the individual to ride further, longer, and on hiller terrain due to the assistance	• 5.1 Information about health consequences • 5.3 Information about the social and environmental consequences	• The instructors will share information with participants about the importance of engaging in physical activity in general and specifically during cancer recovery and the impact this can have on physical and mental health. • Instructors will also share information about how the e-bike can enable individuals to ride further, faster, and on hillier terrain than a conventional bicycle and how the e-bike may open up previously unconsidered journeys.
Goals	• Setting e-cycling targets will encourage engagement	• 1.1 Goal setting (behavior) • 1.5 Review behavior goal	• Individuals will decide (with help from the instructor) upon goals for e-cycling. These goals will be recorded in their intervention booklet. These goals will be SMART[c] in nature and tailored to the individual's circumstances. Goals will not be prescribed; individuals will be encouraged to think about them for themselves. • At the end of each follow-up session, the instructor and individual will review the goals set at the previous session and together will agree to either keep the goal the same, modify the goal, or create a new goal.
Automatic motivation			
Reinforcement	• Creating established routines and habits for e-cycling	• 7.1 Prompts or cues • 10.9 Self-reward	• Individuals are advised to prepare for e-cycling ahead of time and leave equipment together in a visible location to prompt engagement. • Individuals are advised to reward themselves, primarily through self-praise, for meeting their weekly e-cycling goals or making progress toward them and record this reward.
Emotion	• Sense of enjoyment associated with e-cycling • Reduced fear of riding on roads, in traffic, or with other road users	• 5.6 Information about emotional consequences • 11.2 Reduce negative emotions	• Instructor to provide information on the potential positive emotions that can be gained from e-cycling and to discuss how others have felt from e-cycling. Encourage individuals to record how they feel after e-cycling. • Individuals encouraged to try out riding in quiet locations to reduce fear response before building up to busier locations.

[a] COM-B: Capability, Opportunity, Motivation-Behavior.

[b] TDF: Theoretical Domains Framework.

[c]SMART: Specific, Measurable, Achievable, Relevant, and Time-Bound.

In addition, a review of the literature identified the use of Social Cognitive Theory (SCT) and Transtheoretical Model of Behavior Change as appropriate theoretical models to explain why people adopt physical activity behavior, particularly those with breast cancer and prostate cancer [60-63]. The key constructs of these theoretical models were considered when identifying what needs to change for e-cycling to take place. SCT uses the techniques of mastery, vicarious experiences, and modeling to develop skills and build self-efficacy [64]. SCT also highlights the importance of others when changing behaviors. The Transtheoretical Model is a comprehensive model of behavior change [65]. The 10 processes of change focus on "how" individuals change their behavior. In addition, 2 intervening variables of self-efficacy and decisional balance have been identified as impacting movement between the 6 stages of change.

Overall, 11 of the 14 domains of the TDF were identified as needing to be targeted to encourage engagement in e-cycling. These are shown in Tables 1-3 and summarized below. Specifically, ensuring individuals had the physical skill and knowledge to ride the e-bike and navigate traffic was identified as essential for e-cycling engagement, as was having high confidence to ride the e-bike itself and among traffic (belief about capabilities). To compete with the car as a mode of transport, individuals noted that systems must be in place to ensure e-cycling is perceived as the "easy" option (memory, attention, and decision processes) and that establishing a routine was key (reinforcement). In addition, ensuring individuals have the correct equipment and access to a breakdown service would facilitate e-cycling engagement (environmental context and resources). Setting goals, monitoring the process toward these goals (behavioral regulation), and encouraging individuals to seek out support from family and friends (social support) were seen as important factors that will increase the likelihood of e-cycling behavior. Furthermore, holding positive beliefs about the impact of e-cycling both in regard to physical and mental health and social and environmental outcomes (belief about consequences; emotions) was important to influence behavioral engagement.

Identify BCTs

A total of 23 BCTs linked to the theoretical domains, as identified through the theory and techniques of web-based tool [46], psychological theories, and literature on BCTs effective at increasing physical activity among individuals being treated for breast cancer or prostate cancer were identified as shown in Tables 1-3. There was significant overlap in the BCTs identified as potentially useful to target the underlying mechanisms of change. The techniques fall across 12 of the 16 BCT categories of goals and planning, feedback and monitoring, social support, shaping knowledge, natural consequences, comparison of behavior, associations, repetition and substitutions, rewards, regulation, antecedents, and self-belief.

Identify the Mode of Delivery

Intervention Provider

Community-based cycling instructors were considered the most suitable individuals to deliver the intervention due to their nationally recognized cycle training certification. However, interviews with instructors who delivered the previous PEDAL2 intervention revealed that instructors desired more specific training on the intervention content prior to delivery [40]. As such, this intervention (known as CRANK) will involve 2 face-to-face intervention training sessions (3 hours each) for instructors incorporating both education and practice, designed to increase confidence in delivering the specific intervention content. Specifically, the training will focus on (1) providing education on the importance of physical activity for individuals with cancer and the general physical and mental health benefits of engaging in physical activity, (2) teaching instructors motivational interviewing techniques that can be used during training sessions to engage with participants, (3) providing information on specific intervention content, and (4) practicing intervention delivery through role play. The training will take place in the community at the cycling organization headquarters, a location familiar to the instructors. The training will be run by 2 researchers. Instructors will also receive a training manual outlining intervention content.

Intervention Intensity and Duration

For participants, the intervention will involve 2 face-to-face e-bike skill training sessions and behavioral discussions prior to taking the e-bike home, with no longer than 2 weeks apart between training sessions. The 2 training sessions were found to be appropriate for a clinical population engaging in e-cycling as reported by the cycling instructors and so will be incorporated into this intervention [40]. Training sessions will last approximately 2 hours each. Training session 1 will be mandatory for all participants, while session 2 will be optional and based on the needs and desires as perceived by the participant and the instructor. Participants will then receive a 12-week e-bike loan. The cycling sessions will be delivered at a community center where the cycling organization is based. It is situated in a central urban location easily accessible by multiple forms of transport. This location was deemed desirable to the patient group who had spent a considerable amount of time in clinical settings.

During the e-bike loan period, 2 additional face-to-face sessions will be conducted with the instructor, each for approximately 90 minutes. More face-to-face meetings have been incorporated into CRANK based on feedback from PEDAL2 that interacting with the instructor was motivational and made participants feel supported in their e-cycling journey [43]. These additional sessions will occur at a location of the participant's choice approximately 4 and 8 weeks into the 12-week e-bike loan. More training and support sessions will be offered if the individual has specific concerns about riding.

Throughout the loan period, the cycling organization will provide a callout e-bike maintenance service. If required, participants will be instructed to call the maintenance number, and a mechanic will come and repair the e-bike.

Intervention Fidelity

To ensure the intervention is delivered as intended, a series of fidelity check materials will be incorporated into the intervention as proposed by Lambert et al [66]. Specifically, instructors will be provided intervention content training, and an associated instructor manual will be developed. As part of the training, instructors will engage in a series of role-playing activities, which will be observed by the researchers, and feedback will be provided. The purpose of these role-playing activities is to ensure that instructors understand and are able to deliver the proposed intervention content. In addition, researchers will observe a minimum of 2 training sessions with participants at the start of the intervention. During the observations, the researchers will complete observation checklists and will provide feedback to the instructors. Throughout the intervention, instructors will complete session checklists. These checklists provide detailed information about the specific content that is intended to be covered, including BCTs, during each session including the skill level obtained by the participant and discussions that took place. At the end of the intervention, instructors will be invited to participate in qualitative interviews, in which they can share their experiences of delivering the intervention.

To assess the participant's engagement with the intervention, a workbook has been created, in which the participant can record their goals, barriers faced, and thoughts on the sessions. Participants will also be provided with a wearable activity tracker to record their activity. The degree to which self-monitoring tools are engaged with will be ascertained. In addition, at the end of the intervention, participants will be invited to participate in qualitative interviews, in which they will be asked about the extent to which they engaged in the intervention activities.

Intervention Feedback and Refinement

The intervention was refined based on feedback from PPI members, cycling instructors, and experts.

Instructor Intervention Training

It was felt, by PPI members and instructors, that instructors delivering the intervention would benefit from meeting with individuals with prostate cancer and breast cancer to discuss their lived experience as part of the training package. This will enable the instructors to understand the potential barriers to physical activity that this clinical population faces and thereby increase empathy. Instructors felt that the adaptability of the intervention needed to be made explicit throughout the training in order to meet the needs of the individual. As such, the training was tweaked to ensure that the ability to adapt the program to individual needs was emphasized. Instructors highlighted the importance of being reimbursed for administration time (eg, contacting participants), which was not part of regular cycling lessons, and that this needed to be made explicit in the training manual. This would encourage instructors to spend more time engaging with the individuals. As such, an agreement with Life Cycle was made to allow instructors to bill for administration hours in addition to instruction hours.

Instructors felt that it was important to provide sufficient training on how to conduct the behavioral counseling component of the intervention in order to increase their confidence and build buy-in from instructors for this component. To ensure sufficient time was given to review and practice these behavioral components, the second training session was extended by 1 hour. In addition, the ability to trial the self-monitoring tools as part of the training was deemed essential prior to instructing participants on how to effectively use these tools. To address this need, all self-monitoring tools were provided to the instructors prior to delivering CRANK for familiarization. The research team answered any questions or concerns about these devices. The instructors also commented that having allocated time to connect with other instructors, also delivering CRANK, was deemed important to share experiences through the incorporation of peer support sessions. As such, bimonthly instructor peer support sessions were specified.

Intervention Content and Delivery Mode

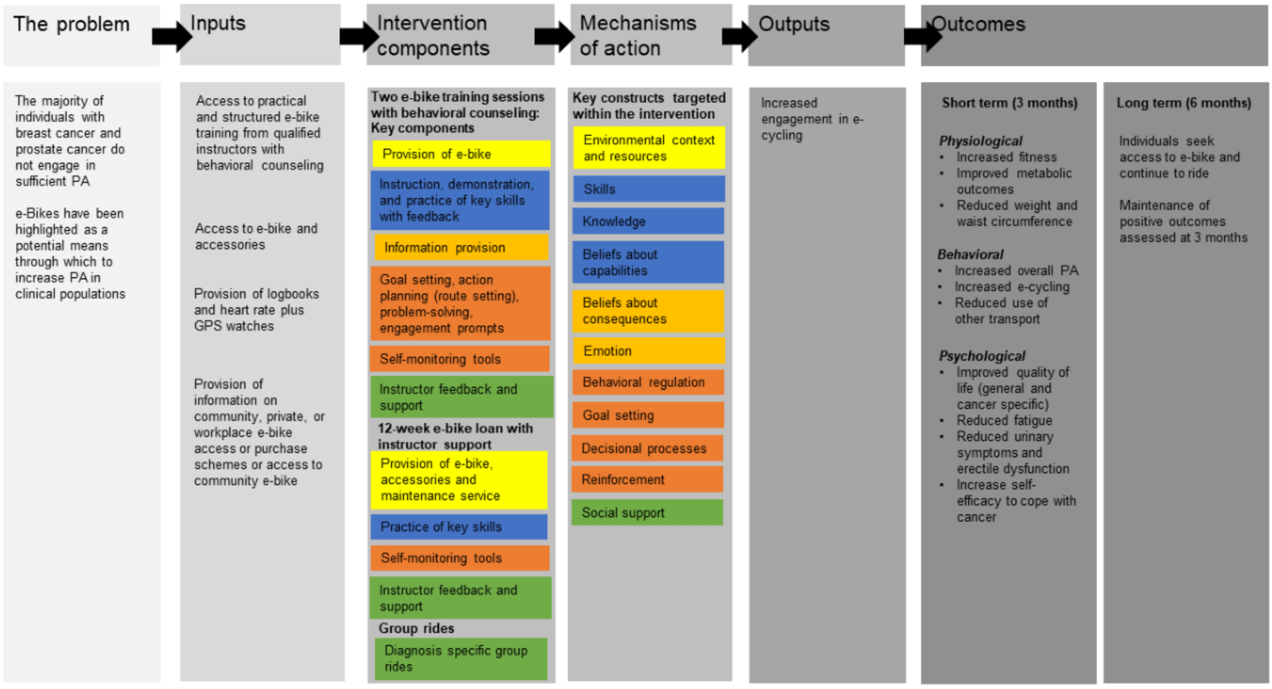
Instructors felt that the behavioral counseling should occur at the end of an e-cycling skills training session in a location that was comfortable for both the participant and the instructor (eg, a seated location) rather than trying to incorporate such discussions during skills training. Instructors felt that this would encourage participants to engage more with the behavioral techniques (eg, setting of goals and action planning) and would not become an "inferior add-on" to teaching participants the skills of e-cycling. This was echoed by members of the PPI group who emphasized that these discussions should occur after skill training, enabling participants to think about the information they are receiving and complete the workbook.

The ability to connect with others, with the same diagnosis, was also deemed as highly important to this group. As such, while general group rides were important, having group rides just for individuals with prostate cancer and breast cancer, separately, was seen as potentially more important. These clinical group–specific rides were seen as an opportunity to connect with others in a similar situation, which could help increase motivation and feelings of social support. As such, clinical group–specific rides were incorporated into the intervention. In addition, a WhatsApp group will be formed for the different clinical groups. The ability to connect with others in a similar situation was highlighted as being of great importance, particularly for male participants.

Members of the PPI group felt that support and practice were needed to encourage participants to engage in self-monitoring and that time to practice should be built into training to increase engagement with this technique. In addition, members of the PPI group identified the potential option of using mobile apps to plan routes, in addition to paper maps.

These changes were considered and incorporated into the intervention material. The final program theory, including mechanisms of action and delivery mode, is provided in a logic model in Figure 2.

Figure 2. CRANK logical model. The constructs of the TDF targeted in this intervention are color-coded to the intervention components used to target them. PA: physical activity; TDF: Theoretical Domains Framework.



Discussion

Principal Findings

This study reports on the development of a behavioral intervention designed to increase e-cycling behavior in individuals living with prostate cancer or breast cancer. The systematic approach to intervention development involved drawing on theory, evidence, and end-user insights to identify appropriate factors to target in this intervention. It is believed that this process will increase the potential efficacy of the intervention and will allow for an in-depth evaluation of the intervention content to gain an understanding of the intervention effects.

In total, 11 of the 14 domains of the TDF, covering all components of the COM-B model, were found to be relevant to increasing physical activity behavior through e-cycling among individuals living with prostate cancer or breast cancer. Constructs of the TDF not targeted in this intervention were professional or role identity, optimism, and intentions. The 11 TDF constructs identified will be targeted through the use of 23 BCTs from 12 overarching BCT categories [47]. The categories of BCTs selected for use in this intervention are similar to those identified by McVicar et al [67] in their development of an e-cycling intervention for overweight and obese adults using participant workshops. In this intervention, the categories of rewards and regulations were incorporated, which were not part of the intervention developed by McVicar et al [67]. Specifically, in this intervention, individuals were encouraged to reward themselves, primarily through self-praise if they met, or made progress toward, their e-cycling goals. The use of self-rewards has been associated with sustained physical activity behavior at least 6 months after intervention [68]. In addition, participants were encouraged to prepare cycling equipment ahead of time to reduce stress and increase the likelihood of e-cycling over using a motorized vehicle. Ways to assist with behavioral regulation were included in this intervention, as interviews with PEDAL2 participants revealed that trying to remember everything needed for a commute via e-bike was stressful and decreased the likelihood of riding. Overall, McVicar et al [67] identified 16 BCTs for inclusion in their intervention, while the current development process identified 23, of which 12 overlapped. The additional 11 unique BCTs used in this intervention were likely due to the incorporation of sources of information that identified the mechanisms of action that broadly impact PA behavior in the current clinical population as well as those that impact e-cycling specifically. For example, BCT 15.3 focus on past success was incorporated as this technique directly aligns with bolstering self-efficacy, a key component of SCT [64], which has been used in previous physical activity interventions among individuals living with cancer. In addition, BCT 6.5 information about emotional consequences was included due to the conceptual model of e-cycling engagement among individuals with T2D and the finding that individuals are more likely to engage in e-cycling because it is perceived as enjoyable [43]. The BCT 2.3 self-monitoring was found to be an important component to prompt behavior change from a theoretical perspective, from the PEDAL2 conceptual model, and based on discussions with end users and was therefore included in this intervention.

Several of the techniques identified for use in this intervention align with action types identified by Kelly et al [69] in a scoping review of 145 initiatives reporting on intervention content, at the organization and individual levels, aimed at increasing cycling behavior. The review identified commonly used action categories, which will also be used in this intervention. These include knowledge of the benefits of cycling and cycle safety and route planning (ie, education), practical cycling training courses (ie, training), provision of bike accessories and bikes, and access to bike maintenance services (ie, enablement). While the review identified a series of actions associated with restructuring the environment, the majority of these were not suitable for this intervention (eg, provide bike storage facilities and bike wheel channels on stairs or workplace or organizational policies). These components are likely more achievable for organization-based interventions.

Strengths and Limitations

The behavioral analysis conducted in this study outlines the systematic process used to develop a theoretical understanding of the behavior we are seeking to impact and the mechanisms that may influence this behavior. From here, we were able to identify the theoretical constructs to target and the techniques through which to target these mechanisms in the current population. This transparent method demonstrates the multifactorial nature of this behavior and the complexity of developing a behavioral intervention. However, documenting this process is important, as it allows others to fully understand how the active ingredients of the intervention were selected.

To gain an in-depth understanding of the behavior of e-cycling and the factors that influence engagement, we drew on theory and literature and engaged stakeholders including individuals living with prostate cancer or breast cancer, cycling instructors, and experts in the field of behavior change. It is hoped that gathering information from multiple sources to guide intervention development will increase the chances of developing an intervention that can effectively increase physical activity behavior through e-cycling participation.

The BCTs selected to target each TDF construct were selected using the links proposed by the Theory and Techniques tool, which links BCTs and mechanisms of action based on evidence in the literature [70] and expert consensus [71] and triangulation of these 2 processes [46]. The use of this tool is more appropriate than the use of the BCW guidance, which links BCTs to mechanisms of action based on the “most used” techniques [32].

A potential limitation of this intervention development is that the conceptual model used to guide this intervention was based on findings from 1 city, the same city in which this intervention will be delivered (Bristol, United Kingdom). While appropriate for this intervention, mechanisms of change identified and associated intervention active components may not be applicable to individuals from other cities in the United Kingdom or internationally. A second limitation is that one intervention has been designed for 2 clinical populations, specifically breast cancer and prostate cancer. These cancers generally impact different genders, and there is the potential that these individuals have different barriers and facilitators to e-cycling engagement that may not have been parsed out in this process. However, this work included PPI discussions with both individuals living with breast cancer or prostate cancer, and no outstanding differences were noted between the 2 PPI groups.

Future Research

This process has led to the development of an intervention with associated participant intervention materials to address some of the barriers identified to e-cycling engagement. In addition, an instructor manual has been created to ensure instructors address these barriers and engage in activities that facilitate e-cycling through training and discussion. The intervention package is currently being tested in a pilot randomized controlled trial [50]. Specifically, the feasibility of delivering this intervention and specific BCTs is being assessed through observations of sessions delivered by instructors with feedback as well as intervention checklists completed during each contact session. The frequency with which each BCT is delivered will be determined and reported. Through workbooks and self-monitoring tools, we will be able to establish the extent to which participants engaged with the BCTs. The impact of omission of BCTs can be compared to effectiveness data and may give insight into the potential efficacy of individual or groups of BCTs selected. In addition, qualitative one-to-one interviews will be conducted with instructors and participants to understand the acceptability of intervention delivery and participation. Testing the delivery of the intervention components is a critical part of intervention development to ensure refinements can be made where required prior to full-scale implementation if suitable. The intervention developed, if appropriate, can be adapted to other groups of individuals being treated for different cancers using the most potent BCTs identified.

Conclusions

This study presents the process of designing a behavior change intervention targeting physical activity behavior using electrically assisted bicycles for individuals living with breast cancer or prostate cancer. The explicit reporting of the development process and program theory with associated intervention content facilitates the application of in-depth evaluation to determine the efficacy of the BCTs included. This evaluation is currently being conducted and will enable future refinement of the intervention as appropriate.

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Data Availability

Data sharing is not applicable to this paper as no data sets were generated or analyzed during this study.

Authors' Contributions

All authors were involved in designing the study. JEB and MEGA conducted the stakeholder discussions. JEB conducted the behavioral analysis and discussed the findings with MEGA and PK. JEB drafted the manuscript and MEGA and PK reviewed the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

APEASE: Acceptability, Practicability, Effectiveness, Affordability, Side-Effects, and Equity
BCT: behavior change technique
BCW: Behaviour Change Wheel
COM-B: Capability, Opportunity, Motivation-Behavior
MRC: Medical Research Council
PPI: patient and public involvement
REC: Research Ethics Committee
SCT: Social Cognitive Theory
T2D: type 2 diabetes
TDF: Theoretical Domains Framework

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Original Paper

Assessing the Quality, Privacy, and Security of Breast Cancer Apps for Arabic Speakers: Systematic Search and Review of Smartphone Apps

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Abstract

Background: Breast cancer is a widespread disease, and its incidence is rapidly increasing in the Middle East and North Africa region. With the increasing availability of smartphone apps for various health purposes, breast cancer apps have emerged as tools for raising awareness, providing support, and empowering women affected by this disease. These apps offer many features, including information on breast cancer risk factors, self-examination guides, appointment reminders, and community support groups or hotlines. Using apps raises the risk of privacy and security issues, and we hope that examining these features of the apps will contribute to the understanding of how technology can be used to improve these apps and provide insights for future development and improvement of breast cancer apps.

Objective: This study aims to critically review the quality, privacy, and security of breast cancer apps available to Arabic speakers.

Methods: Similar to several recent studies, we used a systematic search for apps available in Google Play and Apple App stores using both the web interface and the built-in native stores installed on smartphones. The search was conducted in mid-December 2022 in Arabic using the following keywords: – – – – – (breast cancer, breast cancer treatment, breast cancer disease, breast cancer symptoms, breast cancer screening, and breast test). These preidentified search terms are based on earlier work concerning the top searched breast cancer topics by Arabic speakers through Google's search engine. We excluded apps that did not have an Arabic interface, were developed for non-Arabic speakers, were paid, needed a subscription, or were directed toward health care workers. The Mobile App Rating Scale was used to evaluate the quality of the apps concerning their engagement, functionality, aesthetics, and information. A risk score was calculated for the apps to determine their security risk factors.

Results: Only 9 apps were included, with most (6/9, 67%) being supported by advertisements and categorized as informational. Overall, the apps had low numbers of downloads (>10 to >1000). The majority of the included apps (8/9, 89%) requested dangerous access permissions, including access to storage, media files, and the camera. The average security score of the included apps was 3.22, while only 2 apps provided information about data security and privacy. The included apps achieved an overall average quality score of 3.27, with individual dimension scores of 4.75 for functionality, 3.04 for information, 3.00 for aesthetics, and 2.32 for engagement.

Conclusions: The limited availability of breast cancer apps available to Arabic speakers should be a call to action and prompt health care organizations and developers to join forces and collaboratively develop information-rich, usable, functional, engaging, and secure apps.

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KEYWORDS

apps; Arabic; awareness; breast cancer; consumer health informatics; education; mHealth; mobile health; privacy; quality; security; smartphone; women

Introduction

Female breast cancer is among the most commonly diagnosed cancers worldwide, with a rate of approximately 2.3 million new cases [1]. Over the past decade, breast cancer incidence has been on the rise in the Middle East and North Africa (MENA) region [2]. Breast cancer is the most frequently diagnosed cancer (17.7%-19% of all types of cancer) in the region [3], and it accounts for 30% of all cancer cases [4]. The lack of cancer education and barriers to cancer screening are seen as major health problems [5]. Education is one of the most effective tools in the fight against female breast cancer; it can have positive effects on women's practices, attitudes, and knowledge of the disease [6]. However, recent studies suggest a lack of resources and poor awareness of breast cancer in women in the MENA region [7]. While the digital delivery of health education content has been on the rise through different digital media (eg, websites and social media), the quality of Arabic content for female breast cancer remains poor [8-10].

Smartphone proliferation, ubiquity, and affordability, as well as the increasing availability of mobile apps, may be the long-awaited for "digiceuticals" or digital therapeutics [11-13]. Today, the number of health apps in smartphone app stores exceeds 325,000 [14] and will continue to rise, with estimates of more than 200 apps being added daily to app stores [15], covering a wide spectrum of health purposes, such as well-being, education, and disease management, including chronic conditions [16]. Several apps are available that can help individuals with breast cancer manage their condition. These apps have been used for the purposes of education [17-19], care management [20,21], prevention [22-24], and well-being [25,26]. These apps can be a valuable resource for individuals with breast cancer, helping them stay informed and connected to their care team and manage the symptoms and challenges associated with the disease.

The use of mobile health (mHealth) apps contributes to improving health literacy and facilitating communication between patients and their care providers [27]. Moreover, it improves patient well-being and helps caregivers make informed clinical decisions [28]. In fact, the use of such apps not only benefits patients while receiving treatment but also provides tools such as follow-up care and self-management for breast cancer survivors [29]. Patients' need for self-management techniques is crucial, as it helps them to make their lives better by complying with the treatment needed and, as a result, accepting the disease [30].

However, despite the high number of downloads and star ratings of health apps, including those specifically targeting breast cancer, several challenges remain with respect to their quality and security. Evidence from the literature reports on the existence of poor-quality health apps that fall short with respect to (1) following evidence-based health guidelines and best practices, (2) involving experts and consumers in their development, and (3) demonstrating effectiveness based on empirical evidence, all of which ultimately can be potentially harmful to their users [14,31-33].

Additionally, health apps have been facing critical challenges related to their privacy, confidentiality, and security [14,34,35], especially given their nature of handling sensitive, personal, and health-related data [36]. These challenges have been magnified with the rise of cyberattacks through apps and mobile devices [37] and further highlighted by recent regulations such as the General Data Protection Regulation for member states of the European Union [38]. Such a regulation assesses the privacy score of mobile apps and identifies or measures apps' privacy based on 14 components [39].

As the uptake of these apps increases, it becomes imperative for users to evaluate their quality and safety [40]. Despite the high prevalence of breast cancer among the population of the MENA region, evidence regarding the quality, privacy, and security of breast cancer apps available to Arabic speakers remains poor. This study aimed to conduct a systematic assessment of mobile breast cancer apps available for Arabic speakers to evaluate their functionality, quality, security, and data safety. To the best of our knowledge, no previous study has addressed this gap.

Methods

Overview

Using a similar approach to several recent studies [41-45] and to ensure scientific rigor, this study conducted a systematic search and content analysis of mobile breast cancer apps available for Arabic speakers. We searched both Google Play and Apple App stores between December 18 and 24, 2022.

Search Strategy

Initially, we used the Arabic search terms highlighted in Table 1 to search Google Play and Apple App stores. These search terms were selected based on earlier work that was published concerning the top searched breast cancer topics by Arabic speakers using Google's search engine [8]. To ensure rigor, the researchers searched the app stores both through (1) the web interface and (2) natively on devices running the relevant operating system, thus mimicking how end users will discover such apps.

Table 1. The terms used to search for breast cancer apps available to Arabic speakers and their English translations.

Arabic term	Translated term
	Breast cancer
	Breast cancer screening
	Breast cancer treatment or therapy
	Breast cancer detection or screening
	Breast cancer disease
	Symptoms of breast cancer
	Breast screening

Eligibility

App eligibility was determined by 2 independent researchers blinded to each other's decisions, and the apps were initially screened based on the app's name, the provided screenshots, and the app's description. Discrepancies between researchers were resolved through consensus. Apps were included if they were free of charge, provided content and support for Arabic speakers, and were designed for use by consumers or patients; all apps were considered regardless of release or last update dates (Textbox 1). Apps were excluded if they were paid or were subscription-based, did not support Arabic speakers, or were designed for use by clinicians or health care workers.

Textbox 1. Inclusion and exclusion criteria for the apps.

Inclusion criteria

- Free of charge
- Available on Google Play or Apple App store
- Designed for use by consumers or patients
- Support Arabic speakers
- Considered regardless of release or last update dates

Exclusion criteria

- Paid or subscription based
- Designed for use by clinicians or health care workers
- Does not support Arabic speakers

Data Extraction and Evaluation

Initially, all information provided by the app developers in the app stores was extracted to evaluate the descriptive features and the general characteristics of the included apps, which included the platform, developer name, update date, ratings, number of reviews, number of downloads, app category, and app permissions, as reported by the app developers. Afterward, 2 independent researchers downloaded the apps on their smartphones to assess the quality and privacy risks of the included apps.

We evaluated the quality of the included apps using a standardized form, the Mobile App Rating Scale (MARS), focusing on the following 4 dimensions: engagement, functionality, aesthetics, and information quality [46,47]. All scores were compared among 2 researchers, and the average score for each dimension was reported. To evaluate the apps' privacy risks, we assigned scores to the permissions requested by the apps as reported by the app developers. The scores were informed by previous research, where the score risk is 0 for nonthreatening, 0.5 for potentially threatening, and 1 for threatening permissions [48]. Such permissions include access to restricted data, such as system state and user contact information, and restricted actions, such as connecting to a paired device and recording audio [49]. The 2 researchers independently carried out this evaluation and were unaware of each other's scores; any discrepancies were resolved through consensus.

Results

Overview

The researchers followed the systemic steps, highlighted in Figure 1, resulting in the inclusion of 9 apps, all of which are Android apps found on the Google Play store.

Overall, the included apps were indicated to be appropriate for all ages and were either in the medical, education, lifestyle, personalization, or health and fitness categories as per Google Play store categorization (Table 2). Our investigation suggests that the apps were all informational in nature, mainly providing information about breast cancer. None of the included apps had a language option to make it available in more than 1 language.

At the time of data collection, the results show that the included apps had low overall downloads (>10 to >1000) and more than half (6/9, 67%) were supported by advertisements. Only 5 apps had reviews, with an average of 10.60 reviews and an average star rating of 4.78. Only 1 app was last updated in 2019, while the remaining apps were updated in the past 2 years.

Figure 1. The flow diagram of the systematic search process to identify the relevant apps.

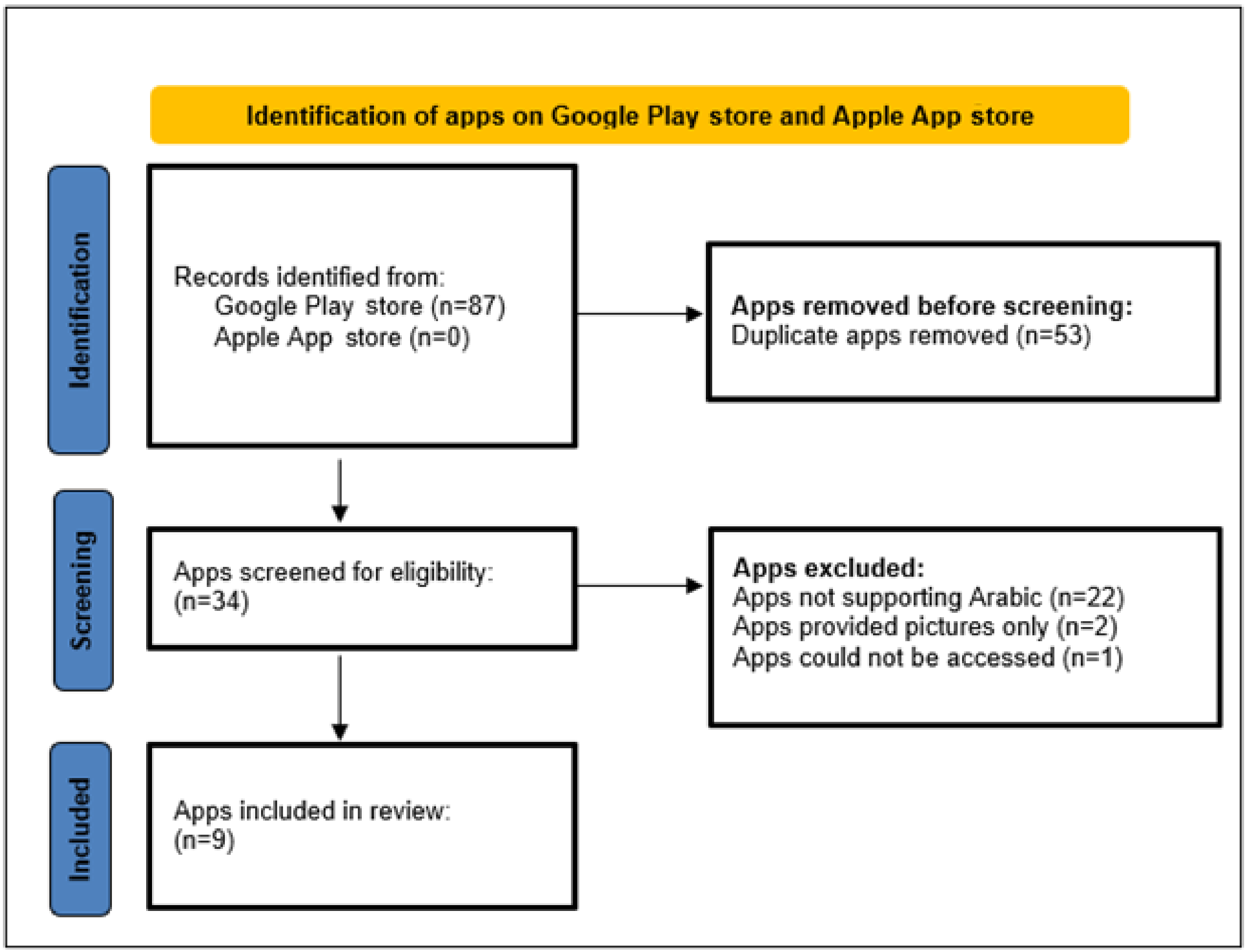

Table 2. Characteristics of the included breast cancer apps in the Google Play store.

App number[a]	Stars	Reviews, n	Advertisement supported	Downloads, n	Rating[b,c]	Updated on[d]	Category[b]
1	5	10	No	>100	3+	May 11, 2021	Medical
2	4.9	23	Yes	>1000	3+	July 26, 2019	Medical
3	—[e]	—	Yes	>100	3+	April 18, 2020	Health and fitness
4	4.2	6	Yes	>1000	3+	November 3, 2020	Education
5	5	8	No	>500	3+	May 11, 2021	Medical
6	4.8	6	No	50	3+	July 11, 2022	Medical
7	—	—	Yes	500	3+	August 9, 2021	Lifestyle
8	—	—	Yes	10	3+	October 8, 2022	Personalization
9	—	—	Yes	10	3+	October 8, 2022	Personalization

[a] Arbitrary number to mask app name.

[b] Based on Google Play store.

[c] Content of apps considered suitable for age group indicated per Google Play store rating.

[d] At data collection.

[e] Not available.

App Permissions and Controls

As described in the Google Play store, the majority of the included apps (8/9, 89%) were requesting dangerous access permissions, including access to storage, media files, and camera permissions (Table 3). Additional permissions were exposed after the researchers downloaded the apps on the testing devices. These permissions included receiving data from the internet; viewing network connections; having full network access; running at start-up; controlling flashlight and vibration; preventing the device from sleeping; reading badge notifications; running foreground services; advertising permissions; reading location from media; playing and installing referrer application programming interface; and lastly, pairing with Bluetooth devices (Table S1 in Multimedia Appendix 1). The researchers considered all permissions and added them up to calculate the final risk score (Table 4).

On average, the security score for the included apps is 3.22 (total points possible: 9.5). The security scores ranged between 0 and 7.5; only 2 apps had a total security score of 0. The apps requested potentially dangerous permissions, namely full network access, advertising ID permission, read location from media collection, precise location (GPS and network-based), take pictures and videos, read the contents of the USB storage, modify or delete the contents of the USB storage, and view Wi-Fi connections.

Table 3. Included apps' permissions as described in the Google Play store.

App number	Location		Camera	Photos and media		Storage		Wi-Fi connection
	Approximate location (network based)	Precise location (GPS and network based)	Take pictures and videos	Read the contents of your USB storage	Modify or delete the contents of your USB storage	Read the contents of your USB storage	Modify or delete the contents of your USB storage	View Wi-Fi connections
1								
2								✓
3	✓	✓	✓	✓	✓	✓	✓	✓
4								
5								
6			✓			✓		✓
7						✓		✓
8								
9								

Table 4. The security score per app based on its permissions requested or declared.

Permission	Weight[a]	App								
		1	2	3	4	5	6	7	8	9
Receive data from the internet	0.5	0	0	1	1	0	1	1	1	1
View network connections	0.5	0	1	1	1	0	1	1	1	1
Full network access	1	0	1	1	1	0	0	1	1	1
Run at start-up	0	0	0	1	1	0	1	1	1	1
Control flashlight	0	0	0	1	0	0	0	0	0	0
Control vibration	0	0	0	1	1	0	1	1	1	1
Prevent device from sleeping	0	1	0	1	1	0	1	1	1	1
Read badge notification	0	0	0	0	1	0	1	1	1	1
Run foreground service	0	0	0	0	1	0	0	1	1	1
Advertising ID permission	1	0	0	0	0	0	1	0	1	1
Read location from media collection	1	0	0	0	0	0	1	1	0	0
Play install referrer API[b]	0	0	0	0	0	0	1	1	0	0
Pair with Bluetooth devices	0	0	0	0	0	0	1	1	0	0
Approximate location (network-based)	0.5	0	0	1	0	0	0	0	0	0
Precise location (GPS and network-based)	1	0	0	1	0	0	0	0	0	0
Take pictures and videos	1	0	0	1	0	0	1	0	0	0
Modify or delete the contents of your USB storage	1	0	0	1	0	0	0	0	0	0
Read the contents of your USB storage	1	0	0	1	0	0	1	1	0	0
Modify or delete the contents of your USB storage	1	0	0	1	0	0	0	0	0	0
View Wi-Fi connections	1	0	1	1	0	0	1	1	0	0
Total security score per app	9.5	0	2.5	7.5	2	0	6	5	3	3

[a] The threat weight was calculated following the guidance provided by Olmstead and Atkinson [48].

[b] API: application programming interface.

Data Safety

Only 3 apps provided information about data safety and how the data are handled (Table S2 in Multimedia Appendix 1). Specifically, only 2 apps reported not sharing user data with other companies or organizations; the same apps reported that their apps do not collect user data. On the other hand, only 1 reported sharing information such as location, health and fitness messages, as well as photos and videos. The 3 apps that declared information about data safety reported that the data are encrypted in transit. Only 1 app reported that the users can request to delete the data.

Apps' Quality Rating

The researchers used MARS to evaluate the included apps' quality. MARS uses 4 dimensions to assess the apps: engagement, functionality, aesthetics, and information. The average overall score rating of the included apps was 3.27 (Table 5). Notably, the evaluation showed that all the apps had a high rate in the functionality dimension, where they all scored 4.75; as for the engagement dimension, all apps had a meager score with an average of 2.32. Considering the other 2 dimensions, aesthetics and information, we can see that the scores vary between apps, where some have a high score and others have a low score, with an average of 3.00 and 3.04, respectively.

Table 5. Mobile App Rating Scale evaluation for Arabic breast cancer apps.

App number	Engagement	Functionality	Aesthetics	Information	Overall
1	2.30	4.75	3.67	3.87	3.60
2	2.40	4.75	3.00	3.00	3.30
3	2.40	4.75	3.00	2.25	3.10
4	2.40	4.75	3.33	2.50	3.20
5	2.40	4.75	3.33	3.50	3.50
6	2.40	4.75	3.67	4.00	3.70
7	2.20	4.75	3.00	2.75	3.20
8	2.20	4.75	2.00	2.75	2.90
9	2.20	4.75	2.00	2.75	2.90
Total mean score	2.32	4.75	3.00	3.04	3.27

Discussion

Principal Findings

To the best of our knowledge, this work summarizes the most extensive collection of the currently available free-of-charge breast cancer apps for Arabic speakers on the Google Play and Apple App stores. Interestingly, this systematic investigation reveals that, at the time of data collection, no breast cancer apps were identified as available to Arabic speakers in the Apple App store. Additionally, none of the apps at the time of data collection provided language options, which can hinder the possibility of translating to multiple languages. Overall, the results of this research showed a lack of breast cancer apps available to Arabic speakers compared to apps available in Turkish [50] and Korean [51] for example.

The analyzed apps in this study are available for free, with the majority of these apps (6/9, 67%) being supported by advertisements. The apps varied in what they are able to access and control on the devices, as shown in Table 3. A total of 44% (4/9) apps use Wi-Fi, 33% (3/9) can access the device's storage, 22% (2/9) have access to the device's camera, and 11% (1/9) are able to access the media as well as the location. Only 33% (3/9) of the apps stated how the collected data would be used (Table S2 in Multimedia Appendix 1), while the rest of the apps did not specify any information.

The results of this study demonstrate that the quality of the considered apps is highly "functional" but less "engaging" (Table 5). The average overall score rating of the included apps (3.27) is slightly above average, suggesting that the majority of the apps may not be considered exceptional by consumers. While there seem to be positive aspects to the included apps, there is still room for improvement. Considering Arabic content related to breast cancer, recent evidence suggests the low quality of informational videos available on YouTube despite the high number of views [9]. Our findings provide evidence suggesting that nearly average-quality information content about breast cancer is available to Arabic speakers.

A recent Spanish study tested 6 apps (2 on iOS, 5 on Android, and 1 on both) using the MARS framework. The results of the study showed relatively diverse scores, with an objective quality mean score of 3.06 and a subjective quality mean score of 1.96 [52]. Another study evaluated the quality of mHealth apps for educational purposes in Iran using the MARS framework. The study reported a mean score of 4.01 for quality and 3.08 for subjective quality [53]. Turkish apps were also evaluated using the MARS framework, and the study found an average score of 3.31 [50], which is similar to the Spanish study's results.

Although many research papers have addressed the importance of using mHealth apps to improve patients' health, provide educational materials, enhance communication between patients and caregivers, and achieve a successful recovery, these studies have stated that such apps are exposed to several challenges and threats as well. For instance, middle- and high-income households had more access to the internet on their mobile devices compared to those with low incomes [28]. Therefore, patients and caregivers who have no or limited access to the internet may not be able to use the app's features effectively, or they might not prefer to use a mobile phone for health-related purposes in general.

Another concern is that the process of storing and transferring personal health data through a mobile app could be insecure and might cause serious security and privacy issues [28,54]. Thus, mobile apps should be designed to accommodate a wide range of possible users while considering health knowledge, different levels of cultural needs, and linguistic requirements. Additionally, recent research suggests that assessing the apps' quality, safety, and usability by involving patients and health care professionals will result in an ideal app that meets patients' requirements and enhances the app's overall safety as well [20].

The literature on breast cancer smartphone apps suggests that these apps can be a valuable resource of information for individuals with the disease [55]. These apps provide information on treatment options, support groups, and local resources. The apps also allow individuals to track their symptoms, set reminders for appointments, and record their progress throughout treatment [56]. Such features can significantly contribute to enhancing patients' well-being [57]. Additionally, studies have found that these apps can improve communication with health care providers and improve self-efficacy and quality of life [30,58]. However, it is important to note that the quality and accuracy of the information provided by these apps can vary, and it is recommended to consult with a health care professional before using any app for managing a medical condition.

A recent study on breast health and breast cancer apps notes that although apps appear to be competitive and useful for patients, some major features have to be considered while developing these apps [59]. The features include notifications, reminders, symptoms tracking, and recording. The study also suggests designing the apps to be user-friendly, even for low-literacy patients, by adding an audio feature (text-to-speech). Developing features with audio support will not only help patients with low literacy but can also support multiple languages.

Recommendations and Implications for Practice

Privacy and Security

We would recommend that the developers of the apps be more transparent and state how the data will be used and that they should not have access to unnecessary data. We recommend that future breast cancer apps be available to Arabic speakers to justify the need for the permissions requested while also transparently disclosing the data safety handling measures to the app users. Security and privacy of apps are considered major requirements as they are accountable for sensitive patient data such as prescriptions, treatments, etc. Thus, to come up with robust apps that could ensure privacy and security appropriately, more evaluation techniques, as well as security mechanisms, should be analyzed and implemented on Arabic apps, in particular, to assess, measure, and control the apps' security and privacy [60].

Quality and Engagement

Involving patients and health professionals in the app design phase is crucial. Several studies have addressed the idea that health applications should be developed and designed based on the combined efforts of health professionals, related academics, and patients [61]. To raise the quality of breast cancer apps, the inclusion of utility features such as appointment booking for mammograms and web-based consultations becomes necessary. In addition, it is recommended to improve health apps' engagement by focusing on specific components such as personalized content, data visualization, reminders and notifications, educational material, self-management functions, and goal-setting features [62]. Providing users and patients with proper communication features and a well-designed interface leads to an ideal user experience as a result [30].

Study Strengths and Limitations

Similar to other studies, a rigorous multistep methodology mimicking systematic reviews is used in this study to assess the breast cancer apps that are available to Arabic speakers. Apps were thoroughly searched through both the web interface as well as the app stores natively on the devices, mimicking how end users will discover such apps. While the results provide an indication of the quality of the evaluated apps, additional investigations are required to consider patients' perspectives about their views about the quality as well as the utility of such apps. Future studies can also involve rigorous assessments with respect to the security measures applied by breast cancer apps available to Arabic speakers.

This study only considered the publicly available apps and may have missed apps that are "prescribed" to patients or consumers or those that are developed locally by health care organizations. Another limitation, which is inherent to the search strategy used in this work as well as similar other work [63], is the fact that the search algorithms used by the app stores are nontransparent and can change without the public's knowledge, potentially undermining the reproducibility of the outcomes. Lastly, the current state of the results as revealed by this work is likely to change quite rapidly since apps are regularly released, updated, and retired.

Conclusions

The battle against breast cancer is not over yet, and breast cancer apps can serve as valuable resources in this ongoing fight. The results of this systematic and thorough examination of breast cancer apps available for Arabic speakers reveal their limited existence at the time of study. The investigations evaluated these apps through the lenses of quality, privacy, and security, revealing that the included apps are rated as highly "functional" but at the same time are less "engaging." The investigations also reveal that some apps were accessing unnecessary data and collecting information that was not relevant to the purpose of the app.

Developers of breast cancer apps that cater to Arabic speakers must focus on consumers' preferences, demographics, usability, and the interface of their apps, as well as enhance measures and mechanisms of privacy and security for their apps. The low number of breast cancer apps available to Arabic speakers, as revealed in this study, should be a call to action for many health care organizations and developers to collaboratively develop information-rich, usable, functional, engaging, and secure apps.

Data Availability

All data generated or analyzed during this study are included in this paper and its supplementary information files.

Authors' Contributions

DA conceptualized the study design and supervised the study. DA and AA participated in data assembly, analysis, and interpretation, and in the writing of the paper. LA contributed to data interpretation and in the writing of the paper. All authors read and approved the final paper.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Included apps' declared permission and safety declarations.
[DOCX File , 17 KB - cancer_v10i1e48428_app1.docx]

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Abbreviations

MARS: Mobile App Rating Scale
MENA: Middle East and North Africa
mHealth: mobile health

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Original Paper

An mHealth App to Support Caregivers in the Medical Management of Their Child With Cancer: Beta Stage Usability Study

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Abstract

Background: Previous research demonstrated that caregivers of children with cancer desired a mobile health (mHealth) tool to aid them in the medical management of their child. Prototyping and alpha testing of the Cope 360 app (Commissioning Agents, Inc) resulted in improvements in the ability to track symptoms, manage medications, and prepare for urgent medical needs.

Objective: This study aims to engage caregivers of children with cancer in beta testing of a smartphone app for the medical management of children with cancer, assess acceptance, identify caregivers' perceptions and areas for improvement, and validate the app's design concepts and use cases.

Methods: In this pilot, study caregivers of children with cancer used the Cope 360 mHealth app for 1 week, with the goal of daily logging. Demographics and a technology acceptance survey were obtained from each participant. Recorded semistructured interviews were transcribed and analyzed iteratively using NVivo (version 12, QSR International) and analyzed for information on usage, perceptions, and suggestions for improvement.

Results: A total of 10 caregivers participated in beta testing, primarily women (n=8, 80%), married, with some college education, and non-Hispanic White (n=10, 100%). The majority of participants (n=7, 70%) had children with acute lymphocytic leukemia who were being treated with chemotherapy only (n=8, 80%). Overall, participants had a favorable opinion of Cope 360. Almost all participants (n=9, 90%) believed that using the app would improve their ability to manage their child's medical needs at home. All participants reported that Cope 360 was easy to use, and most would use the app if given the opportunity (n=8, 80%). These values indicate that the app had a high perceived ease of use with well-perceived usefulness and behavioral intention to use. Key topics for improvement were identified including items that were within the scope of change and others that were added to a future wish list. Changes that were made based on caregiver feedback included tracking or editing all oral and subcutaneous medications and the ability to change the time of a symptom tracked or medication administered if unable to do so immediately. Wish list items included adding a notes section, monitoring skin changes, weight and nutrition tracking, and mental health tracking.

Conclusions: The Cope 360 app was well received by caregivers of children with cancer. Our validation testing suggests that the Cope 360 app is ready for testing in a randomized controlled trial to assess outcome improvements.

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KEYWORDS

oncology; supportive care; mHealth; children; caregivers; mobile phones

Introduction

The necessary changes a parent or guardian has to make in caregiving when a child is diagnosed with cancer are immense and overwhelming [1-3]. In the home setting, caregivers must oversee complicated symptom management and medication administration needs. One viable avenue to address the complex needs of caregivers of children with cancer is through mobile health (mHealth) technology, defined as the application of mobile or wireless communication technologies to health and health care [4]. Many apps have been developed to address the needs of children and adolescents with cancer, yet few focus on the unique needs of caregivers who are overseeing the medical management of a child with cancer [5]. mHealth tools have the unique ability to support caregivers through their portability and ability to share data between multiple parties in real time.

Caregivers of children with cancer are known to use mHealth tools and in a recent survey study, the majority desired a tool to help with medical management [6]. Specifically, they desired a tool that would help with medical knowledge, symptom tracking, and medication reminders [6]. To ensure an effective tool is developed to respond to the gaps identified by caregivers, it is imperative to study and incorporate intended end users' specific perspectives and needs during mHealth tool development [7-9]. Involving end users increases the likelihood the app will both work for them and be used by them.

Developers and researchers of mHealth technology must also address the future acceptance of their product through direct interaction with the end users during the development process. Nadal et al [10] explored the important differences in acceptance versus acceptability and proposed the Technology Acceptance Lifecycle model, which highlights the evolving nature of technology acceptance across different stages of the user journey with the technology tool [10]. The Technology Acceptance Lifecycle explores the preuse acceptability, initial use acceptance, and sustained use acceptance which align with a shift in initial use acceptance from preadoption to postadoption of the tool in use.

To understand and address the needs of caregivers, our team engaged directly with the intended users to create the Cope 360 mHealth tool (Commissioning Agents, Inc). Thus far, caregivers have been involved in the co-design, prototyping, and initial refinement [11,12]. The objective of this study is to evaluate the initial use acceptance, and functionality of the Cope 360 app in a week-long trial by caregivers of children with cancer. The significance of this work is to demonstrate the importance of including the intended end users in acceptance testing outside the research environment in order to inform further refinements of mHealth tools such as Cope 360.

Methods

Study Design

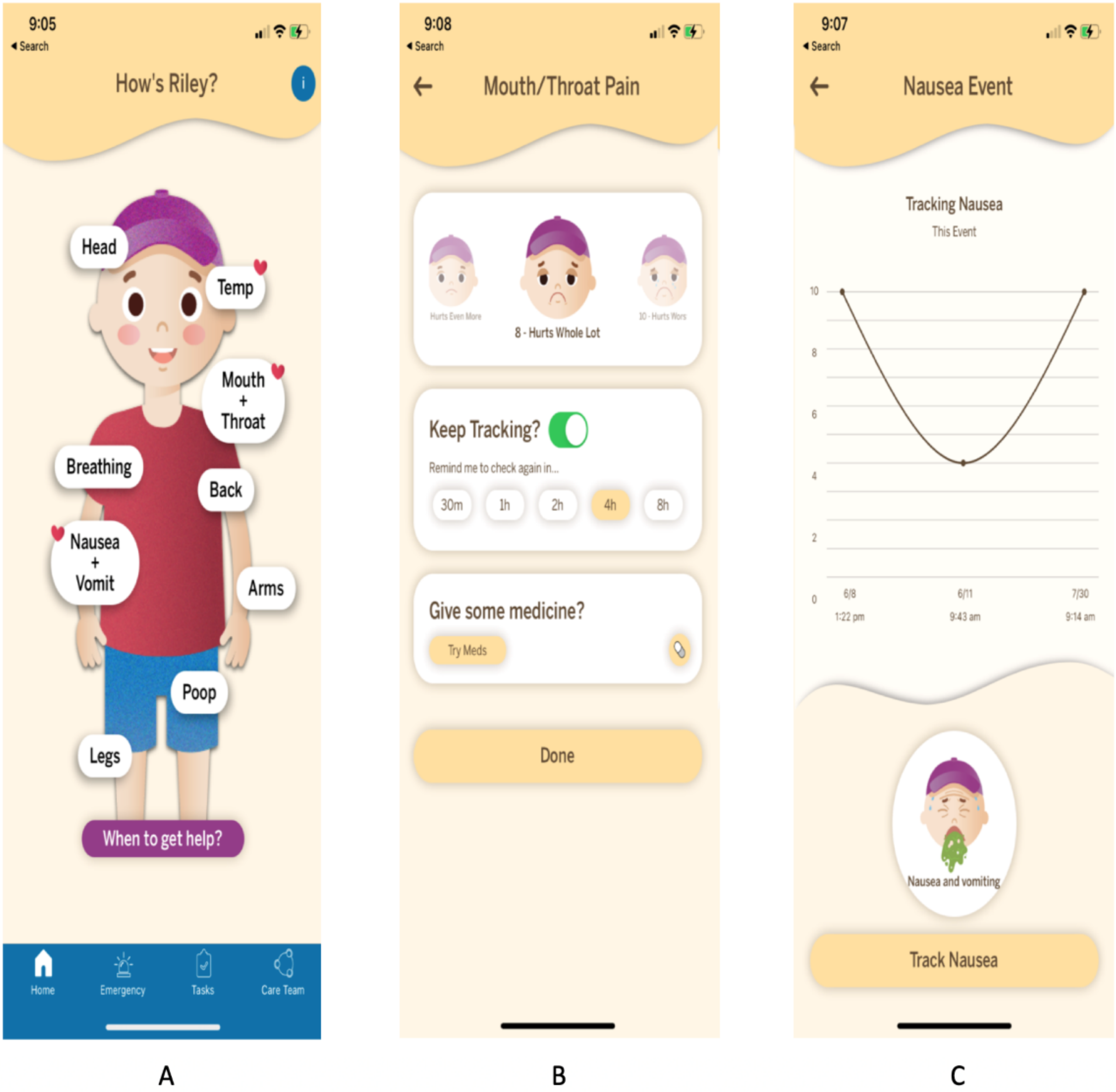
In this pilot study, we performed qualitative interviews and used a validated acceptance survey to engage directly with end users (ie, caregivers of children with cancer) to test an app to support caregivers in the medical management of their child with cancer. There were 3 phases of this project: prototyping of the app (phase 1), followed by alpha testing directly with caregivers (phase 2), and finally, initial use beta testing with caregivers (phase 3), which we evaluate here. Alpha and beta testing are validation methodologies that help researchers and designers assess the initial use acceptance and perceptions of end users. These tests provide opportunities for refinement before launching the product on a larger scale and result in greater success of the product for regular use [13]. In this final phase (phase 3), we collected measures of acceptance of the technology tool and performed qualitative semistructured interviews between May 2021 and October 2021.

Brief Summary of Cope 360 Features

The overall intent of the app is to assist caregivers in the medical management aspects of their child with cancer while they are outside of the hospital setting. It was not intended to be used while patients were being actively treated by a medical professional or under the direct care of an oncologist (such as during hospital admissions for therapy). After developing and prototyping the app, known as Cope 360, we performed alpha testing of the app with 6 nurse coordinators and 8 caregiver participants [12]. Alpha testing of Cope 360 resulted in improvements in clarity of medical information and terminology, improvement in the design of tasks, and tracking of symptoms including adjusting the look and feel of certain buttons and changing the visual graph used to monitor symptoms to include date anchors.

The symptom tracking feature is located on the home screen, where there is a cartoon representation of the patient that can be personalized by sex and 3 skin colors. The three key functions of the app are (1) symptom tracking, (2) medication management, and (3) emergency preparedness. The symptom tracking had nine options for tracking, including (1) temperature, (2) breathing, (3) nausea and vomiting, (4) poop, and pain in the following areas: (5) head, (6) mouth and throat, (7) back, (8) arms, and (9) legs. Each symptom has an individualized tracking scale based on previously published or validated scales. The temperature tracking provides directed feedback based on the temperature input from the caregiver. The medication management portion includes all current medications the patient is taking including oral chemotherapy and supportive medications that are entered by the nurse coordinators. The emergency preparedness plan allows the caregiver to create, practice, and enact a plan for seeking care for an urgent medical issue. Screenshots of the app key screens are included in Figure 1. The Cope 360 app was a fully functioning app that was downloaded by the caregiver onto either Apple or Android smartphones using a web-based download link provided to the participants upon consent.

Figure 1. Screenshots of Cope 360 key screens: (A) home screen, (B) symptom tracking, and (C) symptom monitoring.



Study Population

Participants were caregivers of a child with cancer (the child had to be younger than 21 years), had adequate English-language proficiency with grossly normal cognitive function, and had a child who was currently receiving cancer therapy at Riley Hospital for Children in Indianapolis, Indiana, and at least 1 month had passed after the initial diagnosis. We included caregivers of children up to the age of 21 due to most of our Children's Oncology Group clinical trials allowing for patients up to that age. Caregivers were contacted by phone for recruitment and interview scheduling; interviews were conducted and recorded over Zoom (Zoom Video Communications) videoconferencing due to COVID-19 precautions.

Measurements

For the beta test, demographic information was collected from participants using a web-based survey, including caregiver sex, age, race and ethnicity, marital status, yearly household income, and education. Additional questions included the relationship of the caregiver to the child, the child's type of cancer, and the child's therapy. After enrollment, the physician on the study team (ELM) reviewed the electronic medical record of the patient and added the documented medications into the Cope 360 app; caregivers were able to confirm and correct all medications. The caregivers were then asked to use the app for either actual or simulated situations for a period of 1 week, logging in at least once per day. At the end of the week, they were asked to participate in an audio-recorded semistructured qualitative interview by the research assistant (ARC) during which caregivers were asked open-ended questions including their use of the app, any problems they experienced, recommendations for improvement, and how useful they found the app during the week. See Multimedia Appendix 1 for semistructured interview guide.

At the end, the participants completed a web-based survey that included the modified Technology Acceptance Model (TAM) to measure their perceptions and acceptance of the app [14-16]. TAM is a behavioral model of end-user acceptance of new technologies. The use of TAM in the health care field has been relatively widespread and justified [16]. In this model, 3 factors are needed to explain and predict the actual use of information technology:

- Perceived usefulness: the end user's perception of whether the tool will accomplish its intended purpose.
- Perceived ease of use: the end user's perception of how easy it is to navigate within a tool and their reactions to the overall "look or feel" of the interface.
- Behavioral intention to use: the end user's perceived likelihood that they will engage and use a given tool.

Due to the small number of participants, the Likert scale categories collapsed into agree, neutral, and disagree. Items for this questionnaire were adapted from a study conducted by Venkatesh and Davis [17], which showed high reliability and strong construct validity.

Ethical Considerations

Development and refinement of the app were made possible through a partnership with Coactive Business Solutions of Indianapolis, Indiana. The Indiana University institutional review board approved this study (1903250567). Potential participants received a study information sheet via email that described the project and their ability to withdraw at any point in the interview. This was reviewed and then they consented to enrollment verbally. All data collected from caregivers were saved on a secure, HIPAA (Health Insurance Portability and Accountability Act) safe server with access only by the research team. Caregiver participants were compensated with a US $60 gift card for the 1-week use of the Cope 360 app, survey, and semistructured interview.

Analysis

Characteristics of study participants were summarized by frequency and range. Descriptive statistics of the acceptance survey were performed. To analyze the semistructured interview data, the research team focused on both (1) the usability and functioning of the app and (2) evaluated key caregiver-derived topics related to future improvement. The evaluation of the usability and function included open-ended questions about the following: app usage by the caregiver, including log-in and account creation, symptom tracking experience, perceptions of emergency planning, overall experience, and suggestions for future improvements.

The team conducted deductive and inductive analysis on the interview transcripts. Caregiver semistructured interviews were transcribed by a HIPAA-compliant service and then analyzed using NVivo (version 12; QSR International). First, an initial codebook was created deductively using the interview question topics listed above as the primary themes. In this study, the main themes were focused on the user experience during the beta testing phase of the Cope 360 app, with an emphasis on positive attributes of usability and function and key elements for improvement. Transcription and coding were performed as interviews were conducted and interviews continued until no new information was gathered and thematic saturation was achieved [18,19]. Two team members (ARC and MC) independently reviewed each transcript and assigned codes based on themes using an initial codebook. The codebook was revised based on new themes that emerged through data review [18,19]. The main inductive codes that were added during iterative analysis were the identification of issues with the intended app features, such as the lack of push notifications. A final review was performed by 3 team members (ARC, MC, and ELM) until an agreement on codes and themes was attained. A total of 58 codes were in the finalized codebook.

Results

Demographic Information of Study Participants

A total of 23 caregivers were contacted with 10 caregivers (females: n=8, 80% and males: n=2, 20%) participating in beta testing. All were married parents, and non-Hispanic White (n=10, 100%). Seven (70%) had children with acute lymphocytic leukemia and 3 (30%) had solid tumors. The majority had children being treated with chemotherapy only (n=8, 80%), 1 patient being treated using both chemotherapy and radiation and 1 (10%) with another form of treatment. All caregivers had at least some college education. All caregivers reported a yearly household income of at least US $50,000 to US $74,999 (Table 1).

Table 1. Demographic characteristics of the Cope 360 app beta testing participants (N=10).

Characteristics	Caregivers
Caregiver sex, n (%)	
Male	2 (20)
Female	8 (80)
Caregiver age (years; n=8), median (IQR) 37 (34-43)	38 (8.25; 33-47)
Child age (years; n=10), median (IQR) 6 (4-7)	6 (2.75; 2-9)
Caregiver race and ethnicity, n (%)	
Non-Hispanic White	10 (100)
Type of cancer, n (%)	
Acute lymphoblastic leukemia	7 (70)
Solid tumor	3 (30)
Type of therapy, n (%)	
Chemotherapy only	8 (80)
Chemotherapy and radiation	1 (10)
Other	1 (10)
Type of caregiver, n (%)	
Parent	10 (100)
Caregiver marital status, n (%)	
Married	10 (100)
Caregiver yearly household income (US $), n (%)	
Less than 49,999	0 (0)
50,000-74,999	1 (10)
75,000-99,999	4 (40)
100,000-150,000	1 (10)
Greater than 150,000	3 (30)
Prefer not to answer	1 (10)
Caregiver education, n (%)	
Less than high school	0 (0)
High school or GED[a]	0 (0)
Some college	1 (10)
College graduate	6 (60)
Graduate degree	3 (30)

[a] GED: general educational development.

Participant Initial Use Acceptance

A summary of participants' TAM overall favorability rating is presented in Figure 2. Overall, participants had a favorable opinion of Cope 360. Almost all (n=9, 90%) felt that using the app would improve their ability to manage their child's medical needs at home. The majority agreed that using the app would increase their effectiveness (n=7, 70%) and make it easier for them to manage their child's needs at home (n=8, 80%). All participants felt that Cope 360 was easy to use. Most felt they would use the app if given the opportunity (n=8, 80%) with neutral (n=1, 10%) and disagree (n=1, 10%). These scores indicate that the app had a high perceived ease of use with good perceived usefulness and behavioral intention to use.

Figure 2. Technology Acceptance Model agreement ratings by participants.

Participant Interviews

Analysis of the participant interviews revealed several general themes related to the user experience including initial setup, overall experience, experience with logging in, creating an account, symptom tracking, emergency planning, and a concluding category with questions such as future use of the app if publicly available and caregiving apps currently used.

Perceptions of Initial Set-Up

Participants were asked to use the app at least once a day throughout their week of using the app. When questioned about their actual usage, 9 (90%) participants said they used it every day or tried to use it every day; 1 (10%) participant said they used it about 10 times during the 7-day period. When asked about their experience logging in, 9 (90%) stated that they had no difficulties logging into the app. Two (20%) of the participants mentioned they had difficulties figuring out how to log out. One participant suggested moving the logout button to a more obvious area. All participants mentioned that creating a caregiver account as well as an account for their child was easy. When asked if they added other caregivers to their caregiver team, 3 (30%) did perform this task with no difficulty, while 7 (70%) did not add anyone.

Perception of Symptom Tracking

All participants used the symptom tracking feature of the app when asked what symptoms they had tracked: 8 (80%) tracked poop, 7 (70%) tracked nausea or vomiting, 4 (40%) tracked head pain, 3 (30%) tracked temperature, 2 (20%) tracked arm pain, and 3 (30%) tracked leg pain. When questioned on ease of use, all participants thought symptom tracking was easy to use, with 1 (10%) participant suggesting that they would like the ability to edit previous entries and another mentioning that they had some confusion about the meaning of the nausea or vomiting scale. Features of symptom tracking that were viewed positively included reminders (n=4, 40%), scales (n=4, 40%), and graphing (n=2, 20%). Noted issues or suggestions while using symptom tracking included not receiving notifications (n=9, 90%) and wanting to see more symptoms added (n=1, 10%).

Pulsing heart on symptom tracking shows that a symptom is actively being tracked. When asked if participants preferred a different method for showing they are tracking a symptom, 8 (80%) participants said they had no preference for a different method, while 1 (10%) suggested making it a color scheme instead of a pulsing icon, and 1 (10%) suggested making the icon a clock or timer since there is a time component to the symptom tracking. Finally, when asked about how they stopped tracking a symptom, 4 (40%) participants stated they did not stop tracking, 3 (30%) said stopping symptom tracking was easy for them and made sense, and 3 (30%) suggested other ways to stop tracking, such as an alarm clock you can snooze (n=1, 10%), and moving the tracking on or off to the overview page instead of having to enter a final symptom (n=2, 20%).

Perception of Emergency Planning

Participants were then asked about their experience with the emergency planning part of the app. Eight participants (80%) stated that they set up their emergency plans, but 2 (20%) did not set up the emergency plan. Of those who set it up, all thought it was easy to set up and helpful to them. A total of 6 participants (60%) mentioned that they experienced no issues with their emergency plan. One participant (10%) expressed concern about the phone number to the hospital in their emergency plan and stated it would be helpful to know if it goes to someone directly when it is off hours or if it is voicemail regulated, and 1 participant (10%) was unsure of how to execute the plan after setting it up. Included in the app is an electronic “card” that a caregiver can reference when in contact with a health care provider not familiar with caring for a child with cancer, and 9 participants (90%) felt there was nothing more necessary to add to that section.

Overall Perception of the Cope 360 App

All participants said that they would use or would possibly use Cope 360 if it was publicly available. Those who would possibly use it said that it would depend on whether their child was experiencing symptoms or not. Eight (80%) participants stated that the app assisted with or potentially assisted with the care of their child.

Key Topics for Improvement and Summary of Caregiver Feedback

In Table 2, we present the key topics for improvement along with key quotes from caregivers. Regarding medications, caregivers desired the ability to track and edit medication names or doses and the ability to change the time of a tracked symptom or medication if they did not perform the tracking in real-time. Additionally, they requested to be able to have a notes section to keep track of thoughts and ideas related to the child's clinical experience. They also desired tracking capabilities for skin changes, weight or nutrition, and mental health.

Table 2. Key quotes from Cope 360 improvement suggestions.

Themes	Examples of codes
Tracking all medications	• "For medications when we give him, there's not really a journal or a diary that we have the option on this app to put him in. It's more like you have a headache, okay, you should take Tylenol, or you can take this. It gives you the options. Whereas I give him daily medicine and I need to be able to be like, this is the medicine I'm giving him at this time. You know what I mean?" [Mother of a 6-year-old boy with neuroblastoma] • "I was thinking that like if maybe his daily meds that he has to take, maybe that don't like have to do with any of these other things like nausea and vomiting and that sort of thing. If there was a way to track that he had taken those, that would be helpful. Like administering his daily medications, knowing that we took those somehow that would be helpful in there. For me at least. I don't know about everybody else. And then I was thinking that somewhere on there, if there was an area to track, maybe some other symptoms maybe just put like other on there." [Mother of a 5-year-old boy with ALL[a]]
Editing medications	• "In the patient info, I know that [a healthcare provider] had to enter in the medications. I do think that's something that would be also be helpful if that was like either up-to-date or that I could edit them or something because I think that comes up a lot. Every time we come to clinic, we are talking about medications yesterday. We had a conversation about medications. And so I think if that was up-to-date or easier to edit would be helpful to just like [update] that record. Or if they were constantly, I don't know, it seems like a lot of work for them to constantly update everybody - but yeah, if I could add in stuff here that would be helpful." [Father of a 2-year-old girl with ALL]
Changing the time of tracked symptom or medication	• "There are parts of it that I would maybe change in that like I can't manually input the time post hoc after the event. It would make it appear as though it just happened then versus sometimes it's maybe you're somewhere else and they have to go to the bathroom, or you take their temperature but then you don't write it down for an hour or so. So maybe having something where you could actually like input the time or create kind of a note within the event." [Father of a 3-year-old girl with ALL]
Adding a notes section	• "Well, I like the reminders and that you can see like where you were last time when you go back in. I thought that was good. It might have been good place to have a place to put some notes in because it's very like, just click on a picture. I didn't think of this until now, but it might be handy to be able to put a note in if you wanted to. [Mother of a 7-year-old girl with ALL] • "So maybe having something where you could actually like input the time or create kind of a note within the event. And if that is a possibility that would, I didn't see it, but that would be maybe one thing that I would improve upon, kind of having a note section to kind of further explicate or be able to manually say hey you know, this happened at noon." [Father of a 3-year-old girl with ALL]
Monitoring skin changes	• "Obviously, I just primarily know from our experience and then the experience of some other cancer families that we've gotten to know. Rashes are something that pops up, I wouldn't say fairly regularly, but it has popped up. She's probably had 10 different rashes over the last eight months, so that may be rashes or bruising. Maybe if there was a health tracker for skin where you can then get into, is it rashes and bruising? … I would maybe add another health tracker and just maybe call it skin, and then you have it so you could put in if there was a rash, if there was a cut, if there was a bruise because the rashes, especially with all the medicines pop up quite a bit. Then the bruising, especially when blood counts are low, immunity is low, the bruising can become a pretty significant symptom." [Mother of a 9-year-old girl with ALL]

[a] ALL: acute lymphoblastic leukemia.

Discussion

Principal Findings

In the initial use beta testing of an app to support caregivers in the medical management of children with cancer, our team found that the Cope 360 app was well received by caregivers and offers the potential to impact the outpatient medical care of children with cancer. Specifically, caregivers were able to successfully track the most common symptoms experienced by their child with cancer. Initial use beta testing was able to identify a limitation and several key areas for refinement based on caregivers' usage and needs. Specifically, it was identified that having access to and the ability to adjust medications was desired by caregivers therefore this was prioritized as an improvement in the Cope 360 app refinement. The next step for the Cope 360 app will be to test the feasibility and sustained use acceptance over a longer period with additional emphasis on how a tool to support caregivers could improve their perceptions of their medically focused caregiving roles.

Beta Testing Success and Tradeoffs

The success of the beta testing of the Cope 360 app likely was impacted by the continuous engagement of key stakeholders from conception through prototyping and refining. During the initial work with co-design and creation, we had focused on preparing caregivers for when medical emergencies arose, but the insight and contribution of caregivers helped clarify that providing tracking and overall medical management was integral [12,20]. Allowing caregivers to directly interact with the app outside of the formative testing sessions shed light on the participants' initial use acceptance and created a great opportunity for wider exposure to how the app could be used.

One key challenge in beta testing that was noted, as compared with previous prototyping and alpha testing, was the gap in clarity of the intended notifications and features of the app. For example, many caregivers did not know that they were supposed to be receiving push notifications for medications, which were found to be not working well. One recommendation to overcome this challenge would be to improve clarity for first-time app users by offering a comprehensive review of the app features [12]. Another opportunity to overcome this challenge is to create a notifications section within the user interface that would alert the user to the intention to receive notifications.

Changes Made and Future Directions for Cope 360

Engagement with end users demonstrated the need for further refinement to address the desires of caregivers of children with cancer. The changes we were able to make to the app included the end user (eg, caregivers) are now able to adjust medication names and doses. They are also able to adjust the time of the medication administration if they do not document it in real-time. This was important to caregivers and our team because it allows caregivers to continue to use the app even during holds or adjustments of medications due to patient illness or based on chemotherapy adjustment strategies for toxicity. This ability to adjust medications adds an additional layer of protection to ensure accurate medication dosages in that both health care professionals will be capable of inputting the medications and caregivers will be able to adjust in real time. This is especially important since holds or adjustments can occur overnight or on a weekend when team members are not available. There were several desires for changes by caregivers that were not within the scope of the current project budget but will be incorporated into future research endeavors including adding a notes section and monitoring for skin changes, weight or nutrition, and mental health.

The Cope 360 app performed well in initial use acceptance and has the ability to meaningfully impact both patient and caregiver outcomes. However, before deploying widely, future research on the Cope 360 app will be needed to explore feasibility, usability, and caregiver outcomes using mixed methods to get a more robust understanding of the experience of caregivers as they manage their child's medical needs in the community setting. Building off Van Houtven organizing framework for caregiver interventions [21], our research team plans to evaluate 3 caregiver outcomes and engage with end users through semistructured interviews. The elements of the Van Houtven framework that we believe the Cope 360 app can address are clinical knowledge and caregiver self-efficacy. Therefore, we will be assessing caregiver self-efficacy [22], mastery of caregiving [23], and caregiver stress [24]. We also intend to dive deeper into the feasibility of this app in real-life setting over a prolonged period of time by evaluating which symptoms are most commonly tracked and the frequency of app usage.

Recommendation for mHealth App Development

The process of co-design, creation, and refinement of an mHealth tool holds many lessons for health care professionals interested in engaging in the design and use of mHealth tools for their patient populations. First, incorporating the end users from inception highlighted their unique needs and desires. These were then brought to the forefront of all testing. Evaluation in a controlled research environment allowed an increased understanding of the users' needs related to the interface of the tool. However, evaluation of practical acceptability was best achieved through the initial use testing period. The challenge we found was the missed opportunity for feedback on features the participants were unaware of. There are several ways to overcome this challenge including through a more detailed orientation process with the mHealth tool prior to the initial use testing and through period monitoring of use during the trial period.

Limitations

There are several limitations to the initial use testing of the Cope 360 app in this study. The primary limitation was the small sample size which limited the ability to fully evaluate the TAM. Therefore, general statements about acceptability were included. The qualitative feedback obtained through this sample was robust and covered many key features and future design suggestions. Yet our team appreciates that the sample was lacking in diversity, which may have highlighted other findings not included in this analysis. This study occurred at a single institution with the investment of the study team to incorporate the patient's current medications into the app upon enrollment. Currently, the app is designed to be used by caregivers but has medications generated by health care providers.

Conclusions

The initial use evaluation of the Cope 360 app by caregivers of children with cancer confirmed its acceptability and usability of aid in medical management in the home setting. The next phase will be to perform a randomized controlled trial to evaluate the longitudinal feasibility and impact on outcomes that matter to caregivers. Specifically, we will focus on the caregiver's sense of self-efficacy, mastery of caregiving, and stress and evaluate the frequency of app use over time and the types of features most used by caregivers.

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Generative artificial intelligence was not used in the writing or revising of this manuscript.

Data Availability

The datasets generated during and/or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

ELM and ARC participated in the conceptualization, data curation, formal analysis, investigation, funding acquisition, writing, and revising of the manuscript. MEC participated in the data curation, formal analysis, investigation, and revision of the manuscript. SN, RJH, and ADM participated in the methodology, resources, supervision, and revision of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Semistructured interview guide.
[DOCX File , 17 KB - cancer_v10i1e52128_app1.docx]

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Abbreviations

mHealth: mobile health
HIPAA: Health Insurance Portability and Accountability Act
TAM: Technology Acceptance Model

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Original Paper

Needs of Patients With Gynecologic Cancer and Their Caregivers for Obtaining mHealth-Supported Self-Management: Focus Group Study

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Abstract

Background: Family caregivers of individuals with gynecologic cancer experience high levels of distress. Web-based caregiver support interventions have demonstrated efficacy in improving caregiver outcomes. However, the lack of portability could be a limitation. Mobile health (mHealth) apps could fill this gap and facilitate communication between patient-caregiver dyads.

Objective: We sought to obtain information on desired usage and features to be used to design an mHealth self-management support app targeting both patients with gynecologic cancer and their caregivers.

Methods: We conducted Zoom focus groups with women who had been treated for gynecologic cancers (ovarian, fallopian, primary peritoneal, uterine, endometrial, cervical, and vulvar); patients were also asked to invite a self-identified “closest support person” (caregiver). A semistructured focus group guide was used to elicit information on patients’ and caregivers’ perceived gaps in information and support, desired features of an mHealth app, and interest in and preferences for app usage. After transcription, rapid qualitative analysis using a thematic matrix was used to identify common themes across groups.

Results: A total of 8 groups were held. The final sample included 41 individuals with gynecologic cancer and 22 support persons or caregivers (total n=63). Patients were aged between 32 and 84 years, and most (38/41, 93%) were White and married. For caregivers (n=22), 15 (68%) identified as male and 7 (32%) as female, with ages ranging between 19 and 81 years. Overall, 59% (n=13) of caregivers were spouses. Questions geared at eliciting 3 a priori topics yielded the following themes: topic 1—gaps in information and support: finding relevant information is time-consuming; patients and caregivers lack confidence in deciding the urgency of problems that arise and from whom to seek information and guidance; topic 2—desired features of the mHealth app: patients and caregivers desire centralized, curated, trustworthy information; they desire timely recommendations tailored to specific personal and cancer-related needs; they desire opportunities to interact with clinical and peer experts through the app; and topic 3—interest and preferences for app usage: need for private space in the app for patients and caregivers to get information and support without the others’ knowledge; patients and caregivers desire having control over sharing of information with other family members.

Conclusions: Designing a single mHealth app to be used by patients and caregivers presents unique challenges for intervention designers and app developers. Implications of the study suggest that app developers need to prioritize flexibility in app functionality and provide individuals the ability to control information sharing between patients and caregivers.

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KEYWORDS

gynecologic oncology; gynecologic cancer; self-management support; user-centered design; cancer distress; self-management; caregiver support; cancer information; women's health; family support; informal caregivers; informal care; mhealth

Introduction

Caregivers of a family member with cancer experience high levels of distress and anxiety [1]. Caregivers of those with gynecologic cancer are particularly prone to high levels of distress [2], largely because these cancers are relatively rare, and for most (eg, ovarian, fallopian, and primary peritoneal cancers), no reliable screening exists. Thus, diagnosis is often not made until late stages, requiring intensive treatments with many side effects.

A growing literature documents the needs of caregivers of those with cancer in general and caregivers of those with gynecologic cancer in particular. Top-ranked needs include obtaining information about the cancer and treatment, finding ways to support individuals with gynecologic cancer, and maintaining their own health and well-being while providing care [3]. In busy gynecologic oncology practices where the focus is necessarily on treating the patient’s cancer, caregiver needs frequently are not prioritized or addressed [3], leaving caregivers without a dedicated support mechanism. Moreover, caregivers and patients exhibit a high degree of congruence regarding unmet needs for information and support [4].

A potential scalable solution for supporting individuals with cancer and their caregivers during treatment is the use of technology-based information, professional and/or peer support, and self-management coaching interventions. In particular, web-based self-management interventions that guide participants to develop their own plan of care, and monitor and manage their health proactively, are associated with positive effects on patient and caregiver well-being [5,6].

Our team has carried out a series of self-management support interventions based on the Representational Approach to Patient Education [7,8]; the WRITE Symptoms efficacy trial [9] among women with recurrent ovarian cancer; the SmartCare efficacy trial among caregivers of patients with a primary malignant brain tumor [10]; and a clinical implementation project to integrate family caregiver support into gynecologic oncology practice [11]. Each of these interventions followed the Representational Approach to guide patients or caregivers through self-management problem-solving. Key action steps include (1) representational assessment of symptoms or needs in the care situation; (2) identification of gaps, confusions, or misconceptions; (3) provision of targeted psychoeducation to address gaps in knowledge or correct misconceptions; (4) development of participant-generated goals and strategies to meet their goals; and (5) regular review of goal progress, strategy effectiveness, or barriers encountered and revision of goals and strategies as needed [9,12].

In the WRITE Symptoms 3-arm randomized clinical trial (N=497), the self-directed and nurse-delivered symptom self-management interventions (both computer mediated) were superior in improving patients’ symptom control compared to those receiving enhanced usual care at 8- and 12-week after baseline [13]. Furthermore, there was no difference in outcomes between the nurse-delivered and self-directed arms, and those in the self-directed arm were able to get through more symptoms more efficiently than those in the nurse-delivered arm. In the SmartCare randomized clinical trial, also based on the Representational Approach, caregivers of patients with primary malignant brain tumors receiving the SmartCare intervention reported significantly lower caregiving-specific distress and improved mastery over caregiving tasks compared to those receiving care as usual [10].

Despite the demonstrated benefits of web-based interventions in both patients with gynecologic cancer and in caregivers of individuals with primary malignant brain tumors, their lack of portability may be a limitation. Web-based interventions designed to be delivered via computer may be difficult to access during times of the most acute need. Mobile devices (eg, smartphones, tablets) could fill this gap. Such devices have become ubiquitous in American society: more than 70% of Americans use mobile devices (eg, smartphones) [14], and over 300,000 mobile health (mHealth) apps are available [15], presenting distinct scalability advantages over web-based interventions. Second, mobile platforms offer greater flexibility than computer web-based interventions for providing access to real-time feedback and resources [16]. Studies indicate that patients gain empowerment for managing their health and have positive health outcomes with the use of well-designed mHealth apps [17]. Translating web-based interventions into mHealth platforms presents challenges related to including key intervention ingredients in a mobile device, yet it presents opportunities to offer additional functionality and features not present in the original intervention.

As the first step in translating the SmartCare web-based intervention to an mHealth app, the research questions underlying this study were as follows: (1) What are the gaps in information and support in cancer care perceived by patients with cancer and family caregivers? (2) What are the features and functionality desired by patients and caregivers in an mHealth self-management support app? and (3) Would patients and caregivers use the mHealth app for day-to-day management, and if so, how would they prefer to use it (together or individually)? The objective of this study was therefore to obtain information on needed information and support, as well as desired usage and features, to inform the design of an mHealth self-management support app.

Methods

Sample and Setting

We recruited a convenience sample of women who had been treated for gynecologic cancers (ovarian, fallopian, primary peritoneal, uterine, endometrial, cervical, and vulvar) from a large quaternary care, university-affiliated health system in Western Pennsylvania. Women were also asked to invite a self-identified “closest support person” to participate. Using the health system’s honest broker system (HB015 University of Pittsburgh Medical Center [UPMC] Hillman Cancer Center, Pitt Biospecimen Core, and UPMC Enterprises), members of the cancer registry who had been treated for gynecologic cancer during the previous 5 years received a letter with information about the study from the Chair of the Division of Obstetrics, Gynecology, and Reproductive Sciences inviting interested individuals to participate. The invitation letter permitted recipients to define “family support person” as they wished; we did not specify a required relationship to an individual with cancer. We permitted individuals with cancer and family support people to participate in the same groups to permit identifying information needs and desired app features for both groups of users. Joint participation was also intended to elicit critical information about preferences for using the app individually or in partnership with the patient or caregiver.

Ethical Considerations

The University of Pittsburgh’s Human Research Protections Office (institutional review board) approved this study as an exempt investigation (STUDY19110158). Participants provided informed consent to participate in the focus groups and were paid US $50 each.

Procedure

Recruitment letters were prepared and mailed by registry staff to maintain confidentiality from research team members. Individuals interested in participating in the study after receiving the recruitment letter were asked to telephone the study coordinator to indicate interest in participating in the study.

A series of focus groups were conducted over 6 weeks using a secure, Health Insurance Portability and Accountability Act (HIPAA)–compliant Zoom account. Each group lasted approximately 90 minutes and was recorded using the built-in Zoom record feature. Patients and caregivers/support persons were scheduled for groups based on their convenience. The principal investigators (GBC and HSD) developed a semistructured focus group guide and conducted the focus groups to elicit information on the stated research questions. The focus group guide was designed specifically to elicit critical gaps in the information currently provided to patients with cancer and their families, desired features of a mobile app, and interest in and preference for an mHealth app for information and support.

After briefly sharing their cancer story to establish rapport, participants were asked about gaps in currently available information and support. Subsequently, they received a brief description of a potential mHealth information and support app and were asked about whether or not such an app would interest them; desired content, features, and functionality of such an app; and preferred ways of engaging with an app (ie, individually or in partnership with a caregiver/support person). Participants were also encouraged to verbalize any lack of interest in mHealth apps or in the potential content being discussed, to voice reasons for their disinterest, and for suggestions to make the app and content more appealing to them. A total of 8 groups were initially scheduled. The team debriefed after each focus group to identify any new information identified in each group. After the seventh group, no new themes had been identified. The eighth group was then held as scheduled; subsequently, the team agreed that saturation had been reached and no additional groups were scheduled. A priori topics and sample questions appear in Table 1.

Table 1. Sample focus group questions.

Topics	Sample focus group questions
Gaps in information and support	• How do you currently obtain information and support for your cancer journey? • Have you had difficulty obtaining the information and support you need? • How might you use an app like this for your day-to-day information needs or support?
Desired features of a mobile app	• If you are receiving most of your cancer care in your home community, how would you feel about a nurse from Pittsburgh—that is, not from your own community—reaching out to you to provide information and support? • Tell us about reasons why you might not use such an app? Are there features or content that might make you more interested in it? Are there other things that you imagine that you might want to use it for, or other aspects or features that might make it more useful? • Do you prefer to receive reminders to answer questions every several days, or would you rather answer questions only when you want to?
Interest in and preferences for a mobile app	• Would you prefer to use the app yourself (meaning as a patient or a caregiver, you would use the app to manage your own most important concerns), or with your caregiver/patient together (meaning you would work on it together on shared goals)? Do you have thoughts about how that might work? • This app would be a program that you could use on your own. You could also use it to get information and additional support from a nurse. How interesting would this be to you? • Describe how you could see this app being used by the nurses or other staff in the clinic during the diagnosis and treatment process you experienced. • Would you like a nurse to reach out to you after each time you answer questions through the app, or less frequently than that?

Analysis

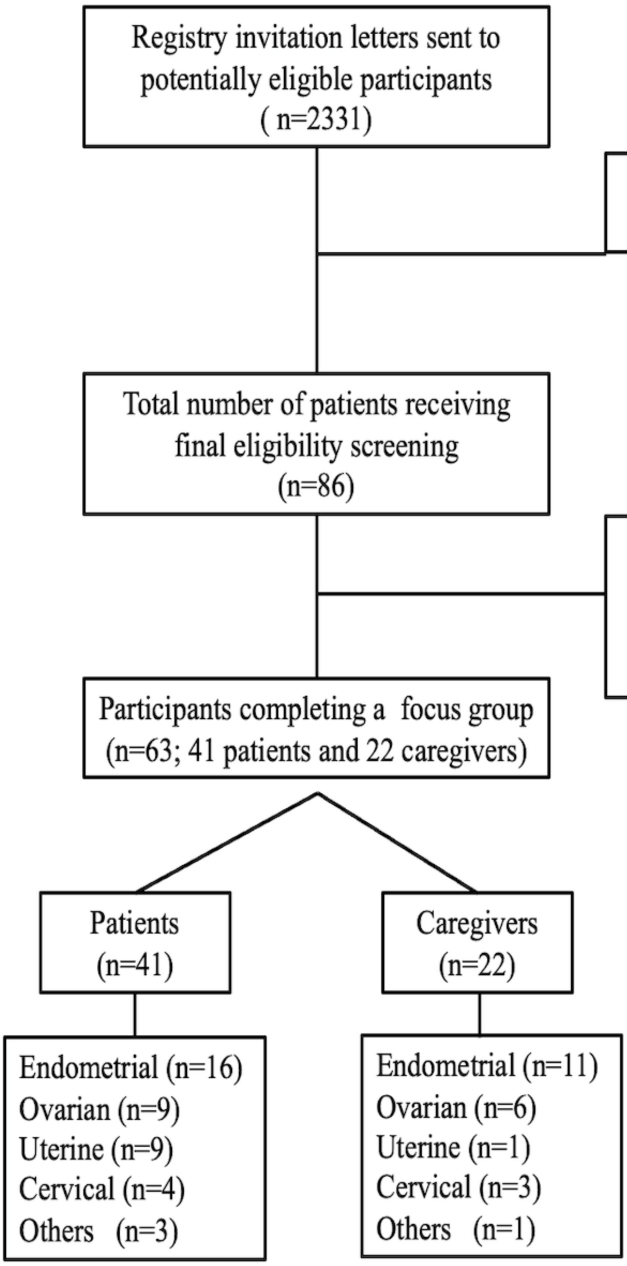
Each group's recording was transcribed verbatim by the Qualitative Data Analysis Program at the University of Pittsburgh's Center for Social and Urban Research. Individual speakers were neither identified nor delineated in transcripts to preserve the focus on the group, rather than on individuals, as the unit of analysis [18]. Following transcription, we used rapid qualitative analysis [19] to elicit thematic feedback from focus groups in a relatively short amount of time. Rapid qualitative analysis is a technique that uses a coding template initially developed from a subset of the data. The template is then expanded iteratively as additional themes are identified during coding of additional data and permits clustering of themes to help organize the data [20]. Rapid analysis thus provides a preliminary understanding of key themes, which can then be used to inform intervention development and implementation [21-23]. Initially, a preliminary codebook of themes was developed by the research team. Four investigators (HK, TK, HSD, and GBC) then independently coded the same transcript and compared agreement regarding transcript codes. The ReCal Reliability Calculator [24] was used to calculate intercoder reliability coefficients. Conflicts were adjudicated by the research team until agreement was achieved, and the preliminary codebook was finalized. Four team members then independently coded 2 more transcripts, and intercoder reliability coefficients were calculated for these 2 transcripts. We achieved a mean Cohen κ of 0.80 for these 2 transcripts. Following a common rapid qualitative analysis paradigm, once acceptable interrater reliability had been achieved, each remaining transcript was then coded by one validated coder. A thematic matrix was constructed using all raters' identified themes to quickly identify common themes across focus groups. These themes will be used to inform the future design of app functionality and implementation strategies.

Results

Sample Characteristics

A total of 86 individuals called the study coordinator after receiving an invitation to participate. Of those 86 individuals, 15 could not be reached further to be scheduled for a focus group. In total, 71 participants were ultimately scheduled to attend a group, although some (4 dyads, n=8) did not attend their scheduled session. The final sample included 41 individuals with gynecologic cancer and 22 family support persons/caregivers (total n=63). The focus group patients were aged between 32 and 84 years, and most (38/41, 93%) were White and married. Patients' cancer diagnoses were endometrial (n=16, 39%), ovarian (n=9, 22%), uterine (n=9, 22%), cervical (n=4, 10%), and other (n=3, 7%). For caregivers (n=22), 15 (68%) individuals identified as male and 7 (32%) as female, with ages ranging between 19 and 81 years. Overall, 59% (n=13) of caregivers were spouses, followed by children, partners, siblings, and parents. Diagnoses of caregivers' loved ones (patients) were endometrial (n=11, 50%), ovarian (n=6, 27%), uterine (n=1, 5%), cervical (n=3, 14%), and other (n=1, 5%). A recruitment diagram appears in Figure 1.

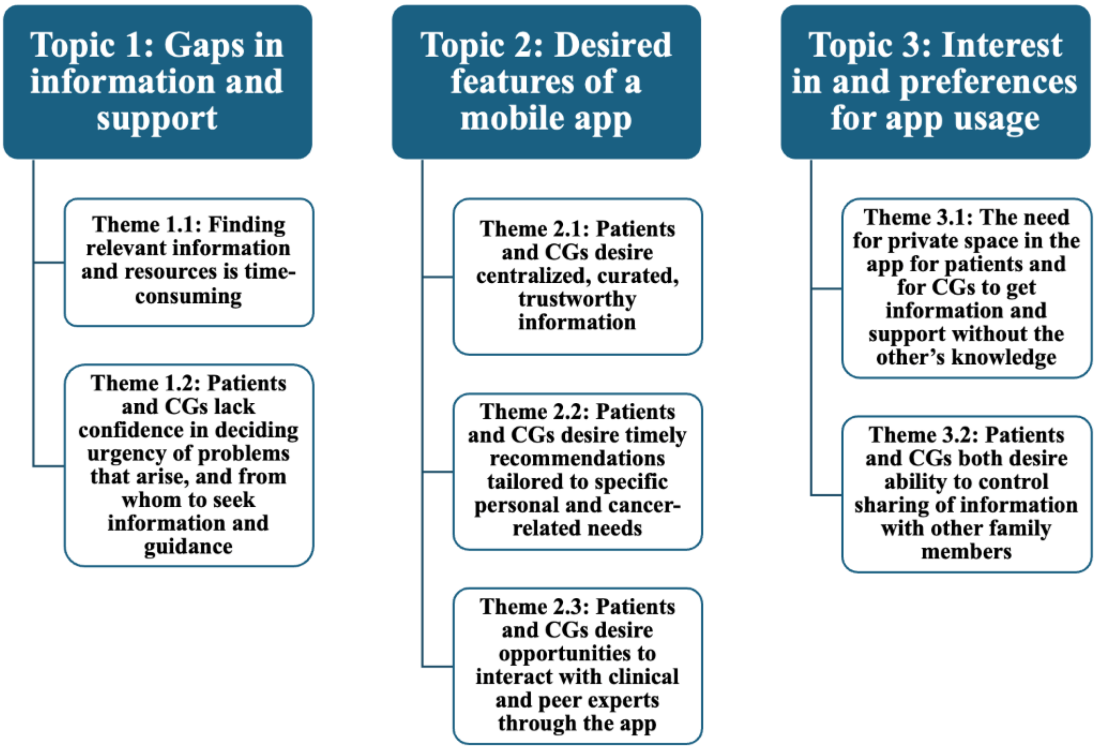
Figure 1. Study enrollment diagram.



Themes

We identified 3 a priori overarching topics to guide focus group conversations (Gaps in information and support; Desired features of a mobile app; and Preferences for app usage). Topics and themes are depicted in Figure 2 and are discussed in detail below. Exemplar quotes that best embody the discussion across groups are provided.

Figure 2. Topics and themes related to needs and preferences for support apps. CG: caregiver.



Topic 1: Current Gaps in Information and Support in Cancer Care

Theme 1.1: Finding Relevant Information and Resources is Time-Consuming

Patients and caregivers in all groups reported seeking information and formal support from their doctors and oncology nurses through phone calls, emails, or text messages when they were experiencing symptoms. Doctors and nurses provided assistance and support to patients who had medical questions. Yet, groups acknowledged still feeling a lack of information, so they sought information outside the clinical setting. One participant even noted that it felt like it was in her “own hands” to locate the help she needed. Participants simultaneously acknowledged that seeking support independently was time consuming, frustrating, and challenging. Consensus across groups suggests that much of the information that patients and caregivers found on their own had limited applicability to their specific situation, so they spent extensive time sifting through irrelevant information in search of something that might apply to them.

> *We spend a lot of time doing external research and kind of like trying to find, just, the information that kind of exists out there in the academic literature on the internet.* [Patient, focus group 7]
>
> *If there was a library that I knew I could log into and look up subjects...something dependable. Not something thrown on the internet. I don’t trust a lot of that stuff.* [Patient, focus group 6]

Theme 1.2: Patients and Caregivers Lack Confidence in Deciding Urgency of Problems That Arise, and From Whom to Seek Information and Guidance

Participants noted that when patients experienced new or concerning problems, such as worsening symptoms, it was difficult to self-triage—that is, to decide who to contact and where to find relevant resources. Patients and caregivers wanted to discuss their health concerns with their health care providers at the earliest onset of new symptoms. However, they were unclear as to what warranted an immediate phone call or visit to the clinic and what could be brought up at the next scheduled appointment. Despite their overall reluctance to seek web-based information, when making decisions about symptom urgency, many participants turn to searching for digital information. Examples from participants highlight how anxiety-provoking it could be to make these kinds of decisions in the middle of the night:

> *I’m just thinking—that at 2:30 in the morning, you look at something, and it specifically says, ‘Yes, this is something to be very concerned with,’ now you have to—what are you going to do at 3:00 in the morning?...That the level of anxiety is constantly being stirred, and it’s a challenge.* [Caregiver, focus group 1]

Finally, participants expressed needing extra reassurance and information about what was normal and not normal when dealing with cancer, particularly for family caregivers who may not have experience with cancer.

> *I would have liked to have known, 'Well, what do I—what happens if she’s bleeding? Or take her to the hospital’? Or, you know...the tiredness, it’s not*

> *something terrible, it's something just happening.* [Caregiver, focus group 8]

Topic 2: Desired Features of a Mobile App

Theme 2.1: Caregivers and Patients Desire Centralized, Curated, Trustworthy Information

According to participants, they were filled with uncertainty regarding the reliability of web-based information. Patients and caregivers spoke about turning to Facebook support groups, the internet, and library resources to obtain information about cancer (eg, nutrition, exercise programs, wigs, meditation, counseling services, etc). Yet many spoke of needing assurance that the information being provided is high quality, trustworthy, and curated by a team of gynecologic oncology experts. They acknowledged that what can be found on the internet is not necessarily helpful or true.

> *So it's like, a place for medical science and psychology and social work, and all that, I think it's important to engage librarians in all of this. Librarians are expert in assessing information, and compiling resources, so involve librarians.* [Patient, focus group 3]
>
> *I love the fact that there'll be accurate supported research data information out there for the cancer patient and her support person.* [Patient, focus group 1]

One request was that the app provide glossaries of health terms with easily understood language. These glossaries would provide gynecological cancer-related information, such as chemotherapy agents and side effects, stages of cancer, symptom management, or medication and drug information, in a single place.

> *For the lay person, and make it easily understood, and they can apply it to what their pathology report, or what they learned at the doctor's office. They have a lot to gain from knowing just the medical terminology, and the meaning behind it. People have no idea what that meant...So, like a glossary, I think, would be good.* [Patient, focus group 4]

Family caregivers also expressed a desire for anticipatory information on how to care for an individual with gynecologic cancer:

> *What do you expect during chemo? What do you expect during radiation? What can you do to help them through this process? That's the information I think I would be most interested in through that app.* [Caregiver, focus group 6]

It should be noted that not all participants thought they would use the app, largely because of a lack of technological proficiency. Because of this, there was consensus that the information on an app would need to be accessible to all users, regardless of their level of technology skills. Participants also suggested that there should be alternative methods for those who are not tech-savvy to engage with needed information and support, such as a call center that can respond to calls or texts.

Theme 2.2: Patients and Caregivers Desire Timely Recommendations Tailored to Specific Personal and Cancer-Related Needs

Group participants, regardless of whether they were patients or caregivers, overwhelmingly voiced a desire for the app to provide specific information about cancer and treatment that is tailored, or "customizable," to their place on the cancer trajectory. For example, participants who were early in the cancer journey wanted to receive information about the most common cancer symptoms, side effects of drugs and chemotherapy, alternative treatments, and nutritional information during treatment. Those who were further along the trajectory expressed the need for information regarding topics such as family genetic history and testing, as well as how to manage "survivor guilt," the feeling that occurs when a person feels guilty after surviving a life-threatening situation while others they meet are not so fortunate.

> *There's an immediate need for information when you're first diagnosed, and then there's a second tier of information after that of after you've gone through your surgery and your treatments. And then there's a third level after that of, you've recovered...what are the information resources that help somebody be okay about the ongoing threat of cancer still being out there...That's gotta be really rough. And so it requires a whole new range of information resources.* [Patient, focus group 3]
>
> *I was happy, and thankful, that I was recovering, and I only had three radiation treatments and no chemotherapy treatments. But my survivor guilt was bigtime...I'm the only one surviving this cancer. And I had a hard time, I still have a hard time with survivor's guilt. So I think an app that would be customizable to survivor's guilt would be good for me.* [Patient, focus group 5]

One topic for which no clear consensus emerged concerned built-in reminders (eg, to complete assessments and learning activities). Some group members noted that reminders would be especially helpful at certain times in the care trajectory, such as at diagnosis, because there are so many new things to remember and keep track of but less helpful during other times (eg, after treatment was completed and symptoms were stable). Those who endorsed reminders talked about the importance of reminders and personalized support for exercise, diet, and other activities related to recovery from cancer. They suggested that the app should send push notifications to remind patients of upcoming appointments or activities and offer personalized support based on their stage of recovery.

> *if it's a push that's coming out—it would be more interesting to me. It could then basically require me to respond, so that I would be able to say, 'Yes, I've got the rash,' or, 'No, I haven't, but my hair is falling out,' or some other reaction.* [Patient, focus group 4]

Some even noted that the reminder could help them to talk with their partner in the cancer journey about topics of interest.

> *If, the same little reminder, or bit of information was being sent to both the patient and the caregiver, it might help to even open conversation. "Oh, did you see what the app sent on us our phone at lunch time today? What do you think about that?"* [Patient, focus group 3]

However, other respondents in our study noted that they would prefer not to have reminders, perceiving them to be intrusive because "Reminders...can come at awkward time..." or can cause unwanted emotions, especially during times when they are able to forget the cancer and go about their daily lives:

> *You're pulling on emotions that've been subdued while you're making the spaghetti.* [Caregiver, focus group 1]

Groups thus agreed that the ability for individual users to customize reminders according to what was most helpful to them is an important app feature. Flexibility to be able to change reminder frequency based on needs was also noted.

Theme 2.3: Patients and Caregivers Desire Opportunities to Interact With Clinical and Peer Experts Through the App

Timeliness was also reflected in the request by several dyads to be able to communicate with a health care professional via the mHealth app. A key stipulation was that the communication should be with someone knowledgeable about the type of cancer and treatment. Group members felt that professionals or providers did not need to be members of the patient's own treatment team; however, they noted that it should be someone who is familiar with the cancer and the treatment trajectory for their particular type of cancer.

> *A nurse or somebody that you would be able to, like, reach out to and talk to...that's an important aspect that should be included no matter what...So having somebody was empathetic, and understood the situation, and would be willing to talk with you and walk through questions. That would be an important thing. It would've been really appreciated by us.* [Patient, focus group 7]

They also recognized the potential of interacting with peers through the app. Participants noted that mHealth platforms could enable them to share concerns and experiences, as well as to receive both practical and emotional support from other cancer patients and their caregivers.

> *I like chat groups for some practical down-to-Earth advice, because those women went through what I'm going through... somebody from a chat room would say, you know, "Put a thick cream on it. That's what helped me in the past." That's the kind of support I need.* [Patient, focus group 2]
>
> *If like maybe caregivers could connect to other caregivers, or patients could connect to other patients. I think it would be really nice if I could like post a question in a forum, or something...like someone could share an article with me, I think that would be really nice.* [Patient, focus group 8]

Their recommended formats for communication included question-and-answer or chat room features that can be monitored and moderated by health care providers to ensure accuracy, provide practical cancer advice, or share concerns.

Topic 3: Interest in and Preferences for App Usage

Theme 3.1: The Need for Private Space in the App for Patients and for Caregivers to Get Information and Support Separately, Without the Other's Knowledge

Consensus across groups indicates that most people would be interested in an app provided it met their previously voiced concerns regarding trustworthiness, efficiency, ability to tailor information gleaned, and ability to interact with peers and knowledgeable clinicians through the app. Both patients and caregivers resoundingly endorsed the need for a private place to commiserate with peers and to have autonomy and privacy from the other member of the dyad when seeking information. Patients and caregivers alike spoke about wanting a place to express themselves openly and confidentially, without concern for how the other might feel if they could see what was being shared.

One participant made the analogy of "separate rooms...to sit on comfy sofas:"

> *It would give the cancer survivor an opportunity to commiserate with other cancer survivors...Sometimes I think the cancer survivors just need a way to be able to express their trepidation and fears with like-minded other survivors. If it can have a separate room—a separate room where survivors can go to commiserate...to sit on comfy sofas digitally, and commiserate...to have an 'adult tantrum!* [Patient, focus group 3]

Caregivers recognized the importance of giving patients privacy and autonomy to make their own decisions on what to share and what not to share. Patients similarly recognized that family members also need a private space to share frustrations or other emotions without the fear of upsetting the patient.

> *I was just thinking about my mother. She passed of cancer. [she] was very private, though. So she would not always want me to know what was going on, much to my frustration, but she does have that right...* [Caregiver, focus group 6]
>
> *And he [the caregiver] may want to share a grievance or a frustration, or, you know, ask a question, or need help, that he might not want me to know that he's seeking out. 'Cause he doesn't want to upset me, or whatever. So I would want him to have autonomy in it also, so that he could feel comfortable sharing and saying what he needed without me being privy to it.* [Patient, focus group 6]

Theme 3.2: Patients and Caregivers Both Desire Ability to Control Sharing of Information With Other Family Members

Several participants mentioned that they would like the ability to share information with family members that they wished to discuss later. They spoke of using app topics as a way to open potentially difficult conversations with a family member. One patient commented on the ability to share articles and information with family caregivers to access at their own convenience:

> *I'd want to...send a link to my husband, or send a link to my daughter. Because when I want to [read information] might not be when they want to do it. So to sit down and say, "Okay, we have to do this together now," would be burdensome. So I think it would be more helpful to have access themselves, then they can go look up whenever it's convenient for each individual.* [Patient, focus group 4]

However, the desire to share information was far from universal; other participants spoke about the dynamic and changing nature of their desires for information sharing and wanting to have ultimate control. Some spoke of the ability to share different information with different support persons:

> *I think it would be helpful to have levels set up. You could designate this person has access to everything; this person has access to this amount of information.* [Patient, focus group 4]

Loss of privacy and control during cancer treatment was a strong theme that resonated with most participants. They felt that the app could empower them to control a small amount of privacy during a process that leaves many feeling as if they no longer have any privacy left:

> *Well—at one point I'm like, "I don't need you to know everything," [laughs]—I don't need him to know that I'm not drinking, because then he's gonna give me a hard time about it. [laughs] But then—I like the idea that your caregiver—your partner—would have the ability to get a snapshot, "How are you doing today." I do appreciate that... Because there's so much loss of privacy already going through this treatment, that like, "I have to tell you* [providers] everything?"... you know what I mean? Like, "I have nothing for me?" Patient, focus group 7]

Discussion

Principal Findings

In this study, we endeavored to identify gaps in information and support in cancer care perceived by patients with cancer and their caregivers; features and functionality desired by patients and caregivers in an mHealth self-management support app; and whether patients and caregivers would prefer to use an mHealth app for support together or individually. A novel finding is that patients and caregivers desire help in determining the urgency of symptoms and concerns in order to "self-triage" regarding whether and when to seek care. Patients and caregivers also want trustworthy, vetted, curated information and support to supplement the care that they receive from their clinicians, and this information should be tailored to their point in the treatment trajectory and to their preferences. Our results suggest that mHealth self-management support apps are a useful and acceptable way to receive such support, provided that specific needs, concerns, desired features, and customizability were included in the app. A second notable novel finding of this study is that both patients and caregivers each desire to have a space that is their own, private from the other, and they each desire to have control over what information about their symptoms and information seeking is shared with the other. We discuss implications of these novel findings for app designers below.

Among our sample of patients with gynecologic cancer, we found nearly universal agreement that getting appropriate, personalized information and support throughout the cancer care trajectory is time-consuming. Patients and caregivers note having spent an extreme amount of time searching for information without any assurance as to the quality of information they located. They also noted a sense of "information overload," consistent with prior literature suggesting that the volume and complexity of internet cancer information is overwhelming [25], leaving them confused and overwhelmed [26]. One study found that 91% of web-based health information seekers either need or want navigational support to locate relevant information. This underscores the importance of designing our app to provide effective navigation for patients with gynecologic cancer and their caregivers [27].

In a novel finding, patients and caregivers expressed feelings of uncertainty as to how to self-triage; that is, they lacked confidence in determining whether a particular symptom warranted an immediate call to the provider or not. They articulated the need for a decision support aid for symptoms to help determine urgency and identify appropriate care, especially during hours when the oncology clinic is closed. These findings extend prior work on electronic support [28], which has primarily focused on treatment-related decision-making.

Designing a single mHealth app to be used by both patients and caregivers presents unique challenges for intervention designers and app developers. Results of this study highlight the need for flexibility in app functionality. Both patients and caregivers spoke of needing "a place of their own" to gather information and get peer and professional support without worrying or burdening their partner. Congruent with our findings, a recent systematic review [29] noted that patients desire the ability to control the sharing of information from health systems' patient portals. Our findings extend this work by describing caregivers' desires to similarly control the sharing of information about their concerns and information needs with their partner (the patient).

Privacy remains a key concern when designing sharing functionality for mHealth apps. Krebs and Duncan [30] found that 29% of US mobile phone users discontinue using mHealth apps due to lack of privacy stemming from apps sharing data with family members or friends. Our dyads noted that they specifically wanted the flexibility to share information and data when *they* chose to do so. Both caregivers and patients voiced the desire to maintain ultimate control over what is shared with their family members. Interestingly, these results contradict a recent study noting that patient and caregiver dyads preferred to use an official health system portal together, rather than individually [31]; this discrepancy could be because patients and caregivers may perceive our app as more personal and more focused on their individual needs, as opposed to a health system portal perceived as an extension of the hospital rather than as a personalized support space. Furthermore, our participants noted that the desire to share information through the app is not static—it may vary among patient or caregiver partners and may also vary over time as they move through the cancer trajectory. Thus, app developers will need to be cognizant of the need for flexibility in app functionality, allowing customization by users as often as desired.

Implications

Our study highlights several key considerations for the development of mHealth apps to support patients with gynecologic cancer and their caregivers in self-management. As patients and caregivers struggle with finding relevant information and lack confidence in deciding the urgency of problems, future apps should prioritize providing easily accessible, reliable information tailored to individual needs. This can be achieved through the development of recommendation algorithms that streamline decision-making processes. While recommender algorithms have existed for years, current algorithms are primarily targeted toward clinicians rather than being patient centered [32,33]. Our findings can inform components that should be incorporated into the recommender algorithms to permit optimal customization for patients and caregivers.

Additionally, our study sheds light on the issue of data sharing between patients and caregivers. Despite ongoing debate about the HIPAA considerations involved in such data sharing [34], there is currently no policy supporting and clarifying data sharing in this context. Our findings can inform policy makers about the need for guidelines on information sharing and flexibility, especially through consumer-centered technology such as web-based or patient portals and mobile apps. This can help ensure that patients and caregivers have the necessary control over sharing information while receiving the support they need.

Strengths and Limitations

Our study has several notable strengths and a few limitations that must be considered. Participants for this study were recruited from a cancer registry at a National Cancer Institute–designated cancer center housed within a university-affiliated tertiary care health system. The cancer center is comprised of urban, suburban, and rural satellite centers and serves individuals from a wide geographic area, yielding a diverse pool of potential participants. We targeted patients currently receiving treatment as well as those who may have completed cancer treatment up to 5 years in the past. This approach provided important perspective regarding the diverse and dynamic needs of cancer dyads throughout the care trajectory. Despite these strengths, respondents to the recruitment letter for this study were largely those who had received care at the urban campus, even though a number lived an hour or more outside the city. Such individuals may differ from those who choose to receive care in rural areas closer to their residence; these differences could reduce the applicability of our results to mHealth design for these individuals. Additionally, our study sample was 94% (59/63) White, reflecting a higher percentage of White individuals than in the overall region (63.8%) [35]. Generalizing our results to non-White and rural-dwelling individuals should therefore be done with caution, and future work should purposively sample for a more diverse sample.

Focus group participants were overwhelmingly positive about the care they had received through the gynecologic oncology practice and were eager to discuss their experiences. The group facilitators (GC and HSD) maintain a clinical affiliation at the gynecologic oncology clinic and were perceived as extensions of a place of trust by participants. Thus, a sense of openness was achieved quickly at each group session, leading to rich discussion related to unmet needs and suggestions for important features. Such an open discussion may not have been achieved in a focus group that was perceived to be conducted by researchers with little clinical benefit for participants. Despite this strength, it must be noted that the presence of both patients and caregivers in the same groups may have inhibited full disclosure of concerns, stresses, and feelings by some participants. Further, patients that attended without a caregiver may have felt reluctant to express opinions about their caregivers' experiences, not wanting to be perceived as speaking for someone who was not present while in the presence of other caregivers. This potential limitation is congruent with our finding that universal sharing of information and concerns is not desirable, but that sharing controlled by each individual within their comfort level, would be a desirable app feature.

An important limitation concerns the timing of this study. Our focus groups were conducted during the COVID-19 pandemic, which may have contributed to our finding that most participants would appreciate an mHealth self-management support option. Because traditional options for face-to-face interaction with the health care team were limited during the pandemic, this may have driven participants' desire for more and better information and opportunities for interaction with others through an app. Yet, the timing of this study could also be a strength: the salience of information and support shortcomings among cancer dyads during the pandemic and the resultant desire for more effective mHealth solutions may have provided deeper insights into this topic than we could have gained outside the pandemic.

Conclusions

Randomized controlled trials have demonstrated that mHealth interventions encourage proactive self-management skills and improve well-being while reducing secondary disease complications and health care costs [36-38]. mHealth apps can also improve adherence to treatment regimens for chronic conditions [39] and can positively impact long-term self-management [40,41]. However, for mHealth interventions to achieve widespread use in real world clinical settings, app developers must focus on end users' desired uses, features, and functionality. Our study provides novel input from potential end users regarding components of a self-management support app for dyads with cancer in a gynecologic oncology program that will spearhead development and testing of a future mobile app.

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Conflicts of Interest

None declared.

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Abbreviations

HIPAA: Health Insurance Portability and Accountability Act
mHealth: mobile health
UPMC: University of Pittsburgh Medical Center

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Evaluating Online Cannabis Health Information for Thai Breast Cancer Survivors Using the Quality Evaluation Scoring Tool (QUEST): Mixed Method Study

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Abstract

Background: Following medical cannabis legalization in Thailand in 2019, more people are seeking medical cannabis–related information, including women living with breast cancer. The extent to which they access cannabis-related information from internet sources and social media platforms and the quality of such content are relatively unknown and need further evaluation.

Objective: This study aims to analyze the factors determining cannabis-related content quality for breast cancer care from internet sources and on social media platforms and examine the characteristics of such content accessed and consumed by Thai breast cancer survivors.

Methods: A mixed methods study was conducted between January 2021 and May 2022, involving a breast cancer survivor support group. The group identified medical cannabis–related content from frequently accessed internet sources and social media platforms. The contents were categorized based on content creators, platforms, content category, and upload dates. Four researchers used the Quality Evaluation Scoring Tool (QUEST) to assess content quality, with scores ranging from 0 to 28. Contents were expert-rated as either high or poor. The QUEST interobserver reliability was analyzed. Receiver-operating characteristic curve analysis with the Youden index was used to determine the QUEST score cut-off point. Statistical significance was set at $P<.05$. Fairclough Critical Discourse Analysis was undertaken to examine the underlying discourses around poor-quality content.

Results: Sixty-two Thai-language cannabis-related items were evaluated. The content sources were categorized as follows: news channels (21/62, 34%), government sources (16/62, 26%), health care providers (12/62, 19%), and alternative medicine providers (12/62, 19%). Most of the contents (30/62, 48%) were uploaded to YouTube, whereas 31% (19/62) appeared on websites and Facebook. Forty of 62 content items (64%) were news-related and generic cannabis advertisements while 8 of 62 (13%) content items had no identifiable date. The interobserver QUEST score correlation was 0.86 ($P<.001$). The mean QUEST score was 12.1 (SD 7.6). Contents were considered “high” when the expert rating was >3. With a QUEST score of 15 as the threshold, the sensitivity and specificity for differentiating between high and poor content quality were 81% and 98%, respectively. Content creation was the only significant factor between high- and poor-quality content. Poor-quality contents were primarily created by alternative medicine providers and news channels. Two discourses were identified: advocacy for cannabis use normalization and cannabis romanticization as a panacea. These discourses overly normalize and romanticize the use of cannabis, focusing on indications and instructions for cannabis use, and medical cannabis promotion, while neglecting discussions on cannabis contraindications and potential side effects.

Conclusions: The varying quality of medical cannabis–related information on internet sources and social media platforms accessed and shared by Thai breast cancer survivors is an issue of concern. Given that content creators are the sole predictive factors of high content quality, future studies should examine a wider range of cannabis-related sources accessible to both the public and patients to gain a more comprehensive understanding of the issue.

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KEYWORDS

cannabis; medical cannabis; Thailand; critical discourse analysis; mixed method study; breast cancer; digital literacy; legislation; health literacy

Introduction

Globally, breast cancer is the most common cancer in women, with an age-standardized rate of 46.8 per 100,000 individuals [1]. The number of new cases is expected to rise from 2.3 million in 2020 to 3.2 million by 2040 [2]. In Thailand, about 21,600 new cases were reported in 2022, with a projection of 25,600 by 2040 [2]. Breast cancer treatments often involve a combination of surgery, radiation therapy, chemotherapy, and targeted therapy. These interventions have proven effective, with a trade-off between side effects, including nausea, vomiting, hair loss, fatigue, neuropathy, and decreased immunity [3].

Currently, alternative medicine approaches are gaining attention as potential complementary therapies to alleviate these side effects and improve patient well-being [4,5]. Hence, medical cannabis use, a complementary therapy, has gained traction in mitigating the side effects of breast cancer treatment [5,6].

Medical cannabis refers to the use of *Cannabis sativa* L. or its extracts for medicinal purposes [5]. The main chemical compounds in cannabis are tetrahydrocannabinol and cannabidiol, which demonstrated anticancer properties in a pre-clinical study [7]. Clinically, there are clear medical indications for cannabis use, including the treatment of intractable chronic pain, nausea, and vomiting [5,8-12].

In Thailand, cannabis has been used as a part of traditional medicine for centuries. The most commonly used forms of cannabis in nontraditional medicine involve the oral intake of crude oil extracts, raw plants (flowers, leaves, or whole plants with roots and stems), and topical skin products.

There are 3 categories of cannabis-based products legalized for medicinal purposes in Thailand. The first category is medicinal grade, which refers to substances that meet rigorous standards of purity, potency, and safety, making them suitable for use in medical treatments and pharmaceutical formulations, with three formulae: (1) high tetrahydrocannabinol concentration (13 mg/mL tetrahydrocannabinol), (2) high cannabidiol concentration (100 mg/mL cannabidiol), and (3) the tetrahydrocannabinol-cannabidiol mixture in a 1:1 ratio (27 mg/mL tetrahydrocannabinol and 25 mg/mL cannabidiol) [13]. The second category comprises 16 formulae of Thai traditional medicine products containing cannabis as an active ingredient. The third category is made of folk medicines produced by folk healers (traditional medicines that are not yet listed by the national Thai traditional medicine formulary). These are currently under development and categorization. [13].

No study has specifically reported the use of medical cannabis in breast cancer survivors. However, the prevalence of cannabis use in Thailand increased from 2.2% in 2019 to 4.2% by 2021, following the legalization of cannabis for recreational use [14]. A study conducted in Northern Thailand showed that 40% of women with breast cancer had requested the use of medical cannabis from their physician, indicating an increasing interest in medical cannabis [15].

Moreover, a law was passed in 2019 which allowed the use of cannabis for medical purposes [14,16]. This law positioned cannabis on the national agenda and was amended in June 2022, allowing cannabis use for any purpose, including home cultivation and recreation [14]. However, the legalization of cannabis use has caused several problems in Thailand. First, the phrase “medical cannabis” remains confusing for Thais, who tend to use it without clear medical indications. They can purchase cannabis from several channels including illegal sources, home growers, traditional medicine providers, and modern medicine providers [16], making it more challenging to determine the safety of these products.

According to Kalayasiri and Boonthae [14], the prevalence of cannabis use in Thailand doubled after the legalization, overshadowing the use of illegal substances, such as kratom and methamphetamine. This is concerning since cannabis use can cause serious adverse effects in patients with breast cancer and reduce the therapeutic efficacy. In particular, the reduced therapeutic efficacy is evident in patients undergoing tamoxifen treatment [17,18].

Second, a person’s decision to use medical cannabis should rely on valid medical advice. However, owing to the lack of reliable resources, patients typically make an uninformed choice or rely on advice from their social circle, which can be misleading [16,19]. Further, people often seek cannabis-related information from easily accessible internet sources and social media platforms, rather than government-validated resources [16,19]. Previous studies on cannabis use, wherein data were collected from social networks, have faced skepticism due to a lack of rigorous scrutiny, allowing for potential bias or misinformation [19]. Moreover, the media has attempted to normalize cannabis use without a critical discussion of safety issues [20-22]. For instance, a content analysis study on cannabis-related information on Facebook in Thailand concluded that there was no discussion of the potential dangers of cannabis use [23].

The current trend of access to medical cannabis in Thailand is problematic since patients with breast cancer may access unvalidated information, which might be harmful, with reduced treatment efficacy. Furthermore, it appears unclear why people with breast cancer choose to seek medical cannabis–related content from internet sources and social media platforms. There is an urgent need to investigate the extent to which patients access cannabis-related information from internet sources and social media and evaluate the quality of the content available on these platforms.

This study aimed to (1) analyze the factors determining the quality of cannabis-related content for breast cancer care on internet sources and social media platforms and (2) examine the characteristics of cannabis-related content on internet sources and social media platforms accessed and used by Thai breast cancer survivors following cannabis legalization in 2019.

Methods

Study Design and Patient and Public Involvement Process

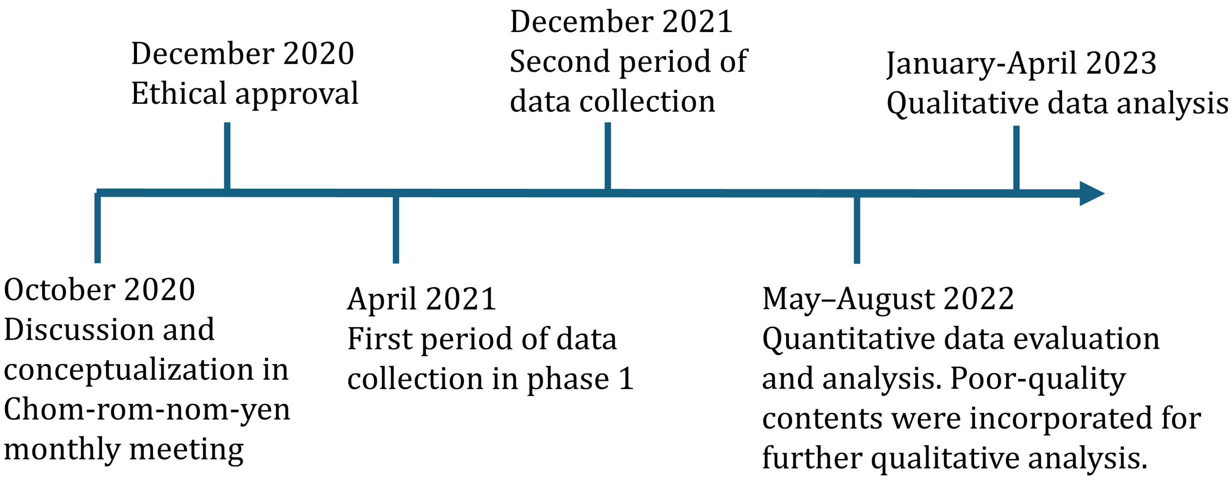
This mixed methods sequential study was conducted in 2 phases between January 2021 and May 2022 at a tertiary hospital in Southern Thailand (Figure 1). We included members of the breast cancer support group "Chom-rom-nom-yen," for patients and public involvement [24], to ensure representation of people with lived experiences of breast cancer. Chom-rom-nom-yen is a social enterprise of women living with breast cancer that aims to raise awareness, provide education, and advocate for and support women living with breast cancer. The organization was established in 2015 and currently comprises 397 breast cancer survivors and their caregivers from diverse socioeconomic backgrounds. The members were aged 30 - 75 years, with the majority aged 50 - 60 years. Most of the members resided in Southern Thailand.

The research began with a discussion of the initial ideas and the conceptualization of the problems and study design with the group in October 2020 at their in-person monthly meetings. Any group member could participate in the study as needed. A researcher (T Peerawong) joined the monthly meetings and discussed with Chom-rom-nom-yen members regarding the potential use of medical cannabis in Thai women with breast cancer postlegislation given that knowledge about medical cannabis use in breast cancer care in Thailand was limited at the time. The group was skeptical about the use of medical cannabis. However, some members indicated that they had already used cannabis-containing products, for example, cannabis tea and cannabis oil with no understanding of potential adverse and side effects. The group reached a consensus that using medical cannabis was worth further exploration. The subsequent group discussions via LINE, the most commonly used instant messaging platform in Thailand, further refined the focus of the study; 2 representatives agreed to join the study as core members to explore and evaluate the trustworthiness of medical cannabis–related information.

The subsequent activities were conducted and coordinated through Chom-rom-nom-yen; other members were contacted by a researcher (PS), the Chom-rom-nom-yen president. This direct involvement from the group helped ensure a focused and cohesive group participation.

The support group confirmed that they typically sought information from websites and popular social media platforms in Thailand namely Facebook, LINE, and YouTube.

Figure 1. Study timeline.



Ethical Considerations

The feedback from Chom-rom-nom-yen discussions was collated and included in the study design and ethical application. Ethical approval was obtained from the Institutional Review Board of the Faculty of Medicine, Prince of Songkla University (REC.63-531-7-1). Since the study involved the use of electronic and unidentifiable private information from internet sources and social media platforms, the ethical committee waived the requirement for informed consent [25].

The Institutional Review Board allowed the secondary analysis without additional consent. Pseudonyms were used to anonymize the content creators that were included in the data analysis process. Collected data were deidentified.

The data were securely stored in encrypted form in the Microsoft OneDrive storage of the university affiliation of the principal researcher, password-protected, and rendered compliant with the Thailand Personal Data Protection Act. Only the researchers (T Peerawong and T Phenwan) had access to the dataset. All the data will be deleted 5 years after the study completion, in compliance with the local regulations. Participants were not compensated.

Procedure

Between April 2021 and December 2021, internet sources and social media content were gathered from women living with breast cancer who were members of the support group. Owing to the organic nature of Chom-rom-nom-yen, which acts as a social support group, demographic details of women participating in the research were not recorded, as anyone from the group could participate or opt out at any time.

The women were instructed to identify the information about medical cannabis that they found relevant from the available platforms during the study period (any websites, Facebook, LINE messages and posts, and YouTube). The unit of analysis included Facebook posts, blog posts, website articles, news updates, LINE messages, and videos. Participants then shared the URLs of these units of analysis with a researcher (NS) who collated all the data. This process was repeated twice over a 6-month period. The collected links were anonymized, merged, screened, and listed for further analysis by another researcher (T Peerawong).

Quantitative Data Analysis

The first phase of the study involved quantitative content analysis and comprised a 3-part evaluation. The first part involved the collection of general information about the social network, such as its creators, platform type, content category, and upload date. The second part involved content quality analysis using the Quality Evaluation Scoring Tool (QUEST) and the Journal of the American Medical Association (JAMA) benchmarks. The QUEST is a validated tool that evaluates the quality of web-based health information. The instrument comprises 7 items: authorship, attribution, study type, conflicts of interest, currency, complementarity, and tone. Each item is scored on a scale of 0 - 28 [26]. The JAMA benchmark is a 5-point scale that assesses: authorship, attribution, disclosure, and currency, with scores ranging from 0 to 4 [27]. Higher scores on both tools indicate higher quality. The third part of the evaluation involved expert assessment of several aspects of the content, such as the tone, accuracy, usefulness, and quality level, with scores ranging from 1 to 5.

The initial evaluation was performed by 2 research team members: one with more than 10 years of experience in radiation oncology and quality of life research (T Peerawong) and the other with 5 years of experience in social sciences research (SS). In this process, T Peerawong navigated the contents received from internet sources and social media platforms and discussed with SS until a consensus was reached. All selected content from internet sources and social media platforms was evaluated for content quality evaluation and expert analysis. All reviewers then independently followed the QUEST and JAMA evaluation guidelines. When necessary, questions were addressed to T Peerawong for clarification. The reviewers included a pharmacist specializing in herbal medicine with over a decade of experience (PP), a radiation oncologist (PT), and a general practitioner (NB), each with 3 years of experience. Additionally, a sixth-year medical student (PW) was included in the review team to provide variability in opinion.

Descriptive statistics were used to analyze the characteristics of social networks. Intraclass correlation was used to assess the interobserver reliability of the QUEST and JAMA benchmarks. The mean QUEST score among the 4 reviewers correlated with the expert opinion score for each aspect. A cut-off point for the QUEST score was determined by comparing QUEST scores with expert opinion scores, and a score of 3 or higher was considered to indicate high quality. After receiver-operating characteristic curve analysis, the Youden index was used to determine the optimal cut-off point owing to the simplicity of its calculation and interpretation [28]. Based on the QUEST scores, internet sources, and social media characteristics were categorized as high or poor content quality. Statistical significance was set at a P value <.05, and data analysis was conducted using R program (R Foundation for Statistical Computing, Vienna, Austria).

Qualitative Data Analysis

Overview

The content deemed of poor quality in the first phase was further analyzed in the second phase of the study using Fairclough Critical Discourse Analysis approach [29]. The analysis aimed to identify visible or hidden discourses within the poor-quality datasets, as well as the ideologies, values, and assumptions of the content creators. The analysis was performed by T Phenwan, a family medicine doctor, and a qualitative researcher with expertise and research interests in breast cancer, quality of life research, and policy analysis. datasets were uploaded to Atlas.Ti to facilitate analysis. The researcher read or watched the content and analyzed the datasets using coding and memo features in Atlas.Ti. The analysis was conducted using the following 3 interrelated dimensions of critical discourse analysis.

Text Analysis (Description)

The microelements of the linguistic discourse in the datasets were examined. This included identifying the use of sensitizing words, linguistic devices (such as metaphors), choice of words, content structures, tones, and sentiments, and how discourses around the use of medical cannabis were framed.

Processing Analysis (Interpretation)

The situational context of the content was also explored, including how the content was produced and enabled the construction of new discourses or the sustainability of existing discourses. This involved examining content distributors and contributors, as well as considering who was included or excluded in content production, along with their positionalities towards medical cannabis.

Social Analysis (Explanation)

The socio-historical contexts and content producers were identified, along with overt and covert ideologies and hegemonies. The slant or style, intended audience, and intended purpose of the content creation were analyzed, along with the how and why of content structure, to explore how certain stakeholders or historical changes in cannabis-related policies influenced the created content.

The initial analysis was discussed among researchers (T Phenwan, MM [a sociologist specializing in social media analysis], and T Peerawong) via Microsoft Team meetings and email communications. The discussion continued until a consensus was reached.

Results

Quantitative Results

Between April 2021 and December 2021, 62 internet content items were included and evaluated, all of which were in Thai. The most accessed content was created by news channels (21/62, 34%), followed by governmental sources (16/62, 26%), health care professionals (HCPs, 12/62, 19%), and alternative medicine providers (12/62, 19%). The most common internet sources and social media platforms were YouTube (30/62, 48%) and websites (19/62, 31%). Video content constituted 36 of the 62 content items (59%), with news (23/62, 37%) and advertisements (17/62, 27%) being the most frequent types (Table 1 and Figure 2).

Most of the contents were uploaded in 2019, with only 2 items uploaded prior to that year. These included news channel updates (sharing experience with cannabis) and a narrative review [30]. Most of the contents with unidentified uploading dates were created by alternative medicine providers. The URLs were sent to the reviewers, who individually evaluated the internet sources and social media content. Some internet sources and social media content were inaccessible and were not included during this stage. Four experts have reviewed, rated 62 websites, and provided 241 responses (Table 2). The evaluated content generally supported the use of cannabis, displaying fair information accuracy and usefulness. Only 64 of 241 expert opinion responses (26.5%) deemed the evaluated contents as high-quality.

The interobserver correlation of the QUEST score and JAMA benchmark between the 4 reviewers was 0.86 ($P<.001$) and 0.55 ($P=.002$), respectively. The QUEST score was 11.9 (SD 6), whereas the JAMA benchmark score was 2.5 (SD 1). The mean QUEST score was positively correlated with the mean JAMA benchmark score, as well as information accuracy, usefulness, and quality (Table 3). Additionally, the mean QUEST score showed a negative correlation with content tone. The correlation between the mean JAMA benchmark score and expert opinions was consistent with these findings.

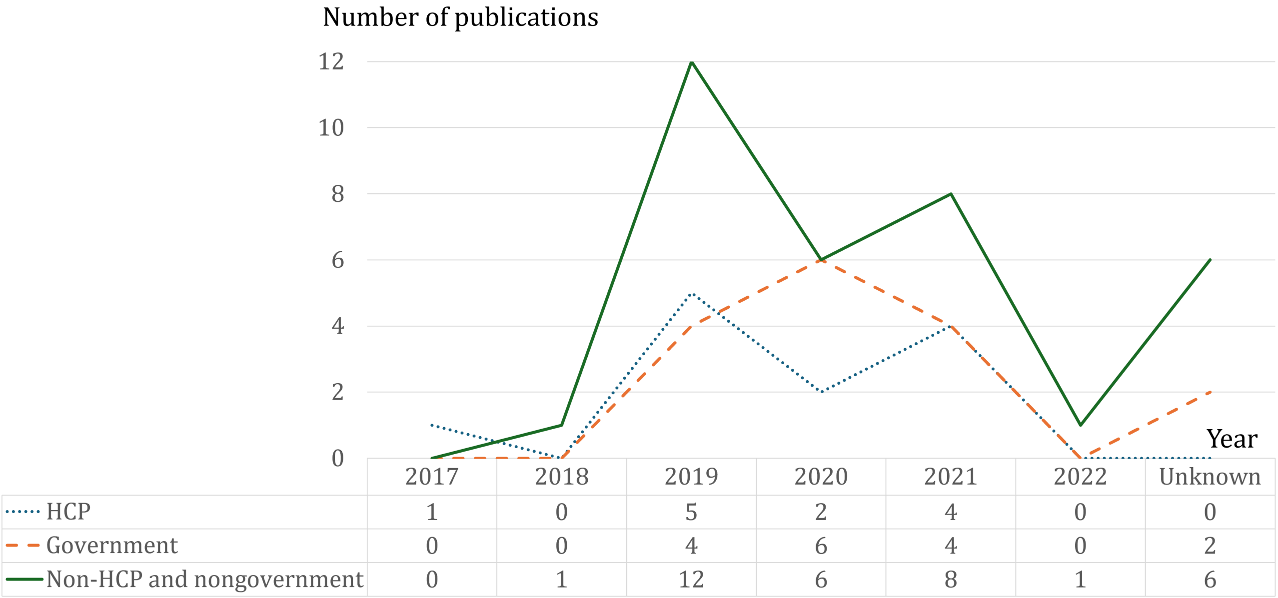
For univariate analysis, a content quality score >3 based on expert opinion was considered indicative of high quality. To determine the optimal cut-off point of the content quality score, the receiver-operating characteristic curve was used to find a balance between sensitivity and specificity for binary classification. The area under the curve was 0.93, and the confidence interval ranged from 0.86 to 1.01. After applying the Youden index, a QUEST score of 15 was identified as the optimal cut-off point for differentiating between high and poor content quality. The sensitivity and specificity of this cut-off point were 81% and 98%, respectively. Univariate analysis of internet sources and social media characteristics revealed that content creator was the only variable with a significant difference between high and poor content quality, with high-quality content mostly originating from the government and HCPs (Table 4).

Twenty-eight contents were considered of poor quality and were mainly created by alternative medicine providers and news channels. These contents covered a range of topics, from instructions on how to plant cannabis to contraindications for medical cannabis use. Most contents (23/28, 82%) focused on the indications for cannabis use, instructions for medical cannabis use, and the general promotion of cannabis use. Only 1 news channel topic addressed the contraindications and side effects of medical cannabis. Of all contents from alternative medicine providers (9/11, 82%) were advertisements, with 8 out of 11 (73%) focusing on indications and instructions for cannabis use. No content from alternative medicine providers addressed the side effects or disadvantages of cannabis use. Of all content from news channels 11 out of 21 (52%) favored medical cannabis use. The information included the personal experiences of cannabis users, advertisements and discussions on cannabis cultivation, interviews with medical cannabis users, and interviews with HCPs. In terms of topics, 14 out of 21 (41%) of the contents were on indications and instructions regarding cannabis use, whereas 4 out of 21 (20%) were on pro-medical cannabis use.

Table . Baseline content characteristics (N=62).

Characteristic	Values, n (%)
Creators	
Alternative medicine provider	12 (19)
Government	16 (26)
Health care provider	12 (19)
Insurance company	1 (2)
Media (news channel)	21 (34)
Internet sources and social media platforms	
Facebook	12 (19)
YouTube	30 (48)
Website	19 (31)
Scientific journal	1 (2)
Content category	
Video	36 (58)
Text	20 (32)
Both	6 (10)
Content type	
News	23 (37)
Advertisement	17 (27)
How to grow cannabis	2 (3)
Academic article	2 (3)
General information on medical cannabis	5 (8)
Instruction of cannabis use	3 (5)
Experience of cannabis use	10 (16)

Figure 2. Distribution of content-uploading date categorized by content creators and years. HCP: health care professional.



	2017	2018	2019	2020	2021	2022	Unknown
HCP	1	0	5	2	4	0	0
Government	0	0	4	6	4	0	2
Non-HCP and nongovernment	0	1	12	6	8	1	6

Table . Expert evaluation of internet and social media content (n=241).

Category	Values, n (%)
Support tone	190 (78.8)
Information accuracy	117 (48.5)
Usefulness	103 (42.7)
High quality	64 (26.5)

Table . Correlation of Journal of the American Medical Association (JAMA) benchmark and Quality Evaluation Scoring Tool (QUEST) score with expert opinion scores for tone, information accuracy, usefulness, and quality. Statistical analysis with Pearson correlation.

	JAMA	Quest	Tone	Information accuracy	Usefulness	Quality
JAMA	1	0.79[a]	−0.61[a]	0.77[a]	0.74[a]	0.82[a]
QUEST	0.79[a]	1	−0.87[a]	0.86[a]	0.90[a]	0.92[a]
Tone	−0.61[a]	−0.87[a]	1	−0.74[a]	−0.73[a]	−0.72[a]
Information accuracy	0.77[a]	0.86[a]	−0.74[a]	1	0.93[a]	0.91[a]
Usefulness	0.74[a]	0.92[a]	−0.73[a]	0.93[a]	1	0.93[a]
Quality	0.82[a]	0.92[a]	−0.72[a]	0.91[a]	0.93[a]	1

[a] *P*<.001.

Table . Univariate analysis of the Quality Evaluation Scoring Tool (QUEST) score between high and poor content.

		Poor, n (%)	High, n (%)	*P* value
Creators				<.001[a]
	Alternative medicine provider	11 (28)	0 (0)	
	Government	7 (17)	8 (50)	
	Health care provider	4 (10)	6 (38)	
	insurance company	1 (2)	0 (0)	
	Media (news channel)	17 (43)	2 (12)	
Internet sources and social media				.14[a]
	Facebook	8 (20)	3 (19)	
	Scientific journal	0 (0)	1 (6)	
	Website	10 (25)	7 (44)	
	YouTube	22 (55)	5 (31)	
Content category				.13[a]
	Both	5 (12)	0 (0)	
	Text	10 (25)	8 (50)	
	Video	25 (63)	8 (50)	

[a] Statistical analysis with Fisher exact test.

Qualitative Results

All poor-quality contents were created between 2018 and 2021, with 5 contents having unspecified dates. Pseudonyms are used throughout this section to protect the identities of the content creators. Almost all content targeted members of the public; one content was explicitly created for policymakers and 4 contents were created for the public and HCPs.

Most content creators were anonymous, making it impossible to authenticate their identities. The creators almost always claimed undue credibility, including a cannabis merchant who claimed to have “five PhDs” and had “graduated from a university in the United States," a farmer who was self-proclaimed as a "doctor," or individuals who claimed to have had "cancer" that was cured by cannabis. The majority (21) of the poor-quality content portrayed a positive sentiment towards medical and general cannabis use. Seven contents had a neutral sentiment towards cannabis. Only 1 website created by the government superficially described the routes of administration of cannabis, with limited information regarding the contraindications and adverse effects of medical cannabis oil use (Multimedia Appendix 1).

Two main discourses were identified as follows: (1) advocacy for the normalization of cannabis use and (2) romanticization of cannabis as a panacea. The first discourse positions and normalizes cannabis as an everyday commodity for the public. In a YouTube video created by a university, a matter-of-fact detailed description of how to cultivate cannabis at home or in industrial-scale greenhouses is indicated by the following content:

> *…There are 3 ways to cultivate cannabis. First, you can grow them outdoors. This method requires a minimal budget since we will be dependent on the natural sunlight as well as the weather. The drawback is that the crop is highly seasonal. There are also issues around insects and locusts…* [Excerpt from a Facebook post from the Institute of Agricultural Study, Weed University, which was linked to YouTube]

The university also provided extensive information regarding cannabis cultivation on its Facebook page and website, further normalizing cannabis use for the public. Content from news outlets also empowered this discourse, since they tended to provide updates regarding cannabis, such as the impact of cannabis legislation at the time, newly opened cannabis clinics nationwide, or places to access free cannabis.

> *Great news! After [date], the geriatric clinic at temple A will provide free cannabis for 10,000 older people. 4,000 have already been enrolled so there are only 6,000 slots left. The registration slot is open twice a day so you should go there in the afternoon since the officers said it is not so packed. You have to be older than 65 to be eligible and it [cannabis oil] can cure your vision, hearing, tremors too!…[cannabis] is also free!* [Excerpt from "Cannabis clinic with new formula to be opened in 15 hospitals" on YouTube]

In the second discourse, all content creators used similar tones to persuade their target audiences, including the use of persuasive arguments with unsupported claims, obfuscations, or emotive statements. The content creators made claims to suit their underlying support for cannabis without providing appropriate evidence. For instance, one website claimed that cannabis oil can "completely cure 14 illnesses," ranging from nausea and hemorrhoids to Alzheimer disease:

> *…in terms of benefits of cannabis, abundant articles report various benefits of cannabis which includes […] Curing of asthma. All anti-asthmatic drugs are bad and have limitations due to their side effects [to your body], unlike cannabis which helps dilate your windpipe […] [cannabis] cures Parkinson's and Alzheimer's disease […] reducing the size of your hemorrhoid, once applied topically.* [Excerpt from a blog post from "14 benefits of cannabis. Extremely useful! What can cannabis cure?"]

The content creator, an anonymous administrator, provided evidence supporting the claims; however, the source of the claims was not clarified.

Even content created by academic institutions used similar techniques to persuade the public to use medical cannabis, as seen in a YouTube video titled "Cannabis root helps with joint pain."

> *…[cannabis root] can help with your joint pain so well. Like, we still have limited use in the country, but it has been widely used overseas, like, by Persian doctors, Polish and English. They used cannabis root to help with joint pain, gouts, burns, like, everything really. Mix it with butter, all [of its use is] recorded. You can just boil the root and either apply it on your skin or even ingest it… [these benefits] are all evidence-based by modern medicine! And, like, it is super safe since it is, like, not addictive at all.* [Excerpt from "Cannabis root helps with joint pain" on YouTube]

The next section discusses the findings from both phases of the study.

Discussion

Principal Findings

The study results align with the existing literature, revealing a significant shift in public sentiment regarding cannabis views and the use of internet sources and social media platforms. Prior to 2019, public sentiment from internet sources and social media platforms over cannabis use in Thailand was positive overall, with no discussion around its potential harm [23]. However, after 2019, there was a growing positive sentiment from both the public and patients towards medical cannabis use [15,31].

Research indicates that the legalization of medical cannabis use is linked to a reduced perception of its related risks and an increase in the frequency of cannabis use for both medical and recreational purposes [32]. In the United States, with the majority of cannabis legalization-related research, Melchior et al [33] concluded that the presence of medical cannabis–related laws and policies neither affects the first recreational use nor is correlated with reduced cannabis use, particularly among people younger than 25 years. However, the cannabis use frequency has increased among adults (aged at least 26 y) following its medical legalization [32,34]. Given that medical cannabis–related policies are nonhomogenous and subject to change, analyses that overlook heterogeneity in the key elements of these policies may inaccurately represent their effects on both recreational and medical cannabis use [34].

Furthermore, the legalization of medical cannabis use may reduce its associated stigma, thereby enhancing its acceptance and normalization among adults [35]. Additionally, the liberalization of cannabis-related laws has created new opportunities for individuals and businesses to promote their products, leading to a proliferation of advertisement and marketing efforts for cannabis-containing products, especially on the internet. This surge may be associated with increased cannabis use [36,37].

In Thailand, breast cancer survivors now have much greater access to various sources of cannabis-related information on internet sources and social media platforms. Notably, there has been a trend of survivors requesting more medical cannabis prescriptions over the years, despite a limited understanding of its potential adverse effects on their treatment [15].

This trend reflects a broader societal shift where individuals, including breast cancer survivors, increasingly rely on internet sources and social media platforms for health information [19,22,23,38]. The advantage of this information source is that the user has direct information access without geographical restrictions [38]. However, it is crucial to consider the quality and reliability of the health-related information available on internet. The lack of integration of information between mainstream health care and medical cannabis use may lead to adverse situations, particularly compounded by the often limited knowledge of cannabis use among both HCPs and medical cannabis users [39]. Moreover, web-based sources may vary in the quality of information provided, with some disseminating inaccurate or misleading information regarding medical cannabis use, a common pitfall associated with web-based health information [38].

As confirmed by the quantitative analysis, content creators are pivotal elements that can enable patients to accurately evaluate the veracity of web-based health information. This study identified an inverse relationship between the tonality of the content and its corresponding QUEST score, which is similar between medical cannabis use and glaucoma treatment [40]. That is, the content created by HCPs typically advises against the use of medical cannabis for glaucoma, which has superior quality over those created by non-HCPs. Jia et al [40] quantitatively analyzed the content quality and characteristics of popular internet search results related to glaucoma and medical cannabis use. The Sandvik score was used to quantitatively evaluate the content quality included in their study. This differs from our study because QUEST has been validated as an exclusive tool for mitigating web-based misinformation, demonstrating a significant positive correlation with the Sanvik scale. The QUEST incorporates additional evaluation criteria, including content tone, potential conflicts of interest, and extent of complementary information provided, thereby rendering the analysis more robust [26].

Our qualitative analysis generated 2 interrelated concerning discourses that underpin the poor-quality content accessed by breast cancer survivors. These 2 discourses validate, normalize, and somewhat romanticize the prevailing public perception of medical cannabis before its legalization in 2019 [14,23]. The first discourse tended to objectively update the public with information regarding cannabis use and cultivation in Thailand; nevertheless, it posed issues of concern as it did not discuss the potential adverse effects of cannabis. Instead, the first discourse implied that cannabis use should be normalized postlegislation, and its cultivation should be further encouraged.

This encouragement was compounded by the second discourse. The content creators used several persuasive techniques and false information to present cannabis as a “panacea” that cures or alleviates symptoms of various diseases, thereby downplaying its potential risks and side effects and contradicting its actual medical indications, such as intractable chronic pain, nausea, and vomiting [5]. Cannabis use is commonly perceived in internet sources and social media platforms as the last resort when modern medicine has failed in patient treatment or symptom alleviation [19,41]; nonetheless, this discourse repositions cannabis as the preferred therapy and is held in high esteem by all poor-quality content creators. This is alarming given these content creators claim to be “experts” in issues pertaining to cannabis and make false assertions without evidence.

This raises concerns about the potential impact of such narratives in shaping societal attitudes, particularly as they gain traction through their reproduction on internet sources and social media platforms. However, the quality and credibility of the information disseminated through these channels exacerbate this concern.

The influence of these discourses on fostering a more accepting stance towards medical cannabis use in the public is disconcerting, particularly because of the lack of discussion on the potential adverse effects of cannabis on cancer treatment. This information gap poses a considerable risk, as patients with breast cancer and the general public can access content created by anyone on the internet. While this accessibility empowers individuals, it also introduces the possibility that people may accidentally hurt themselves through uninformed cannabis use. Safeguarding the well-being of those seeking guidance and insight requires addressing this misinformation and ensuring that individuals are equipped with the knowledge needed to make informed decisions regarding cannabis use [36,42], particularly in the context of cancer treatment.

In Thailand, individuals who create and share such content face no legal repercussions because cannabis use is legal for medical and recreational purposes [16]. Findings from this study suggest that the Thai Government needs to address the varying cannabis-related content on the internet. This could be achieved by implementing stricter advertising and marketing policies for cannabis promoted through web-based sources and social media platforms or establishing mechanisms for accountability [37]. This approach could help protect the public and those living with breast cancer who may be more influenced by misleading or inaccurate information about cannabis products.

To our knowledge, this is the first mixed method study to analyze the quality of cannabis-related internet sources and social media content in Thailand. Although not all the findings are generalizable, certain aspects could be transferred to other contexts [43]. Specifically, we discussed the varying quality of medical cannabis–related internet content that requires mitigation and the need to regulate such content, which are more applicable to this field of study.

The integrated results from both study phases provide more contextual insights into the medical cannabis–related contents shared over the internet, and the underlying postlegislation discourses in Thailand. To this end, our interdisciplinary team members, including one person with lived experiences, offer a more comprehensive understanding and insight.

Moreover, this is the first study in Thailand to include people with lived experiences of breast cancer as research partners throughout the project. Preliminary results from this study have been shared with the breast cancer support group via short lay summaries and group representatives.

Future Implications

One way to tackle the internet flood of biased information on cannabis is to promote health literacy. Health literacy refers to “the personal characteristics and social resources needed for individuals and communities to access, understand, appraise, and use information and services to make decisions about health” [44]. Health literacy has a direct correlation with better health outcomes and health-seeking information behavior [45,46]; hence, it should be promoted. However, approximately half of the Global Southern population, including the Thai population, have inadequate health literacy levels. Low health literacy levels are more prevalent among people from rural areas and those with low educational levels [45]. This highlights the importance of addressing health literacy divides, particularly in regions with limited access to health care resources and educational opportunities.

Another relevant aspect to consider is the notion of electronic health literacy, which is particularly significant in today’s society where individuals have easy access to vast amounts of information via the internet [47-49]. Therefore, it is imperative to promote public health literacy and digital health literacy to ensure that people, including patients with breast cancer, can critically evaluate the quality and validity of any content they access [50]. This can be achieved through several strategies, such as addressing the unmet needs of patients with breast cancer or developing easily accessible and user-friendly educational materials [50,51]. These recommendations are equally applicable to medical cannabis–related content.

As revealed by this study and supported by existing literature, there is a notable scarcity of validated educational resources on medical cannabis [52]. This deficiency poses a challenge as HCPs may lack the necessary knowledge to offer well-informed advice to their patients. Conversely, patients driven by a growing interest in medical cannabis use may resort to unvalidated sources, exposing themselves to inaccurate information. To mitigate this, the government should establish a dedicated task force that would prioritize the development of validated educational resources for both HCPs and the public. Future research should also focus on benchmarking and validating cannabis-related content for HCPs and end users.

In Thai contexts, most patients still rely on HCPs for health-related information [45,46]. Therefore, it may be beneficial to begin with educational resources specifically tailored to HCPs. This strategic approach recognizes the pivotal role that HCPs play in disseminating accurate information and ensures that they are well-equipped with the necessary knowledge about medical cannabis.

It is noteworthy to further explore the unmet needs and expectations of patients that drive them to seek out additional information from the internet. This could be explored using qualitative research designs, which would allow for a deeper understanding of patient’s needs and expectations, thereby improving the ability of HCPs to meet their informational needs more effectively.

Finally, although the study predominantly focused on identifying “poor-quality” content, it may lack an in-depth exploration of sources or characteristics associated with high-quality content. This limits a comprehensive understanding of the factors contributing to reliable medical cannabis–related information. Therefore, “high-quality” content should be further explored in the future.

Limitations

This study has some limitations. First, the analyzed contents were exclusively obtained from a single group of women living with breast cancer. The contents may not fully represent all publicly available cannabis-related content in Thailand. However, the results offer valuable insights into the current state of publicly available information on cannabis in the country. Future studies should explore a broader range of cannabis-related sources available to the public, as well as patients, to provide a fuller picture of the situation. Additionally, future research should encompass a more diverse range of sources and larger sample sizes to ensure a more comprehensive analysis of cannabis-related content.

Second, the study faced challenges in determining content quality due to accessibility issues. Some experts could not access certain content pages (n=6), albeit the reasons for these difficulties were not documented by participants from Chom-rom-nom-yen. This barrier potentially compromised the thoroughness of our evaluation, raising concerns regarding the accuracy and completeness of our content quality analysis. This emphasizes the critical need to ensure that all pertinent contents are readily accessible to researchers and experts for effective and comprehensive evaluation.

In the qualitative analytical phase, the study specifically focused on Thai cannabis-related content shared on internet sources and social media platforms. Therefore, the results may not be fully generalizable to other populations with different cultural backgrounds, health care systems, or attitudes towards cannabis. This study primarily analyzed content quality based on the creator’s identity. However, it may have overlooked other factors, such as audience engagement, context, and evolving social media trends, which could have influenced the perception of content quality. The categorization of contents as “high” or “poor” may have been subjective and influenced by the perspectives of the project members. Different individuals or groups may have varying opinions on what constitutes reliable and accurate information regarding medical cannabis. Furthermore, internet sources and social media content are highly dynamic, and this study may not have captured the evolving nature of information over time.

Conclusions

This study highlights the varying quality of medical cannabis–related information accessed and shared on internet sources and social media platforms among Thai breast cancer survivors. Given that content creators are the primary predictors of high content quality, future studies should explore a broader range of cannabis-related sources available to the public and patients for a more comprehensive understanding of the situation.

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Authors' Contributions

Conceptualization was led by T Peerawong, with contributions from SS and PS. Methodology was developed by T Peerawong and T Phenwan. Validation efforts were equally shared between T Peerawong and T Phenwan. Formal analysis was conducted by T Peerawong and T Phenwan. Investigation was carried out by PS and SS. Resources were provided by PS and NS. Data curation was handled by T Peerawong. T Phenwan took the lead in writing the original draft, with contributions from T Peerawong. Review and editing of the manuscript were conducted by T Phenwan, T Peerawong, SS, MM, and PP. Visualization was prepared by T Peerawong, and project administration was managed by T Peerawong.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Bad content characteristics and identified discourses.
[DOCX File, 22 KB - cancer_v10i1e55300_app1.docx]

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Abbreviations

HCP: health care professional
JAMA: Journal of the American Medical Association
QUEST: Quality Evaluation Scoring Tool

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Original Paper

Comparison of the Real-World Reporting of Symptoms and Well-Being for the HER2-Directed Trastuzumab Biosimilar Ogivri With Registry Data for Herceptin in the Treatment of Breast Cancer: Prospective Observational Study (OGIPRO) of Electronic Patient-Reported Outcomes

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Abstract

Background: Trastuzumab has had a major impact on the treatment of human epidermal growth factor receptor 2 (HER2)-positive breast cancer (BC). Anti-HER2 biosimilars such as Ogivri have demonstrated safety and clinical equivalence to trastuzumab (using Herceptin as the reference product) in clinical trials. To our knowledge, there has been no real-world report of the side effects and quality of life (QoL) in patients treated with biosimilars using electronic patient-reported outcomes (ePROs).

Objective: The primary objective of this prospective observational study (OGIPRO study) was to compare the ePRO data related to treatment side effects collected with the medidux app in patients with HER2-positive BC treated with the trastuzumab biosimilar Ogivri (prospective cohort) to those obtained from historical cohorts treated with Herceptin alone or combined with pertuzumab and/or chemotherapy (ClinicalTrials.gov NCT02004496 and NCT03578731).

Methods: Patients were treated with Ogivri alone or combined with pertuzumab and/or chemotherapy and hormone therapy in (neo)adjuvant and palliative settings. Patients used the medidux app to dynamically record symptoms (according to the Common Terminology Criteria for Adverse Events [CTCAE]), well-being (according to the Eastern Cooperative Oncology Group Performance Status scale), QoL (using the EQ-5D-5L questionnaire), cognitive capabilities, and vital parameters over 6 weeks. The primary endpoint was the mean CTCAE score. Key secondary endpoints included the mean well-being score. Data of this prospective cohort were compared with those of the historical cohorts (n=38 patients; median age 51, range 31-78 years).

Results: Overall, 53 female patients with a median age of 54 years (range 31-87 years) were enrolled in the OGIPRO study. The mean CTCAE score was analyzed in 50 patients with available data on symptoms, while the mean well-being score was evaluated in 52 patients with available data. The most common symptoms reported in both cohorts included fatigue, taste disorder, nausea, diarrhea, dry mucosa, joint discomfort, tingling, sleep disorder, headache, and appetite loss. Most patients experienced minimal (grade 0) or mild (grade 1) toxicities in both cohorts. The mean CTCAE score was comparable between the prospective and historical cohorts (29.0 and 30.3, respectively; mean difference –1.27, 95% CI –7.24 to 4.70; *P*=.68). Similarly, no significant difference was found for the mean well-being score between the groups treated with the trastuzumab biosimilar Ogivri and Herceptin (74.3 and 69.8, respectively; mean difference 4.45, 95% CI –3.53 to 12.44; *P*=.28).

Conclusions: Treatment of patients with HER2-positive BC with the trastuzumab biosimilar Ogivri resulted in equivalent symptoms, adverse events, and well-being as found for patients treated with Herceptin as determined by ePRO data. Hence, integration of an ePRO system into research and clinical practice can provide reliable information when investigating the real-world tolerability and outcomes of similar therapeutic compounds.

Trial Registration: ClinicalTrials.gov NCT05234021; https://clinicaltrials.gov/study/NCT05234021

(JMIR Cancer 2024;10:e54178) doi:10.2196/54178

KEYWORDS

breast cancer; biosimilar; trastuzumab; electronic patient-reported outcome; ePRO; medidux; app

Introduction

Biosimilars and reference biologics play a key role in the treatment of cancer and account for approximately 70% of the growth in costs of drugs from 2010 to 2015 [1]. Therefore, pricing is an important challenge for the medical society and biosimilars offer an attractive option for a value-based care environment with cost-saving potential [2].

Trastuzumab (Herceptin), a human epidermal growth factor receptor 2 (HER2) antibody, has had a major impact on the treatment of patients with HER2-positive breast cancer (BC) worldwide, which now has indications for the treatment of small tumors in both (neo)adjuvant and palliative settings [3,4]. This provides a good opportunity to compare the efficacy and safety of trastuzumab biosimilars to those of trastuzumab in clinical trials. For several anti-HER2 biosimilars, safety and clinical equivalence to the reference product have been demonstrated [2,5]. In a randomized, parallel-group phase 3 equivalence study of patients with HER2-positive metastatic BC, Rugo et al [6] demonstrated equivalent efficacy and similar safety profiles between the trastuzumab biosimilar Ogivri (MYL-1401O) and trastuzumab (Herceptin) [6].

The enhanced assessment of electronic patient-reported outcomes (ePROs) in clinical routine and cancer trials is of growing interest [7-9]. Several studies indicate that the proactive use of PROs can identify otherwise undetected symptoms and improve symptom management for patients with various types of cancer [9] as well as offer improvements in well-being and awareness of adverse events (AEs) between outpatient visits. Using a mobile app, especially in collaboration with the treating physician, might improve clinical care in patients with early or advanced disease [10-13]. In addition, the benefits of digital patient monitoring have been demonstrated during immune and targeted cancer therapies in terms of more efficient symptom assessment and patient-physician communication as well as a reduced need for telephone consultations [14].

Medidux is an interactive patient empowerment app that enables physicians, especially oncologists, to monitor the progression of well-being and symptoms of patients undergoing cancer treatment. Based on the documented symptom progression, the software notifies patients to contact the treatment team if symptoms defined according to the Common Terminology Criteria for Adverse Events (CTCAE) standards are outside the acceptable range. More than 110 available symptoms and severity classifications (according to the CTCAE), as well as high numbers of standardized symptom reports from patients, contribute to the collection of high-quality ePRO data for the timely management of treatment-related AEs and toxicities and their communication to treatment teams [11,13]. Thus, the medidux smartphone app is helpful to stabilize daily functional activities and leads to more frequent reporting of AEs and more precise entries regarding symptoms [11]. The continuous measurement of ePROs enables structured and standardized data recording of patients' daily health state.

An increased level of concordance (κ=0.68) for common symptoms, including pain, fever, diarrhea, constipation, nausea, vomiting, and stomatitis, between the patient and treating physician was recently demonstrated for the medidux platform [13].

However, to the best of our knowledge, no real-world observation of side effects, tolerability, and quality of life (QoL) has been performed using ePRO data collected from patients treated with anti-HER2 biosimilars. Thus, the aim of this observational study was to investigate real-word data on daily functional activity, symptoms, and therapy side effects recorded with the medidux smartphone app in patients undergoing Ogivri antibody therapy. In addition, historical ePRO data of 38 patients with HER2-positive BC treated with Herceptin from two previous studies [7,13] were used for comparative analysis.

Methods

Study Design

OGIPRO was a noninterventional, multicenter, prospective, observational study conducted at 5 study sites in Switzerland over a duration of 20 months.

Patients 18 years and older with a histologically or cytologically proven diagnosis of HER2-positive primary, locally advanced, or metastatic BC were eligible to participate after providing written informed consent. In addition, patients had to own a personal iOS or Android smartphone.

Eligible patients received anti-HER2 treatment containing the trastuzumab biosimilar Ogivri (initial dose of 8 mg/kg body weight [BW] intravenously, followed by 6 mg/kg BW) with or without pertuzumab and/or chemotherapy and hormone therapy in (neo)adjuvant and palliative settings. At the beginning of the study, patients were provided with the medidux app and were prompted to record their symptoms, well-being, EQ-5D-5L questionnaires, cognitive capabilities, and vital parameters every day. Patients underwent 3 regular study visits scheduled on days 1, 21, and 42 during their 3 weekly chemotherapeutic interventions. All anticancer treatments used in this study were approved drugs, and the therapy was compliant with national treatment guidelines.

The observational period for each patient was 6 weeks. At the end of the observational period, patients decided whether to continue their therapy with the biosimilar Ogivri or with the reference substance Herceptin.

After the study observational period, prospectively collected data of patients treated with Ogivri (prospective cohort) were compared to historical ePRO data of patients treated with Herceptin (historical cohort) in two previous studies: a prospective randomized controlled trial (PRO1 study; ClinicalTrials.gov NCT02004496) of 139 patients with early stage BC who underwent chemotherapy [7] and an observational noninterventional trial (Consilium1 study; ClinicalTrials.gov NCT03578731) of patients with breast, colon, prostate, or lung cancer undergoing cancer treatment [13]. In both studies, patients were encouraged to document data on well-being and standardized symptoms using earlier versions of the medidux app during the course of their therapies. More than 5000 continuously measured data entries from 38 patients overall (14 from Consilium1 and 24 from PRO1) were available for the comparative analysis [7,13]. The historical ePRO data were recorded in the same manner using the earlier versions of the mobile app [11] and were therefore comparable to the prospective ePRO data.

Ethical Considerations

This study was approved by the Swiss Institutional Review Board (KEK-ZH: 2021-D0051) and was conducted in accordance with the principles of the Declaration of Helsinki (current version). The study was also registered on ClinicalTrials.gov (NCT05234021). All patients in the prospective and historical cohorts provided written informed consent prior to enrollment and were informed that participation in the study is voluntary and can be revoked at any time. All study documents were deidentified by assigning a unique ID to each patient. Functional data security was ensured by identification only made possible via the patient's ID. The data on the patients' devices were encapsulated in the app and the data exchange was encrypted with the patient's ID. There was no compensation provided to participants.

Objectives

Primary Objective

The primary objective of the study was to evaluate ePRO data reported in the medidux app by patients with HER2-positive BC treated with the trastuzumab biosimilar Ogivri with respect to their treatment side effects and to compare these data with ePRO data obtained from a historical cohort of 38 patients treated with Herceptin in two previous studies (NCT02004496, NCT03578731) [7,11,13]. No difference was expected for the CTCAE score between the two cohorts. The aims of the study were therefore to confirm that the average CTCAE scores were similar in both cohorts and that the recording of side effects with the app was reliable.

Secondary Objectives

Secondary objectives included well-being in both cohorts as well as electronically reported symptoms with respect to the therapy regimen and demographic characteristics only in the prospective cohort.

Mobile App

The medidux app (version 3.2) used in the study is a patient-centered, therapy-accompanying app that supports the structured, standardized, and dynamic documentation of symptoms and therapy side effects. Use of this tool does not represent an invasive intervention on the patient and consequently did not pose any specific risks of physical injury.

Data Collection

The app has two basic components: (1) a browser-based app for the treatment team (web app) and (2) a mobile app for cancer patients. There was no need for 24-hour monitoring by medical staff in connection with use of the app.

The medidux app for patients enabled recording symptoms, vital signs, and well-being in a structured and standardized manner. Patients were encouraged to regularly enter data on symptoms according to the CTCAE (version 4.0), general well-being according to the Eastern Cooperative Oncology Group Performance Status (ECOG PS), EQ-5D-5L questionnaire (weekly), vital signs (weight, blood glucose, blood pressure, and pulse), and optionally a neuropsychological cognitive test (Trail Making Test [TMT]), concomitant medications, and private notes. Patients were asked daily about their general well-being and symptoms using a visual analog scale. Recording usually started on the day of therapy initiation (or the change in therapy) and continued through an observational period of 6 weeks. The frequency of app use and data entry was logged throughout the course of the study treatment, which served as an indicator of patients' active participation in the study and as a relevant process parameter for evaluating the usability of the app itself.

The mobile app also recommended contacting the investigator or treatment site in case of high intensity of symptoms (ie, treatment side effects). Furthermore, the app provided patients with self-efficacious recommendations and tips on how to treat and reduce treatment side effects.

Recording of AEs

AEs in the app were classified according to the CTCAE (version 4.0). For the app, grade 5 “Death related to AE” had been removed. Instead, category 0 was added, representing no or very mild symptoms. The 5 severity levels were translated into a visual analog scale from 0.1 to 10, with 0.1 representing the weakest possible symptom and 10 representing the strongest possible symptom. Scores 0.1-2.0 corresponded to grade 0, scores 2.1-4.0 corresponded to grade 1, scores 4.1-6 corresponded to grade 2, scores 6.1-8 corresponded to grade 3, and scores 8.1-10 corresponded to grade 4 AEs. When patients selected a score between 0.1 and 10, they received a summary and information for the selected range, which was displayed in the app. Classification into adapted grades based on the CTCAE resulted in the following categories: minimal symptoms (0), mild symptoms (1), moderate symptoms (2), severe symptoms (3), and very severe symptoms (4).

Well-Being Assessment

Self-assessment of well-being was carried out in the medidux app with the help of a slider on a visual analog scale that allows for the continuous selection from 0 to 100. At the same time, short definitions appear for the standardized and structured reporting of the gradings, which should help the patient to correctly categorize their well-being. Selected values between 81 and 100 correspond to an ECOG PS of 0, values of 61-80 correspond to ECOG PS 1, values of 41-60 correspond to ECOG PS 2, values of 21-40 correspond to ECOG PS 3, and values of 0-20 correspond to ECOG PS 4. As mentioned above, grade 5 “Dead” was removed for the app.

Statistical Analyses

Sample Size Calculation

The research objective was to investigate the difference between prospective and historical cohorts regarding patient-reported side effects, operationalized by the CTCAE score over a period of 6 weeks. To assess the hypothesis of equal CTCAE scores in both cohorts, the method of interval estimation was selected using the 95% CI for the mean difference between cohorts. A statistical analysis plan (SAP) prospectively determined the required sample size for a prospective cohort based on the data from the historical cohort (as available from the previous studies NCT02004496 and NCT03578731 [7,11,13]; see the Study Design section above for further details). First, the SD for the CTCAE scores of the 38 patients in the historical cohort was calculated retrospectively as 9.7 and the assumption of an equal SD in the prospective cohort was made. Second, the sample size for the prospective cohort was chosen to achieve a certain minimum precision in estimating the mean difference between cohorts (width of the 95% CI). For a range of feasible sample sizes, the SAP reported 95% CI precisions based on the *t* distribution (calculated using the R package presize [15]), assuming an equal SD of 9.7 in both cohorts and using a pooled variance estimate. From this range, a sample size of 60 patients was prospectively selected in the SAP to achieve 51 evaluable patients, given an expected dropout rate of 15%. The corresponding 95% CI for the mean difference between the historical and prospective cohorts was estimated to have a precision of 8.3, which was deemed acceptable for the planned assessment in the given study context.

Statistical Methods

All analyses of the primary and secondary endpoints (CTCAE score, well-being score) were performed using univariate analyses, followed by multivariate linear regression to report (adjusted) mean differences between historical and prospective cohorts, with the *P* values based on *t* tests and corresponding 95% CIs. All multivariate models extended the respective univariate models in a supplementary fashion to adjust for potential imbalances in patient age, tumor stage, and therapy setting. These covariates were prospectively defined in the study’s SAP; no model selection procedures were employed. All analyses were performed using R version 4.2.0 (The R Foundation for Statistical Computing) [16]. Two-sided *P* values ≤.05 were considered statistically significant.

Primary Endpoint

The primary endpoint, a CTCAE score based on the severity grades of the 10 most relevant side effects (sensory disturbance, diarrhea, fatigue, nausea, vomiting, headache, fever, edema of the limbs, joint pain, and loss of appetite) after 6 weeks, was compared between the prospective and historical cohorts. The CTCAE score was calculated by averaging the score per patient and symptom and then averaging the score per patient over all symptoms. The mean difference in the CTCAE scores between cohorts was estimated using univariate linear regression with 95% CIs. To adjust for potential differences between the two cohorts in covariates relevant for the primary outcome, a supplementary multivariate analysis was performed including the additional covariates patient age, tumor stage, and therapy setting.

Secondary Endpoint

The well-being score according to the ECOG PS was collected continuously using a visual analog scale (range 0-100) implemented in the medidux app and averaged across measurements during the observational period. The analysis protocol was analogous to that described above for the primary endpoint.

Additional Analysis

Cognitive tests in the prospective cohort were collected continuously throughout the observation period and descriptively assessed by administering a modified version of the TMT. The time (in seconds) to complete each task (execution time) was used in the analysis.

Results

Baseline Characteristics

Overall, 53 female patients were enrolled in the OGIPRO study. The median age was 57 (range 34-87) years in the prospective cohort and 51 (range 31-78) years in the historical cohort. Most patients (38.9%) had tumor stage 2 (Table 1). With regard to the treatment setting, relatively fewer patients (22.2%) received palliative treatment than neoadjuvant or adjuvant treatment. More than half of the patients (59.3%) received dual anti-HER2 blockade with trastuzumab and pertuzumab (Table 1).

Table 1. Baseline characteristics.

Parameter	Historical cohort (n=38)	Prospective cohort (n=53)	Total (N=91)	*P* value
Age (years)				.001[a]
Mean (SD)	51.3 (10)[b]	59.09 (12.193)	55.89 (11.924)[b]	
Median (range)	51 (31-78)	57 (34-87)	54 (31-87)	
Tumor stage (T), n (%)				.07[c]
T1	8 (21.05)	10 (19.23)[b]	18 (20.0)[b]	
T2	19 (50.0)	16 (30.77)[b]	35 (38.89)[b]	
T3	8 (21.05)	11 (21.15)[b]	19 (21.11)[b]	
T4	3 (7.89)	15 (28.85)[b]	18 (20.0)[b]	
Treatment setting, n (%)				.02[c]
Neoadjuvant	17 (44.74)	18 (34.62)[b]	35 (38.89)[b]	
Adjuvant	18 (47.37)	17 (32.69)[b]	35 (38.89)[b]	
Palliative	3 (7.89)	17 (32.69)[b]	20 (22.22)[b]	
Treatment, n (%)				.01[c]
Trastuzumab	1 (2.63)	10 (18.87)	11 (12.09)	
Trastuzumab+pertuzumab	21 (55.26)	33 (62.26)	54 (59.34)	
Trastuzumab+pertuzumab+paclitaxel	13 (34.21)	10 (18.87)	23 (25.27)	
Ado-trastuzumab emtansine	3 (7.89)	0 (0)	3 (3.3)	
ECOG PS[d], n (%)				.26[c]
0	13 (34.21)	16 (30.77)[b]	29 (32.22)[b]	
1	15 (39.47)	29 (55.77)[b]	44 (48.89)[b]	
2	6 (15.79)	4 (7.69)[b]	10 (11.11)[b]	
3	2 (5.26)	3 (5.77)[b]	5 (5.56)[b]	
4	2 (5.26)	0 (0)[b]	2 (2.22)[b]	

[a] Student *t* test.

[b] Data missing for 1 participant.

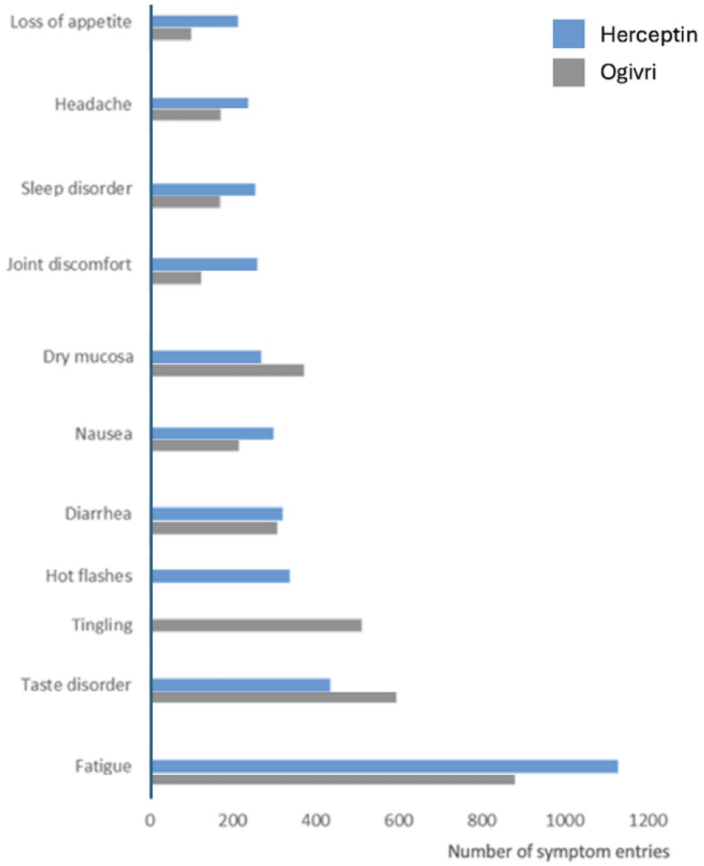
[c] χ^2 test.

[d] ECOG PS: Eastern Cooperative Oncology Group Performance Status.

ePRO Data

In the prospective cohort, 84 of the 92 available different symptoms were entered (average >4 symptoms/day), resulting in a total of 9680 symptoms, whereas 54 of the 82 different symptoms were reported in the historical cohort (average >3 symptoms/day), resulting in a total of 6904 symptom entries. The most common symptoms reported in both groups included fatigue, taste disorder, nausea, diarrhea, dry mucosa, joint discomfort, tingling, sleep disorder, headache, and appetite loss (Figure 1).

Figure 1. Frequency of the 10 most common symptoms recorded with the app by patients treated with the trastuzumab biosimilar Ogivri (prospective cohort) and patients treated with Herceptin (historical cohort). Absolute numbers of symptom entries are presented.



Overall, the distribution of symptom grades in the Ogivri cohort revealed that most patients experienced minimal (grade 0) and mild (grade 1) toxicities, followed by grade 2, grade 3, and grade 4 toxicities (Table 2). The results for QoL (based on the EQ-5D-5L questionnaire), which was also assessed in this study, will be reported elsewhere.

Table 2. Distribution of symptom grades in the Ogivri prospective cohort (N=9680 symptoms reported).

App symptom score and grade	Entries, n (%)
≤2 (Grade 0=minimal)	4167 (43.1)
>2 to ≤4 (Grade 1=mild)	4040 (41.7)
>4 to ≤6 (Grade 2=moderate)	1268 (13.1)
>6 to ≤8 (Grade 3=severe)	164 (1.7)
>8 to ≤10 (Grade 4=very severe)	41 (0.4)

CTCAE Score

The primary endpoint was analyzed in 50 patients (3 patients were excluded due to missing data on symptoms) treated with Ogivri (prospective cohort) and in all 38 patients treated with Herceptin (historical cohort). The mean CTCAE scores were comparable between the two cohorts (Table 3) with a mean difference of –1.27 (95% CI –7.24 to 4.70; *P*=.68) (Figure 2). In the multivariate analysis, the adjusted mean CTCAE scores also did not differ between the two cohorts (2.51, 95% CI –3.27 to 8.29) (Table S1 in Multimedia Appendix 1).

Figure 2. CTCAE score in the prospective (Ogivri) and historical (Herceptin) cohorts. The CTCAE score (primary endpoint) was analyzed in 50 patients (3 patients were excluded due to missing data on symptoms) treated with Ogivri and in all 38 patients treated with Herceptin. CTCAE: Common Terminology Criteria for Adverse Events.

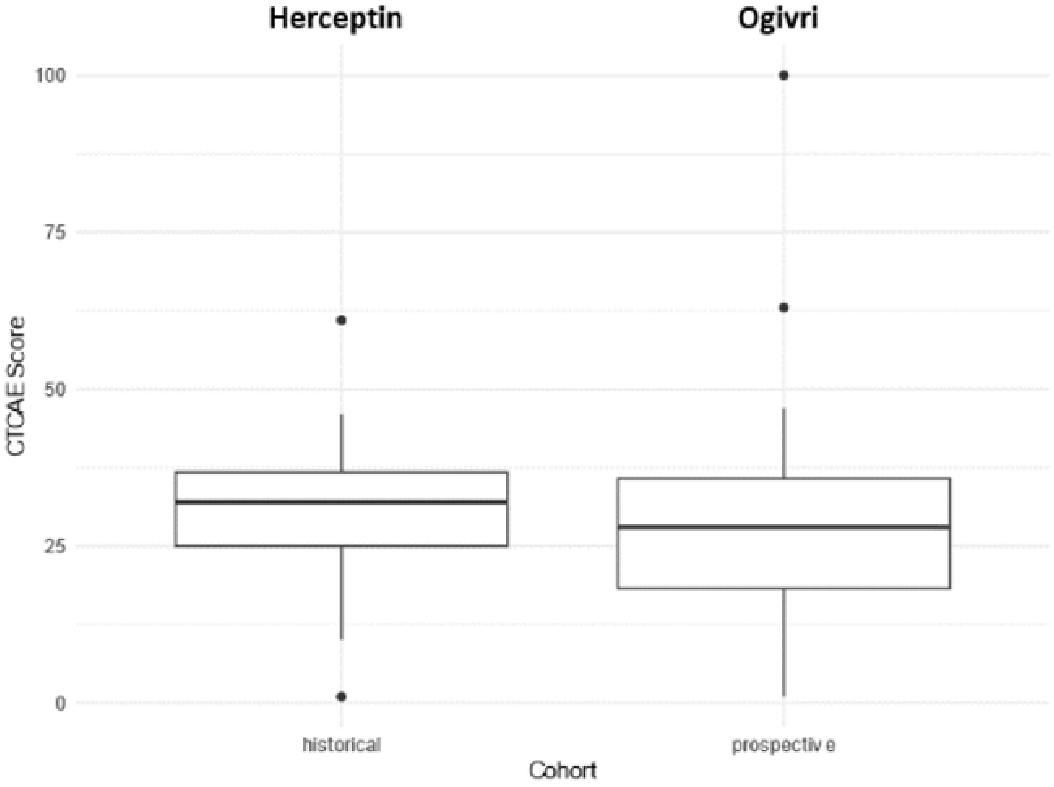


Table 3. Descriptive statistics of treatment side effects according to Common Terminology Criteria for Adverse Events (CTCAE) scores and well-being according to the Eastern Cooperative Oncology Group Performance Status (ECOG PS).

Parameter	Historical cohort (n=38)	Prospective cohort (n=53)	Total (N=91)	*P* value[a]
CTCAE score[b]				.68
Mean (SD)	30.29 (11.618)	29.02 (15.804)	29.57 (14.088)	
Median (range)	32 (1-61)	28 (1-100)	29.5 (1-100)	
ECOG PS[c]				.28
Mean (SD)	69.82 (23.006)	74.27 (15.66)	72.39 (19.117)	
Median (range)	76 (0-100)	74.5 (35-100)	76 (0-100)	

[a] Reported *P* values correspond to mean differences between cohorts.

[b] Missing scores for 3 participants in the prospective cohort.

[c] Missing score for 1 participant in the prospective cohort.

Well-Being Score

The secondary endpoint, the well-being score, was analyzed in 52 patients (one patient was excluded due to missing data on well-being) from the OGIPRO study and in all 38 patients from the historical cohort. The mean well-being score did not differ significantly between patients treated with Ogivri and those treated with Herceptin (Table 3), with a mean difference of 4.45 (95% CI –3.53 to 12.44; *P*=.28). The adjusted mean well-being scores also did not differ between the two cohorts (3.78, 95% CI –4.64 to 12.19) (Table S2 in Multimedia Appendix 1).

Cognitive Abilities in the Prospective Cohort

A total of 767 cognitive tests were entered and the data of 37 patients (70%) who had performed at least one test were included in the analysis (see Figure S1 in Multimedia Appendix 1). Overall, the mean execution time was 42.9 (SD 26.3) with an absolute difference between the maximum and minimum execution time of 197 seconds. Because of the low sample size and limited number of cognitive tests recorded, no correlation analysis between cognitive abilities and treatment was performed.

Discussion

The treatment of patients with HER2-positive BC with the trastuzumab biosimilar Ogivri resulted in equivalent symptoms, AEs, and well-being to those experienced under treatment with Herceptin as determined by ePROs. Ogivri treatment in the context of HER2-positive BC was well tolerated and no new important safety risks were observed. The results of this study are consistent with previously reported evidence on the safety comparability of the trastuzumab biosimilar Ogivri to the reference product Herceptin for the treatment of HER2-positive BC [6,17].

The use of biosimilars in oncology could reduce health care costs and thus expand access to drugs worldwide. The European Medicines Agency as well as the US Food and Drug Administration have developed guidelines requiring biosimilars to demonstrate comparable results in relevant clinical trials to those obtained using the original product [18]. Recent studies have demonstrated that anti-HER2 therapy can be switched safely to trastuzumab biosimilars and successfully implemented in clinical practice [19].

In our study, the incidence and distribution of symptoms associated with Ogivri were similar to those reported with Herceptin. However, the slightly lower mean symptom score related to Ogivri might be attributed to the higher number of treatments in this cohort for advanced cancer stages, including antihormone treatments and dual HER2 blockade.

To our knowledge, this study represents the first real-world evaluation on efficacy and safety in patients treated with HER2 biosimilars using ePRO data. Use of the app in this study was intended to help patients gain a better overview of their disease history and improve their symptom management. Our analysis of ePRO data demonstrated comparable CTCAE scores between the prospective Ogivri cohort and the historical Herceptin cohort. These findings further support the previously reported similar safety profiles between the trastuzumab biosimilar and the corresponding reference product [6,17] with no new safety concerns observed.

Importantly, the well-being score based on the ECOG PS did not differ between the two cohorts. In a pooled analysis of data from three randomized clinical trials including patients with HER2-positive advanced BC, PROs were identified as an independent prognostic factor for both survival and toxicity outcomes. In addition, patient-reported physical well-being and clinically interpreted ECOG PS provided independent prognostic information [20]. In our prospective Ogivri cohort, we did not focus on the prognostic value of the ePRO with regard to clinical outcomes, but we were able to demonstrate that an eHealth patient empowerment app can provide reliable information on side effects and well-being when comparing a biosimilar with reference treatments. Hence, the use of continuous eHealth-based symptom reporting together with biosimilars can result in a potential economic benefit by reducing the cost of drug treatment and hospitalization. Further detailed analyses of randomized trials with biosimilars will help to quantify these resources more comprehensively.

In general, the diary characteristic of apps might appear helpful to capture and recall disease-related information such as cognitive impairments [21]. In the OGIPRO study, patients had the possibility to complete a TMT, which is one of the most widely used neuropsychological tests in clinical practice; this test is perceptive, easy to understand for patients, has a short administration time, and has shown consistent results in multiple clinical populations [22-24]. A study investigating the impact of chemotherapy on cognitive functions of patients with BC demonstrated increased cognitive impairment throughout chemotherapy treatment, which did not recover 2 months after chemotherapy was completed [25]. In contrast, in the OGIPRO study, the cognitive performance of the patients receiving Ogivri showed potential improvement throughout the study treatment. However, due to the low number of cognitive tests recorded during app use, the cognitive abilities were analyzed descriptively and no association could be made with regard to the trastuzumab biosimilar treatment. Further analyses are needed to evaluate the electronically collected cognitive test results in patients treated with biosimilars and corresponding reference products.

Our study has several strengths and limitations. The limitations of the study included the design that lacked a prospective control group so that the study was not randomized. However, the comparison between prospectively collected data of patients treated with Ogivri and the historical ePRO data of patients treated with Herceptin in two previous studies [7,13] demonstrated no difference with regard to symptoms, well-being, and AEs. The earlier versions of the mobile app used in the historical cohort were developed to record symptoms and treatment side effects continuously and according to the CTCAE in patients with cancer, but were not designed to send questionnaires to patients. Nevertheless, the ePRO data of the historical cohort were recorded in the same way in the earlier versions of the mobile app [11] and are thus comparable to those of the prospective cohort. An exploratory analysis on cognitive abilities was performed only in the prospective cohort as these data were not available in the historical cohort. Further studies that are randomized and sufficiently powered to evaluate the real-word cognitive functions in patients with HER2-positive BC treated with anti-HER2 biosimilars are needed.

The major strength of our proof-of-concept study is that it was able to provide the first evidence that data collected via an autonomous eHealth app can also be used longitudinally to determine the similarity of a trastuzumab biosimilar to the reference product for the treatment of HER2-positive BC. Furthermore, our study has reached its primary endpoint, showing a similar average CTCAE score between patients treated with the trastuzumab biosimilar Ogivri and those treated with the reference drug Herceptin. Our results suggest that the use of a patient empowerment eHealth app in patients treated with anti-HER2 biosimilars is reliable and can support therapy management.

In conclusion, in patients with HER2-positive BC, treatments with the trastuzumab biosimilar Ogivri and the reference drug Herceptin resulted in equivalent symptoms, AEs, and well-being reported by ePRO. Hence, the integration of an ePRO tool into research and clinical practice can provide reliable information when investigating the real-world tolerability and safety outcomes of similar therapeutic compounds.

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Data Availability

The data sets generated and/or analyzed during this study are available from the corresponding author on reasonable request.

Conflicts of Interest

AT received medical writing support from Palleos Healthcare, funding from the Swiss Tumor Institute, payment or honoraria for presentations from Viatris, support for attending ESMO 2023 from Viatris, and is the founder and stock owner of Mobile Health AG. YK reports stock or stock options from Viatris and is the Head of Project Management at Mobile Health AG. GAKU reports stock or stock options from Novartis. MA reports consulting fees from Aptar. AE reports consulting fees from Daiichi-Sankyo, Gilead, Merck, Novartis, and Seagen, and institutional financial support for clinical trials from AstraZeneca, Roche, Pfizer, and Novartis. All other authors have declared no conflicts of interest.

Multimedia Appendix 1
Multivariate analyses of Common Terminology Criteria for Adverse Events (CTCAE) scores (Table S1) and well-being scores (Table S2); distribution of cognitive performance scores (Figure S1).
[DOCX File , 294 KB - cancer_v10i1e54178_app1.docx]

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Abbreviations

AE: adverse event
BC: breast cancer
BW: body weight
CTCAE: Common Terminology Criteria for Adverse Events
ECOG PS: Eastern Cooperative Oncology Group Performance Status
ePRO: electronic patient-reported outcome
HER2: human epidermal growth factor 2
QoL: quality of life
SAP: statistical analysis plan
TMT: Trail Making Test

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Original Paper

Assessing the Relationship Between Neighborhood Socioeconomic Disadvantage and Telemedicine Use Among Patients With Breast Cancer and Examining Differential Provisions of Oncology Services Between Telehealth and In-Person Visits: Quantitative Study

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Abstract

Background: Since the COVID-19 pandemic began, we have seen rapid growth in telemedicine use. However, telehealth care and services are not equally distributed, and not all patients with breast cancer have equal access across US regions. There are notable gaps in existing literature regarding the influence of neighborhood-level socioeconomic status on telemedicine use in patients with breast cancer and oncology services offered through telehealth versus in-person visits.

Objective: We assessed the relationship between neighborhood socioeconomic disadvantage and telemedicine use among patients with breast cancer and examined differential provisions of oncology services between telehealth and in-person visits.

Methods: Neighborhood socioeconomic disadvantage was measured using the Area Deprivation Index (ADI), with higher scores indicating greater disadvantages. Telemedicine and in-person visits were defined as having had a telehealth and in-person visit with a provider, respectively, in the past 12 months. Multivariable logistic regression was performed to examine the association between ADI and telemedicine use. The McNemar test was used to assess match-paired data on types of oncology services comparing telehealth and in-person visits.

Results: The mean age of the patients with breast cancer (n=1163) was 61.8 (SD 12.0) years; 4.58% (52/1161) identified as Asian, 19.72% (229/1161) as Black, 3.01% (35/1161) as Hispanic, and 72.78% (845/1161) as White. Overall, 35.96% (416/1157) had a telemedicine visit in the past 12 months. Of these patients, 65% (266/409) had a videoconference visit only, 22.7% (93/409) had a telephone visit only, and 12.2% (50/409) had visits by both videoconference and telephone. Higher ADI scores were associated with a lower likelihood of telemedicine use (adjusted odds ratio [AOR] 0.89, 95% CI 0.82-0.97). Black (AOR 2.38, 95% CI 1.41-4.00) and Hispanic (AOR 2.65, 95% CI 1.07-6.58) patients had greater odds of telemedicine use than White patients. Compared to patients with high school or less education, those with an associate's degree (AOR 2.67, 95% CI 1.33-5.35), a bachelor's degree (AOR 2.75, 95% CI 1.38-5.48), or a graduate or professional degree (AOR 2.57, 95% CI 1.31-5.04) had higher odds of telemedicine use in the past 12 months. There were no significant differences in providing treatment consultation (45/405, 11.1% vs 55/405, 13.6%; *P*=.32) or cancer genetic counseling (11/405, 2.7% vs 19/405, 4.7%; *P*=.14) between telehealth and in-person visits. Of the telemedicine users, 95.8% (390/407) reported being somewhat to extremely satisfied, and 61.8% (254/411) were likely or very likely to continue using telemedicine.

Conclusions: In this study of a multiethnic cohort of patients with breast cancer, our findings suggest that neighborhood-level socioeconomic disparities exist in telemedicine use and that telehealth visits could be used to provide treatment consultation and cancer genetic counseling. Oncology programs should address these disparities and needs to improve care delivery and achieve telehealth equity for their patient populations.

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KEYWORDS

telemedicine; telehealth equity; Area Deprivation Index; neighborhood socioeconomic disadvantage; disparities; oncology services; treatment consultation; genetic counseling; in-person visits; breast cancer; mobile phone

Introduction

Background

In the United States, telemedicine use has risen over the years. According to the 2019 American Hospital Association annual survey, the percentage of telehealth programs implemented across hospitals increased from 43.1% in 2015 to 61.2% in 2017 [1]. Since the COVID-19 pandemic began, we have seen rapid and unprecedented growth in the demand for, and use of, telemedicine. A recent report from the Centers for Disease Control and Prevention has documented that the frequency of telehealth visits increased by 50% from 2019 to 2020 [2]. The increase in the use of telemedicine is also observed in populations of patients with cancer; for example, several studies conducted during 2020 and 2021 estimated that the prevalence of telemedicine use ranges from 34.9% to 64.9% among patients with breast or other cancers [3-11]. In 2020, the Centers for Medicare & Medicaid Services introduced policies that offered regulatory waivers and flexible reimbursement to Medicaid and Medicare providers for telehealth, contributing in part to the observed increase in telemedicine use and implementation [12,13]. In 2021, the American Society of Clinical Oncology performed a systematic literature review on telemedicine and published standards and recommendations for telehealth services and practices in the oncology setting [14]. Telemedicine helps facilitate access to health care and services for patients with cancer and their caregivers or family members. However, telehealth care and services are not equally distributed, and not all patients with cancer have equal access to telehealth care and services across different US regions. There are notable gaps in existing literature regarding the influence of neighborhood-level socioeconomic status (SES) on telemedicine use in patients with breast cancer and oncology services offered through telehealth versus in-person visits.

Neighborhood-level SES is a fundamental component of the social determinants of health framework [15,16]. Neighborhood socioeconomic disadvantage has been shown to negatively affect health outcomes [17,18], access to care and preventive services [19,20], survival outcomes [18,21], and quality of life [22] among patients with cancer [23]. Previous investigations have also found neighborhood socioeconomic disadvantage to be associated with a lower likelihood of telemedicine use among patients in primary care and hematology or oncology clinics, as well as among outpatients [8,24-28]. A study of 627 patients with cancer experiencing financial distress during the COVID-19 pandemic reported a 3% decrease in the rate of telemedicine use per 10-unit increase in the Area Deprivation Index (ADI) [8], a validated composite measure of neighborhood-level SES [29,30]. Fassas et al [27] conducted a univariate analysis of 64 patients with head and neck cancer, revealing no significant differential interest in telehealth visits based on the ADI. Another study noted a higher percentage of telehealth visits among patients residing in the least socioeconomically deprived neighborhoods (54%) than those in the most deprived neighborhoods (46.1%) in a large cohort of patients with hematologic malignancies and patients with cancer from Kaiser Permanente [28]. These prior studies either lacked significant sample sizes or included heterogeneous populations of patients with cancer. Therefore, these findings may not be generalizable to the population of patients with breast cancer.

In addition, whether provisions or receipts of oncology services differ between telemedicine and in-person office visits among patients with breast cancer is unclear. A recent retrospective analysis of 311 patients with cancer indicated that clinical practices, such as molecular test ordering and palliative care referrals, conducted through telehealth visits achieve similar efficiency to in-person visits [31]. A pilot study of 45 patients with advanced cancer in Mexico has suggested the feasibility of supportive care delivery via telemedicine [32]. Multiple studies have found telehealth provisions or visits to be feasible, effective, and safe for patient follow-ups after ambulatory or breast surgeries [33-36]. Earlier research has also demonstrated that, when comparing telehealth to in-person visits, patients with cancer in the United States, Canada, and Europe reported similar communication experiences or satisfaction with the oncology care consultations they received [7,37,38]. Moreover, telemedicine-based cancer genetic counseling has been shown to be feasible and effective and to achieve high degrees of satisfaction among providers as well as patients with colorectal, breast, or gynecologic cancer residing in remote or rural areas [39-42]. Although prior studies have elucidated the successful implementation of telemedicine and shown that certain types of cancer care and services delivered through telemedicine are equivalent to in-person office settings in mixed cohorts of patients with cancer, the results may not be applicable to patients with breast cancer. Furthermore, most of these studies were not able to examine the distributions of oncology services comparing telehealth and in-person visits because of small sample sizes and therefore are primarily descriptive. Understanding these associations can help oncology programs identify telehealth disparities and patient's unmet needs, improve telemedicine practice and care delivery, reduce health disparities and inequities, and provide optimal support to patients with breast cancer.

Objectives

To fill these critical gaps in the literature, we undertook this study primarily seeking to evaluate (1) the association between neighborhood socioeconomic disadvantage and telemedicine use and (2) the differences in provisions of oncology services comparing telehealth and in-person office visits. The secondary objectives of this study were to describe (1) common perceived challenges or concerns related to telehealth visits and (2) patient satisfaction with oncology services delivered via telemedicine in this cohort of patients with breast cancer.

Methods

Study Design and Population

This study used a cross-sectional design and analyzed data from patients with breast cancer enrolled in the ongoing Chicago Multiethnic Epidemiologic Breast Cancer Cohort (ChiMEC), which is a hospital-based cohort established at the University of Chicago Medicine in 1993 [43]. From July to September 2022, a total of 1868 questionnaires were sent to ChiMEC participants who consented to follow-up surveys, of whom 1236 (66.17%) responded. The study survey is provided in Multimedia Appendix 1. For this analysis, of the 1236 respondents, we included 1163 (94.09%) patients who reported having had either telemedicine or in-person visits in the past 12 months.

Ethical Considerations

The University of Chicago Institutional Review Board reviewed and approved this study (approval 16352A). All participants provided written informed consent before taking part in the ChiMEC study and follow-up surveys.

Measures

Neighborhood socioeconomic disadvantage was defined by the ADI, a composite measurement of patients' neighborhood-level income, education, employment, and housing quality based on linked zip codes and US Census block groups [29,30]. For this study, participants' residential addresses were geocoded to census block groups and then linked with the corresponding ADI national ranking percentile, which ranks neighborhoods by socioeconomic disadvantage at the national level in the United States. ADI scores range from 1 to 100, with higher scores reflecting higher levels of neighborhood socioeconomic deprivation. We further categorized ADI scores into quartiles. The first quartile represented the least socioeconomically deprived neighborhoods, whereas the fourth quartile represented the most deprived neighborhoods.

Telemedicine use was defined as having had a telehealth visit with a physician or other health providers in any specialty in the past 12 months and dichotomized as *yes* or *no*. For patients who used telemedicine, we asked whether their visits were conducted through telephone, videoconferencing, or both. Similarly, in-person visits were assessed by asking participants whether they had had an in-person office visit with a physician or other health providers in the past 12 months. Furthermore, participants were asked whether their telemedicine or in-person visits were related to 6 different types of oncology services: treatment consultation; review of laboratory, screening, and pathology test results; management of cancer symptoms and treatment side effects; cancer genetic counseling; cancer clinical trial follow-up; and informed consent for a cancer clinical trial. Common cancer symptoms and treatment side effects discussed during telehealth or in-person visits were also assessed, including hot flashes; chemotherapy-induced neuropathy, nausea, and vomiting; pain related to cancer or cancer treatment; depressive symptoms or mood changes; fatigue or tiredness; anxiety or stress; lymphedema; and insomnia or sleep problems.

In addition, we asked participants to report any challenges or concerns when using telemedicine, such as technology difficulty or lack of comfort with technology, lack of electronic device (eg, desktop computer, laptop computer, smartphone, or iPad), lack of high-speed internet or slow internet connection at home, compromised patient-provider communication, compromised patient-provider relationship, telemedicine not being offered at the clinic or by a provider, cost, and telemedicine not being covered by health insurance. We then asked how satisfied participants were with their telehealth or in-person visits, using a 5-point Likert scale (ie, *not at all*, *a little*, *somewhat*, *very*, and *extremely satisfied*). Participants were also asked how likely they were to continue using telemedicine, using another 5-point Likert scale (ie, *very unlikely*, *unlikely*, *neutral*, *likely*, and *very likely*).

Individual-level sociodemographic and clinicopathologic characteristics included age at survey, race, ethnicity, highest level of education, marital status, type of health insurance coverage, duration from cancer diagnosis to survey, Charlson comorbidity index (excluding breast cancer diagnoses), histologic type, American Joint Committee on Cancer stage group, molecular subtype, tumor grade, receipt of cancer treatment (chemotherapy, hormone therapy, or radiotherapy), and type of surgery. We obtained patients' clinicopathologic information from electronic health records and the hospital cancer registry. Distance from residence to hospital (in miles) was geocoded and calculated by taking the differences of coordinates (longitudes or latitudes) between the patient's address and the University of Chicago Medicine Comprehensive Cancer Center's address based on the Haversine formula.

Statistical Analysis

We described patients' characteristics using summary statistics. Means and SDs or medians and IQRs were calculated for continuous variables, and we used 2-tailed t tests, Wilcoxon rank sum tests, or Kruskal-Wallis tests to conduct bivariate analyses. For nominal data, we tabulated frequencies and percentages and compared the distributions using Pearson chi-square or Fisher exact tests. To examine the association between neighborhood socioeconomic disadvantage (continuous ADI scores) and telemedicine use, we fitted 3 separate multivariable logistic regression models. For modeling, we implemented a stepwise regression approach. Potential confounders were selected and adjusted for in the models based on a *P* value of <.10 from bivariate analyses or a priori knowledge. Model 1 included ADI, age at survey, race, ethnicity, duration from cancer diagnosis to survey, highest level of education, marital status, type of health insurance coverage, Charlson comorbidity index, and distance from residence to hospital. Model 2 was controlled for histologic type, American Joint Committee on Cancer stage, molecular subtype, and tumor grade, in addition to the covariates in model 1. Model 3 contained all variables in model 2 plus receipt of chemotherapy, hormone therapy, or radiotherapy, as well as type of surgery. Adjusted odds ratios (AORs) and corresponding 95% CIs were calculated. To evaluate the differences in types of oncology services between telemedicine and in-person office visits, we conducted McNemar tests on match-paired data of patients having both visit modalities. *P* values (2-tailed) <.05 were considered statistically significant. All statistical analyses were performed using Stata 17 (StataCorp LLC).

Results

Patient Characteristics

Overall, the 1868 study surveys received 1236 (66.17%) responses. Of the 1236 participants who responded, 1163 (94.09%) had had either telemedicine or in-person visits in the past 12 months. These participants' mean age was 61.8 (SD 12.0) years; 4.48% (52/1161) identified as Asian, 19.72% (229/1161) as Black, 3.01% (35/1161) as Hispanic, and 72.78% (845/1161) as White. Furthermore, 69.94% (747/1068) were married, 38.73% (450/1162) had a graduate or professional degree, 70.77% (823/1163) were privately insured, and 22.96% (267/1163) were on Medicaid or Medicare. The median distance from residence to hospital was 19.9 (IQR 9.5-32.3) miles, and the median duration from cancer diagnosis to survey was 6.5 (IQR 3.6-11.0) years. By ADI quartile, patients with breast cancer living in the most socioeconomically disadvantaged neighborhoods (fourth quartile) tended to be older, Black, at a lower level of education, and on Medicaid or Medicare (Table 1).

Table 1. Characteristics of patients with breast cancer overall and by neighborhood socioeconomic disadvantage (n=1163).

Variable	Total (n=1163)	Area Deprivation Index[a]				*P* value[b]
		First quartile (n=381)	Second quartile (n=376)	Third quartile (n=252)	Fourth quartile (n=99)	
Age (y) at survey, mean (SD)	61.8 (12.0)	60.9 (11.5)	61.6 (11.7)	62.0 (12.9)	64.2 (12.5)	.68
Age (y) at survey, n (%)						.03
<45	107 (10.2)	33 (9.5)	37 (10.8)	26 (11.4)	7 (7.8)	
45-54	179 (17)	64 (18.4)	59 (17.3)	38 (16.7)	12 (13.3)	
55-64	308 (29.2)	116 (33.3)	99 (28.9)	58 (25.4)	22 (24.4)	
≥65	460 (43.6)	135 (38.8)	147 (43)	106 (46.5)	49 (54.4)	
Race and ethnicity, n (%)						<.001
Asian	52 (4.5)	26 (6.8)	14 (3.7)	6 (2.4)	3 (3)	
Black	229 (19.7)	16 (4.2)	40 (10.7)	98 (38.9)	56 (56.6)	
Hispanic	35 (3)	5 (1.3)	20 (5.3)	5 (2)	4 (4)	
White	845 (72.8)	333 (87.6)	301 (80.3)	143 (56.7)	36 (36.4)	
Highest level of education, n (%)						<.001
High school, GED[c], or less	115 (9.9)	12 (3.1)	45 (12)	37 (14.7)	16 (16.2)	
Associate’s degree or some college	259 (22.3)	52 (13.6)	86 (22.9)	70 (27.8)	44 (44.4)	
Bachelor’s degree	338 (29.1)	127 (33.3)	102 (27.2)	69 (27.4)	20 (20.2)	
Graduate or professional degree	450 (38.7)	190 (49.9)	142 (37.9)	76 (30.2)	19 (19.2)	
Marital status, n (%)						<.001
Married	747 (69.9)	282 (80.3)	259 (73.4)	136 (59.6)	36 (40.4)	
Single or not married	192 (18)	44 (12.5)	53 (15)	59 (25.9)	30 (33.7)	
Divorced, separated, or widowed	129 (12.1)	25 (7.1)	41 (11.6)	33 (14.5)	23 (25.8)	
Type of health insurance, n (%)						<.001
Private	823 (70.8)	302 (79.3)	276 (73.4)	162 (64.3)	49 (49.5)	
Medicaid	50 (4.3)	5 (1.3)	8 (2.1)	17 (6.7)	15 (15.2)	
Medicare	217 (18.7)	54 (14.2)	74 (19.7)	55 (21.8)	24 (24.2)	
Other or unknown	73 (6.3)	20 (5.2)	18 (4.8)	18 (7.1)	11 (11.1)	
Distance from residence to hospital (miles)[d], median (IQR)	19.9 (9.5-32.3)	20.5 (10.9-31.9)	22.5 (13.3-33.2)	16.4 (4.6-30.5)	11.9 (3.3-27.6)	<.001
Duration (y) from cancer diagnosis to survey, median (IQR)	6.5 (3.6-11.0)	6.8 (3.7-10.9)	6.2 (3.6-10.3)	6.5 (3.6-11.5)	8.3 (4.2-11.6)	.61
Duration (y) from cancer diagnosis to survey, n (%)						.63
≤3	199 (17.1)	58 (15.2)	68 (18.1)	48 (19)	14 (14.1)	
4-6	319 (27.4)	107 (28.1)	107 (28.5)	67 (26.6)	23 (23.2)	
≥7	645 (55.5)	216 (56.7)	201 (53.5)	137 (54.4)	62 (62.6)	
Charlson comorbidity index, n (%)						.03
0	994 (88.5)	333 (90.5)	335 (91.5)	209 (85)	77 (82.8)	
1	62 (5.6)	19 (5.2)	11 (3)	21 (8.5)	6 (6.5)	
≥2	67 (6.0)	16 (4.3)	20 (5.5)	16 (6.5)	10 (10.8)	
Histologic type, n (%)						.08

Variable	Total (n=1163)	Area Deprivation Index[a]				P value[b]
		First quartile (n=381)	Second quartile (n=376)	Third quartile (n=252)	Fourth quartile (n=99)	
Ductal	742 (80.2)	247 (77.9)	238 (79.9)	159 (81.1)	64 (88.9)	
Lobular	92 (10)	38 (12)	34 (11.4)	15 (7.7)	1 (1.4)	
Ductal and lobular	55 (6)	19 (6)	18 (6)	12 (6.1)	3 (4.2)	
Other	36 (3.9)	13 (4.1)	8 (2.7)	10 (5.1)	4 (5.6)	
AJCC[e] stage group, n (%)						.002
0	200 (18.1)	51 (14.2)	69 (19)	51 (21.1)	21 (22.6)	
I	515 (46.5)	189 (52.5)	160 (44.1)	104 (43)	36 (38.7)	
II	271 (24.5)	88 (24.4)	91 (25.1)	58 (24)	24 (25.8)	
III	112 (10.1)	31 (8.6)	42 (11.6)	24 (9.9)	10 (10.8)	
IV	10 (0.9)	1 (0.3)	1 (0.3)	5 (2.1)	2 (2.2)	
Molecular subtype, n (%)						.06
HR[f]+/HER2[g]−	571 (66.2)	208 (69.3)	180 (66.2)	120 (65.6)	35 (53.8)	
HR+/HER+	98 (11.4)	34 (11.3)	36 (13.2)	15 (8.2)	8 (12.3)	
HR−/HER2+	51 (5.9)	12 (4)	17 (6.2)	19 (10.4)	3 (4.6)	
TNBC[h]	142 (16.5)	46 (15.3)	39 (14.3)	29 (15.8)	19 (29.2)	
Tumor grade, n (%)						.047
1	149 (14.3)	59 (17.3)	47 (13.8)	27 (11.9)	9 (10.3)	
2	471 (45.3)	159 (46.6)	146 (42.9)	99 (43.8)	42 (48.3)	
3	420 (40.4)	123 (36.1)	147 (43.2)	100 (44.2)	36 (41.4)	
Receipt of chemotherapy, n (%)						.92
No	572 (54.3)	190 (54.6)	182 (53.2)	125 (54.8)	48 (53.3)	
Yes	482 (45.7)	158 (45.4)	160 (46.8)	103 (45.2)	42 (46.7)	
Receipt of hormone therapy, n (%)						.03
No	341 (32.4)	100 (28.7)	113 (33)	74 (32.5)	39 (43.3)	
Yes	713 (67.7)	248 (71.3)	229 (67)	154 (67.5)	51 (56.7)	
Receipt of radiation therapy, n (%)						.08
No	394 (37.4)	140 (40.2)	125 (36.5)	83 (36.4)	26 (28.9)	
Yes	660 (62.6)	208 (59.8)	217 (63.5)	145 (63.6)	64 (71.1)	
Type of surgery received, n (%)						.006
None	13 (1.3)	5 (1.5)	3 (0.9)	2 (0.9)	3 (3.4)	
Lumpectomy	615 (59.3)	185 (53.8)	194 (57.4)	146 (66.1)	61 (68.5)	
Mastectomy	307 (29.6)	116 (33.7)	107 (31.7)	50 (22.6)	25 (28.1)	

Variable	Total (n=1163)	Area Deprivation Index[a]				P value[b]
		First quartile (n=381)	Second quartile (n=376)	Third quartile (n=252)	Fourth quartile (n=99)	
Bilateral mastectomy	102 (9.9)	38 (11.0)	34 (10.1)	23 (10.4)	0 (0)	

[a] The Area Deprivation Index (national ranking percentile) is a composite measure consisting of the domains of income, education, employment, and housing quality. It ranks neighborhoods by socioeconomic disadvantage at the national level and is scored from 1 to 100, with higher scores representing greater neighborhood socioeconomic deprivation.

[b] *P* values were calculated using Kruskal-Wallis tests.

[c] GED: General Educational Development Test.

[d] Distance from residence to hospital was calculated by taking the differences of coordinates (longitudes or latitudes) between the patient's address and the University of Chicago Medicine Comprehensive Cancer Center's address based on the Haversine formula.

[e] AJCC: American Joint Committee on Cancer.

[f] HR: hormone receptor.

[g] HER2: human epidermal growth factor receptor 2.

[h] TNBC: triple-negative breast cancer.

Telemedicine Use and Association With ADI

Overall, 35.95% (416/1157) of the patients with breast cancer had a telehealth visit in the past 12 months (Table 2). By modality of telemedicine, 65% (266/409) of the clinic visits were conducted through videoconferencing only, followed by 22.7% (93/409) through telephone only and 12.2% (50/409) through both videoconferencing and telephone. The mean ADI score for telemedicine users was 37.7 (SD 24.2) compared to 39.5 (SD 24.0) for nonusers (Table 2). By ADI quartile, 38.3% (145/379) of the patients living in the least socioeconomically disadvantaged neighborhoods (first quartile) used telemedicine, followed by 37.9% (58/153), 35.1% (132/356), and 32.5% (81/249) in the fourth, second, and third quartiles, respectively. On multivariable regression analysis (model 3), higher ADI scores (per 10-unit increase) were associated with lower odds of telemedicine use (AOR 0.89, 95% CI 0.82-0.97; Table 3).

Table 2. Characteristics of patients with breast cancer by telehealth visit (n=1157).

Variable	Had a telehealth visit in the past 12 months		*P* value[a]
	No (n=741)	Yes (n=416)	
Modality of telemedicine (n=409), n (%)			—[b]
Telephone or audio call	—	93 (22.7)	
Videoconference	—	266 (65)	
Both	—	50 (12.3)	
Area Deprivation Index[c], mean (SD)	39.5 (24.0)	37.7 (24.2)	.18
Area Deprivation Index, n (%)			.13
First quartile	234 (61.7)	145 (38.3)	
Second quartile	224 (64.9)	132 (35.1)	
Third quartile	168 (67.5)	81 (32.5)	
Fourth quartile	95 (62.1)	58 (37.9)	
Age (y) at survey, mean (SD)	62.2 (11.9)	60.9 (12.2)	.09
Age (y) at survey, n (%)			.04
<45	56 (52.3)	51 (47.7)	
45-54	121 (67.6)	58 (32.4)	
55-64	201 (66.3)	102 (33.7)	
≥65	299 (65.1)	160 (34.9)	
Race and ethnicity, n (%)			.08
Asian	37 (71.2)	15 (28.9)	
Black	136 (60.2)	90 (39.8)	
Hispanic	17 (48.6)	18 (51.4)	
White	550 (65.3)	292 (34.7)	
Highest level of education, n (%)			.002
High school, GED[d], or less	92 (80)	23 (20)	
Associate’s degree or some college	163 (63.4)	94 (36.6)	
Bachelor’s degree	208 (61.9)	128 (38.1)	
Graduate or professional degree	277 (61.8)	171 (38.2)	
Marital status, n (%)			.70
Married	481 (64.7)	263 (35.4)	
Single or not married	116 (61.4)	73 (38.6)	
Divorced, separated, or widowed	83 (64.3)	46 (35.7)	
Type of health insurance, n (%)			.25
Private	515 (63)	302 (37)	
Medicaid	28 (56)	22 (44)	
Medicare	147 (67.7)	70 (32.3)	
Other or unknown	51 (69.9)	22 (30.1)	
Distance (miles) from residence to hospital[e], median (IQR)	19.9 (9.8-32.3)	20.4 (9.3-32.3)	.96
Duration (y) from cancer diagnosis to survey, median (IQR)	6.8 (3.7-0.9)	6.3 (3.5-11.0)	.22
Duration (years) from cancer diagnosis to survey, n (%)			.009
≤3	109 (55)	89 (45)	

Variable	Had a telehealth visit in the past 12 months		P value[a]
	No (n=741)	Yes (n=416)	
4-6	217 (68)	102 (32)	
≥7	415 (64.8)	225 (35.2)	
Charlson comorbidity index, n (%)			.31
0	635 (64.3)	353 (35.7)	
1	34 (54.8)	28 (45.2)	
≥2	44 (65.7)	23 (34.3)	
Histologic type, n (%)			.27
Ductal	459 (62.1)	280 (37.9)	
Lobular	63 (68.5)	29 (31.5)	
Ductal and lobular	38 (69.1)	17 (30.9)	
Other	19 (52.8))	17 (47.2)	
AJCC[f] stage group, n (%)			.26
0	135 (68.5)	62 (31.5)	
I	333 (64.9)	180 (35.1)	
II	161 (59.6)	109 (40.4)	
III	75 (61.5)	47 (38.5)	
IV	5 (50)	5 (50)	
Molecular subtype, n (%)			.91
HR[g]+/HER2[h]−	358 (62.8)	212 (37.2)	
HR+/HER+	64 (65.3)	34 (34.7)	
HR−/HER2+	34 (66.7)	17 (33.3)	
TNBC[i]	87 (62.1)	53 (37.9)	
Tumor grade, n (%)			.10
1	87 (59.6)	59 (40.4)	
2	316 (67.4)	153 (32.6)	
3	258 (61.6)	161 (38.4)	
Receipt of chemotherapy, n (%)			.19
No	377 (66.4)	191 (33.6)	
Yes	300 (62.5)	180 (37.5)	
Receipt of hormone therapy, n (%)			.92
No	217 (64.4)	120 (35.6)	
Yes	460 (64.7)	251 (35.3)	
Receipt of radiation therapy, n (%)			.68
No	255 (65.4)	135 (34.6)	
Yes	422 (64.1)	236 (35.9)	
Type of surgery received, n (%)			.35
None	6 (46.2)	7 (53.8)	
Lumpectomy	404 (66)	208 (34)	
Mastectomy	190 (62.5)	114 (37.5)	

Variable	Had a telehealth visit in the past 12 months		P value[a]
	No (n=741)	Yes (n=416)	
Bilateral mastectomy	68 (66.7)	34 (33.3)	

[a] *P* values were calculated using 2-tailed *t* tests or Wilcoxon rank sum, Pearson chi-square, or Fisher exact tests, as appropriate.

[b] Not applicable.

[c] The Area Deprivation Index (national ranking percentile) is a composite measure consisting of the domains of income, education, employment, and housing quality. It ranks neighborhoods by socioeconomic disadvantage at the national level and is scored from 1 to 100, with higher scores representing greater neighborhood socioeconomic deprivation.

[d] GED: General Educational Development Test.

[e] Distance from residence to hospital was calculated by taking the differences of coordinates (longitudes or latitudes) between the patient's address and the University of Chicago Medicine Comprehensive Cancer Center's address based on the Haversine formula.

[f] AJCC: American Joint Committee on Cancer.

[g] HR: hormone receptor.

[h] HER2: human epidermal growth factor receptor 2.

[i] TNBC: triple-negative breast cancer.

In the same model (model 3), patients with breast cancer aged 45 to 54 years had lower odds of having a telehealth visit than those aged <45 years (AOR 0.49, 95% CI 0.27-0.91). Patients aged 55 to 64 years (AOR 0.63, 95% CI 0.36-1.12) or ≥65 years (AOR 0.63, 95% CI 0.34-1.18) also had a lower likelihood, but these differences were not statistically significant. Black (AOR 2.38, 95% CI 1.41-4.00) or Hispanic (AOR 2.65, 95% CI 1.07-6.58) patients had greater odds of telemedicine use than White patients. Compared to patients with high school or less education, those with an associate's (AOR 2.67, 95% CI 1.33-5.35), bachelor's (AOR 2.75, 95% CI 1.38-5.48), or graduate (AOR 2.57, 95% CI 1.31-5.04) degree had higher odds of telemedicine use in the past 12 months. Longer distance from residence to hospital (per 10-mile increase) was associated with greater odds of use of telemedicine, although this was not statistically significant (AOR 1.02, 95% CI 0.96-1.09; Table 3). Clinicopathologic and treatment factors were not significantly associated with telemedicine use (Table S1 in Multimedia Appendix 2). In subgroup analyses, ADI scores were not significantly different between videoconference and telephone visits (AOR 0.88, 95% CI 0.73-1.07). We also observed that patients with a graduate or professional degree had greater odds of using videoconference visits (AOR 5.78, 95% CI 1.03-32.55), and patients on Medicare had lower odds of videoconference visit use than privately insured patients (AOR 0.26, 95% CI 0.07-0.91; Table S2 in Multimedia Appendix 2).

Table 3. Association between neighborhood socioeconomic disadvantage and telemedicine use in patients with breast cancer.

Variable	Model 1, adjusted odds ratio[a] (95% CI)	*P* value	Model 2, adjusted odds ratio[b] (95% CI)	*P* value	Model 3, adjusted odds ratio[c] (95% CI)	*P* value
Area Deprivation Index[d] (continuous)[e]	0.93 (0.87-0.99)	.03	0.89 (0.82-0.96)	.005	0.89 (0.82-0.97)	.004
Distance from residence to hospital[e]	1.04 (0.99-1.10)	.13	1.03 (0.97-1.09)	.40	1.02 (0.96-1.09)	.48
Age (y) at survey						
<45	1.0 (reference)		1.0 (reference)		1.0 (reference)	
45-54	0.55 (0.33-0.94)	.03	0.53 (0.29-0.97)	.04	0.49 (0.27-0.91)	.02
55-64	0.57 (0.35-0.93)	.02	0.64 (0.37-1.11)	.11	0.63 (0.36-1.12)	.11
≥65	0.65 (0.39-1.09)	.10	0.62 (0.34-1.13)	.12	0.63 (0.34-1.18)	.16
Race and ethnicity						
Asian	0.55 (0.26-1.17)	.12	0.50 (0.20-1.22)	.13	0.50 (0.20-1.23)	.16
Black	1.86 (1.21-2.86)	.005	2.50 (1.48-4.20)	.001	2.38 (1.41-4.00)	.001
Hispanic	2.12 (1.02-4.41)	.04	2.85 (1.17-6.91)	.02	2.65 (1.07-6.58)	.03
White	1.0 (reference)		1.0 (reference)		1.0 (reference)	
Highest level of education						
High school, GED[f], or less	1.0 (reference)		1.0 (reference)		1.0 (reference)	
Associate’s degree or some college	2.66 (1.47-4.81)	.001	2.76 (1.40-5.44)	.003	2.67 (1.33-5.35)	.006
Bachelor’s degree	2.43 (1.35-4.38)	.003	2.61 (1.33-5.10)	.005	2.75 (1.38-5.48)	.004
Graduate or professional degree	2.46 (1.39-4.38)	.002	2.55 (1.32-4.93)	.005	2.57 (1.31-5.04)	.006
Duration (y) from cancer diagnosis to survey						
≤3	1.0 (reference)		1.0 (reference)		1.0 (reference)	
4-6	0.63 (0.41-0.96)	.03	0.67 (0.42-1.08)	.12	0.75 (0.46-1.21)	.24
≥7	0.67 (0.45-1.01)	.05	0.60 (0.38-0.96)	.04	0.65 (0.40-1.05)	.09

[a] Additionally adjusted for marital status, health insurance, and Charlson comorbidity index.

[b] Additionally adjusted for marital status, health insurance, Charlson comorbidity index, histologic type, stage, molecular subtype, and tumor grade.

[c] Additionally adjusted for marital status; type of health insurance; Charlson comorbidity index; histologic type; stage; molecular subtype; tumor grade; receipt of chemotherapy, hormone therapy, or radiotherapy; and type of surgery.

[d] The Area Deprivation Index (national ranking percentile) is a composite measure consisting of the domains of income, education, employment, and housing quality. It ranks neighborhoods by socioeconomic disadvantage at the national level and is scored from 1 to 100, with higher scores representing greater neighborhood socioeconomic deprivation.

[e] Odds ratios were per 10-unit increase.

[f] GED: General Educational Development Test.

Comparisons of Provisions of Oncology Services Between Telehealth and In-Person Visits

Figure 1 displays the breakdown of oncology services by visit type for the patients with breast cancer. Overall, 31.3% (130/416) of the patients used telemedicine for the purpose of treatment consultation; 22.4% (93/416) for reviewing laboratory, screening, and pathology test results; 13.5% (56/416) for managing cancer symptoms and treatment side effects; 4.3% (18/416) for cancer genetic counseling; and 3.4% (14/416) for cancer clinical trial follow-ups. Among patients who had in-person visits, reviewing laboratory, screening, and pathology test results was reported the most (322/1072, 30.04%), followed by treatment consultation (265/1072, 24.72%), management of cancer symptoms and treatment side effects (169/1072, 15.76%), genetic counseling (54/1072, 5.04%), and cancer clinical trial follow-ups (54/1072, 5.04%). After analyzing match-paired data (Table 4), we observed significant differences between telemedicine and in-person visits in the provision of management of cancer symptoms and treatment side effects; review of laboratory, screening, and pathology test results; and cancer clinical trial follow-ups. However, there were no significant differences in offering treatment consultation (45/405, 11.1% vs 55/405, 13.6%; *P*=.32) or cancer genetic counseling (11/405, 2.7% vs 19/405, 4.7%; *P*=.14) between telehealth and in-person visits (Table 4).

Among the patients with breast cancer who reported management of cancer symptoms and treatment side effects (Figure 2), those with in-person visits had greater proportions of instances of discussions of fatigue (85/169, 50.3% vs 23/56, 41%), hot flashes (77/169, 45.6% vs 19/56, 34%), lymphedema (44/169, 26% vs 11/56, 20%), chemotherapy-induced neuropathy (42/169, 24.9% vs 11/56, 20%), or nausea and vomiting (27/169, 16% vs 5/56, 9%) than patients with telehealth visits, whereas a higher proportion of patients had discussed depressive symptoms through telemedicine than in-person visits (21/56, 38% vs 50/169, 29.6%). By modality of telemedicine, a higher percentage of patients used both telephone and video visits for treatment consultation than video visit or telephone visit alone (Table S3 in Multimedia Appendix 2). In addition, there were no significant differences in the distributions of various methods of managing cancer symptoms and treatment side effects across the 3 telemedicine modalities (Table S4 in Multimedia Appendix 2).

Figure 1. Percentages of oncology services by type of visit among patients with breast cancer.

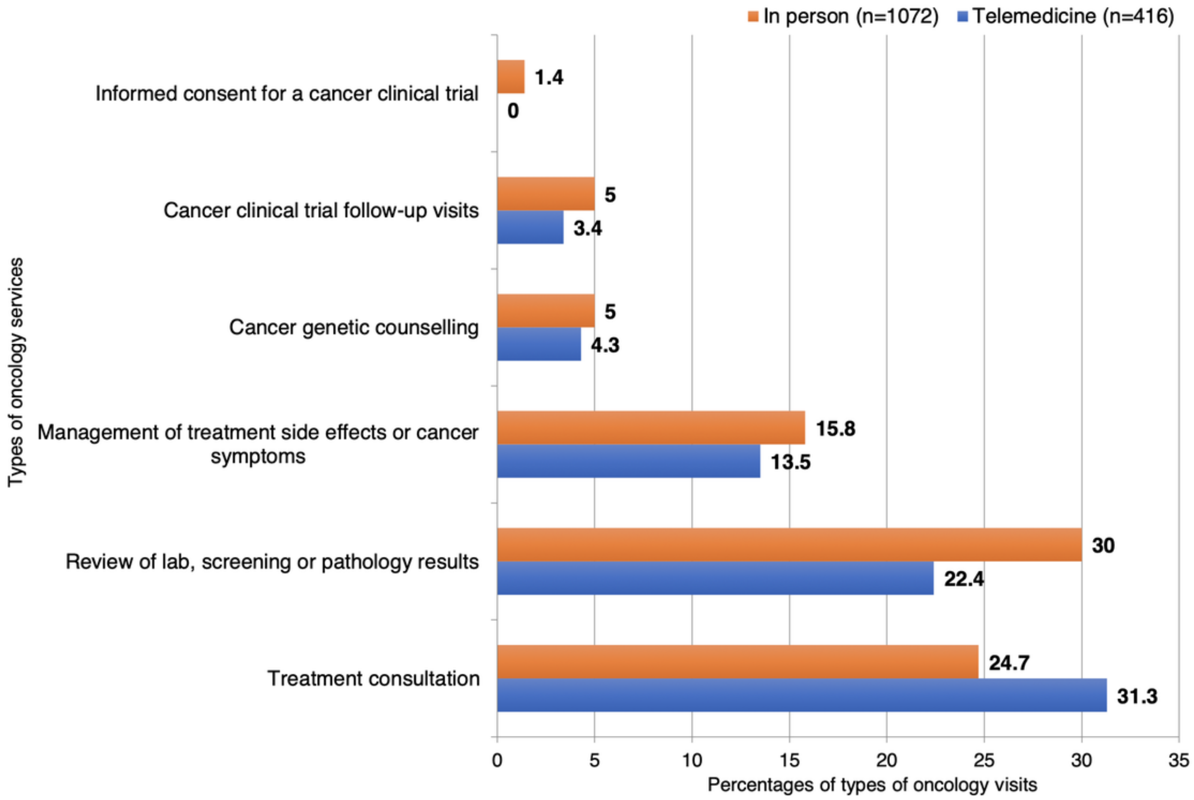
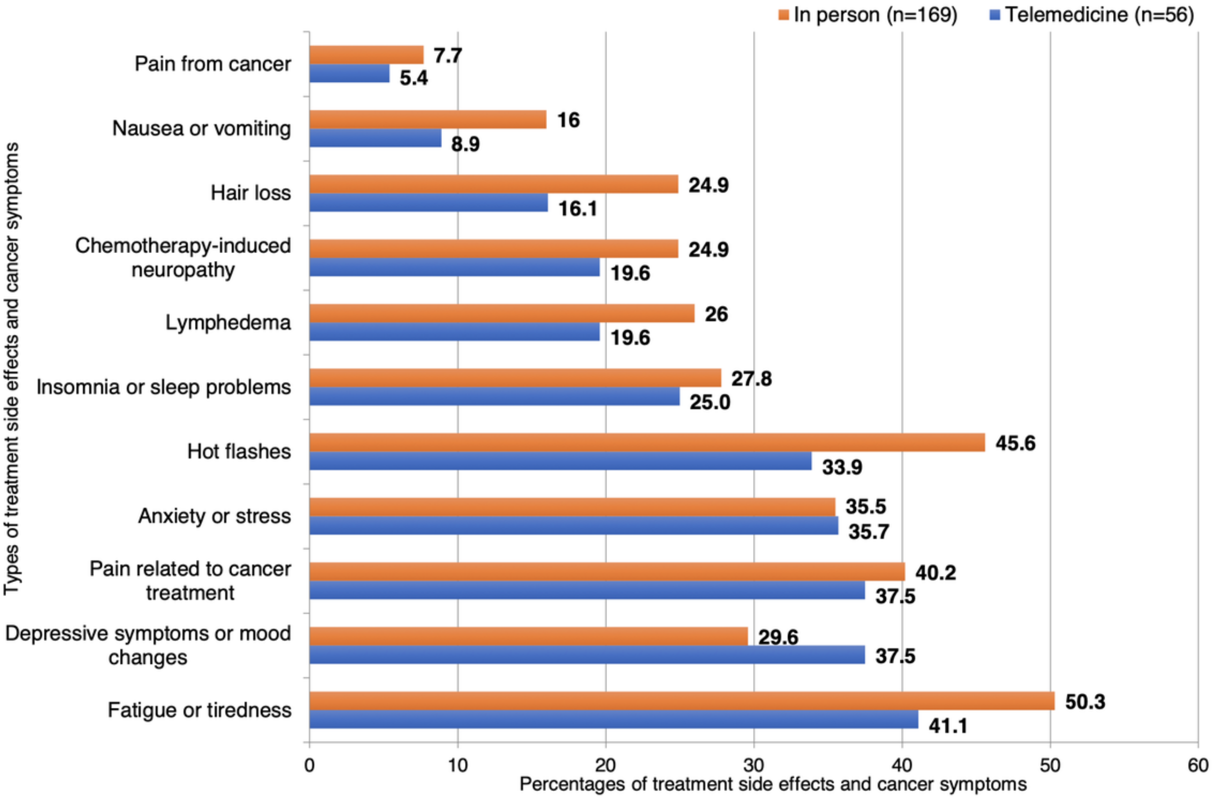


Table 4. Analysis of match-paired data on oncology services by type of visit among patients with breast cancer (n=405).

Type of visit and variable	Telemedicine visits, n (%)		*P* value[a]
	No	Yes	
In-person visits, n (%)			
Treatment consultation			.32
No	222 (54.8)	45 (11.1)	
Yes	55 (13.6)	83 (20.5)	
Management of treatment side effects or cancer symptoms			<.001
No	295 (72.8)	15 (3.7)	
Yes	54 (13.3)	41 (10.1)	
Review of laboratory, screening, and pathology test results			<.001
No	224 (55.3)	26 (6.4)	
Yes	90 (22.2)	65 (16)	
Cancer genetic counseling			.14
No	368 (90.9)	11 (2.7)	
Yes	19 (4.7)	7 (1.7)	
Cancer clinical trial follow-up visits			.046
No	379 (93.6)	4 (1)	
Yes	12 (3)	10 (2.5)	

[a] *P* values were calculated using the McNemar test.

Figure 2. Percentages of cancer symptoms and treatment side effects discussed during telemedicine or in-person visits reported by patients with breast cancer.



Telemedicine Use Challenges or Concerns and Satisfaction

Compared with the patients with breast cancer who did not use telemedicine, those who did reported a higher percentage of technology difficulty or lack of comfort with technology (51/416, 12.3% vs 21/741, 2.8%; *P*<.001), compromised patient-provider communication (28/416, 6.7% vs 16/741, 2.2%; *P*<.001), and compromised patient-provider relationship (35/416, 8.4% vs 12/741, 1.6%; *P*<.001; Table 5). Furthermore, of the telemedicine users, 93.7% (132/141) and 95.5% (301/315) reported being somewhat to extremely satisfied with their telephone visit and videoconference visit experiences, respectively, and 61.8% (254/411) were likely or very likely to continue using telemedicine (Table S5 in Multimedia Appendix 2). In addition, no significant differential distributions of satisfaction with telehealth visits across all oncology services were observed, stratified by modality of telemedicine (Tables 6 and 7) or overall (Table S6 in Multimedia Appendix 2).

Table 5. Percentages of challenges or concerns regarding telemedicine use reported by patients with breast cancer (n=1157).

Variables	Overall (n=1157), n (%)	Had a telehealth visit in the past 12 months		*P* value[a]
		No (n=741), n (%)	Yes (n=416), n (%)	
Technology difficulty or lack of comfort with technology				<.001
No	1085 (93.8)	720 (97.2)	365 (87.7)	
Yes	72 (6.2)	21 (2.8)	51 (12.3)	
Lack of an electronic device (eg, desktop computer, laptop computer, smartphone, or iPad)				.20
No	1151 (99.5)	739 (99.7)	412 (99)	
Yes	6 (0.5)	2 (0.3)	4 (1)	
Lack of high-speed internet or slow internet connection at home				.06
No	1133 (97.9)	730 (98.5)	403 (96.9)	
Yes	24 (2.1)	11 (1.5)	13 (3.1)	
Compromised patient-provider communication				<.001
No	1113 (96.2)	725 (97.8)	388 (93.3)	
Yes	44 (3.8)	16 (2.2)	28 (6.7)	
Compromised patient-provider relationship				<.001
No	1110 (95.9)	729 (98.4)	381 (91.6)	
Yes	47 (4.1)	12 (1.6)	35 (8.4)	
Not being offered at the clinic or by a provider				.80
No	1140 (98.5)	729 (98.4)	411 (98.8)	
Yes	17 (1.5)	12 (1.6)	5 (1.2)	
Cost				.30
No	1148 (99.2)	737 (99.5)	411 (98.8)	
Yes	9 (0.8)	4 (0.5)	5 (1.2)	
Not being covered by health insurance				.22
No	1146 (99)	736 (99.3)	410 (98.6)	
Yes	11 (1)	5 (0.7)	6 (1.4)	

[a] *P* values were calculated using Pearson chi-square or Fisher exact tests.

Table 6. Percentages of satisfaction with telephone visit by oncology service among patients with breast cancer (n=141).

Were your telemedicine visits related to the following oncology services?	How satisfied were you with your telephone visit with physicians or other health care providers?					*P* value[a]
	Not at all (n=2), n (%)	A little (n=7), n (%)	Somewhat (n=28), n (%)	Very (n=62), n (%)	Extremely (n=42), n (%)	
Treatment consultation						.70
No	1 (1)	5 (5)	20 (19.8)	44 (43.6)	31 (30.7)	
Yes	1 (2)	2 (5)	8 (20)	18 (45)	11 (27.5)	
Review of laboratory, screening, and pathology test results						.92
No	1 (1.0)	3 (3.0)	25 (24.8)	41 (40.6)	31 (30.7)	
Yes	1 (2.5)	4 (10.0)	3 (7.5)	21 (52.5)	11 (27.5)	
Management of treatment side effects or cancer symptoms						.22
No	1 (0.8)	7 (5.7)	24 (19.5)	51 (41.5)	40 (32.5)	
Yes	1 (5.6)	0 (0)	4 (22.2)	11 (61.1)	2 (11.1)	
Cancer genetic counseling						.58
No	2 (1.5)	7 (5.3)	26 (19.6)	57 (42.9)	41 (30.8)	
Yes	0 (0)	0 (0)	2 (25)	5 (62.5)	1 (12.5)	
Cancer clinical trial follow-up visits						.95
No	2 (1.4)	7 (5.0)	28 (20.0)	61 (43.6)	42 (300)	
Yes	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)	

[a] *P* values were calculated using Wilcoxon rank sum tests.

Table 7. Percentages of satisfaction with videoconference visit by oncology service among patients with breast cancer (n=315).

Were your telemedicine visits related to the following oncology services?	How satisfied were you with your videoconference visit with physicians or other health care providers?					*P* value[a]
	Not at all (n=8), n (%)	A little (n=6), n (%)	Somewhat (n=56), n (%)	Very (n=157), n (%)	Extremely (n=88), n (%)	
Treatment consultation						.78
No	4 (2)	5 (2.5)	36 (17.7)	104 (51)	55 (27)	
Yes	4 (3.6)	1 (0.9)	20 (18)	53 (47.8)	33 (29.7)	
Review of laboratory, screening, and pathology test results						.77
No	6 (2.4)	4 (1.6)	47 (19.1)	117 (47.6)	72 (29.3)	
Yes	2 (2.9)	2 (2.9)	9 (13)	40 (58)	16 (23.2)	
Management of treatment side effects or cancer symptoms						.20
No	8 (3)	6 (2.2)	50 (18.5)	132 (48.9)	74 (27.4)	
Yes	0 (0)	0 (0)	6 (13.3)	25 (55.6)	14 (31.1)	
Cancer genetic counseling						.98
No	7 (2.3)	6 (2)	54 (17.9)	150 (49.8)	84 (27.9)	
Yes	1 (7.1)	0 (0)	2 (14.3)	7 (50)	4 (28.6)	
Cancer clinical trial follow-up visits						.48
No	8 (2.7)	6 (2)	54 (17.9)	146 (48.5)	87 (28.9)	
Yes	0 (0)	0 (0)	2 (14.3)	11 (78.6)	1 (7.1)	

[a] *P* values were calculated using Wilcoxon rank sum tests.

Discussion

Principal Findings

This study built on previous work investigating the relationship between neighborhood socioeconomic disadvantage and telemedicine use among patients with breast cancer and comparing provisions of oncology services between telehealth and in-person office visits. Telemedicine use has expanded dramatically since the COVID-19 pandemic began. However, not all patients with breast cancer benefited from the expansion; as our study uncovered, patients with higher ADI scores (ie, lower neighborhood-level SES) were less likely to have used telemedicine in the past 12 months. Although patients cited technology difficulty or lack of comfort with technology as well as compromised patient-provider communication and compromised patient-provider relationship as common challenges or concerns, they expressed high degrees of satisfaction with telehealth experiences and willingness to continue using telehealth care and services in the future. In addition, both telemedicine and in-person visits were equally likely to deliver treatment consultation and cancer genetic counseling, while services that were more likely to be offered in person were management of cancer symptoms and treatment side effects; review of laboratory, screening, and pathology test results; and cancer clinical trial follow-ups.

One key study finding is that patients with breast cancer living in greater socioeconomically disadvantaged neighborhoods were less likely to use telemedicine for care and services, consistent with previous studies of patients in primary care, adult outpatient, and hematology or oncology settings [8,24-28]. A descriptive study suggested no correlation between ADI scores and interest in telehealth visits among 64 patients with head and neck cancers (interested: median ADI score=4.0 vs not interested: median ADI score=5.0; P=.79) [27], but the small sample size limited the reliability of these findings. Lee et al [28] analyzed a cohort of 341,089 patients with hematologic malignancies and patients with cancer, demonstrating a significant difference in the distribution of telemedicine use between patients living in the most socioeconomically disadvantaged neighborhoods and those living in the least socioeconomically disadvantaged neighborhoods (46.1% vs 54%) [28]. However, the proportion of patients with breast cancer as well as adjusted estimates are unknown due to the descriptive nature of this analysis. In another study, Hassan et al [8] observed a 3% decrease in the number of telemedicine visits per 10-unit increase in the ADI score among patients with cancer who were financially distressed, whereas an 11% decrease in telemedicine use was observed in our cohort of patients with breast cancer. Our estimated effect is larger possibly due to our large sample size and the heterogeneous group of patients with breast cancer. Our findings indicate that neighborhood-level SES may have a bigger impact on the use of telemedicine among patients with breast cancer. Neighborhood socioeconomic disadvantage is associated with lower access to telehealth care and services. Strategies to enhance the accessibility of telehealth are needed to reduce neighborhood-level socioeconomic disparities in telemedicine use among patients with breast cancer, particularly among patients living in socioeconomically deprived neighborhoods and regions.

Consistent with prior research in patients with breast, gynecologic, or other cancers [3,4,11], we found that >1 in 3 patients with breast cancer had had a telehealth visit in the past 12 months. With respect to race and ethnicity, Black or Hispanic patients were more than twice as likely as their White counterparts to have used telemedicine. In previous studies, Campos-Castillo and Anthony [44] observed that Black or Latinx American adults were more likely to have telehealth visits, and Reed et al [45] documented a higher likelihood of patients using both telephone and video visits for primary care. However, a study at an outpatient oncology care center revealed that Asian or Hispanic patients were less likely than White patients to have used telemedicine, while no significant difference existed between Black and White patients [11]. These inconsistent results are possibly due to sampling variability and the heterogeneous characteristics of patient populations in oncology and other clinical settings. Nevertheless, our finding indicates that patients belonging to racial and ethnic minority groups with breast cancer may have unique and greater needs for telehealth. Similarly, compared to patients with high school or less education, those with an associate’s, bachelor’s, or graduate degree had >2-fold greater odds of telemedicine use. Older age groups were associated with a lower likelihood of telemedicine use. These findings are well documented in the literature and highlight the influence of individual-level SES on the use of telemedicine. Telemedicine may have the potential to improve telehealth care and service use among patients belonging to racial and ethnic minority groups with breast cancer. Oncology programs should also ensure that patients who are older and those with lower levels of education have equal access to telehealth care and services.

Another notable finding is that patient-reported treatment consultations and cancer genetic counseling services occur with an equal frequency when comparing telemedicine and in-person office visits. Our study supports existing literature on the feasibility and acceptability of teleoncology consultations and telehealth-based cancer genetic counseling among providers and their patients with cancer [7,31-42]. However, only a few prior studies compared these oncology services between telemedicine and in-person visits, and most samples were small. A univariate analysis of 509 patients with cancer from the University of Texas MD Anderson Cancer Center reported a similar distribution of patients seeking integrative oncology consultation between telehealth and in-person settings [37]. McDonald et al [46] illustrated no significant differences in providing cancer genetic services (in-person vs telegenetics) by residential area or perceived cancer risk. We also observed that patients were particularly more likely to join treatment consultations through videoconference than telephone. However, we found significant variations between telehealth and in-person office visits in provisions of management of cancer symptoms and treatment side effects; review of laboratory, screening, and pathology test results; and cancer clinical trial follow-ups. In the subgroup of patients with breast cancer who reported management of cancer symptoms and treatment side effects, more than one-third of the patients discussed depressive symptoms or mood change (23/56, 41%) or anxiety or stress (20/56, 36%) during telehealth visits with their providers. This finding indicates that telemedicine may be in greater need among these patients. Taken together, our data demonstrate the variations in provisions of oncology services between telemedicine and in-person visits among patients with breast cancer. Cancer programs and providers may consider tailoring the delivery of care and services according to patients' care needs and preferences. Future research will be necessary to explore reasons or factors that explain these variations and whether there are unmet telehealth needs in patients with breast cancer experiencing certain mental health symptoms.

With regard to challenges or concerns related to telemedicine use, we found that significantly higher proportions of the patients with breast cancer who had telehealth visits cited technology difficulty or lack of comfort with technology, compromised patient-provider communication, or compromised patient-provider relationship. Possibly, the telemedicine nonusers in our study did not have firsthand experience of technology difficulty. Our finding is aligned with previous research [27] but not with 2 cross-sectional studies [9,38] that reported similar patient-provider communication experiences when comparing telehealth and in-person visits. Analyses are further needed to determine the correlations between telemedicine use and these challenges or concerns among patients with breast cancer. Despite these challenges or concerns, patients reported a remarkably high level of satisfaction with their telemedicine use experiences (390/407, 95.8%), and 61.8% (254/411) expressed the willingness to continue telemedicine use, congruent with prior studies in patients with cancer [6,7,10,33,34]. However, prior research evaluated only overall satisfaction, whereas we found a similar level of satisfaction by type of oncology service or across various cancer symptoms and treatment side effects discussed during telehealth visits, irrespective of the modality of telemedicine. These findings offer a practical implication for telehealth implementation and care and service delivery, but future research in telemedicine program evaluation is necessary.

Limitations

Several limitations of this study should be considered. First, the survey data were per self-report, which is prone to recall error or social desirability. However, this bias is likely very minimal because our research staff had limited to no interaction with the participants that would influence the survey responses. Second, the study sample included only patients with breast cancer who were willing to respond to our survey. The proportions of self-reported visits for oncology services and perceived challenges or concerns related to telemedicine use have probably been underestimated. Our estimated effect of neighborhood socioeconomic disadvantage on telehealth use in patients with breast cancer may also be underestimated. Third, this study evaluated broader access to telehealth care and services, including oncology; therefore, the results may not be specific to breast oncology. However, it is important to point out that, regardless of treatment status and duration since diagnosis, patients have other care and service needs across the cancer care continuum and different clinical settings. Fourth, distance from residence to hospital was not associated with telemedicine use. It was calculated based on the Haversine formula, which did not account for travel time, traffic patterns, lack of transportation, road conditions, weather, and other environmental factors. In addition, we were not able to assess other unmeasured potential confounding factors, such as the availability and density of telehealth clinics or cancer programs in the geographic area and local technology or digital infrastructure, that could affect the associations or variability we observed in this analysis. Thus, this warrants future research. Finally, participants in the ChiMEC study may not be representative of all patients with breast cancer nationally, which limits the generalizability of our findings.

Conclusions

In conclusion, our findings from ChiMEC patients with breast cancer offer insights into the impact of neighborhood socioeconomic disadvantage on telemedicine use and comparing provisions of oncology services between telehealth and in-person office visits, underscoring the importance of identifying neighborhood-level socioeconomic disparities and patients' unmet needs for telemedicine. Oncology programs should address these disparities and needs to improve care delivery and achieve telehealth equity for their patient populations. Meanwhile, as cancer centers and research organizations further embrace telemedicine and other digital platforms, it is essential to tackle patients' perceived challenges or concerns and consider allocating these platforms to particular care and services, such as genetic counseling, treatment consultation, and management of depressive symptoms and anxiety, to provide high-quality telehealth care and services to patients with breast cancer.

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Data Availability

The data sets generated and analyzed during this study are not publicly available due to patient confidentiality and privacy concerns but are available from the corresponding author on reasonable request.

Authors' Contributions

JQF was responsible for conceptualization, methodology, design, survey development, data analysis, formatting tables and figures, and writing the initial manuscript. FZ was responsible for methodology, design, survey development, research implementation, and data collection. FMH was responsible for conceptualization, methodology, and design. RN was responsible for methodology, design, survey development, and research implementation. OIO was responsible for methodology, design, and research implementation. DH was responsible for conceptualization, methodology, design, survey development, research implementation, and overall supervision. All authors contributed to the interpretations of the findings; writing, reviewing, and editing the manuscript; and the approval of the final manuscript and submission.

Conflicts of Interest

RN has advisory board involvement with, and research funding from, Arvinas, AstraZeneca, BeyondSpring Pharmaceuticals, Celgene, FujiFilm, Genentech, Gilead, Infinity, iTeos, Merck, OBI Pharma, OncoSec, Pfizer, Relay Therapeutics, Seagen, Sun Pharma, and Taiho Pharma. OIO has financial relationships with CancerIQ, 54gene, HealthWell Solutions, and Tempus, as well as research funding from Ayala Pharmaceuticals, Cepheid, Color Genomics, Novartis, and Genentech. All other authors declare no other conflicts of interest.

Multimedia Appendix 1
Survey questions regarding telehealth and in-person office visits.
[DOCX File , 25 KB - cancer_v10i1e55438_app1.docx]

Multimedia Appendix 2
Associations between neighborhood socioeconomics disadvantage and telemedicine use (video conference versus telephone); comparing provisions of oncology services by modality of telemedicine; and patient satisfaction with telemedicine.
[DOCX File , 50 KB - cancer_v10i1e55438_app2.docx]

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Abbreviations

ADI: Area Deprivation Index
AOR: adjusted odds ratio
ChiMEC: Chicago Multiethnic Epidemiologic Breast Cancer Cohort
SES: socioeconomic status

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Original Paper

Experiences of a Digital Behavior Change Intervention to Prevent Weight Gain and Promote Risk-Reducing Health Behaviors for Women Aged 18 to 35 Years at Increased Risk of Breast Cancer: Qualitative Interview Study

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Abstract

Background: Breast cancer is the most common form of cancer in women. Adult weight gain and modifiable health behaviors, including smoking, alcohol intake, and lack of physical activity, are well-known risk factors. Most weight gain in women occurs between the ages of 18 and 35 years. Digital interventions have the potential to address logistical challenges that arise in reaching women in this age range. We designed a digital intervention targeting weight gain prevention and other modifiable health behaviors for young women at increased risk of breast cancer. Women aged 18 to 35 years were recruited to this single-arm intervention study over 2 months to test the acceptability and usability of the intervention, which comprised a group welcome event held via videoconferencing, app, and private Facebook group.

Objective: This nested qualitative substudy explored women’s views and experiences of being part of the digital health intervention to inform future intervention development for a feasibility study.

Methods: A total of 20 women aged 23 to 35 years who were at increased risk of breast cancer were interviewed via telephone within 1 month after completing the intervention, between February 2023 and March 2023. The women were asked about their experiences of the digital intervention and the extent to which it may have influenced their health behaviors. Data were analyzed thematically and organized using the framework approach.

Results: The interviews lasted for a median of 37 (IQR 30-46) minutes. Overall, the women perceived the digital health intervention comprising education, tracking, and support to be acceptable for weight gain prevention. In total, 4 themes were generated. *A “missed opportunity” in breast cancer prevention services* encompasses the lack of services that currently exist for young women at increased risk of breast cancer. *The pros and cons of being part of a community* encompasses the divergent views that the women had regarding engaging with other women at increased risk. *The importance of an interactive app* focuses on features that the women would want from the app to promote engagement with the intervention. *The different wants and needs of different age groups* highlights that an intervention such as this one would need to be customizable to suit the needs of women at different life stages.

Conclusions: There is an unmet need in prevention services for young women aged 18 to 35 years at increased risk of breast cancer. The women perceived the app to be an acceptable intervention for weight gain prevention but emphasized that the intervention would need to be customizable to meet the needs of different age groups within the group of women aged 18 to 35 years. The digital intervention could be a scalable behavior change strategy for UK family history clinics.

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KEYWORDS

breast cancer; health behavior; weight gain; weight control; BMI; app; acceptability; feasibility

Introduction

Background

Breast cancer is the most common form of cancer in women, with >55,000 diagnoses in the United Kingdom each year, and figures are predicted to increase [1]. In the United Kingdom, women aged 50 to 70 years are invited by the National Health Service breast screening program for 3-yearly mammograms. Guidance from the UK National Institute for Health and Care Excellence recommends that women who are known to be at increased risk of breast cancer (due to a strong family history of breast or ovarian cancer) should be offered annual breast cancer screening from the age of 40 years [2]. In the United Kingdom, women at increased risk of breast cancer have the option to attend family history clinics, which play a potentially important role in breast cancer prevention as women at increased risk experience proportionally more cancers. Access is currently via self-referral of concerned women or via general practitioner referral. Family history clinics undertake comprehensive assessments of breast cancer risk using established risk assessment tools (eg, the Tyrer-Cuzick model [3] or the CanRisk tool [4]). Those found to have an estimated lifetime risk are entered into these clinics for breast cancer surveillance and the offer of risk-reducing interventions (eg, surgery and risk-reducing medications such as tamoxifen [2]).

National Institute for Health and Care Excellence guidance recommends that family history clinics provide advice on healthy weight and health behaviors (ie, limited alcohol consumption, avoidance of smoking, and physical activity) to lower breast cancer risk [2]. These factors have an equal or greater effect on relative risk of breast cancer among women who have a family history of breast cancer compared to those without a family history [5-8]. Many women attending these clinics have obesity or overweight (60%) and health behaviors associated with risk (ie, 30% fail to meet physical activity recommendations, and 45% exceed alcohol consumption recommendations [9]). Hence, there is an unmet need to implement prevention through weight control and health behavior change (ie, reduced alcohol consumption, smoking cessation, and increased physical activity) in these clinics.

We previously highlighted that most weight gain in women occurs between the ages of 18 and 35 years [9], and once weight is gained, it is often difficult to lose [10]. Therefore, preventing weight gain in young women will potentially be more effective than dealing with weight problems once they have occurred. Records from the Manchester Family History Clinic since 1987 show that 23.5% of women are seen by the family history clinic and provided with their estimated breast cancer risk before the age of 35 years (Prof Gareth Evans, personal communication). Women are then asked to return to the clinic some years later when they can start breast cancer screening and can be offered preventive medicines. These women do not receive any further behavior change support in the interim. Digital interventions (eg, apps, social media, and wearable devices) have the potential to aid behavior change through allowing individuals to engage with health-related content remotely, which may potentially address logistical challenges (eg, travel, work, and childcare) that arise when attending face-to-face interventions [11], which are barriers that young women in particular face [12]. A weight gain prevention program delivered via an app could also be scalable to UK family history clinics.

Objectives

A search of the literature identified no evidence-based apps that covered weight gain prevention and all relevant health behaviors for women at increased risk of breast cancer [13]. Thus, with patient and public involvement from the target population, this research team developed a digital intervention including an app (the “health behavior intervention”) focused on preventing weight gain and improving health behaviors among women aged 18 to 35 years at increased risk of breast cancer. The protocol for this intervention has been described previously [13]. This intervention was tested in a feasibility study to assess the study procedures for a planned future efficacy study and test the acceptability and usability of the intervention over a 2-month period. An analysis of the use of the intervention is provided elsewhere [14].

A key component of feasibility is acceptability to the target audience [15]. This qualitative interview study explored the views of a subset of women on their experiences during and after taking part in the health behaviors intervention. The feedback from participants will inform the feasibility of effectiveness and cost-effectiveness research of the app-based intervention.

Methods

The methods are reported in accordance with the Standards for Reporting Qualitative Research [16] (Multimedia Appendix 1) and the COREQ (Consolidated Criteria for Reporting Qualitative Research) guidelines [17] (Multimedia Appendix 2).

Design

This research is nested within a single-arm intervention study (trial registration NCT05460650) [13]. Semistructured qualitative interviews asked participants for their experiences using the health behaviors intervention for a 2-month duration.

Participants and Recruitment

Participants were female individuals who had taken part in the health behaviors intervention. Inclusion criteria for participation in the health behaviors intervention were female sex, age of 18 to 35 years, residence in the United Kingdom, a moderate or high risk of breast cancer [2], ability to communicate in English, and the ability to download and use an app. Participants were excluded if they had a previous diagnosis of breast cancer, a previous bilateral preventative mastectomy, or medical conditions that influence diet or weight. Further exclusion criteria for the trial are detailed elsewhere [13].

Women were recruited to take part in the health behaviors intervention via mailshot from the Manchester Family History Clinic and via social media posts to expand diversity within the recruited population and reach women outside of the Greater Manchester region. Prevent Breast Cancer (registered charity number 1109839) promoted the study via their social media feeds during the recruitment period. Following use of the health behaviors intervention for 2 months, a member of the research team (MP) contacted participants inviting them to take part in an interview about their experiences of taking part in the digital intervention. Women who had completed the study (n=35) [14] were purposively selected, aiming to recruit a range of ages, ethnicities, and levels of engagement with the app. Those participants who agreed to be interviewed gave their permission to be contacted by another member of the research team (REH) to arrange a suitable time for the interview. Of the 21 women who were approached for an interview, 1 (5%) later declined due to time constraints.

Intervention

The health behaviors intervention consisted of a videoconferencing welcome event hosted on Microsoft Teams, an app with an embedded microsite containing educational topics, and a private Facebook group (Meta Platforms). Participants used the intervention for 2 months. The aim of the health behaviors intervention was to prevent weight gain (by encouraging behaviors such as healthy eating and physical activity) and improve other health behaviors associated with breast cancer, including reduced alcohol intake and smoking cessation.

A number of behavior change techniques were included in the app that have been shown to have efficacy in primary weight gain prevention settings. These techniques included self-monitoring of behaviors and frequent monitoring of body weight [18,19], goal setting [18,20], automated feedback on behaviors and outcomes [18,21], social rewards (ie, positive reinforcement included as part of the automated feedback) [21], and social support provided via the Facebook group [18,22]. The app interface was designed to allow users to record progress and see this in relation to their set goals. These behavior change techniques have all been found to be effective in weight gain prevention interventions in young adults [18] and in digital health interventions for young adults [21,22]. The health behaviors intervention is described in more detail elsewhere [13]. The immediate research team also had access to participants' tracking data, and results of intervention use are described in a separate analysis [14]. Multimedia Appendix 3 includes screenshots of the app interface. The 3 intervention components are briefly summarized in the following paragraphs.

At the start of the study, participants were invited to attend one of several videoconferencing welcome events held on the Microsoft Teams digital meeting application, lasting up to an hour, with up to 10 other participants and a member of the research team (MP). The aim of these events was to (1) provide an overview of the study; (2) provide a simple outline of the evidence for the association among health behaviors, body weight, and breast cancer risk; (3) meet and build relationships with other participants involved in the study; and (4) build rapport with the research team.

The app included the functionalities for participants to log their weight, physical activity, diet, alcohol consumption, and smoking on a weekly, fortnightly, or monthly basis, and participants could set goals for themselves (Multimedia Appendix 3). The app also included an embedded microsite containing information on topics such as alcohol and its impact on breast cancer, the importance of fruit and vegetables in the diet, and how to limit weight gain during pregnancy. Participants could access the app beyond the 2-month study duration but were made aware that their use of the app after the end of the 2 months would not be monitored by the research team.

Alongside the app, participants were given the opportunity to join a private, hidden Facebook group to allow for access to social and peer support for behavior change and contact with the research team. Participants were encouraged to post within the group, and educational information on breast cancer and healthy behaviors was posted weekly by the research team to promote interaction. The research team acted as moderators and checked the group daily to respond to messages and comments.

Procedures

One-to-one semistructured interviews were conducted by a female researcher (REH; research associate) who had a background in health psychology and training in qualitative methods and was independent from the study delivery team. REH described the aim of the research to participants as wanting to understand their experiences of being a part of the study and their feedback on the health behaviors intervention. Interviews took place on one occasion over the telephone between February 2023 and March 2023 within 1 month after participants had completed the study. There was nobody else present for the interview besides researcher REH and the participant. Full consent had already been obtained before the interview, although

REH asked participants to confirm that they were happy for the interview to be audio recorded and transcribed before commencing the interview, and participants' permission was audio recorded. Each interview was recorded using an encrypted audio-recording device, transcribed verbatim by a university-approved transcription company, and pseudonymized for analysis. The interviews lasted between 30 and 60 minutes. Transcripts were not returned to participants for comment. Recruitment was stopped when the researchers (REH, MP, DPF, and MH) felt that no new content was discussed (in what became the final 2 interviews) according to the concept of "information power" (ie, information from the sample that is relevant for the study [23]).

Materials

A topic guide was used to organize the semistructured interviews, with open-ended questions and additional probes (Multimedia Appendix 4). Questions were asked in line with the overall study objectives [13]. These included participants' experiences of taking part in the digital intervention, the usability of the app, the extent to which the intervention was useful in helping participants change their health behaviors, and the extent to which the intervention may have influenced participants' health behaviors or feelings toward breast cancer. Although the topic guide was not pretested, the interviewer (REH) maintained an audit trail after each interview had taken place to document initial thoughts that may contribute to later analyses. Following the first 2 interviews, the interviewer (REH) amended the ordering of some of the interview questions to improve the flow (eg, asking about participants' behavior changes at the end of the interview, after interviewees had discussed their suggestions for improvements to the app).

Researcher Positioning

The interviewer and lead author (REH) was female, aged 29 years (and thus was familiar with the participants' life stage and had life experiences in common with some participants), and had a BMI within the "healthy" range but, to the knowledge of the author, did not have a history of breast cancer in her family. She had worked in prevention research (including diabetes prevention and breast cancer prevention and early detection) for >5 years and had previous experience delivering behavior change interventions in the community, thus reflecting her positive views on disease prevention.

In total, 2 members of the research team who conceptualized this intervention were research dieticians specializing in health behavior change and breast cancer prevention (MP and MH), thus reflecting their positive views on weight gain prevention in this population, and both had >15 years of experience in this field. Other members of the research team were breast cancer clinicians working in breast cancer prevention and early detection (AH, DGE, and SJH) or had experience designing, developing, and evaluating apps and behavior change interventions in industry and academia (REH, DPF, AD, and JM). The backgrounds of the wider team may have influenced some of the questions asked in the interviews (eg, with more of a focus on the individuals rather than wider socioeconomic status constraints) and the interpretation of some of the findings.

Analysis

Data were analyzed using inductive thematic analysis [24] and organized using the framework approach (Multimedia Appendix 5) to identify any differences in the findings across participants. As the researchers wanted to understand participants' views and experiences of specific features of the intervention (including support, logging health behaviors, and educational topics) and their overall views of taking part in the intervention, data were analyzed from a critical realist perspective, which seeks to understand participants' experiences but where participants' interpretations define their subjective realities. Participants did not provide any feedback on the findings.

The data were analyzed by 1 researcher (REH) and discussed among the authors to identify themes relevant to the research questions, with illustrative extracts and interpretive themes refined through discussion. The NVivo software (version 12; QSR International) was used to facilitate coding and analysis of the data.

Ethical Considerations

This study was reviewed and approved by the Wales Research Ethics Committee 3, Cardiff (reference 22/WA/0164). All participants provided full informed consent before they downloaded the app for the study. The wider study that this qualitative study is a part of is registered on the web at ClinicalTrials.gov (reference NCT05460650). There were no financial incentives for participating in the study. Interview data were pseudonymized at the point of transcription.

Results

Overview

The 20 interviewees comprised female individuals with a median age of 32 (IQR 27-35) years. The sample had little ethnic diversity but a good spread in terms of age range and engagement with the app (Table 1). The interviews lasted for a median of 37 (IQR 30-46) minutes.

Table 1. Participant characteristics (N=20).

Characteristic	Values
Age (y), median (range; IQR)	32.5 (23.7-35.6; 27-35)
Ethnicity, n (%)	
White British	18 (90)
Other	2 (10)
English Index of Multiple Deprivation quintile, n (%)	
1 (most deprived)	1 (5)
2	4 (20)
3	7 (35)
4	5 (25)
5 (least deprived)	3 (15)
Baseline BMI[a] (kg/m^2), median (range)	24.2 (19.5-31.6)
Estimated lifetime risk of breast cancer (Tyrer-Cuzick model; %)[b], median (range)	28.2 (17-50)
Level of education, n (%)	
A-levels or post-16 qualifications	2 (10)
Degree	6 (30)
Postgraduate degree	12 (60)
Recruitment method, n (%)	
Mailshot	14 (70)
Instagram	6 (30)
Attendance to Microsoft Teams welcome event, n (%)	
Yes	16 (80)
No	4 (20)
Member of private Facebook group, n (%)	
Yes	15 (75)
No	5 (25)
Engagement with the app, n (%)[c]	
High user	11 (55)
Low user	9 (45)

[a] Underweight: <18.5 kg/m^2; healthy weight: 18.5-24.9 kg/m^2; overweight: 25-29.9 kg/m^2; obesity: 30-39.9 kg/m^2; severe obesity: ≥40 kg/m^2.

[b] Near population risk of breast cancer: <17%; moderate risk of breast cancer: >17%-<30%; high risk of breast cancer: ≥30% [3].

[c] Participants were classified as "low" or "high" users based on the number of dates on which they entered information into the app. High users entered information on ≥6 dates, and low users entered information on ≤2 dates.

A total of 4 themes were generated from the analysis (*A "missed opportunity" in breast cancer prevention services*, *The pros and cons of being part of a community*, *The importance of an interactive app*, and *The different wants and needs of different age groups*). Quotes are presented with pseudonyms for the participants and their age.

Theme 1: A "Missed Opportunity" in Breast Cancer Prevention Services

The women recounted their experiences of being told at a young age that they were at increased risk of breast cancer but then not having a service that they could access to help manage and reduce this risk until they were aged 35 or 40 years. Their accounts centered on feeling forgotten, "fobbed off" (Isabelle), and not always taken seriously by health care professionals. Stephanie described feeling like she was currently in "no man's land," where the knowledge of being at increased risk is at the back of her mind but there is little she can do until she can take risk-reducing medication when she reaches the age of 40 years:

> *You do feel a bit lost to be honest because, you know, you kind of get this letter from clinic and that's it. You kind of are just sent on your way and then years tick by and I suppose you haven't got that support in the interim.* [Stephanie; aged 35 years]

Many women recalled finding out that they were at increased risk of breast cancer at an early age, usually because of the diagnosis of a close family member. Some women reflected on this as a burden they had lived with for a long time, as Alice described: “...it feels like it’s leaning over you.” In contrast, Amelia described her breast cancer risk as a “future thing to worry about” as she did not want to ruminate about something that might or might not happen. Regardless of how the women perceived their own breast cancer risk, they were unanimous in that there was a gap in service provision for women of this age group, which was described by Isabelle, who found out she was at increased risk of breast cancer when she was aged 15 years, as a “missed opportunity.” Charlotte reported feeling let down by the National Health Service and the lack of funding or time that is invested in women’s health:

> *They can’t just kind of brush it off and say, oh, come in when you’re forty. That’s just not good enough to me.* [Charlotte; aged 26 years]

Therefore, the women described feeling dutiful to take part in the research study as it provided an opportunity to shape services for future women in a similar situation and prioritize research in women’s health:

> *I wanted to do something that might help other women and people in the future.* [Olivia; aged 31 years]

Therefore, taking part in this intervention provided some women with a sense of control and empowerment. It was an opportunity to learn more about how they could actively try to reduce their breast cancer risk and, thus, “taking matters into their own hands” (Zoe). Some participants described feeling reassured that they had not been completely forgotten about:

> *You feel a bit helpless, because it’s just a case of waiting and hoping that nothing happens in that time, which it could do. So yeah, I’d rather be doing something I guess, or exploring things that might help, rather than just sitting and waiting for a few years...So it seemed like this was something that I could proactively do, rather than just wait until I’m thirty-five.* [Josie; aged 33 years]

Theme 2: The Pros and Cons of Being Part of a Community

The women had diverging views as to whether support from other women at increased risk of breast cancer was of interest to them. Naomi noted the lack of community available to women aged <40 years known to be at increased risk of breast cancer:

> *There’s a huge community for people who have had breast cancer, is there a community for people who are high risk but are going through the same thing?* [Naomi; aged 26 years]

Of those who were keen to connect with other women at increased risk of breast cancer, the Microsoft Teams welcome meeting was reported as the first opportunity to speak with other women in a similar position to them. The women described feeling reassured that there were others “in a similar boat” (Emily), which helped validate their own feelings when meeting like-minded women who could empathize with them:

> *I think it was more to just know. Like when I first started at the Welcome Teams meeting, it was just to know that there is other people in that situation because on a weekly basis I do worry and I check myself continuously and things like that. It’s kind of nice to know that there’s other people in that situation that are also of a similar age group.* [Lucy; aged 24 years]

Emily noted that support from other women with similar lived experiences has the potential to fulfill emotional support needs, which is notably different from the support she would receive from health care professionals at the family history clinic, although she perceived support from both sources as important:

> *I suppose [support from other women provides] some kind of context to your situation, so I think, you know, hearing other women who were about my age who’d got similar family history to me. You’ve kind of got what they experience and how they manage that kind of uncertainty, I thought that was quite useful, but wouldn’t necessarily get from a clinic appointment. So I think sometimes you miss the contact in a clinic appointment, and it’s all about reducing risk, which obviously is important but I also think that a bit of contact in how other women manage it, or live with it I guess, is useful.* [Emily; aged 29 years]

Most women who did attend the Microsoft Teams welcome meeting expressed that they would have liked to stay in touch with the women on the call via another follow-up meeting. They suggested that the 5 minutes that they had to talk to each other within the meeting could be increased in future group calls to enable them to establish more of a rapport with the other women.

In contrast, others viewed a support system or community as potentially unhelpful. Josie recalled that speaking with others on the Microsoft Teams call brought to her attention that others had started a family before the age of 30 years, but Josie was unaware that this could contribute to breast cancer risk reduction and had not yet had children:

> *...so in some ways it was good, because it was nice that people were there who’d had similar experiences of obviously having had breast cancer in their family and stuff. But in other ways it kind of brought home some of the things that people have done to reduce the risks that I hadn’t.* [Josie; aged 33 years]

Conversely, others presented fatalistic views and perceived breast cancer as inevitable, thus viewing support as redundant “because although support is great, no one can change your outcome” (Charlotte). Alice explained that she would not view interacting with other women as “support” until she was diagnosed with cancer:

> *But I think to have it [support] there prior to that [diagnosis] and then having the knowledge of these people that you might have built a relationship around you getting cancer and you might just feel like you’re on a waiting list to get cancer. Do you know what I mean?* [Alice; aged 35 years]

Therefore, it was suggested that the opportunity to meet others on the web via Microsoft Teams could be optional; some might want an introduction to the study without sharing their own experiences or hearing others' stories. Even those who expressed a desire to connect with other women acknowledged that support will look different for different people and not everyone will want this:

> *I don't want to get into a hole about it. I've said that I understand my family history, I understand, you know, it's a possibility it could happen to me. I think being told about it, or being ah, kind of reminded about it often, it didn't really appeal to me. And I think for my sake and my mental health, I just find it easier knowing what I know and not being kind of reminded of it constantly.* [Carly; aged 28 years]

Theme 3: The Importance of an Interactive App

Should such an intervention be rolled out, all the women discussed the need for an interactive app that provided trustworthy information specific to breast cancer risk reduction. Although most of the women described themselves as quite knowledgeable about breast cancer risk factors, many recalled something that they had learned and implemented as a result of engaging with the intervention. For example, in the following quote, Rebecca recalls learning about the link between breast cancer and alcohol consumption, which prompted her to reflect on her own alcohol intake:

> *It just kind of made me think a little bit more about my own alcohol intake and any changes that I can make to my own intake of it really because I was surprised about how, like, I think it was the amounts of units that women were supposed to drink in a week or something kind of surprised me at how sort of low it was in comparison to my own intake.* [Rebecca; aged 23 years]

However, others mentioned wanting more in-depth information about breast cancer prevention and risk management in addition to health behaviors, including information about how the contraceptive pill influences breast cancer risk and how to perform a breast check:

> *So, like you know, like self-breast examination and what are the steps you can take to, you know, if you find a lump, if you find swelling so where to go and like that.* [Amara; aged 35 years]

The desire for more interactive app features was described as another way to increase engagement with the intervention. This ranged from including more tailored information relevant to yearly events to the functionality to link to other apps:

> *If the notifications pulled that through that would be great. And even if they engage in stuff wider about evidence based things, about national drives that are happening, or like breast cancer awareness week, something like that.* [Stephanie; aged 35 years]

> *So I like apps that integrate everything. So, I've got a fitness tracker. So everything that I do like if I record a run, it pings on about three different apps. So like if it did that. If it linked with fitness devices, if it linked with other health apps, so that all the information fed into one place. So potentially maybe you wouldn't have to re-input it, if it just pulled through other apps, if that makes sense.* [Grace; aged 34 years]

During the study, members of the research team posted educational topics on the Facebook group each week. For some, this was a useful prompt to engage with content that was often missed on the app. Others who were not part of the Facebook group had fewer recollections of the educational content and, therefore, suggested that the app itself could include notifications of the weekly educational topics alongside quizzes and challenges to facilitate learning. The women viewed the ideal app as including tracking, education, and support features in one place to increase interactivity:

> *I think on the app if things were sort of revealed weekly, that would be good. Rather than just having all the information there together. Just because like I can get busy, you know, get sidetracked but if it's like a weekly thing...I think that can help with the engagement. Help keep you looking for if there's something new coming up, rather than this just sort of static app that, you know, you very easily could just sort of get to put to the side. I think people need reminding.* [Holly; aged 35 years]

> *I think for me as well almost having like an interactive element would be really helpful, so, you know, it's almost like testing your skills but like a quiz or something. And just to make it as I say a bit more interactive, so you feel like you're, you know, you're taking the learning but then you're also embedding it a little bit as well.* [Amelia; aged 32 years]

Most of the women expressed the need for an intervention such as this one to include more tailored signposting to services available in their local area (eg, running groups and weight loss groups) pointing them to the practical support available to maintain a healthy lifestyle. Thus, it would be up to the individuals themselves whether they wanted to seek further information and support for their health behaviors at a time when they might need them.

Theme 4: The Different Wants and Needs of Different Age Groups

Participants felt that, if an intervention such as this one was to be rolled out, it would need to be appropriate for the different age groups between 18 and 35 years engaging with the family history clinic, who each might have different wants and needs from such an intervention "because what I might want might be completely different to what a twenty-two-year-old these days want" (Alice; aged 35 years). Thus, when developing a digital intervention for women aged 18 to 35 years, aspects of the intervention would need to be modified for different age ranges within this group of women. For example, raising awareness about the modifiable risk factors was perceived by the women to be important for all age groups, whereas Rebecca described that tracking health behaviors on an app might not always appeal to younger age groups:

> *As I'm only twenty-three and I was told that I wouldn't really be eligible for any sort of monitoring or anything until I was like in my thirties, for me, it seems like something that is so far off, it's hard for me to feel any, like any kind of reasoning to do it [tracking health behaviours] right now. ... I'd be much more inclined to read the information. Because I think, you know, that's relevant at any stage of life and it's interesting as well, to kind of know things. So I'd be happy to read more about that and get the information and stuff. But the logging for me, it's just not personally, something I'm interested in doing right now.* [Rebecca; aged 23 years]

Therefore, the women's accounts continually emphasized that there is not a "one size fits all" approach and such an app would need to be customizable to provide the women with the autonomy to manage their health at different stages of their lives, echoing accounts from the previous themes. The women gave examples of having options to receive notifications or reminders from the app, seek further information on topics that were relevant, meet with other women at increased risk of breast cancer, receive signposting for health behaviors, or track different health behaviors on the app. This highlights the complexity of needs that such an app would need to accommodate. For example, Sophie reflected on the importance for women to choose what kinds of app notifications they want to receive:

> *I think that it could be optional for the user to decide whether they want the information. And then it's like if they change their mind, they've got the option to stop those notifications, so that it suits the person using it.* [Sophie; aged 25 years]

The women also discussed the need for wider education about health behaviors and breast cancer risk. Amber reflected on the current limited education on breast cancer risk reduction and the need for increased societal efforts to raise awareness:

> *I think there's a lot of people out there that don't realise how much their lifestyle can impact their breast cancer risk. Obviously there's many, many risks that cannot be changed by an individual, you know, their genetics, etc. However, some people don't realise that they are affecting their risk by their health behaviours.* [Amber; aged 29 years]

Thus, in addition to an interactive app, social media was regarded as another appropriate platform to raise this awareness. Zoe stated that choosing to engage with a social media app is more "automatic" compared to an app to track health behaviors, suggesting that bite-sized information via videos might be more beneficial for younger age groups who are higher social media users:

> *Well, they're on it all the time, aren't they [laughs]? So if you're on it and it's popping up and if you look at one thing, something pops up so I don't know. Yeah, maybe little reminders on there like little posts, you know, remember to check yourself, remember smoking increases risks of X, Y and Z, you know. Keep your BMI healthy. Try and, you know, try and do a bit of exercise. Do you know like those kind of little posts?* [Zoe; aged 35 years]

This was perceived as important for all women regardless of their family history:

> *Because, breast cancer is an issue, not just for people who it's running in the family, it's a huge issue across the board.* [Grace; aged 34 years]

Cervical screening was one avenue that the women felt could help raise awareness of health behaviors and breast cancer in younger women given that women are invited to attend cervical screening from the age of 25 years. The women also suggested that nonclinical settings such as gyms and national campaigns should be raising awareness about the importance of health behaviors:

> *But yeah, I think that's the key, there's always going to be people who are seeking it out and interested in, you know, or a bit more aware, but there's also people who sort of at similar risk, like in the same group as us, who perhaps will be a bit more reluctant to sort of address their behaviours and things. So I think just getting it out there in a more sort of—in a less clinical setting perhaps, I think that's a big thing.* [Isabelle; aged 34 years]

Discussion

Principal Findings

The accounts of the women in this study drew on the lack of services available for women aged 18 to 35 years and the lack of education and awareness raising in breast cancer risk reduction for younger women, thus highlighting such an intervention as a missed opportunity in breast cancer prevention services. The women had diverging views regarding the extent to which they would value being part of a community with other women at increased risk of breast cancer. If an intervention were to be rolled out, the women described various interactive features that would promote engagement (eg, quizzes, unlocking educational content over time, and app notifications). However, the women also described the complexity of such an intervention aimed at multiple age groups with different wants and needs. Thus, a customizable app with options to engage with different intervention features to varying degrees (eg, education, tracking, and support) was perceived as vital to allow women the autonomy to manage their health at different stages of their lives.

Comparison With Previous Literature

There are many qualitative studies on weight loss and weight loss maintenance [25]; however, to date, very few qualitative studies have focused on primary weight gain prevention in women at increased risk of breast cancer. Previous research with women aged 26 to 35 years at increased risk of breast cancer explored women's ideas about a hypothetical weight gain prevention intervention to reduce breast cancer risk, which was welcomed [26]. This study builds on those findings and presents reactions to a digital intervention targeting weight gain prevention and modifiable health behaviors for women at increased risk of breast cancer; the women in this study perceived this not only as acceptable but also as an important intervention that is missing from current service provision.

Other qualitative research among women at high risk of breast cancer has suggested that some see little value in making changes to their health behaviors if they are well [27], and a recent systematic review found that many women at high risk of breast cancer often view it as “inevitable,” including some misunderstandings of their own breast cancer risk factors [28]. Further qualitative research has found that women are sometimes uncertain of the preventative value that positive health behaviors can have, particularly when they have a family history of breast cancer [29]. However, this study found that, when the women learned about the links among weight reduction, health behaviors, and breast cancer risk, they reported that they had started implementing behavior changes that allowed them to gain a sense of control over their risk, in line with the study by Wright et al [30].

Previous qualitative research has highlighted the importance of providing women with credible information about weight control and health behaviors in relation to breast cancer risk [26,30]. Recent qualitative research has also reported that providing advice on health behaviors was perceived by some women aged 47 to 74 years as an acceptable means of controlling breast cancer risk [31]. This study found that the proposed digital intervention was also perceived as an acceptable way to provide credible information for younger women. However, the women in this study also emphasized the importance of an interactive app, such as quizzes and push notifications, to increase the usefulness of the intervention. This is in line with user engagement research in the wider digital behavior change literature, which has reported that sending push notifications containing tailored health messages was associated with greater engagement with a mobile health app [32].

Implications

The women in this study found the health behaviors intervention acceptable as a cancer risk reduction strategy, and an app was considered an acceptable format of delivery. However, such an intervention will need to be customizable to the different wants and needs of women at different stages of their lives. Subject to future feasibility studies, a digital health intervention for women at increased risk of breast cancer could be a scalable behavior change strategy for all UK family history clinics. Further research would need to assess whether this leads to additional supportive needs and resource requirements for participating clinics, as well as the skill set of staff and the capabilities required to meet this need if this intervention is part of a sustained future service. Current initiatives and research in breast cancer risk assessment are seeking to identify more young women at increased risk [33]. For example, there is now a greater awareness that family history clinics are not capturing women at high risk of breast cancer who have no known family history of breast cancer [34], and there have recently been calls for primary care involvement in identifying these target populations [35]. Therefore, it is likely that the number of women aged <40 years attending UK family history clinics—and, hence, the demand for such an intervention—will increase.

There is potential for further development of this intervention. The women in this study particularly valued information about alcohol consumption and breast cancer risk as many reported being previously unaware of this link. Clinicians should explain how women can modify specific health behaviors, including alcohol consumption, and why this is important for modifying future breast cancer risk. In addition to health behaviors, the women also reported wanting more information about other breast cancer risk factors such as the contraceptive pill, risk-reducing medications, and breast self-examination. Furthermore, including SMS text messaging with novel information that requires less active seeking of information and increasing the interconnectivity of the app with existing technologies are other fruitful avenues to explore for future developments. Strengthening the social media element of the intervention may help increase engagement for some groups of women. Given the merit that the women attributed to social media in raising awareness about health behaviors and breast cancer risk, research could also evaluate young women’s engagement with educational posts about breast cancer risk on social media. This might establish whether social media can fill a gap in awareness raising in those who might not seek out information or regularly engage with an app.

This research also highlighted the lack of support or community in place for young women known to be at increased risk of breast cancer. Although the women had differing views as to whether such a community was of interest to them, it was acknowledged that preferences for support could change over time depending on personal circumstances and life stage, thus highlighting a clear unmet need for this population. Therefore, future developments of this intervention should consider how to incorporate an optional community for those who would benefit, for example, through group meetups or campaigns.

Future evaluative research with the app should embed qualitative work to understand the barriers to engagement experienced by women of a low socioeconomic status and from ethnic minority groups; these groups are disproportionately affected by cancer but are underrepresented in cancer prevention research [36]. Future research could also consider whether this intervention is applicable to other groups, such as women at increased risk of breast cancer aged >35 years or people with Lynch syndrome.

Strengths and Limitations

This analysis involved researchers from diverse backgrounds, and the lead author was independent from the previous app development [13] and from the study team, thereby reducing the likelihood of the results being influenced by the wider team. There was a fairly even spread of level app engagement across interviewees, enabling a range of views to be captured on reasons for engagement or lack thereof. The interviews were conducted in a timely manner at the end of the intervention, within 1 month of the women completing the study.

We acknowledge the limitations of this study. Although efforts were made to secure a broad representation of participants regarding age, ethnic groups, and engagement with the intervention, the sample had little ethnic diversity, and we were unable to interview women who did not opt to join the study. The sample of interviewees was highly educated; the women described themselves as fairly knowledgeable about their health behaviors, and some were already implementing such behaviors at the time of taking part in this intervention. Therefore, the women in this study were likely to be a motivated sample, and caution should be taken when transferring these findings to the wider population of women at increased risk of breast cancer. The interviewees discussed their experience of 2 months' participation in the intervention. We acknowledge that this pragmatic acceptability study was short and that future research will need to assess longer-term interventions to assess the efficacy of the app for sustained behavior change.

Conclusions

There is a gap in prevention services for young women aged 18 to 35 years at increased risk of breast cancer. The women perceived a digital intervention incorporating education, tracking, and support to be an acceptable way to manage health behaviors and weight gain prevention for this target population. However, such an intervention would need to be customizable to meet the wants and needs of different age groups of women aged between 18 and 35 years engaging with family history clinics at different life stages during this period.

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Data Availability

The data sets generated during and analyzed during this study are available in the University of Manchester Figshare repository [37].

Authors' Contributions

MP, MH, DPF, AD, JM, AH, DGE and SJH contributed to study concept and design. MP and REH contributed to acquisition of data. REH, MP, MH and DPF contributed to the analysis and interpretation of data. REH, DPF, MH and MP were involved in drafting the manuscript. All authors contributed to revision of the manuscript.

Conflicts of Interest

JM is a former Trustee and current member of the Operations Committee for the Association of the Study of Obesity (unpaid role) and has organized educational events funded by Boehringer Ingelheim Ltd and Rhythm Pharmaceuticals.

Multimedia Appendix 1
Standards for Reporting Qualitative Research checklist.
[DOC File , 66 KB - cancer_v10i1e57964_app1.doc]

Multimedia Appendix 2
COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist.
[PDF File (Adobe PDF File), 534 KB - cancer_v10i1e57964_app2.pdf]

Multimedia Appendix 3
Screenshots of the app interface.
[DOCX File , 453 KB - cancer_v10i1e57964_app3.docx]

Multimedia Appendix 4
Interview topic guide.
[DOCX File , 31 KB - cancer_v10i1e57964_app4.docx]

Multimedia Appendix 5

Coding framework.
[DOCX File , 29 KB - cancer_v10i1e57964_app5.docx]

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Abbreviations

COREQ: Consolidated Criteria for Reporting Qualitative Research

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Original Paper

Relationship Between Perceived COVID-19 Risk and Change in Perceived Breast Cancer Risk: Prospective Observational Study

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Abstract

Background: Whether COVID-19 is associated with a change in risk perception about other health conditions is unknown. Because COVID-19 occurred during a breast cancer study, we evaluated the effect of COVID-19 risk perception on women's breast cancer risk perception.

Objective: This study aims to evaluate the relationship between perceived risk of COVID-19 and change in perceived breast cancer risk. We hypothesized that women who perceived greater COVID-19 risk would evidence increased perceived breast cancer risk and this risk would relate to increased anxiety and missed cancer screening.

Methods: Women aged 40-74 years with no breast cancer history were enrolled in a US breast cancer prevention trial in outpatient settings. They had provided breast cancer risk perception and general anxiety before COVID-19. We performed a prospective observational study of the relationship between the perceived risk of COVID-19 and the change in perceived breast cancer risk compared to before the pandemic. Each woman was surveyed up to 4 times about COVID-19 and breast cancer risk perception, general anxiety, and missed medical care early in COVID-19 (May to December 2020).

Results: Among 13,002 women who completed a survey, compared to before COVID-19, anxiety was higher during COVID-19 (mean T score 53.5 vs 49.7 before COVID-19; difference 3.8, 95% CI 3.6-4.0; $P<.001$) and directly related to perceived COVID-19 risk. In survey wave 1, anxiety increased by 2.3 T score points for women with very low perceived COVID-19 risk and 5.2 points for those with moderately or very high perceived COVID-19 risk. Despite no overall difference in breast cancer risk perception (mean 32.5% vs 32.5% before COVID-19; difference 0.24, 95% CI –0.47 to 0.52; $P=.93$), there was a direct relationship between change in perceived breast cancer risk with COVID-19 risk perception, ranging in survey wave 4 from a 2.4% decrease in breast cancer risk perception for those with very low COVID-19 risk perception to a 3.4% increase for women with moderately to very high COVID-19 risk perception. This was not explained by the change in anxiety or missed cancer screening. After adjustment for age, race, education, and survey wave, compared to women with very low perceived COVID-19 risk, perceived breast cancer risk increased by 1.54% (95% CI 0.75%-2.33%; *P*<.001), 4.28% (95% CI 3.30%-5.25%; *P*<.001), and 3.67% (95% CI 1.94%-5.40%; *P*<.001) for women with moderately low, neither high nor low, and moderately or very high perceived COVID-19 risk, respectively.

Conclusions: Low perceived COVID-19 risk was associated with reduced perceived breast cancer risk, and higher levels of perceived COVID-19 risk were associated with increased perceived breast cancer risk. This natural experiment suggests that a threat such as COVID-19 may have implications beyond the pandemic. Preventive health behaviors related to perceived risk may need attention as COVID-19 becomes endemic.

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KEYWORDS

breast cancer; COVID-19 risk perception; cancer screening; anxiety; cancer; COVID-19; prevention; medical care; screening; survey

Introduction

COVID-19 posed a new serious threat that caused Americans to change how they led their lives. People who perceived themselves to be at higher risk for developing COVID-19 were more likely to engage in protective behaviors [1,2]. Lack of access, higher perceived risk of COVID-19, more symptoms of anxiety or depression, and risk factors for severe COVID-19 were associated with missed medical care and cancer screening [3]. The longer the pandemic persisted, the greater the importance of the influence of COVID-19 on activities to promote health, such as preventive behaviors, including cancer screening, which is associated with earlier detection and better survival [4]. Preventive behaviors, such as mammograms, are dependent—at least in part—on the perceived risk of the condition [5,6]. However, little is known about how the perceived risk of a condition is affected by the imposition of a new risk from another condition. COVID-19 created a natural experiment in the midst of a breast cancer prevention study, permitting elucidation of how a new perceived risk affects the perception of a prior health risk.

Prior to the pandemic, the WISDOM (Women Informed to Screen Depending On Measures of Risk) breast cancer prevention study enrolled women, elicited their perceptions of the risk of breast cancer and levels of anxiety, and presented personalized or routine screening recommendations. During COVID-19, WISDOM added surveys to study the relationship between the perceived risk of COVID-19 and perceived breast cancer risk and explored factors associated with the relationship. Because of evidence that anxiety and distress related to risk perception [7,8] and evidence that people were missing cancer screening due to COVID-19 concerns [3], we hypothesized that individuals who perceived greater COVID-19 risk would have increased perceived breast cancer risk during the contemporaneous survey wave and that this risk would be related to increased general anxiety [9] and missed cancer screening [10].

Methods

Study Sample and Baseline Data

In this prospective observational study, women aged 40-74 years with no breast cancer history were enrolled at mammogram facilities and physician offices, and via health system communication and media [11]. At study entry, women provided demographic information, estimated their risk of breast cancer, and answered questions about anxiety. Numerical breast cancer risk was assessed by asking “What do you think your chance is of developing breast cancer in your lifetime? Please choose a number between 0% (no chance of breast cancer) and 100% (definitely will get breast cancer)” [12]. General anxiety was assessed using the 4-item PROMIS (Patient-Reported Outcome Measurement Information System) short form [13]. The raw score was rescaled into a standardized T score, with higher scores indicating more anxiety. A score of 50 (SD 10) represents the mean score for the general population. A change of 2.5 T score points appears to represent a minimally important difference [14]. Surveys were web based. The pre–COVID-19 survey was completed a mean of 9 months before the pandemic began.

Surveys

Participants were asked to complete 4 supplemental COVID-19 surveys, collected from May 10 to June 15, 2020; from July 11 to August 21, 2020; from October 5 to 28, 2020; and from December 8 to 30, 2020. Approximately 25,000 women were sent the optional web-based survey each wave (Table S1 in Multimedia Appendix 1). Participants received an initial email and follow-up email reminders.

Surveys included the items on breast cancer risk perception and general anxiety that were completed in pre–COVID-19 WISDOM surveys. Perceived COVID-19 risk was assessed with an item adapted from the National Cancer Institute’s Health Information National Trends Survey [15]: “How likely is it that you will get COVID-19 in the next 30 days?” with response options of “Very low,” “Moderately low,” “Neither high nor low,” “Moderately high,” or “Very high.” The survey asked whether the respondent or a household member believed they had COVID-19 and whether the respondent had significant medical diagnoses (heart disease, lung disease, diabetes, hypertension, cancer, and others).

The survey asked about missed medical appointments as follows [3]: “Over the last 2 months, have any of your health care providers canceled or postponed scheduled visits or services for physical or mental health?” Response options were “Yes,” “No,” “I did not have anything scheduled,” and “Not sure.” Respondents also were asked if they had canceled or postponed scheduled visits or services. These 2 items were combined to describe whether the respondent had a medical visit that was canceled or postponed. Concerning cancer screening, the survey asked the following: “Over the last 2 months, have you canceled or postponed getting routine cancer screening (breast cancer mammography, colonoscopy, etc)?” with the response options of “Yes,” “No,” “I did not have anything scheduled,” and “Not sure.” Concerning the future, respondents were asked “In the upcoming 2 months, do you plan to cancel or postpone getting routine cancer screening (breast cancer mammography, colonoscopy, etc)?” and the same question was asked concerning visits or services for physical or mental health.

Ethical Considerations

This study was approved by the University of California Los Angeles Institutional Review Board (#20-000786) and the University of California San Francisco Institutional Review Board (#15-18234). All participants provided written informed consent. Data were deidentified prior to analysis. No compensation was offered for study participation or survey completion.

Statistical Analysis

All survey respondents were eligible for inclusion in the analysis, even if they did not complete all 4 surveys or did not have baseline data for anxiety or perceived breast cancer risk. We calculated the change in perceived breast cancer risk by subtracting the pre–COVID-19 survey score from the scores on the COVID-19 surveys. We calculated the change in anxiety by subtracting the T score on the pre–COVID-19 survey from the scores on the COVID-19 surveys. This was repeated at each survey wave for respondents who completed more than 1 wave. If participants had more than 1 WISDOM survey before COVID-19, the last survey before COVID-19 was used.

Change in anxiety and perceived breast cancer risk was estimated using paired 2-tailed *t* tests that compared participants’ responses from before COVID-19 to responses during COVID-19. We evaluated the relationship between perceived COVID-19 risk and change in perceived breast cancer risk and general anxiety using all 4 survey waves. These relationships were explored without adjustment and after adjusting using ordinary least squares regression for age (40-64 years and 65 years or older), race (White, Black, Asian, multiracial, American Indian or Alaska Native, Native Hawaiian or other Pacific Islander, or other race), and education (high school or less, some college or technical school, or college graduate or more) with standard errors clustered by respondent. We predicted missed medical appointments and cancer screening due to COVID-19 and plans to cancel medical care and cancer screening, across the 4 survey waves and from perceived COVID-19 risk in the same survey wave. These models using ordinary least squares regression adjusted for age, education, race, COVID-19 status, number of medical conditions, and survey wave through the inclusion of these variables as predictors in the regression model with standard errors clustered by respondent.

In order to explore whether perceived COVID-19 risk influences patients’ perceived risk of breast cancer, as well as their anxiety levels, we conducted a longitudinal analysis using a regression framework including a series of separate regression models. The first 2 models include the 6981 participants who completed 2 COVID-19 survey waves in a row and provided baseline assessments of anxiety and breast cancer risk. The first model included perceived COVID-19 risk, age, race, education, and wave. The second model added change in general anxiety between the prior survey wave and baseline in order to explore the influence between antecedent change in anxiety and the relationship between perceived COVID-19 risk and change in perceived breast cancer risk. The third model (N=16,311 because all cases are included) included a change in anxiety between the current survey wave and baseline. In a fourth model, we added the report during the current wave of canceled cancer screening during the past 2 months.

We repeated the analyses of the relationship between perceived COVID-19 risk and perceived breast cancer risk on the 1524 women who completed all 4 surveys. Because the results are similar to the full sample, the results are not described in the text but are displayed in Multimedia Appendix 1.

All analyses were performed on unweighted data. Binary outcomes (eg, cancellation of medical appointments) were analyzed using logistic regression, and continuous outcomes (eg, PROMIS4 anxiety scale) were analyzed using ordinary least squares regression. Analyses used R (version 4.1.2; R Foundation for Statistical Computing).

Results

Patient Sample and Characteristics

The 13,002 women who responded to at least 1 survey had a mean age of 58 years; 27% (n=3540) of women were aged 65 years or older, 84% (n=10,975) of women were White, and 76% (n=9898) of women graduated from college. A total of 64% (n=8298) of women reported no serious medical conditions and 47% (n=6120) of women reported no anxiety at baseline. There was little difference in demographic and clinical characteristics among respondents across waves (Table S2 in Multimedia Appendix 1). In pre–COVID-19 surveys, 9282 women provided general anxiety responses and 8839 provided perceived breast cancer risk responses.

Perceived COVID-19 Risk, Breast Cancer Risk, and Anxiety

In their first survey response, 29.4% (n=3827) of respondents felt their COVID-19 risk over the next month was very low, 37.4% (n=4867) of respondents felt their risk was moderately low, 21.1% (n=2742) of respondents felt their risk was neither high nor low, 5.1% (n=659) of respondents felt their risk was moderately high, 0.5% (n=63) of respondents felt their risk was very high, 5.4% (n=704) of respondents did not provide a response, and 1.1% (n=140) of respondents were not asked the question because they had tested positive for COVID-19 (Table S2 in Multimedia Appendix 1).

Compared to before COVID-19, participants’ general anxiety was higher during the first COVID-19 survey completed (mean T score 53.5 vs 49.7 before COVID-19; mean difference 3.8, 95% CI 3.6-4.0; *P*<.001), but there was no overall difference in perceived breast cancer risk (mean 32.5% first COVID-19 survey vs 32.5% before COVID-19; mean difference 0.24, 95% CI –0.47 to 0.52; *P*=.93). Mean T scores by survey wave for general anxiety and perceived breast cancer risk were stable across waves (Table 1).

"During survey wave 1 (May-June 2020), 31% (2204/7186) of women reported that they had no general medical care scheduled. Of those with scheduled care over the prior 2 months, 83% (4112/4982) of women missed medical care. During that same period, 35% (1209/3426) of respondents with scheduled cancer screening missed the appointment. Projecting over the next 2 months, 17% (679/3987) of women planned to cancel general medical care, and 20% (547/2685) of women planned to cancel cancer screening.

Table 1. General anxiety and perceived breast cancer risk before and during COVID-19[a].

Period	PROMIS4[b] anxiety (range 40.3-81.6), mean T score (95% CI)	Perceived breast cancer risk (range 0-100), mean probability (%; 95% CI)
Before COVID-19	49.8 (49.7-50.0)	32.9 (32.5-33.4)
COVID-19 wave 1	53.7 (53.5-53.8)	31.9 (31.4-32.4)
COVID-19 wave 2	54.0 (53.8-54.2)	31.6 (31.1-32.2)
COVID-19 wave 3	53.3 (53.1-53.6)	31.3 (30.7-31.9)
COVID-19 wave 4	53.1 (52.9-53.3)	31.6 (31.0-32.2)

[a] Cell entries present unweighted averages with 95% CI in parentheses. The range of the PROMIS4 anxiety mean T-score is from 40.3 to 81.6 and the range of the perceived breast cancer risk is from 0% to 100%. Cell counts may vary by outcome measure as not all respondents answered each question. Data in the table differ slightly from the data presented in the text, which is a paired comparison. See also longitudinal cohort comparison in Table S5 in Multimedia Appendix 1. Baseline data are from the most recent response before COVID-19.

[b] PROMIS4: Patient-Reported Outcomes Measurement Information System 4-item.

Relationship of Perceived COVID-19 Risk With Change in Anxiety, Change in Perceived Breast Cancer Risk, and Missed Medical Care

Higher perceived COVID-19 risk was associated with increased general anxiety across all survey waves. For example, in survey wave 4, a mean increase of 5.2, 3.8, 2.7, and 2.3 in PROMIS4 anxiety T score from baseline was noted for respondents with moderately or very high, neither high nor low, moderately low, and very low perceived COVID-19 risk, respectively (Figure 1 and Table 2).

Change in breast cancer risk perception had a more complex relationship with perceived COVID-19 risk. Perceived breast cancer risk decreased from pre–COVID-19 levels for people with very low perceived COVID-19 risk. For women with moderately low perceived COVID-19 risk, the pre- or postpandemic difference is not statistically distinguishable from zero. However, for women for whom the perceived COVID-19 risk was “neither high nor low” or perceived risk was moderately high or very high, perceived breast cancer risk increased during most survey waves. Survey wave 4 demonstrates this trend best: change in perceived breast cancer risk increased from –2.4 to –1.2 to +3.1 to +3.4 across the 4 levels of perceived COVID-19 risk from very low to moderately or very high, respectively (Figure 2 and Table 2).

After adjusting for age, race, education, and survey wave, both changes in general anxiety and change in perceived breast cancer risk remain statistically significantly, directly related to perceived COVID-19 risk. Compared to women with very low perceived COVID-19 risk, those with moderately low perceived COVID-19 risk increased 1.07 (95% CI 0.75-1.39) anxiety T score points from before COVID-19. This change was 1.26 (95% CI 0.86-1.66) for neither high nor low perceived COVID-19 risk and 2.38 (95% CI 1.67-3.09) for moderately or very high perceived COVID-19 risk. Concerning change in perceived breast cancer risk, after adjustment, compared to women with very low perceived COVID-19 risk, those with moderately low perceived COVID-19 risk increased 1.54% (95% CI 0.75%-2.33%) in perceived breast cancer risk; this increase was 4.28% (95% CI 3.30%-5.25%) for women with neither high nor low perceived COVID-19 risk and 3.67% (95% CI 1.94%-5.40%) for women with moderately or very high perceived COVID-19 risk (Table 3).

Perceived COVID-19 risk was not consistently associated with whether women missed medical care or cancer screening during the prior 2 months or planned to cancel medical care or cancer screening in the next 2 months, without (Table S3 in Multimedia Appendix 1) or with adjustment for age, education, race, COVID-19 infection status, number of medical diagnoses, and survey wave (Table S4 in Multimedia Appendix 1).

Figure 1. Change in general anxiety by perceived COVID-19 risk.

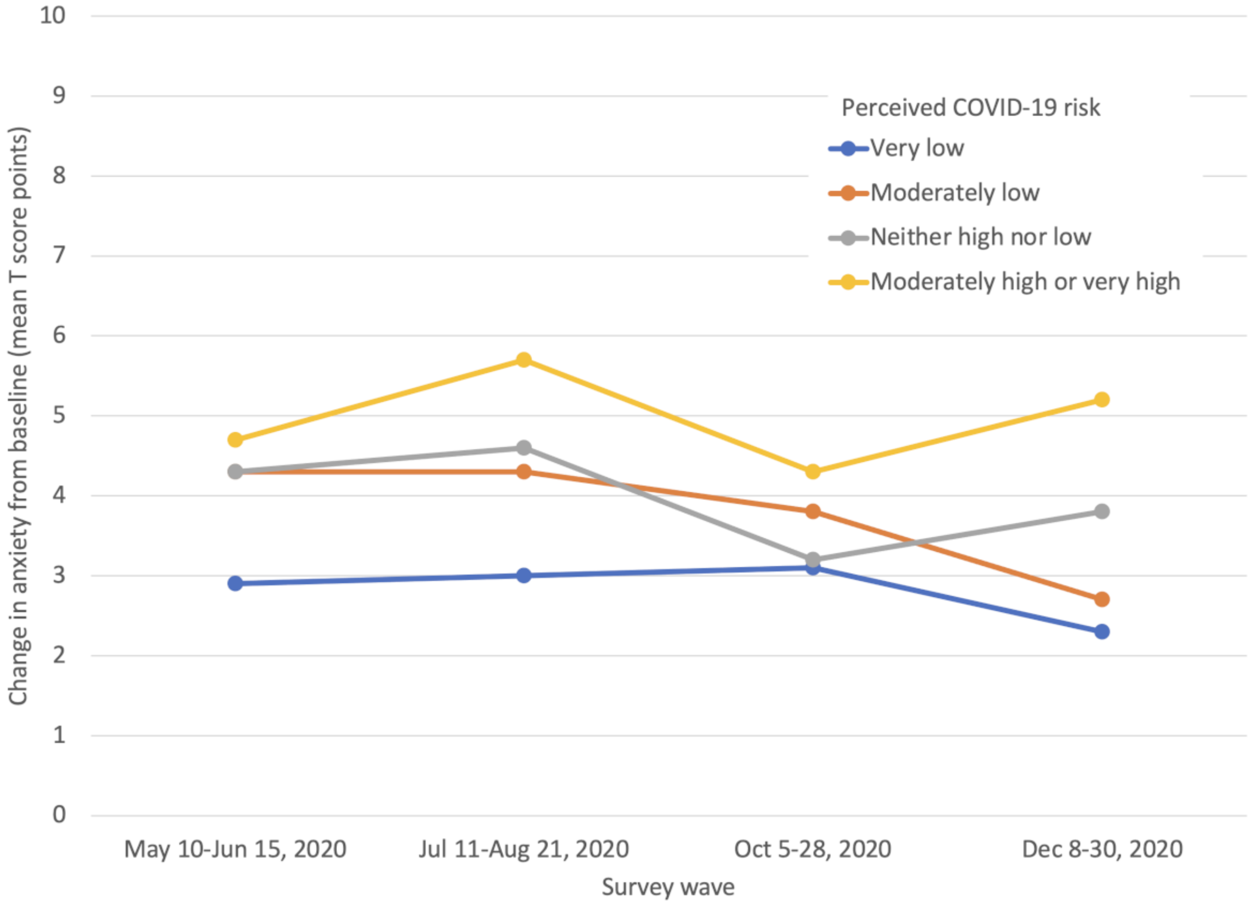

Table 2. Changes in general anxiety and perceived breast cancer risk by perceived COVID-19 risk[a].

Change and wave	Perceived COVID-19 risk (next 30 days), mean T score (95% CI)				Total, n
	Very low	Moderately low	Neither high nor low	Moderately high or very high	
Change in general anxiety (range 40.3-81.6)	**n=5361**	**n=7368**	**n=4092**	**n=999**	
Wave 1	2.9 (2.5 to 3.2)	4.3 (4.0 to 4.6)	4.3 (3.9 to 4.8)	4.7 (3.6 to 5.8)	6128
Wave 2	3.0 (2.6 to 3.5)	4.3 (4.0 to 4.7)	4.6 (4.1 to 5.0)	5.7 (4.7 to 6.7)	4772
Wave 3	3.1 (2.7 to 3.6)	3.8 (3.4 to 4.2)	3.2 (2.7 to 3.8)	4.3 (3.1 to 5.4)	3509
Wave 4	2.3 (1.8 to 2.8)	2.7 (2.3 to 3.1)	3.8 (3.2 to 4.3)	5.2 (4.1 to 6.2)	3411
Change in breast cancer risk (range 0-100)	**n=4871**	**n=7121**	**n=3902**	**n=965**	
Wave 1	–1.9 (–2.8 to –1.1)	0.0 (–0.7 to 0.8)	2.8 (1.7 to 3.9)	0.6 (–1.8 to 3.1)	5829
Wave 2	–1.3 (–2.3 to –0.2)	0.0 (–0.8 to 0.9)	2.8 (1.6 to 3.9)	1.8 (–0.8 to 4.3)	4505
Wave 3	–2.3 (–3.5 to –1.2)	–0.3 (–1.3 to 0.8)	1.9 (0.5 to 3.4)	3.5 (0.4 to 6.6)	3314
Wave 4	–2.4 (–3.7 to –1.0)	–1.2 (–2.1 to –0.2)	3.1 (1.6 to 4.5)	3.4 (1.0 to 5.9)	3211

[a] Cell entries present the mean with 95% CI in parentheses for change in PROMIS4 (Patient-Reported Outcomes Measurement Information System 4) anxiety and perceived breast cancer risk from baseline to the survey wave for individuals who perceived a certain level of COVID-19 risk over the next 30 days in that wave. The survey was conducted in the following time periods: wave 1: from May 10 to June 15, 2020; wave 2: from July 11 to August 21, 2020; wave 3: from October 5 to 28, 2020; and wave 4: from December 8 to 30, 2020.

Figure 2. Change in perceived breast cancer risk by perceived COVID-19 risk.

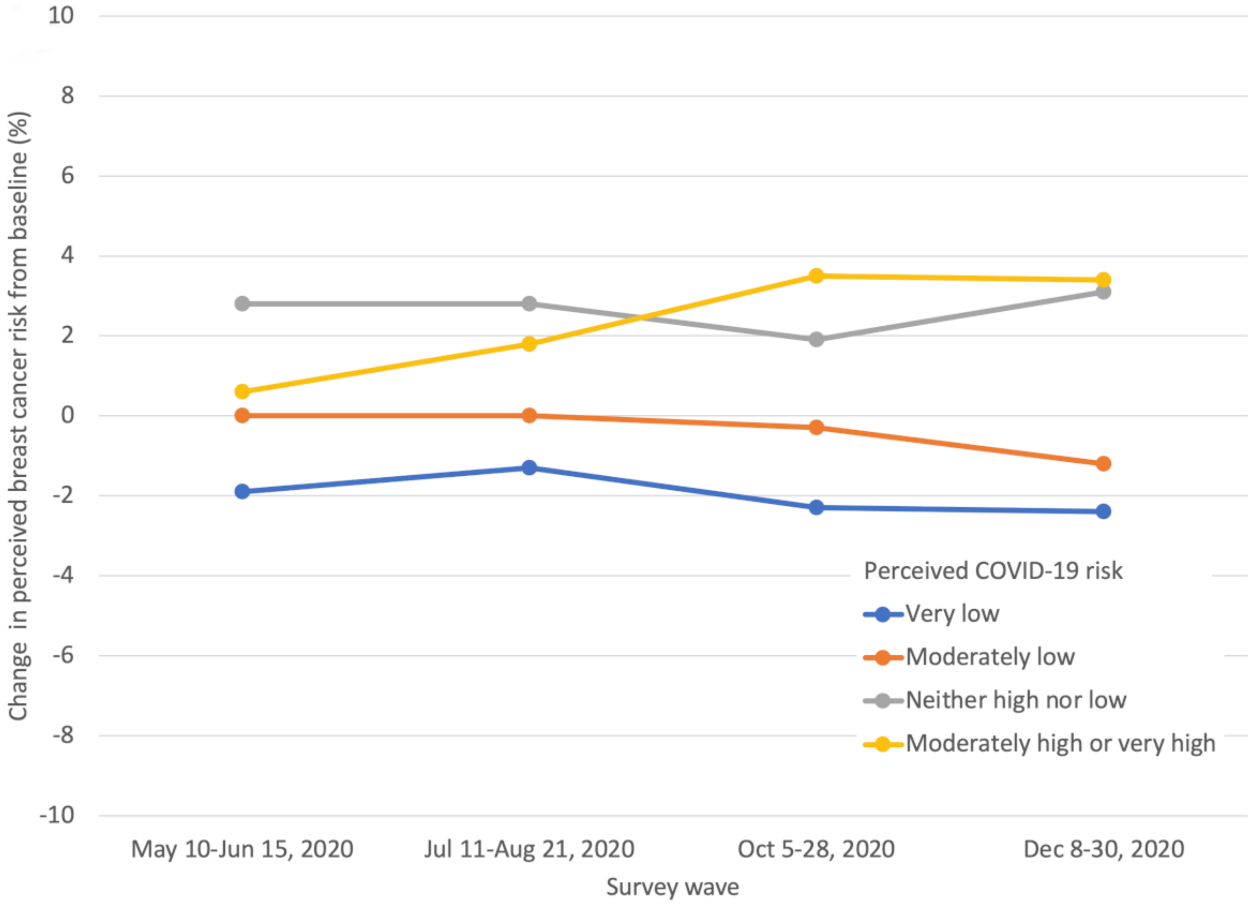

Table 3. Change in anxiety and change in perceived breast cancer risk with perceived COVID-19 risk after adjustment for patient characteristics and time[a].

	Change in PROMIS4[b] anxiety (range 40.3-81.6)	Change in perceived breast cancer risk (range 0-100)
Perceived COVID-19 risk (30 days), OLS[c] estimate (95% CI)		
Moderately low	1.07 (0.75 to 1.39)***	1.54 (0.75 to 2.33)***
Neither high nor low	1.26 (0.86 to 1.66)***	4.28 (3.30 to 5.25)***
Moderately or very high	2.38 (1.67 to 3.09)***	3.67 (1.94 to 5.40)***
Age (years), OLS estimate (95% CI)		
≥65	0.39 (0.028 to 0.76)*	–1.26 (–2.16 to –0.37)**
Race or ethnicity, OLS estimate (95% CI)		
Asian, Native Hawaiian, or other Pacific Islander	–0.025 (–1.01 to 0.96)	0.36 (–1.82 to 2.54)
Black	0.40 (–0.92 to 1.71)	1.15 (–3.62 to 5.92)
Multiracial	0.64 (–0.28 to 1.56)	0.64 (–1.61 to 2.89)
Other, unknown, or American Indian or Alaskan Native	0.32 (–0.81 to 1.45)	–1.24 (–4.46 to 1.97)
Education, OLS estimate (95% CI)		
College graduate or more	1.55 (1.11 to 1.99)***	0.65 (–0.43 to 1.73)
Time fixed effects, OLS estimate (95% CI)		
Wave 2	0.14 (–0.098 to 0.37)	0.29 (–0.31 to 0.89)
Wave 3	–0.47 (–0.74 to –0.21)**	–0.26 (–0.96 to 0.44)
Wave 4	–1.053 (–1.33 to –0.77)**	–0.32 (–1.04 to 0.41)
Intercept, OLS estimate (95% CI)	1.70 (1.22 to 2.19)***	–1.81 (–3.00 to –0.63)**
N	17,466	16,524
R^2	0.015	0.009
Adjusted R^2	0.014	0.008
Akaike information criterion	121,852.0	144,696.7
Bayesian information criterion	121,960.8	144,804.7
Root mean square error	7.91	19.27
F test (*df*)	15.97 (12, 8493)	8.295 (12, 8055)

[a] *P* value thresholds are **P*<.05, ***P*<.01, and ****P*<.001. Ordinary least squares regression model predicting change in general anxiety T score and change in perceived breast cancer risk from perceived COVID-19 risk. SEs are clustered at the participant level. Reference categories: age 40-64 years; education: some college or technical school or less; race: White; perceived COVID-19 risk: very low; time: wave 1. Cell entries indicate the ordinary least squares estimate followed by the approximate 95% CI, in brackets, and the *P* value threshold, described above.

[b] PROMIS4: Patient-Reported Outcomes Measurement Information System 4-item.

[c] OLS: ordinary least squares.

Exploring the Relationship Between Perceived COVID-19 Risk and Change in Perceived Breast Cancer Risk

We explored our hypotheses that higher perceived COVID-19 risk was associated with increased anxiety and canceled cancer screening that, in turn, led to increased perceived breast cancer risk. Table 4 shows the series of regression models predicting change in perceived breast cancer risk. Column 1, which includes a restricted cohort of 6981 women who completed surveys in 2 adjacent waves, shows that after accounting for age, race, education, and survey wave, compared to women with very low perceived COVID-19 risk, women with neither high nor low and moderately or very high perceived COVID risk had increases in perceived breast cancer risk of 3.47% (95% CI 2.08%-4.87%) and 5.40% (95% CI 2.87%-7.93%), respectively. To investigate whether these results are driven by increased anxiety during the COVID-19 pandemic, column 2 adds the change in general anxiety from before COVID-19 to the prior survey wave. This regression model, which avoids some issues of simultaneous measurement, demonstrates that prior wave change in general anxiety from baseline has virtually no impact on change in perceived breast cancer risk. The next model includes changes in anxiety from before the pandemic to the current survey wave (analogous to the change in breast cancer risk) and finds a weak statistically significant relationship with change in perceived breast cancer risk. However, the relationship between perceived breast cancer risk and perceived COVID-19 risk is only slightly altered (column 3). Finally, in column 4, patient cancellation of cancer screening in the prior 2 months was unrelated to the change in perceived breast cancer risk and does not appear to drive the relationship with perceived COVID-19 risk. Taken together, these models suggest that higher perceived COVID-19 risk is related to an increase in perceived breast cancer risk that is not mediated by a change in anxiety or missed cancer screening. When perceived COVID-19 risk was removed from the model in column 2, the effect on the relationship between anxiety and change in perceived breast cancer risk was minimal (data not shown).

Table 4. Relationship of change in perceived breast cancer risk to perceived COVID-19 risk while controlling for change in anxiety and missed cancer screening[a].

	Change in perceived breast cancer risk			
	Restricted sample	Restricted sample (model includes change in general anxiety from prior survey wave)	Full sample (model includes change in general anxiety from current survey wave)	Full sample (model includes self-reported missed cancer screening)
Perceived COVID-19 infection risk (30 days), OLS[b] estimate (95% CI)				
Moderately low	0.513 (–0.649 to 1.676)	0.503 (–0.660 to 1.666)	1.482 (0.685 to 2.279)***	1.522 (0.729 to 2.314)***
Neither high nor low	3.473 (2.077 to 4.869)***	3.463 (2.065, 4.861) ***	4.170 (3.190 to 5.151)***	4.252 (3.277 to 5.228)***
Moderately or very high	5.399 (2.872 to 7.926)***	5.378 (2.851 to 7.905)***	3.510 (1.761 to 5.260)***	3.676 (1.945 to 5.407)***
Change in PROMIS4[c]anxiety scale T score, OLS estimate (95% CI)				
Previous wave	Not included	0.019 (–0.051 to 0.090)	—[d]	—
Current wave	Not included	—	0.060 (0.011 to 0.110)*	—
Cancer screening cancellations, OLS estimate (95% CI)				
Yes	Not in model	—	—	0.580 (–0.496 to 1.656)
Nothing scheduled or not sure	—	—	—	–0.015 (–0.709 to 0.679)
Age (years), OLS estimate (95% CI)				
≥65	–1.301 (–2.525 to –0.076)*	–1.307 (–2.531 to –0.084)*	–1.366 (–2.267 to –0.465)**	–1.310 (–2.209 to –0.411)**
Race and ethnicity, OLS estimate (95% CI)				
Asian, Native Hawaiian, or other Pacific Islander	–0.418 (–3.647 to 2.810)	–0.399 (–3.625 to –2.827)	0.396 (–1.802 to 2.594)	0.340 (–1.832 to 2.512)
Black	–2.076 (–11.049 to 6.898)	–2.085 (–11.066 to 6.896)	0.893 (–4.055 to 5.842)	0.943 (–3.849 to 5.736)
Multiracial	1.601 (–1.744 to 4.946)	1.582 (–1.761 to 4.925)	0.579 (–1.679 to 2.837)	0.613 (–1.639 to 2.865)
Other, unknown, or American Indian or Alaskan Native	–0.972 (–6.367 to 4.423)	–0.979 (–6.373 to 4.415)	–1.228 (–4.541 to 2.086)	–1.302 (–4.535 to 1.931)
Education, OLS estimate (95% CI)				
College graduate or more	0.020 (–1.501 to 1.542)	–0.007 (–1.530 to 1.515)	0.553 (–0.526 to 1.633)	0.623 (–0.457 to 1.702)
Time fixed effect				
Wave 2	—	—	0.272 (–0.326 to 0.869)	0.327 (–0.271 to 0.924)
Wave 3	–0.362 (–1.137 to 0.412)	–0.356 (–1.131 to 0.418)	–0.212 (–0.915 to 0.490)	–0.229 (–0.933 to 0.474)
Wave 4	–0.701 (–1.624 to 0.223)	–0.688 (–1.611 to 0.236)	–0.283 (–1.011 to 0.446)	–0.266 (–0.993 to 0.462)
Intercept, OLS estimate (95% CI)	–0.341 (–2.051 to 1.369)	–0.389 (–2.113 to 1.334)	–1.881 (–3.074 to –0.688)**	–1.858 (–3.125 to –0.592)**
N	6,981	6,981	16,311	16,476
R^2	0.01	0.011	0.01	0.009
Adjusted R^2	0.009	0.009	0.009	0.008
Akaike information criterion	60717.2	60718.8	142749.4	144249.9
Bayesian Information Criterion	60806.3	60814.7	142864.9	144373.3
Root mean square error	18.68	18.68	19.22	19.26
F test (*df*)	4.427 (11, 3804)	4.101 (12, 3804)	8.095 (13, 7959)	7.249 (14, 8041)

[a] Ordinary least squares regression model predicting change in perceived breast cancer risk from perceived COVID-19 risk. Columns 1 and 2 include the restricted sample of women (n=6981) who completed 2 adjacent survey waves. Column 1 includes age, race, education, wave as a fixed effect, and perceived COVID-19 risk from the current wave. Column 2 adds the change in general anxiety between the prior wave and baseline. Column 3 adds to the column 1 model the change in general anxiety between the current wave and baseline. Column 4 adds to the column 1 model missed cancer screening in the prior 2 months. Reference categories: age 40-64 years; education: some college or technical school or less; race: White; perceived COVID-19 risk: very low; time: wave 1. Cell entries indicate the ordinary least squares estimate followed by the approximate 95% CI, in brackets, and the *P* value threshold as follows: **P*<.05, ***P*<.01, and ****P*<.001.

[b] OLS: ordinary least squares.

[c] PROMIS4: Patient-Reported Outcomes Measurement Information System 4-item.

[d] Not applicable.

Discussion

Principal Findings and Implications

Prospectively collected information compared with data collected during the COVID-19 pandemic provides insight into the magnitude and direction of the effect of a new risk on the ongoing perception of risk of another clinical condition and general anxiety. This is an unstudied issue that could have broad implications for at-risk individuals who have reason to engage in preventive behavior and are newly confronted by an unrelated threat. This study shows that the perceived risk of COVID-19 is associated with changes in the perceived risk of breast cancer. While it appeared overall that perceived breast cancer risk was unchanged before or after COVID-19, these data hid a clear dose-response relationship with perceived COVID-19 risk ranging from a 2% decrease among those with very low perceived COVID-19 risk to a 3% increase among those with highest perceived COVID-19 risk. This magnitude of change is about half that seen with a breast cancer risk feedback intervention [16]. While the implications of this change in breast cancer risk perception remain to be elucidated, perceived breast cancer risk is linked reliably, albeit not strongly, with early detection and preventive behavior [17,18]. Perceived risk of a potentially threatening condition is a key determinant of health behavior [10,19]. Demonstration that a new threat (eg, COVID-19) alters other health risk perceptions could have implications for disease prevention.

The mechanism by which COVID-19 perceived risk affects breast cancer perceived risk is unclear. Neither increase in anxiety nor missed cancer screening—both hypothesized to relate to the change in breast cancer risk perception—appear to play a role. Risk perception is complex with cognitive and emotional underpinnings [20,21]. Perceived risk of a clinical condition relates to family or genetic factors, salience [22], and anxiety, among others. Factors underlying perceived COVID-19 risk also include availability [23], gender [24], age [25], anxiety [26], and attention to and trust in the media [27]. While information about breast cancer risk and salience should not have been affected by COVID-19, risk perception is also influenced by contextual factors, such as the immediacy of a threat [28], perceived level of control, and fear [29]. These constructs may have affected both perceived COVID-19 risk and breast cancer risk. More exploration is needed into the linkage between change in breast cancer risk perception and COVID-19 risk perception.

This study confirms that COVID-19 was associated with an increase in general anxiety among a large cohort of middle-aged women, the majority of who did not have anxiety at baseline. General anxiety increased by one to two times the minimally important difference in the PROMIS4 measure, depending on perceived COVID-19 risk, and did not change appreciably over the first year of COVID-19. This confirms what a small number of pre– or post–COVID-19 longitudinal studies have found [30-32] and provides insight into the degree of anxiety and relationship to perceived COVID-19 risk.

Limitations

Several factors limit the generalizability of these findings. Data are derived from women in a select age range who enrolled in a trial of breast cancer prevention. There was limited variation in race and education. Younger participants, who sustained greater emotional effects of COVID-19 [33], are not included. Moreover, the levels of change in anxiety and perceived breast cancer risk were modest and we have no preventive behavior data to link with changes in perceived breast cancer risk. Finally, while perceptions of COVID-19 risk are related to the perceived risk of breast cancer in substantively and statistically significant ways, we note that COVID-19 risk perceptions do not explain much of the variation in perceptions of breast cancer risk. This is likely because many things affect a person’s beliefs about their likelihood of being diagnosed with breast cancer and we do not measure all of those things here. While perceptions of COVID-19 risk are but one of many things associated with breast cancer risk perceptions—and do not drive these perceptions as much as other factors not measured here—the link between these 2 outcomes, one longstanding and the other novel, provides some insight into how patients connect disparate health risks.

Conclusions

COVID-19 affected the perceived risk of developing breast cancer. This natural experiment merits experimental replication because the implications for disease prevention are formidable. The effect of a global threat, such as COVID-19, may have broad implications for health beyond the pandemic. These findings suggest that attention to preventive health behaviors will be needed as COVID-19 becomes endemic.

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Data Availability

The data analyzed during this study are not publicly available because the study is ongoing but are available from the corresponding author upon reasonable request.

Authors' Contributions

RB-K participated in the conceptualization of the study and performed statistical analysis and interpretation, and writing of the paper. AN obtained funding, conceptualized the study, interpreted the data, and wrote the paper. TQH participated in the interpretation of data and writing the paper. KS, AS, RR, and LV participated in the conceptualization of the study, interpreted the data, and wrote the paper. AR participated in statistical analysis and interpretation of the data. LS and ASF provided access to data and edited the paper. LE obtained funding, conceptualized the study, interpreted the data, and edited the paper. The Athena Breast Health Network Investigators and Patient Advocates recruited the sample for the study and provided insight into and approved study materials and questionnaires. NW conceptualized the study and analysis, interpreted the data, and drafted the paper. All authors approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Supplementary tables.
[DOCX File , 49 KB - cancer_v10i1e47856_app1.docx]

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Abbreviations

PROMIS: Patient-Reported Outcome Measurement Information System
WISDOM: Women Informed to Screen Depending On Measures of Risk

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Original Paper

Identifying Factors Associated With Heightened Anxiety During Breast Cancer Diagnosis Through the Analysis of Social Media Data on Reddit: Mixed Methods Study

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Abstract

Background: More than 85% of patients report heightened levels of anxiety following breast cancer diagnosis. Anxiety may become amplified during the early stages of breast cancer diagnosis when ambiguity is high. High levels of anxiety can negatively impact patients by reducing their ability to function physically, make decisions, and adhere to treatment plans, with all these elements combined serving to diminish the quality of life.

Objective: This study aimed to use individual social media posts about breast cancer experiences from Reddit (r/breastcancer) to understand the factors associated with breast cancer–related anxiety as individuals move from suspecting to confirming cancer diagnosis.

Methods: We used a mixed method approach by combining natural language processing–based computational methods with descriptive analysis. Our team coded the entire corpus of 2170 unique posts from the r/breastcancer subreddit with respect to key variables, including whether the post was related to prediagnosis, diagnosis, or postdiagnosis concerns. We then used Linguistic Inquiry and Word Count (LIWC) to rank-order the codified posts as low, neutral, or high anxiety. High-anxiety posts were then retained for deep descriptive analysis to identify key themes relative to diagnostic progression.

Results: After several iterations of data analysis and classification through both descriptive and computational methods, we identified a total of 448 high-anxiety posts across the 3 diagnostic categories. Our analyses revealed that individuals experience higher anxiety before a confirmed cancer diagnosis. Analysis of the high-anxiety posts revealed that the factors associated with anxiety differed depending on an individual's stage in the diagnostic process. Prediagnosis anxiety was associated with physical symptoms, cancer-related risk factors, communication, and interpreting medical information. During the diagnosis period, high anxiety was associated with physical symptoms, cancer-related risk factors, communication, and difficulty navigating the health care system. Following diagnosis, high-anxiety posts generally discussed topics related to treatment options, physical symptoms, emotional distress, family, and financial issues.

Conclusions: This study has practical, theoretical, and methodological implications for cancer research. Content analysis reveals several possible drivers of anxiety at each stage (prediagnosis, during diagnosis, and postdiagnosis) and provides key insights into how clinicians can help to alleviate anxiety at all stages of diagnosis. Findings provide insights into cancer-related anxiety as a process beginning before engagement with the health care system: when an individual first notices possible cancer symptoms. Uncertainty around physical symptoms and risk factors suggests the need for increased education and improved access to trained medical staff who can assist patients with questions and concerns during the diagnostic process. Assistance in understanding technical reports, scheduling, and patient-centric clinician behavior may pinpoint opportunities for improved communication between patients and providers.

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KEYWORDS

breast cancer; anxiety; NLP; natural language processing; mixed methods study; cancer diagnosis; social media apps; descriptive analysis; diagnostic progression; patient-centered care

Introduction

Background

In 2020, more than 2.3 million women worldwide were diagnosed with breast cancer, and over 685,000 died from the disease. Every 14 seconds, a woman is diagnosed with breast cancer worldwide, and in the United States, someone is diagnosed every 2 minutes. Breast cancer is the most common cancer diagnosis in 140 of 184 countries worldwide. In the United States, it is the most common cancer after nonmelanoma skin cancer [1,2]. Research has demonstrated that breast cancer diagnosis is associated with an increase in anxiety surrounding self-concept, mortality, cancer recurrence, treatment, and altered body image [3-7]. Furthermore, increased anxiety is associated with impaired physical functioning, reduced quality of life, decision-making ability, delayed return to work, and poor adherence to treatment [8]. Yet, for many, anxiety has its roots much earlier in the process of a cancer diagnosis, specifically when an individual first notices physical changes or risk factors that may represent an increased risk of cancer diagnosis, and for many, this increases stress [8,9]. Researchers have largely acknowledged increased anxiety following diagnosis [10,11], but less research has explored the anxiety associated with suspecting one may have breast cancer [12]. Untreated anxiety increases and amplifies the emotional and physical symptoms of patients with breast cancer. By increasing understanding of the relationship between anxiety and breast cancer, clinicians can provide more advanced interventional care to support better overall patient well-being. Advancing the scientific understanding of the ways that individuals experience anxiety during the different stages of cancer diagnosis, including the very early stages when breast cancer is suspected rather than officially diagnosed, provides an opportunity to support whole-person care. By connecting and cotreating breast cancer diagnostics and elevated anxiety, clinicians are better able to manage the process of adverse health diagnoses with mental health outcomes. Considering the ways these 2 health processes interact allows clinicians to provide appropriate support for an individual's mental health as they proactively seek medical treatment.

Evaluating mental health outcomes like anxiety after an individual suspects disease but before they have received a diagnosis requires specific types of data capable of providing insight into each individual person's dynamic mental and physical health status over a very specific time period related to the diagnosis. Time-varying, individual-level data capable of capturing the linkages between these processes are rarely, if ever, collected in studies of breast cancer and anxiety because it requires information about individuals based only on suspicion of disease rather than a medical diagnosis. The goal of this study is to explore anxiety, with specific attention to potential drivers of anxiety, across the diagnostic continuum during breast cancer diagnosis for people who are in different diagnostic phases. To conduct this research, we designed a unique dataset derived from social media posts, analyzed and interpreted through computational and descriptive methods. We collected data from the Reddit community r/breastcancer. Reddit is a social media platform that focuses on community engagement by offering subcommunities known as "subreddits" of specific areas of interest, like breast cancer. Reddit has over 1 billion registered users, with 47% of active users in the United States [13]. We analyzed all thread-initiating posts from the r/breastcancer subreddit. We began by assessing all posts to determine what stage in the diagnostic process the original poster (OP) is. We then used computational methods to identify posts characterized by a high relative frequency of anxiety-related terms. The "high-anxiety" posts were then retained for descriptive analysis to determine key themes that could provide insight into factors associated with anxiety and to assess whether those topics differ based on the individual's stage in the diagnostic process.

Theoretical Framing

Research has shown that up to 85% of patients with breast cancer experience elevated rates of anxiety related to changes in body image and sexual functioning, new responsibilities regarding treatment and treatment management, personal relationships, and logistical and financial concerns. Lazarus [14] defines stress as a multistage process beginning with assessment and ending with coping strategies. Opton and Lazarus [15] go on to describe the perception and interpretation of stress in several stages, beginning with an assessment of the stress event as an anticipation of harm. This event is then categorized as harmful, benign, or beneficial. According to Lazarus [14], cognitive appraisal of a threat is influenced by personal factors and situational factors. Personal factors include motivation, belief, intelligence resources, education, and knowledge. Situational factors include novelty, predictability, event uncertainty, temporal factors, and ambiguity [14,16]. When coupled with high levels of uncertainty, stress may be experienced as anxiety. Lazarus [14] defines ambiguity as a lack of situational clarity in contrast to uncertainty, which relates to a person's confusion about the meaning of the environmental situation. Ambiguity can intensify a threat by limiting a person's sense of control and increasing a sense of helplessness over the perceived danger. Monat et al [17] link anxiety to uncertainty about the nature of a threat, including the probability and timing of experiencing the threat, as well as an understanding of what can be done about the threat [17,18]. Hilton [19] describes coping resources, according to Folkman et al [20], to include planful problem-solving, confrontation, distancing, self-control, seeking social support, accepting responsibility, escape-avoidance, and positive reappraisal. Our study focuses on the coping strategy of support seeking by a specific breast cancer social media community hosted on the social media platform Reddit.

Anxiety levels can be categorized as "state anxiety," meaning the anxiety is associated with a condition or situation, whereas "trait anxiety" is the propensity to worry and experience fear on a regular basis. Our study focuses on conditions of "state anxiety" related to the suspicion of having breast cancer. A total of 45% of patients reported severe state anxiety in the early stages of breast cancer diagnostics and treatment [9,21,22]. These heightened levels of anxiety can result in a host of adverse mental and physical health outcomes alongside diminished quality of life, potentially negatively impacting both immune response and cognitive functioning [23,24].

While nearly all patients with breast cancer experience some anxiety surrounding diagnosis, research has identified risk factors that have been shown to exacerbate anxiety among patients with breast cancer [4,25]. These risk factors can be divided into four distinct categories: (1) staging and cancer progression, (2) mental health history, (3) physical symptoms, and (4) patient (demographic) characteristics. Research on "staging and cancer progression" shows higher levels of anxiety for individuals diagnosed with metastatic breast cancer [25,26], while "mental health predictors" include a prediagnosis history of diagnosed anxiety or depression [3,25,27-30] or a precancer history of diagnosed personality disorder [27]. "Physical symptoms," including pain, fatigue, insomnia, digestive disorders, and mobility issues, were associated with elevated anxiety levels during treatment and up to 12 months following treatment completion [5,10,31]. Patient or demographic characteristics, including age and race, were also shown to influence anxiety levels both directly and indirectly [28,31-35].

The preponderance of research on breast cancer–related anxiety has focused on anxiety following cancer diagnosis. This postdiagnosis focus encourages a unilateral conceptualization of anxiety. Specifically, unlike trait anxiety, state anxiety is a transitory emotional state that depends on a host of context-level factors [36]. These context-level factors change as an individual moves from suspecting to confirming breast cancer diagnosis. These changes are associated with disruption and ambiguity and lead to heightened levels of anxiety [37]. More to the point, evidence suggests that cancer-related anxiety does not emerge at the time of diagnosis [12]. For example, Lerman et al [38] showed spikes in cancer-related anxiety associated with abnormal and potentially problematic breast cancer screenings. Furthermore, research exists to support the notion that not only do cancer-related anxieties first emerge before cancer diagnosis, but those anxieties may diminish in the aftermath of a confirmed diagnosis [39]. Taken together, these studies suggest that anxiety has roots much earlier in the diagnostic process and evolves as patients encounter new challenges and gather new information.

Breast Cancer–Related Anxiety and Social Media Support

We collected data from Reddit, a virtual space where many users find support through sharing their testimonials and asking for advice. Social support has been shown to be an effective tool to help people cope with anxiety. The transfer of advice, resources, and information in response to a stressor has been shown to reduce anxiety and to buffer against the deleterious effects of stress through a variety of mechanisms and in a variety of contexts (for a broader discussion, see, eg, [40-43]). Despite this, changes in support needs often coincide with moments of limited support availability [44]. In light of this, many individuals have turned to breast cancer support networks created and maintained online. Often associated with benefits similar to those of face-to-face social support exchange, computer-mediated social support, like that potentially offered through Reddit, offers notable advantages in the transmission of social support, including anonymity [45], improved congruence between the nature of support sought and support received [46], reduced communication barriers [47], and increased agency in support seeking [48].

Support seeking in the context of online communities provides unique data opportunities for using automated text processing methods to measure the relative levels of anxiety among individuals at different stages of their breast cancer diagnosis journey and to identify high anxiety posts for subsequent descriptive analysis. Combining descriptive and computational methods, this study reconstructs a diagnostic timeline to examine the evolution of anxiety beginning when an individual first suspects breast cancer. We then use descriptive analysis to identify factors associated with anxiety and how those factors shift before, during, and following a cancer diagnosis. Our mixed methods, computational-descriptive analysis is designed to identify possible factors associated with anxiety among individuals suspecting breast cancer and to observe how those factors evolve through the diagnostic and treatment processes.

Methods

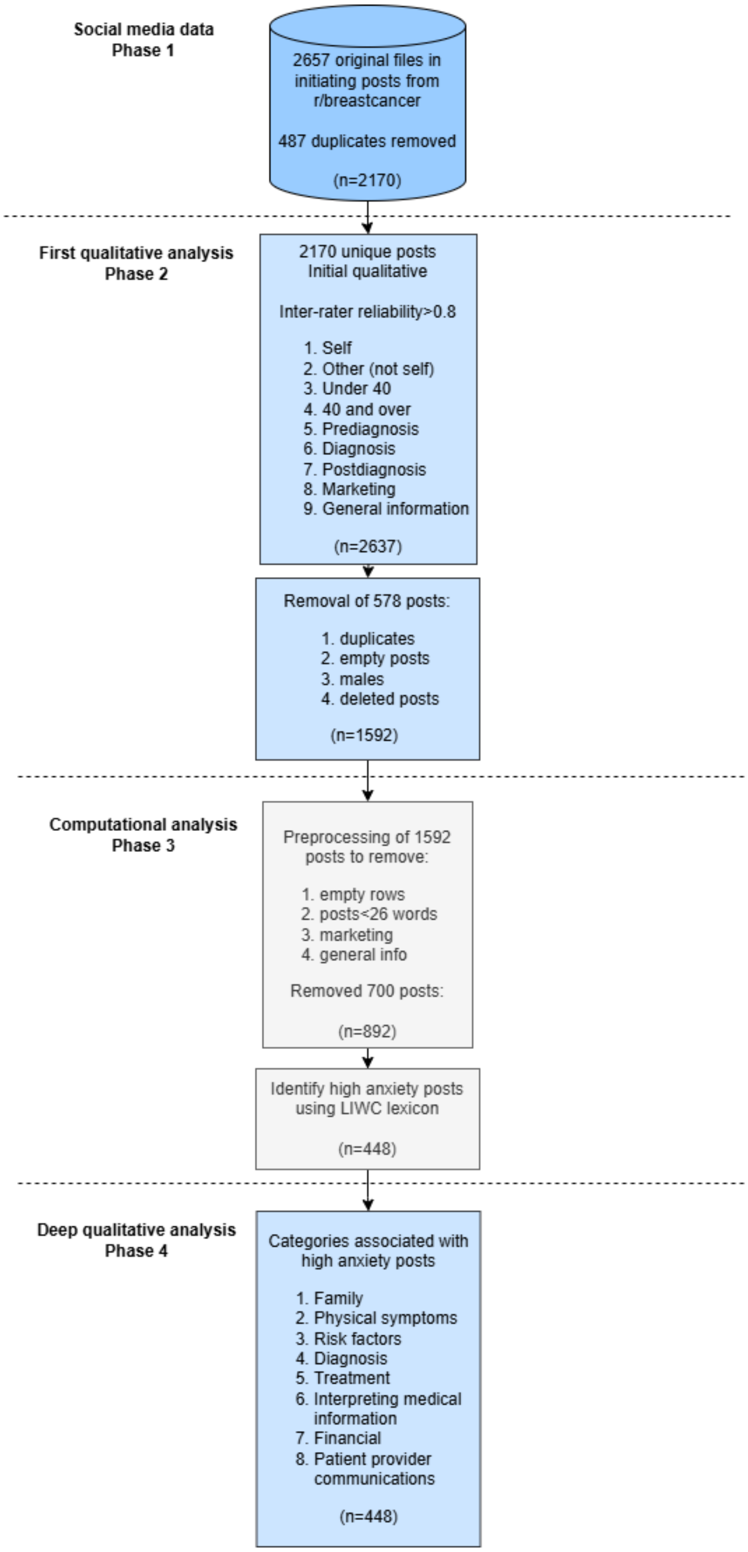
Overview

The objective of this study was to identify potential contributors to high levels of anxiety among individuals suspecting breast cancer. Relying on Reddit's broad and diverse user base, we extracted breast cancer and anxiety data from the r/breastcancer subreddit, a community for individuals who suspect or have been diagnosed with breast cancer (or are supporting someone who has).

We approached this objective using a mixed methods analysis consisting of three phases: (1) exploratory analysis for codification and categorization of cancer-related posts into broad categories; (2) computational analysis of linguistic markers of elevated anxiety and identification of original posts characterized by high levels of anxiety; and (3) descriptive analysis for the evaluation of statistical differences in anxiety levels between categories, analysis of original posts for both principal causes of anxiety, as well as the evolution of those anxieties over time [49-51].

Our study focused only on high levels of "state anxiety" for different people who were in various diagnostic phases for breast cancer. State anxiety is defined as a transient state of arousal subjectively experienced as anxiety. It is a momentary emotional condition characterized by subjective feelings of apprehension and tension [21,22,52]. The analysis procedures and associated phases are depicted in Figure 1, and each phase is discussed in greater detail below (more details are provided in Multimedia Appendix 1).

Figure 1. Multiphase analytic approach. IRR: interrater reliability; LIWC: Linguistic Inquiry and Word Count.



Exploratory Analysis and Classification

Given our interest in anxiety and its associated factors, we focused on initiating posts or posts that propose a topic or question to which users can respond. Using the PushShift application programming interface (API), we collected all initiating posts from Reddit's r/breastcancer subreddit. This yielded a total dataset of 2170 posts. Authors JM, JP, and MC evaluated all posts independently following a bottom-up coding technique, identifying broad content classifications that had the potential to influence the degree and nature of anxiety expressed in the online posts. Authors then met weekly to consolidate and collapse categories.

Bottom-up inductive analysis revealed three dimensions with the potential to influence the degree and cause of individuals' anxiety: (1) whether an individual had a confirmed breast cancer diagnosis, (2) the age of the user, and (3) whether an individual was posting about their own or another person's cancer diagnosis. In addition, 2 subsequent categories also emerged with considerable overlap between them: general information posts and advertisements. General information posts were posts that included general information about breast cancer, cancer treatment, or risk factors; advertisements included any solicitation of cancer patients for products and services and participation in scientific studies. General information and advertisement posts were often generated by bots or individuals other than those suspecting breast cancer; thus, these posts were excluded from final tabulation and analysis. In all, 1592 posts were retained for analysis.

The final coding classification scheme had nine dichotomous categories: (1) identification of breast cancer risk (prediagnosis), (2) engagement with medical practitioners to confirm breast cancer diagnosis (diagnosis), (3) confirmed breast cancer diagnosis (postdiagnosis), (4) aged younger than 40 years (under 40), (5) aged 40 years and older (40 and over), (6) posting about own breast cancer (self), (7) posting about another's breast cancer (other), (8) general information about breast cancer, and (9) advertisements. After removing all posts for general information and advertisements, we retained 7 final classification categories, as shown in Table 1.

Table 1. Initial classification of Reddit posts.

Category	Variable type	Description
Self	y/n[a]	OP[b] discusses own cancer risk or diagnosis.
Other	y/n	OP discusses someone else's cancer risk or diagnosis.
Under 40	y/n	OP reported age younger than 40 years.
40 and over	y/n	OP reported age 40 years and older or did not report age.
Prediagnosis	y/n	Post refers to events or concerns that occur before seeking medical attention.
Diagnosis	y/n	Post refers to concerns during or resulting from engagement with the medical system while seeking out a diagnosis.
Postdiagnosis	y/n	Post refers to events or concerns following formal diagnosis.

[a] y/n: yes/no.

[b] OP: original poster.

To quantify the agreement between coders, we used Cohen κ. After 3 rounds of annotation (coders MC, JP, and JM), we achieved an agreement score of 0.81. Cohen κ>0.7 is generally considered an acceptable agreement [53].

Computational Analysis Using Natural Language Processing

The data were first classified into the coding categories described above (self, other, age, etc), and we excluded posts that were duplicates, empty posts, and deleted posts. Following this, we used an automated text analytics method to assign an anxiety score to all 1592 posts (ie, a score that indicates the extent to which a particular comment exhibited anxiety). To achieve this, we used lexicons derived from the Linguistic Inquiry and Word Count (LIWC) 2007 lexicon [54,55], a widely used resource [56-58] that automatically quantifies the presence of salient psychological categories from the text (eg, positive affect, negative affect, cognitive processes, perceptual processes, and swearing).

In the context of social media analysis, LIWC lexicons have been used extensively to study the emotional and cognitive consequences of various scenarios, including (1) romantic breakup [59], (2) studying expressions of loneliness [60], and most salient to our current research question, (3) to study emotional expression in cancer survivors [61]. A key feature of LIWC that makes it well suited to our goal is the fact that "anxiety" is among the 63 psychological dimensions encoded in LIWC. The "anxiety" category consists of 91 terms (eg, alarm*, asham*, and uneas*) that can be used to quantify the extent to which a given text exhibits anxiety. Note that the asterisk is a wildcard that allows the pattern to match relevant derivational and inflectional morphemes (eg, the pattern alarm* will match "alarm," "alarmed," and "alarming").

We used the LIWC anxiety lexicon in conjunction with the Python text-processing library, the Natural Language Toolkit [62]. We used the Natural Language Toolkit to first tokenize each comment into its constituent word tokens, then (programmatically) counted the number of words in each post that matched a term in the LIWC anxiety lexicon. We excluded posts relating to marketing and general discussion of breast cancer issues, as in this research, we are primarily interested in the lived experience of Reddit users experiencing breast cancer. From our starting point of 1592 posts, these preprocessing steps led to a final dataset of 892 posts.

We calculated anxiety scores to distinguish high-anxiety posts from low-anxiety posts. Anxiety scores were determined by first calculating the normalized frequency of LIWC anxiety terms per post expressed as a percentage. This approach accounts for the fact that posts varied in length. Next, we calculated the median percentage across the 892 posts and then converted the percentage to an ordinal variable (ie, 0 [None]=no LIWC terms; 1 [Low anxiety]=percentage>0 but less than the median percentage; and 2 [High anxiety]=percentage≥median value). Table 2 shows frequency counts for each category.

Table 2. Ordinal values.

Breakdown of ordinal variables	Score	Count, n
No anxiety	0	336
Low anxiety	1	108
High anxiety	2	448

Descriptive Analysis of High-Anxiety Post Themes

The computational analysis and codification described in step 2 began with the analysis of 1592 posts. We removed 578 posts due to duplicates, empty posts, and deleted posts, which yielded a subset of 892 posts. Out of those, 448 posts were categorized as high-anxiety posts across (1) diagnostic stage, (2) patient age, and (3) self versus other. To account for multiple categorizations for a single post, we created 3 separate datasets for prediagnosis concerns, concerns surrounding diagnosis and care engagement, and concerns that emerged after a confirmed breast cancer diagnosis.

Posts were again analyzed using a bottom-up, constant comparison approach. Authors JM and JP immersed themselves in the datasets to identify what social media data reveals about the sources of anxieties among individuals suspecting breast cancer, along with factors that may exacerbate cancer-related anxiety, and how those anxieties may evolve between an individual’s discovery of cancer risk, through testing to eventual diagnosis.

Authors JM and JP independently coded 50 posts from each of the 3 datasets and met weekly to identify emerging categorical themes with the goal of identifying the array of themes that captured the largest number of original posts across all 3 of the datasets. Once the authors had completed the original coding of the first 150 posts, we met to consolidate and collapse themes. The final list of categorical themes is presented in the *Results* section.

Once the final list of anxiety categories had been established, authors JM and JP divided the remaining 448 posts between them, and each researcher independently evaluated each post. Mentions of each of the anxiety types were tabulated to track the frequency of each within and between each of the diagnostic stages: prediagnosis, diagnosis, and postdiagnosis. The authors also conducted a close reading to identify factors that may exacerbate anxiety or how anxiety is likely to evolve over time. Results of the computational analysis, tabulation, and descriptive analyses are presented in text and table form in the *Results* section.

Ethical Considerations

This study involved a secondary analysis of publicly available data posted on social media. All data used in this study were anonymized and aggregated. An ethics review was not sought due to the public nature of the data, along with the absence of identifying information for the person creating the social media post. Informed consent was not required as each participant voluntarily posted their data in a public forum on social media. No compensation was offered (more details are provided in Multimedia Appendix 2).

Results

Our cross-sectional analysis of anxiety among individuals suspecting breast cancer as they move from suspecting to screening for and eventually confirming a breast cancer diagnosis consisted of a three-phase analysis plan: (1) classification, (2) computational analysis of linguistic markers, and (3) deep detailed descriptive analysis of anxiety in social media posts. Results are organized according to these methods.

Classification

Our first-round classification of the entire r/breastcancer subreddit (ie, 1592 original initiating posts) yielded three principal classification categories: (1) an individual’s stage in the diagnostic process (ie, prediagnosis, diagnosis, or postdiagnosis), (2) an individual’s age (ie, 40 and over or under 40), and (3) whether the post related to the poster’s own cancer experience or that of a loved one. Tabulations can be found in Table 3.

Table 3. Principle classification categories.

Principle classification categories and subcategories	Posts, n
Diagnostic stage	
Prediagnosis	235
Diagnosis	185
Postdiagnosis	352
Patient age	
Under 40	298
40 and over	594
Person	
Self	539
Other	353

Computational Analysis

Out of the 892 initiating posts that remained after the preprocessing steps in phase 3, shown in Figure 1, a total of 336 posts were classified as having no evidence of anxiety, 108 were classified as low anxiety, and the remaining 448 were classified as high anxiety. Posts varied in length with a mean number of words of 193 (SD 155; median 152, range 26-1766). Our analysis (more details are provided in Multimedia Appendix 1) revealed that anxiety was substantially higher for younger individuals, individuals posting about their own cancer diagnosis, and individuals in the prediagnosis and screening phases of cancer diagnosis. More detailed descriptive statistics are shown in Table 4.

Table 4. Descriptive statistics.

Category	Posts (n=892), n (%)	Median anxiety score	Most common anxiety terms
All	892 (100)	2 (high anxiety)	Worried, scared, risk, worry, and anxiety
Under 40	298 (33.4)	2 (high anxiety)	Worried, scared, risk, worry, and anxiety
40 and over	594 (66.6)	1 (low anxiety)	Worried, scared, risk, anxiety, and worry
Self	539 (60.4)	2 (high anxiety)	Worried, scared, risk, anxiety, and worry
Other	284 (31.8)	1 (low anxiety)	Worried, scared, worry, afraid, and fear
Prediagnosis	235 (26.3)	2 (high anxiety)	Scared, worried, risk, anxiety, and worried
Diagnosis	185 (20.7)	2 (high anxiety)	Scared, worried, worry, anxiety, and nervous
Postdiagnosis	352 (39.5)	1 (low anxiety)	Worried, scared, risk, anxiety, and worry

Descriptive Analysis of High-Anxiety Post Themes

General inductive analysis revealed 9 themes associated with high-anxiety posts (Table 5). While research on cancer and anxiety has typically focused on the stresses faced by patients with breast cancer following diagnosis, our results provide compelling evidence that not only does anxiety have its roots much earlier in the diagnostic process, but that anxiety manifests differently based on whether an individual is first discovering breast cancer risk, engaging with the medical system, or have already received a formal breast cancer diagnosis. Our findings also suggest that those risks may change as individuals move from one diagnostic group to the next.

General inductive analysis revealed 9 key themes (more details are shown in Table 5). Themes centered around (1) family concerns, (2) physical symptoms, (3) risk factors, (4) diagnosis, (5) treatment, (6) interpreting medical information, (7) financial, (8) patient-provider communication, and (9) emotional distress.

Table 5. Categorical themes from high-anxiety posts.

Anxiety theme	Definition
Family	Refers to the impact of potential diagnosis on children or family, preparation for life after diagnosis or after cancer, communicating diagnosis, or health concerns
Physical symptoms	Physical symptoms concerns indicating cancer, cancer type, or gravity
Risk factors	Concerns regarding family history, lifestyle, genetic predisposition, or carcinogenic exposure
Diagnosis	Issues with diagnosis, missed diagnosis, persistent symptoms, or inconclusive initial test results
Treatment	Questions regarding treatment, treatment decisions, or side effects
Interpreting medical information	Anxiety resulting from online research and Google searches; difficulty in understanding or interpreting medical reports or lab reports; and interpreting clinician behavior
Financial	Concerns regarding insurance, treatment costs, or costs of tests; job-related issues
Patient-provider communication	Confusion or anxiety resulting from engagement with health care staff and clinicians
Emotional distress	Difficulty in managing emotions; fear that emotions were interfering with daily functioning or thinking clearly

Characteristics of the 3 phases (prediagnosis, diagnosis, postdiagnosis) are listed in Tables 6-8 below. The tables show a clear evolution of cancer concerns. Prediagnosis concerns across age categories (40 and over) tended to focus primarily on physical symptoms and risk factors. Notably, 65 (83%) of the 78 self and under-40 posts included mention of physical symptoms, while 44 (83%) of the 53 self and 40-and-over posts included mention of changes in physical symptoms. A substantial number of posts also focused on health care engagement. Health care engagement posts often included requests for information about how, when, and from whom to seek care for marked physical changes.

Table 6. Prediagnosis data.

Anxiety-related categories	Prediagnosis			
	Self (n=131)		Other (n=14)	
	Under 40 (n=78), n (%)	40 and over (n=53), n (%)	Under 40 (n=78), n (%)	40 and over (n=53), n (%)
Family	3 (4)	4 (8)	0	0
Physical symptoms	65 (83)	44 (83)	3	7
Risk factors	30 (38)	22 (42)	1	3
Diagnosis	2 (3)	3 (6)	2	5
Treatment	3 (4)	3 (6)	0	1
Interpreting medical information	7 (9)	4 (8)	1	4
Financial	2 (3)	3 (6)	0	0
Patient-provider communication	12 (15)	4 (8)	1	3
Emotional distress	5 (6)	3 (6)	2	0

Table 7. Diagnosis data.

Anxiety-related categories	Diagnosis			
	Self (n=92)		Other (n=12)	
	Under 40 (n=48), n (%)	40 and over (n=44), n (%)	Under 40 (n=4), n (%)	40 and over (n=8), n (%)
Family	6 (13)	0 (0)	0 (0)	0 (0)
Physical symptoms	42 (88)	29 (66)	4 (100)	6 (75)
Risk factors	20 (42)	7 (16)	2 (50)	1 (13)
Diagnosis	9 (19)	9 (20)	2 (50)	1 (13)
Treatment	1 (2)	1 (2)	1 (25)	2 (25)
Interpreting medical information	19 (40)	5 (11)	0 (0)	1 (13)
Financial	4 (8)	2 (5)	0 (0)	0 (0)
Patient-provider communication	15 (31)	16 (36)	0 (0)	0 (0)
Emotional distress	4 (8)	3 (7)	0 (0)	0 (0)

Table 8. Postdiagnosis data.

Anxiety-related categories	Postdiagnosis			
	Self (n=70)		Other (n=14)	
	Under 40 (n=29), n (%)	40 and over (n=41), n (%)	Under 40 (n=4), n (%)	40 and over (n=10), n (%)
Family	14 (48)	8 (20)	0 (0)	0 (0)
Physical symptoms	5 (17)	12 (29)	3 (75)	7 (70)
Risk factors	4 (14)	4 (10)	1 (25)	3 (30)
Diagnosis	3 (10)	6 (15)	2 (50)	5 (50)
Treatment	14 (48)	24 (59)	0 (0)	1 (10)
Interpreting medical information	3 (10)	2 (5)	1 (25)	4 (40)
Financial	1 (3)	3 (7)	0 (0)	0 (0)
Patient-provider communication	1 (3)	5 (12)	1 (25)	3 (30)
Emotional distress	4 (14)	8 (20)	2 (50)	0 (0)

Moving from Table 6 to Table 7, the incidence of physical symptoms and risk-related anxiety remains very high. However, a closer read of the post content reveals that physical symptoms or risk factor discussions tended to present physical symptoms and risk factors primarily as a backdrop to more specific questions about treatment, financial distress, or issues with the health care engagement process.

During the diagnostic process, individuals tended to report more anxieties stemming from either patient-provider communication or interpreting medical information. Anxiety stemming from patient-provider communication frequently resulted from individuals’ own attempts to reduce ambiguity by gleaning additional information from clinician behaviors. Posters noted specific instances where technicians interrupted screenings and left the room. Posters also reported being contacted by clinic staff to move up an appointment date. When clinicians did not provide additional information, posters often interpreted these behaviors as indicating a potential problem.

“Interpreting medical information” might include instances where individuals were unable to decipher complex medical reports or cases in which individuals took to the internet to research their own symptoms. In one instance, an adolescent posted that he needed help translating a medical report for an English language–learning parent who had been provided screening results in English.

There are several notable changes in content themes in the postdiagnosis table (Table 8). Following diagnosis, individuals were significantly less likely to report physical changes and risk factors, which were dominant themes in the prediagnosis and diagnosis tables. Rather, anxious posts about an individual’s own cancer tended to focus on issues related to treatment, most notably in the under-40 group. These individuals were often seeking advice from individuals who had been through cancer diagnosis and treatment and could provide insights related to cancer treatment, treatment side effects, or reconstructive surgery.

Another marked shift that occurred in the postdiagnosis table was a shift in the proportion of posts about one’s own cancer. In the prediagnosis and diagnosis datasets, most of the high-anxiety posts were from individuals suspecting they may have breast cancer. These were individuals who were, themselves, seeking a breast cancer diagnosis (14/145, 10% of prediagnosis posts and 12/104, 12% of diagnosis posts). The postdiagnosis group was characterized by a significantly larger proportion of high-anxiety posts originating from someone other than the person with breast cancer (85/155, 55% of posts).

Discussion

Principal Findings

Many patients experience the highest levels of anxiety during the early stages of investigating a possible breast cancer diagnosis before a confirmed diagnosis. When diagnostic uncertainty is high, some patients seek information and communication through social media channels and online patient education sites. Our study found 9 categories associated with elevated anxiety levels with suspected breast cancer. These categories include family, physical symptoms, risk factors, diagnosis, treatment, interpreting medical information, financial, patient and provider communications, and emotional distress. We found categories of concern shifted by age (under 40 and 40 and over) across the diagnostic stages. In the prediagnostic stage, both age categories showed physical symptoms and risk factors associated with high anxiety. For patients younger than 40 years of age, patient-provider communication gaps and interpreting medical information contributed to frustration and associated anxiety. In the diagnostic stage, both age categories showed physical symptoms, and patient-provider communications were associated with high anxiety. For patients younger than 40 years of age, risk factors and interpreting medical information were associated with high anxiety in the diagnostic stage. In the postdiagnostic stage, we found a marked shift by age category in the factors associated with anxiety. Patients younger than 40 years of age showed high anxiety associated with family, while patients aged 40 years and older showed high anxiety associated with physical symptoms, emotional distress, and breast cancer in others close to them. Both age categories showed high anxiety associated with treatment.

Our deeper analysis of the content also revealed high levels of anxiety associated with navigating and engaging the health care system and financial matters. Patients experience increasing anxiety associated with understanding and interpreting the early physical symptoms associated with breast cancer and the anticipated course of diagnostic events. These gaps included a lack of empathy and confusing or limited medical information. Social support structures appeared as a high priority for people experiencing possible breast cancer diagnosis for themselves and the people close to them.

Our descriptive content analysis and post tabulations provide key insights into how anxiety manifests in each of the diagnostic phases: prediagnosis, diagnosis, and postdiagnosis. Notably, our results indicate a need for additional public information regarding early breast cancer warning signs. Many of the high-anxiety prediagnosis posts were associated with changes in physical symptoms or identification of new family or behavioral risk factors. Nearly all users participated in the breast cancer subreddit community to assess their likelihood of a breast cancer diagnosis based on the physical symptoms and risk factors they identified in their original post. Several sought advice about whether the physical symptoms they described merited medical attention, cancer screenings, or where to seek treatment. Others who discovered risk factors were unclear about what should be done once they became aware of a high likelihood of a subsequent cancer diagnosis.

Results also pointed to the potential for improvements in patient-provider communication. For example, in addition to direct reports of feeling mistreated or dismissed by clinic staff, informational ambiguity emerged as a factor associated with elevated anxiety. High-anxiety posts were often related to difficulties understanding complex medical reports or understanding clinic or clinician behaviors (eg, leaving appointments midscreening to find an oncologist, scheduling follow-up appointments, or even moving previously scheduled appointments). Furthermore, many individuals used websites like WebMD or Google to try to understand medical reports, physical symptoms, risk factors, or the behavior of their clinician or clinical staff, but results of independent and unguided searches often contributed to individuals' anxiety and ended up reported in patient posts as associated with anxiety.

Numerical and descriptive results are also highly suggestive that anxiety be viewed as a process and that the risk of high anxiety is actually higher before breast cancer is diagnosed. While we looked at a cross-section of data between individuals, our results show a clear evolution in the primary factors associated with anxiety based on an individual's staging within the diagnostic process.

There was also a marked shift in the postdiagnosis table. In the prediagnosis and diagnosis groups, most of the original posters were individuals who were concerned about their own cancer. In the postdiagnosis table, over half of the posts came from individuals worried about the possible diagnosis of a close friend or family member. This shift may highlight the need for additional formal support structures for friends and family of cancer patients. The corresponding drop in the number of posts from patients with cancer may be an artifact of the more formal structures in place to provide support to individuals as they cope with treatment decisions, including social workers, nurses, and practitioners, as well as websites such as PatientsLikeMe.com. These structures and friendships may not be in place for individuals coping with the breast cancer of a loved one. The subreddit sites may provide invaluable secondary support. However, they may also signal the need for more formal networks of support and support groups for individuals providing care and support to a patient with cancer.

Comparison to Previous Work

Our study findings are consistent with previous research results for studies focused on breast cancer and anxiety. These studies consistently report anxiety to be highest during the early stages of diagnosis when uncertainty is high, and the diagnosis may be undermined. Furthermore, uncertainty is associated with increased stress, which can translate to anxiety for some people [4,8-10,12,34,39,63-65]. We are not aware of other research studies that study the factors associated with high anxiety by age brackets across the diagnostic stages.

Strengths and Limitations

By looking at individuals in different phases of the diagnostic process, we were able to obtain a good sense of what the evolution of stress might look like as individuals move from suspicion to confirmation of breast cancer. This approach may be advantageous in that our dataset includes the concerns of individuals who are ultimately not diagnosed with cancer.

First, our study does not include longitudinal data and, therefore, can only suggest a possible evolutionary trajectory associated with anxiety. The cross-sectional nature of the data does not allow for the study of self-reported experiences of state anxiety throughout the diagnostic phases for each patient.

Second, the data used in this study are not broadly representative of patients with breast cancer due to the source of the data, which is a social media forum. Contributors to health-related discussion platforms are estimated to represent only a small proportion of overall users. In a study of 63,990 social media users, van Mierlo [66] found that 90% of users were silent observers or “lurkers” rather than active participants [66]. In addition, 9% of users contributed sparingly, and only 1% were actively engaged in online dialogue. We estimate some derivative of these ratios translates to the r/breastcancer subreddit, thus limiting representation of the full range of views in this community.

Third, this study identified factors associated with elevated levels of anxiety related to suspected breast cancer. However, these associations do not provide evidence of causation for elevated anxiety. Consequently, the results of our findings may lead to inaccurate conclusions, including spurious correlations.

Future Directions

Future studies could focus on longitudinal data associated with individual patients to understand the transient nature of state anxiety for individuals. Furthermore, experimental studies with informational interventions provided early in the diagnostic process could elucidate measurable effect data, which could guide future patient education and support tools aimed at reducing anxiety. More studies using new modalities, such as digital health interventions, could advance the research base for targeted and scalable patient information tools.

Conclusions

The significance of this study is the identification of factors associated with high anxiety during the earliest stages of breast cancer diagnosis. The findings have been categorized by age and whether the expressed anxiety was related to self or another person (other). These categories can be used for individualized, targeted interventions to manage high-anxiety levels associated with breast cancer. Our findings in this study suggest that early intervention for anxiety during the breast cancer diagnostic process may help patients cope with high levels of anxiety found in the early and midstages of breast cancer diagnosis. Diagnostic delays and associated uncertainty appear to amplify breast cancer–related anxiety, indicating that communicating early and often is important. Access to medically sound information is critical since patients are using the internet and social communities to gather information and advice. While online communities offer immediate access to information, they can serve as a source of misinformation, which may exacerbate anxiety unnecessarily.

Implications for Cancer Survivors

The findings of this study suggest that improving access and awareness around breast cancer information, peer coping communities, health coaching, and forward contingency planning would benefit patients who have high levels of anxiety related to breast cancer diagnosis. Focusing on person-centered care to include psychosocial support systems when people are coping with the possibility of breast cancer is expected to improve the anxiety associated with breast cancer investigation and diagnosis.

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Data Availability

The datasets generated during and/or analyzed during this study are not publicly available to ensure the privacy of the Reddit breast cancer community members is maintained but are available from the corresponding author on reasonable request.

Authors' Contributions

JP and JM wrote the original draft for the manuscript and created Tables 1-8. JP created Figure 1 and led project administration. MC conducted all data curation, text analytics, and computational analyses. MC and JM conceptualized the research and recommended the research methodology. JP, JM, MC, and KG reviewed and edited the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Descriptive and comparative statistics.
[DOCX File , 17 KB - cancer_v10i1e52551_app1.docx]

Multimedia Appendix 2
Institutional policy on ethics review.
[PDF File (Adobe PDF File), 166 KB - cancer_v10i1e52551_app2.pdf]

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Abbreviations

API: application programming interface
LIWC: Linguistic Inquiry and Word Count
OP: original poster

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Correlation Between Electronic Patient-Reported Outcomes and Biological Markers of Key Parameters in Acute Radiation Cystitis Among Patients With Prostate Cancer (RABBIO): Prospective Observational Study

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Abstract

Background: Despite advances in radiation techniques, radiation cystitis (RC) remains a significant cause of morbidity from pelvic radiotherapy, which may affect patients' quality of life (QoL). The pathophysiology of RC is not well understood, which limits the development of effective treatments.

Objective: The Radiotoxicity Bladder Biomarkers study aims to investigate the correlation between blood and urinary biomarkers and the intensity of acute RC symptoms and QoL in patients undergoing localized prostate cancer radiotherapy.

Methods: This study included patients with low- or intermediate-risk localized prostate cancer who were eligible for localized radiotherapy. Blood and urinary biomarkers were analyzed before radiotherapy was initiated and at weeks 4 and 12 of radiation therapy. Patients completed questionnaires related to RC symptoms and QoL (International Prostate Symptom Score and Functional Assessment of Cancer Therapy-Prostate [FACT-P]) using a digital remote monitoring platform. The information was processed by means of an algorithm, which classified patients according to the severity of symptoms and adverse events reported. Levels of blood and urinary biomarkers were tested with the severity of acute RC symptoms and patient-reported QoL.

Results: A total of 401 adverse events questionnaires were collected over the duration of this study from 20 patients. The most frequently reported adverse events at week 4 were pollakiuria, constipation, and diarrhea. In comparison with baseline, the mean FACT-P score decreased at week 4. A significant increase in the proportion of M2 phenotype cells (CD206+, CD163+, CD204+) at W12 compared to W0 was observed. An increase in serum and urine levels of macrophage colony-stimulating factor (M-CSF), hepatocyte growth factor, and macrophagic inflammatory protein was observed at week 12 compared to baseline levels. Baseline serum and urine M-CSF concentrations showed a significant negative correlation with FACT-P scores at weeks 4 and 12 ($r=-0.65$, $P=.04$, and $r=-0.76$, $P=.02$, respectively).

Conclusions: The Radiotoxicity Bladder Biomarkers study is the first to explore the overexpression of inflammatory proteins in blood and urine of patients with symptoms of acute RC. These preliminary findings suggest that serum and urine levels of hepatocyte growth factor, M-CSF, and macrophagic inflammatory protein, as well as macrophage polarization, are mobilized after prostate radiotherapy. The elevated M-CSF levels in serum and urine at baseline were associated with the deterioration of

QoL during radiotherapy. The results of this study may help to develop mitigation strategies to limit radiation damage to the bladder.

Trial Registration: ClinicalTrials.gov NCT05246774; https://clinicaltrials.gov/study/NCT05246774

(JMIR Cancer 2024;10:e48225) doi:10.2196/48225

KEYWORDS

prostate cancer; acute radiation cystitis; e-PRO; quality of life; biomarkers; electronic patient-reported outcome

Introduction

Prostate cancer is the most commonly diagnosed cancer among men in France, with 50,400 new cases and 8100 deaths in 2018 [1]. Between 2010 and 2018, improved diagnostic strategies and therapeutic management led to a 3.7% reduction in mortality while the survival rate has increased to 93% at 5 years and 80% at 10 years [1,2]. However, treatment-related adverse events can be serious and have an impact on compliance with treatment, frequency of hospitalization, and associated costs, as well as on patients' quality of life (QoL) [3].

Radiation therapy (including conventional radiation therapy, stereotactic body radiation therapy, and brachytherapy) is an important therapeutic technique in the management of pelvic cancers, including prostate cancer [4-9]. Despite improvements in radiation techniques, pelvic radiotherapy is nonetheless associated with potential acute and late adverse events involving the bladder, which are collectively described referred to as radiation cystitis (RC). Though most treatment-related urinary events occurring after radiotherapy are of low grade, some patients may still present with severe symptoms of RC [10].

Early symptoms of RC include those which occur during treatment and up to 3 months after the cessation of radiotherapy, with an estimated all-grade incidence of nearly 50% after pelvic irradiation [10]. These side effects are characterized by frequent and urgent urination day and night, irritative symptoms, or pain. Obstructive symptoms or less hematuria may also be present [11]. In 5% to 10% of cases, complications appear later, more than 6 months after radiotherapy, whether or not they were preceded by early signs [10,12,13]. Such late-onset adverse events involve blood vessel damage and fibrosis of the bladder wall, which may progress chronically and lead to bladder atrophy and even retraction in the most extreme cases [10]. The clinical signs vary depending on the dominant clinical form: cystalgia, pollakiuria, bladder hyperactivity, or isolated mictional disorders. Classic clinical features dominate with recurrent and abundant hematuria, of variable frequency, which may even result in urinary retention with bladder clotting. The chronic and recurrent nature of hemorrhagic cystitis often has a considerable impact on patients' QoL. The most severe forms, with clot formation and acute urinary retention, can be life threatening [10,13].

Immunity plays an important role in radiation-induced toxicity or inflammation [14,15]. During the repair process of radiation-induced injuries, inflammatory cells (macrophages, neutrophils, or lymphocytes) are recruited to the site of injury. Late inflammatory tissue diseases may develop through a continuous mechanism involving inflammation, hypoxia, and fibrosis [16]. The balance between M1 and M2 macrophages plays a central role in the fibrotic process, with a polarization toward M1 macrophages [17,18]. Moreover, functional tests measuring the apoptosis of CD4+ and CD8+ T lymphocytes after irradiation have demonstrated a significant association between these apoptotic lymphocytes and the risk of occurrence of late genitourinary toxicity [19].

The characteristics of interstitial cystitis are similar to RC both in terms of collagen accumulation and symptoms. Patients with interstitial cystitis have very severe genitourinary pain, and many are diagnosed as depressed and anxious. A positive correlation has been reported between elevated proinflammatory cytokines (IL-4 and macrophage-derived chemokines) in urine and the severity of interstitial cystitis [20,21].

The pathophysiology of RC thus remains poorly studied and not well understood. A number of factors have been identified, such as the dose of radiation, fractionation, and comorbidities (diabetes or tobacco smoking), but the risks of complications arising from access to bladder tissue postirradiation limits our knowledge and ability to develop therapies targeting this process [22,23]. It is essential to gain a better understanding of RC from the acute phase onward. This would help ensure the antitumor therapeutic efficacy of irradiation while minimizing undesirable effects on healthy tissue, particularly in the bladder. The identification of serum and urine biomarkers linked to RC is essential in order to characterize the kinetics of RC onset and predict the toxic effects of irradiation. This clinical trial thus aims to combine patient-related outcomes on adverse events and QoL following radiotherapy, with an analysis of serum and urinary biomarkers that may be predictive of toxicity.

The main objective of the Radiotoxicity Bladder Biomarkers (RABBIO) study is to identify markers of the inflammatory and remodeling processes involved in the occurrence of early (<3 months) RC in patients with localized prostate cancer.

Methods

Study Design

The RABBIO study is an observational, prospective, single-arm, exploratory study to identify factors potentially related to radiation-induced bladder toxicity in patients treated with radiotherapy for localized prostate cancer. This study was carried out at Bégin Military Hospital and Institut de Recherche Biomédicale des Armées. All eligible patients going through the hospital were presented the information about this study and were given the opportunity to participate upon consent.

Ethical Considerations

This study was validated by the national ethics committees (IDRCB: 2021-A03196-35; favorable opinion of the South Mediterranean Committee for the Protection of Persons I February 3, 2022) and the French Data Protection Agency and was registered on ClinicalTrials.gov (NCT05246774). The survey complied with the principles set out in the Declaration of Helsinki. All patients were informed that the data collected may be used for research purposes and have given their written consent. The full, nonanonymized study data are only available to the investigator, and its storage in treatment follows the French regulations. In particular, the data are deidentified before it is used for analysis.

Patient Population

The eligibility criteria for the RABBIO trial are listed in Textbox 1. As this study was exploratory, the sample size was not based on statistical reasoning. The variability and evolution of biomarkers over time and the history of the disease were not known. We hypothesized that about half the patients included will develop cystitis. In order to explore the links between biomarkers and the occurrence of RC, a sample size of 20 participants seemed acceptable [24,25].

Textbox 1. Inclusion and exclusion criteria.

Inclusion criteria. Patients eligible for inclusion in Radiotoxicity Bladder Biomarkers (RABBIO) study must meet all of the following criteria:

- Collection of signed informed consent form prior to participation in this study.
- Patient aged ≥18 years at the time of selection.
- Histologically confirmed adenocarcinoma of the prostate.
- Localized adenocarcinoma of the prostate according to the D’Amico classification.
- Eligible for external radiotherapy or brachytherapy.
- Patient affiliated to a social security scheme.
- Patient able to communicate well, understand, and comply with the requirements of this study according to the physician-investigator.
- Patient with a smartphone or computer to use the Cureety platform.

Exclusion criteria. Patients meeting any of the following criteria are not eligible for inclusion in RABBIO study:

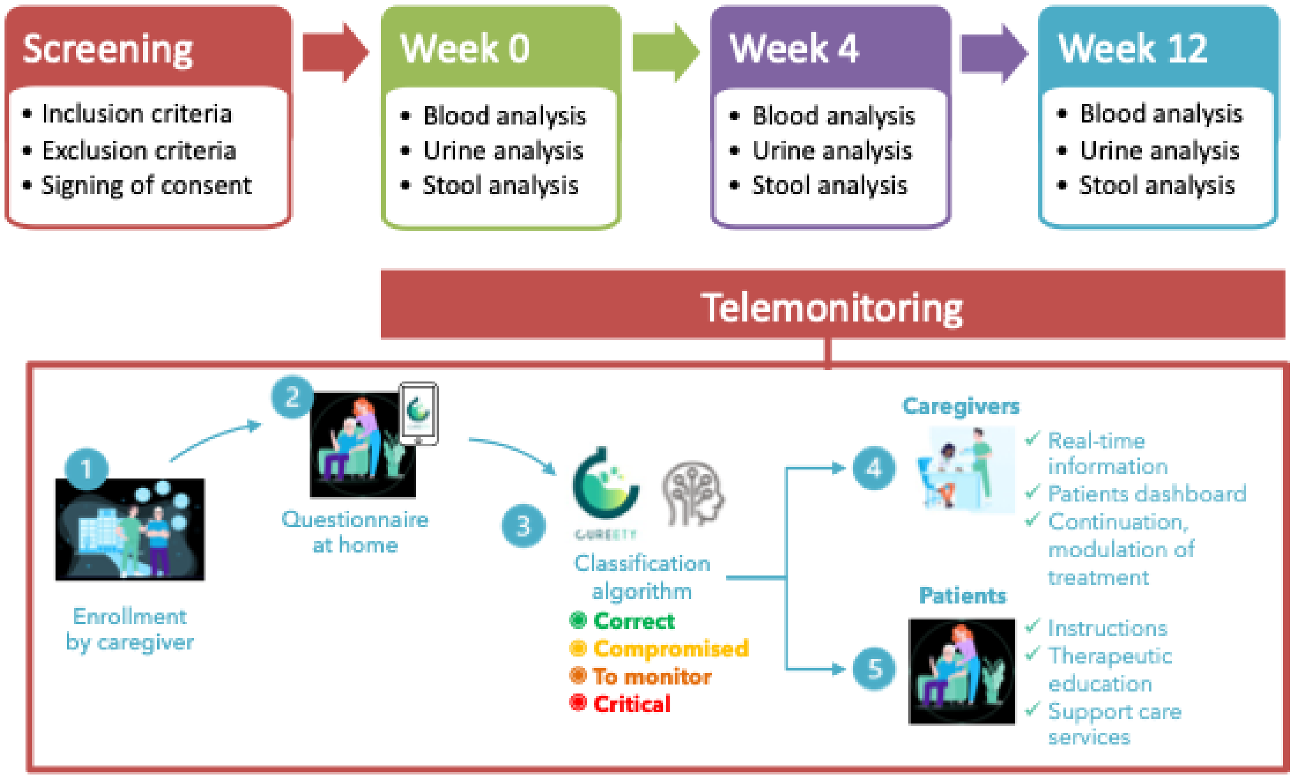
- Patients with advanced or metastatic prostate cancer.
- Patients receiving preirradiation hormone therapy.
- Patients with bladder or urethral cancer or a history of cancer.
- Previous urinary tract surgery (bladder augmentation or cystectomy).
- Patient participating in an interventional clinical study.
- Patient with a history of pelvic irradiation.

Participants’ Calendar

Early symptoms of RC are likely to occur during treatment or within 3 months of radiotherapy in about half of the patients. Therefore, the early manifestations of radiation-induced bladder toxicity were monitored for 3 months (W1 to W12) in order to identify biomarkers that could be related to the symptoms of acute RC.

The RABBIO study design is shown in Figure 1.

Figure 1. The RABBIO study design. RABBIO: Radiotoxicity Bladder Biomarkers.



Data Collection

Clinical Data

Demographics and Disease Characteristics

Patients' demographic data and cancer characteristics (localized or biologically relapsed prostate cancer, stage of disease, radiation regimen, concomitant treatments, and comorbidities) were collected.

Clinical Examination

The clinical examination at each visit included performance index (performance status), weight, blood pressure, heart rate, and oxygen saturation.

Collection of Patient-Reported Outcomes Using the Cureety App

All questionnaires were completed by the patients in a digital form using the Cureety application. The various questionnaires and outcomes are detailed in the following sections: *Adverse Events*, *International Prostate Symptom Score*, and *Functional Assessment of Cancer Therapy-Prostate*.

Adverse Events

Remote monitoring of urinary symptoms reported by patients was ensured by means of the Cureety platform [26] according to the Common Terminology Criteria for Adverse Events. Patients completed the Pelvic Radiation Adverse Events Questionnaire at the inclusion visit, then once a week for 3 months (wk 1 to wk 12). The questionnaire includes 15 items on fatigue, nausea or vomiting, pain, hematuria, frequency of urination (pollakiuria), urinary burning, diarrhea, fecal incontinence, urinary leakage, blood in the stool (rectorrhagia), constipation, weight loss, and dysuria.

Clinical Classification and Remote Patient Monitoring With the Cureety Platform

Using the data from the adverse events questionnaires, the *conformité européenne*–marked Cureety TechCare algorithm classified patients into 1 of 4 states [26]:

- Normal or minor (green)
- Fragile (yellow)
- At risk (Orange)
- Critical (Red)

Each patient received therapeutic advice depending on the severity of the symptoms. If the patient's condition changes to orange (at risk) or red (critical), rapid management of the patient was initiated by the health care team (Figure 1).

International Prostate Symptom Score

The International Prostate Symptom Score (IPSS) is a structured and validated self-report questionnaire that assesses lower urinary tract voiding disorders. The questions cover the following items: incomplete emptying of the bladder, frequency of micturition, intermittent micturition (stopping and restarting the stream), urgent micturition (feeling of "urgency"), weak stream, effort to urinate (forcing or pushing), and nocturia.

The total of the 7 items gives the international score for prostate symptoms in terms of severity. Each question has a score from 1 to 5, for a total of 35 points maximum:

- Score of 0 - 7: no or mild symptoms
- Score of 8 - 19: moderate symptoms
- Score of 20 - 35: severe symptoms

Functional Assessment of Cancer Therapy-Prostate

The Functional Assessment of Cancer Therapy-Prostate (FACT-P) is a prostate cancer-specific self-report questionnaire that assesses weight loss, appetite, pain, physical comfort, urinary, sexual and bowel function in 12 items. The score ranges from 0 to 156, with higher scores reflecting better QoL.

The IPSS, FACT-P were completed by each patient via the Cureety platform at inclusion and in the course of visits at weeks 4 and 12.

Biological Data Collection

Biological Biomarkers

The variation in expression of major biomarkers reported in the literature, including both serum inflammatory and remodelling biomarkers as well as urine biomarkers, was assessed at baseline, week 4, and week 12. Further, 6 mL of blood and 5 mL of urine per patient or visit were used for the analysis. The biomarkers measured with these methods were as follows:

- Biomarkers related to inflammation: macrophage migration inhibitory factor; cytokines IL-1α, IL-1β, IL-4, IL-6, IL-7, IL-8, IL-10, IL-13, IL-17α; macrophagic inflammatory protein (MIP-1α); tumor necrosis factor (TNFα); vascular cell adhesion molecule-1 (VCAM-1); intercellular adhesion molecule-1; chemotactic cytokines (MCP-1, MCP-3, RANTES); C-X-C chemokine motif (CXCL10); M1/M2 ratio; CD4+ and CD8+ T lymphocytes; and C-reactive protein.
- Biomarkers of remodeling: plasminogen activator inhibitor 1 (PAI-1), metalloproteinases (MMP-9), matrix metalloproteinase inhibitors (TIMP1 and TIMP2); hepatocyte growth factor (HGF), placental growth factor, vascular endothelial growth factor, epidermal growth factor, heparin-binding epidermal growth factor, nerve tissue growth factor, and GP51 glycoprotein.

The variation in expression of circulating markers was analyzed by means of the MILLIPLEX MAP (Multi-Analyte Profiling) technique, using Luminex xMAP technology assessed on the principle of Enzyme-Linked Immunosorbent Assay (Table S1 in Multimedia Appendix 1).

Protocol for Analysis of the Circulating Immune Population by Flow Cytometry

Analysis of the immune cell population by flow cytometry was performed at baseline, week 4, and week 12 after the start of irradiation.

Statistical Analysis

Patients' characteristics were compared using chi-square and Student 1-tailed Student *t* tests. Correlations between patients' characteristics, tumor characteristics, treatment toxicities, and blood and urinary biological parameters were assessed using the Pearson correlation test. Follow-up was scheduled at weeks 4 and 12.

Basic statistics were used for continuous variables, missing n (if applicable), mean, type of deviation, median, first and third quartile (Q1 and Q3), and minimum and maximum. Frequency and percentage were used for categorical variables. A Mann-Whitney *U* test was used to compare groups for nonparametric variables, based on the data distribution.

The type I error (α) was 5% (two-sided), and type II error (β) was 20%, that is, a power (1 – β) of 80%.

These statistical analyses were carried out with SAS (version 9.4; SAS Institute Inc) and R (R Foundation for Statistical Computing) [27].

Results

Patient Population

From March 2022 to January 2023, a total of 20 patients were included in our study. The median age was 76 (IQR 65-89) years. Of these, 65% (n=13) had at least one comorbidity, and 35% (n=7) had type 2 diabetes mellitus. All patients had localized disease. Seventeen patients (80%) had de novo localized prostate cancer and 3 (15%) had biochemical recurrence without metastases. The median Gleason score was 7 (IQR 6 - 7). The median prostate specific antigen was 7.85 (IQR 0.27 - 35). Per the inclusion criteria, all patients had a performing status in the 0 - 1 range.

The median dose to the prostate was 60 (IQR 60 - 78) Gy. Twelve patients received 60 Gy in 20 fractions. The other 8 received 78 Gy.

A total of 112 blood and urine samples were collected.

Compliance with the digital platform was 100% at baseline, 93% at W4, and 100% at W12. Patients' baseline characteristics are summarized in Table 1.

Table . Baseline patients' characteristics.

Variable		Values
Number of patients, n (%)		20 (100)
Age (years), median (IQR)		73 (63 - 89)
Prostate-specific antigen (ng/mL), median (IQR)		7.85 (0.27 - 35)
Gleason score, median (IQR)		7 (6-7)
Tumor stage, n (%)		
	T1c	4 (20)
	T2	2 (10)
	T2a	1 (5)
	T2b	1 (5)
	T2c	2 (10)
	pT3R1	1 (5)
	Tx	9 (45)
N0 (no nodes metastasized), n (%)		20 (100)
M0 (no metastasis), n (%)		20 (100)
Comorbidities, n (%)		
	Cardiac (yes)	13 (65)
	Diabetes (yes)	7 (35)
Localized prostate cancer de novo, n (%)		17 (85)
Biochemical recurrence, n (%)		3 (15)
Dose prostate delivered (Gy), median (IQR)		60 (60 - 78)

Clinical Data

To date, we have collected a total of 401 adverse event questionnaires over the duration of this study. Patients reported the largest number of adverse events at week 4 (Figure 2A), at which point the associated clinical classifications also indicated a worsened health state (Figure 2B).

The most frequently reported adverse events at week 4 were pollakiuria (10/17 grade 1 or 2, 58.8%), constipation (5/17 grade 1 or 2, 29%), and diarrhea (6/18 grade 1 or 2, 33%; Figure 2A).

At week 4, 53% (9/17) of the clinical classifications of the patients were evaluated as "minor" and 12% (2/17) as "fragile" (Figure 2B).

In this study, patients monitoring was reported up to 12 weeks and Figure 3 displays patients' tolerance in the form of a visual timeline showing the clinical classifications (green, yellow, orange, or red) over the monitoring period, including irradiation (indicated by a purple line under the timeline).

All patients with complications received symptomatic treatments adapted to the reported adverse events.

Figure 2. (A) Adverse events W0 to W12. (B) Clinical classifications W0 to W12. The clinical classifications were determined by the software medical device Cureety TechCare (scoring from the combination of adverse events). W: week.

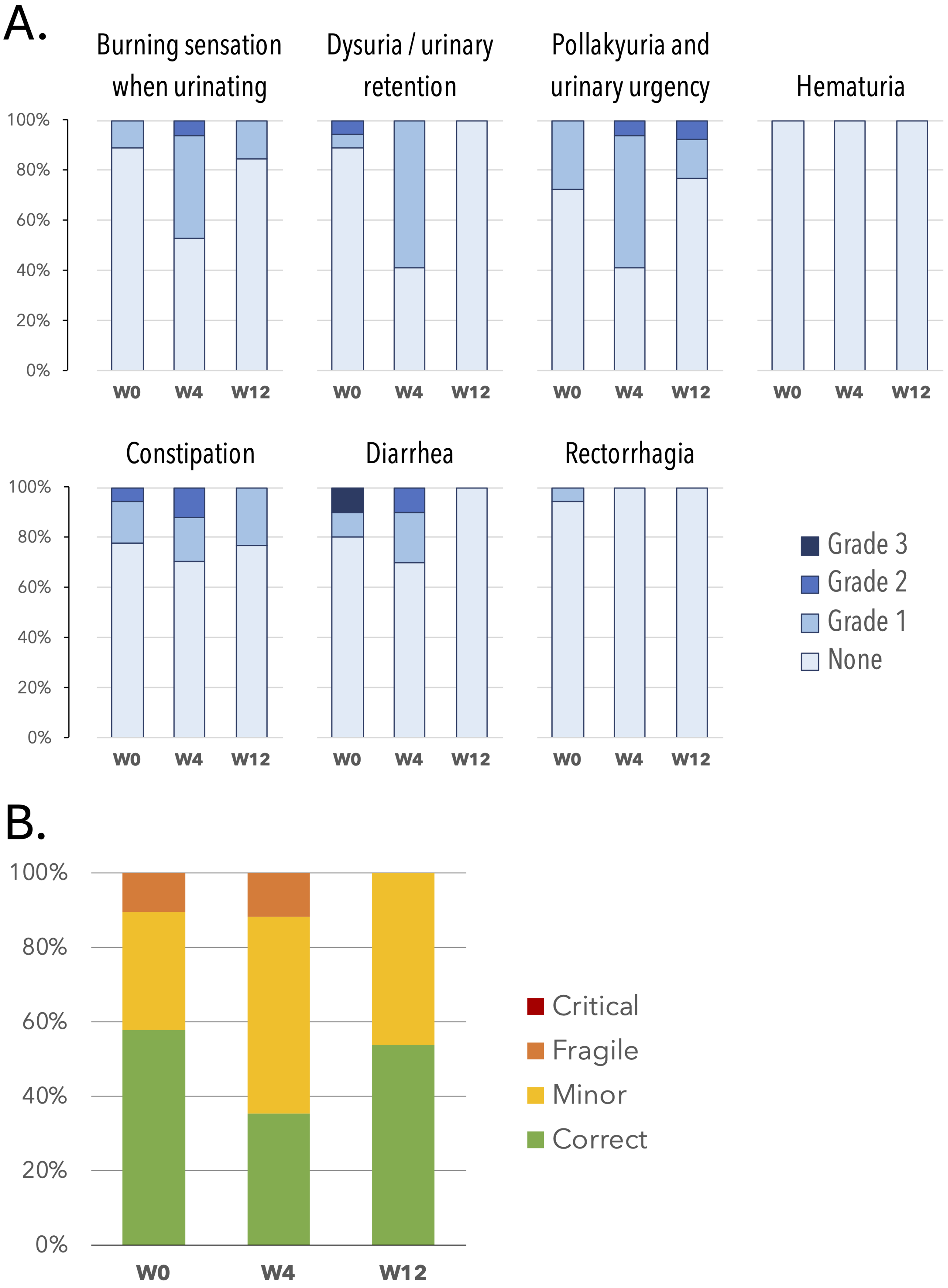
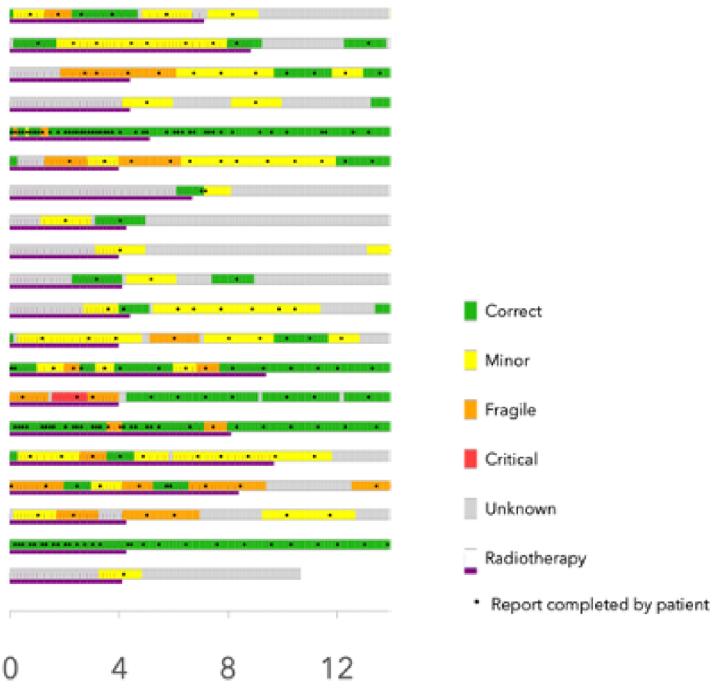


Figure 3. Timelines for each patient during irradiation: each line represents the monitoring of a patient and shows the clinical classifications computed by the device algorithm (green, yellow, orange, or red) from the completed questionnaires (black dots). The end of each timeline corresponds to the end of this study's analysis.

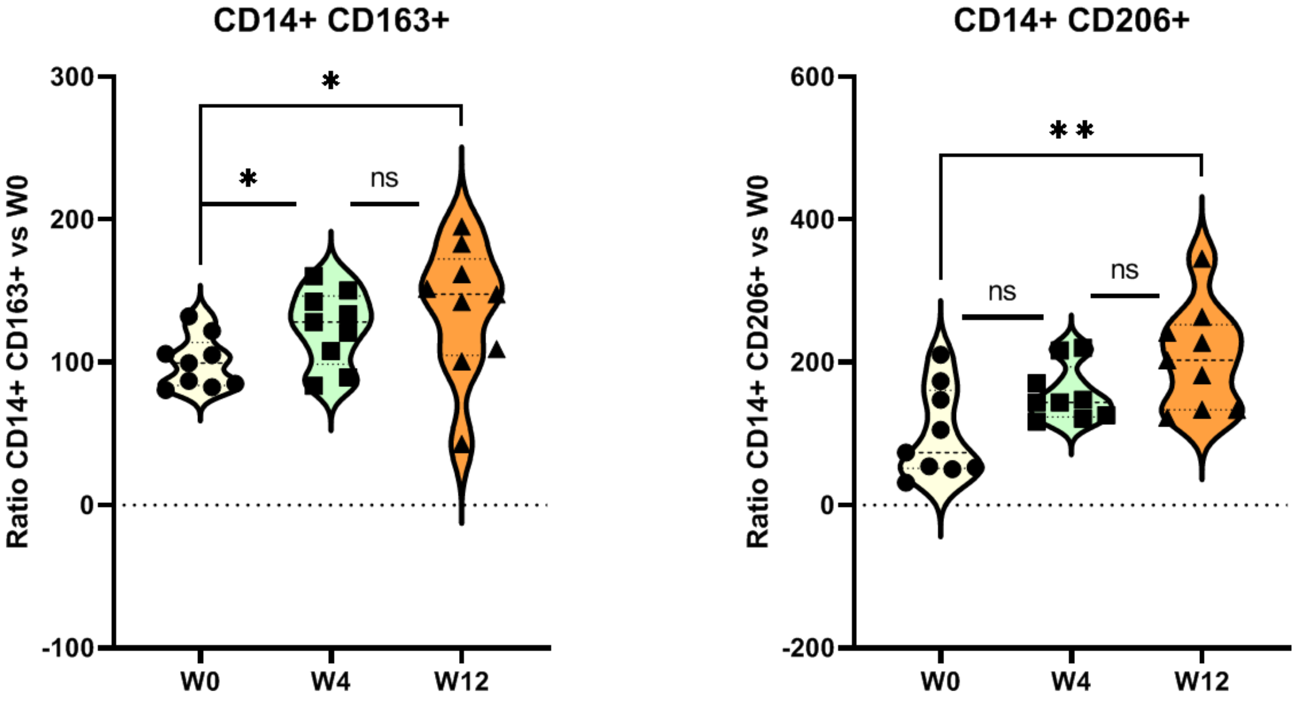


IPSS and FACT-P Status

Patients were followed for a full year. IPSS was assessed at W0, W4, and W12 for all patients. At baseline, 60% of patients reported minor urinary symptoms. Symptoms were moderate for 50% of patients and severe for another 20% at W4. At W12, 80% of the patients reported minor symptoms.

Similarly, FACT-P was assessed for all patients at W0, W4, and W12. The mean FACT-P score at baseline for all patients was 34 (SD 24-40), which changed to 30 (SD 20-35) at W4, and 39 (SD 37-42) at W12. Evolution of FACT-P score before, during, and after irradiation is reported in Figure 4.

Figure 4. Quality of life measured via the FACT-P score. FACT-P: Functional Assessment of Cancer Therapy-Prostate.

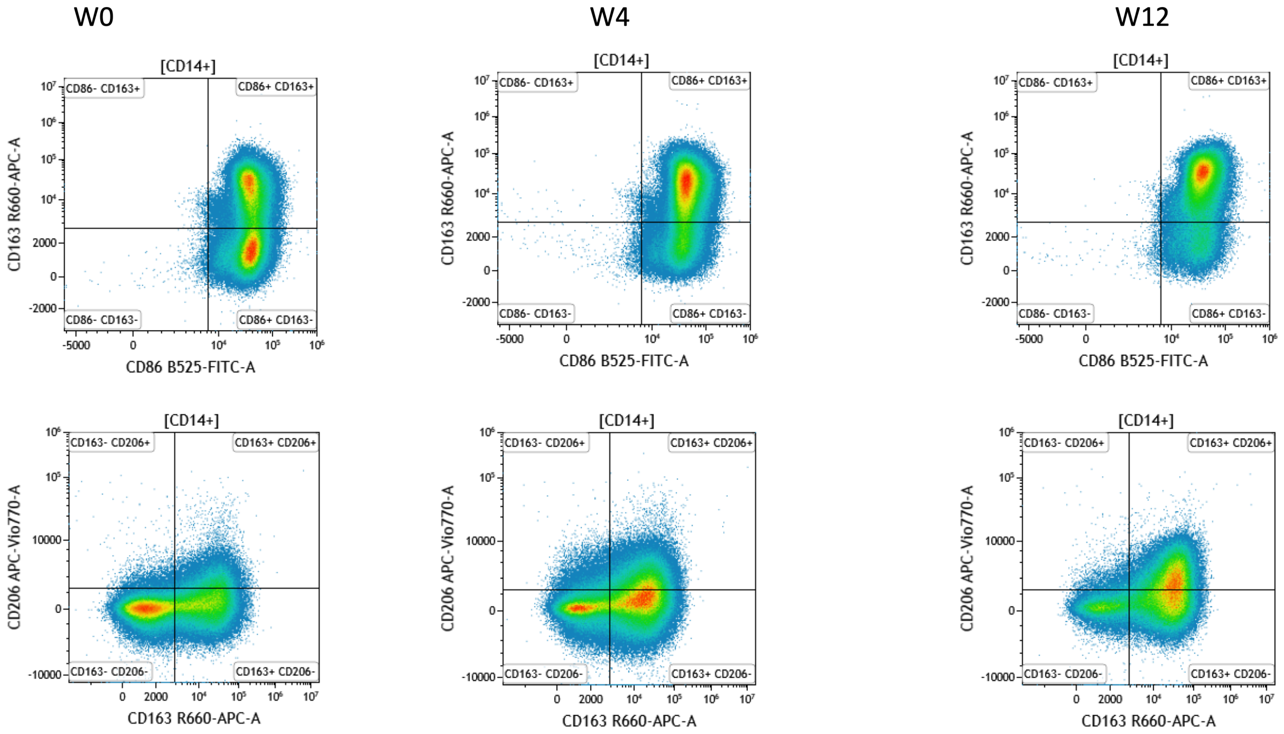


Macrophage Polarization During Prostate Irradiation

We assessed the change in polarization of peripheral macrophages following irradiation. The results showed a significant increase in the proportion of M2 phenotype cells (CD206+, CD163+, and CD204+) at W12 compared to W0.

A significant decrease in the proportion of M1 phenotype cells (CD86+) was observed at W4 following irradiation (Figure 5).

Figure 5. Analysis of the circulating immune cell population by flow cytometry. (A) Representative FACS dot plots to identify macrophage M2a (CD86+ CD163+) and M2c (CD163+ CD206+). (B) Increased ratio of macrophage phenotype M2 (macrophage M2a [CD86+ CD163+] and M2c [CD163+ CD206+]). Mann Whitney test: ratio versus W0 (before radiotherapy), **P*<.05, ***P*<.01, ns. FACS: flow cytometry; ns: not significant; W: week.



Changes in Serum Cytokine Levels

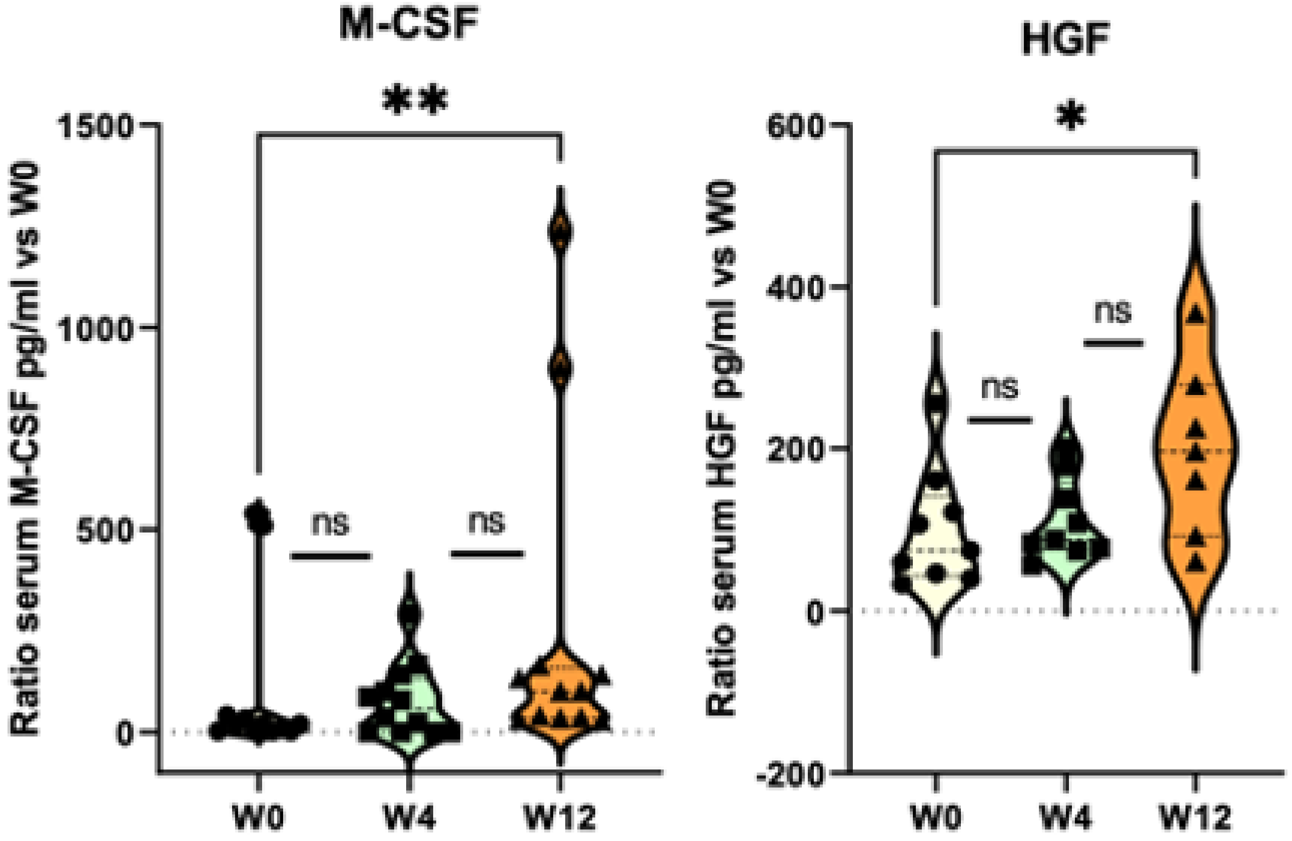
A total of 180 blood samples were taken before the start of treatment, and then at W4 and W12.

Serum HGF levels in patients with prostate cancer were found to be significantly higher at W12 than before radiotherapy (*P*<.001; Figure 6).

Among the inflammatory proteins measured, a significant increase in serum macrophage colony-stimulating factor (M-CSF) levels was also observed at W12 compared to levels determined before radiotherapy (*P*<.001; Figure 6).

In our cohort, no significant increase in profibrotic proteins was observed during the acute phase.

Figure 6. Changes in serum cytokine levels. Mann Whitney test: ratio versus W0 (before radiotherapy), **P*<.05, ***P*<.01, ns. HGF: hepatocyte growth factor; M-CSF: macrophage colony-stimulating factor; ns: not significant; W: week.

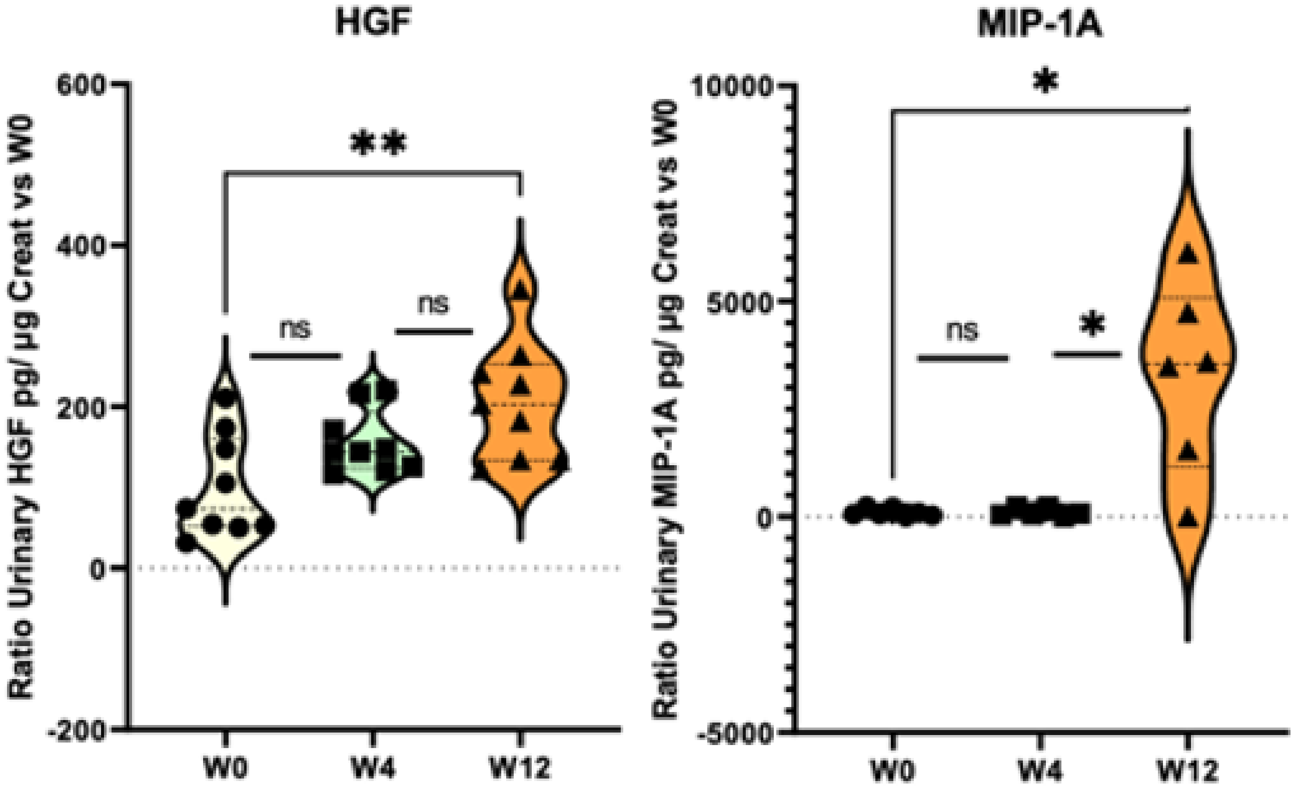


Changes in Urine Cytokine Levels

To investigate possible changes in cytokine profiles during irradiation, the concentrations of 33 proteins were measured in patients' urine before radiotherapy treatment initiation, and again at W4 and W12.

Among the inflammatory proteins measured, a significant increase in urine MIP-1A and HGF levels was found at week 12 compared to baseline (*P*<.001, Figure 7).

Figure 7. Changes in urine cytokine levels. Mann Whitney test: ratio versus W0 (before radiotherapy), *$P<.05$, **$P<.01$, ns. HGF: hepatocyte growth factor; MIP: macrophagic inflammatory protein; ns: not significant; W: week.

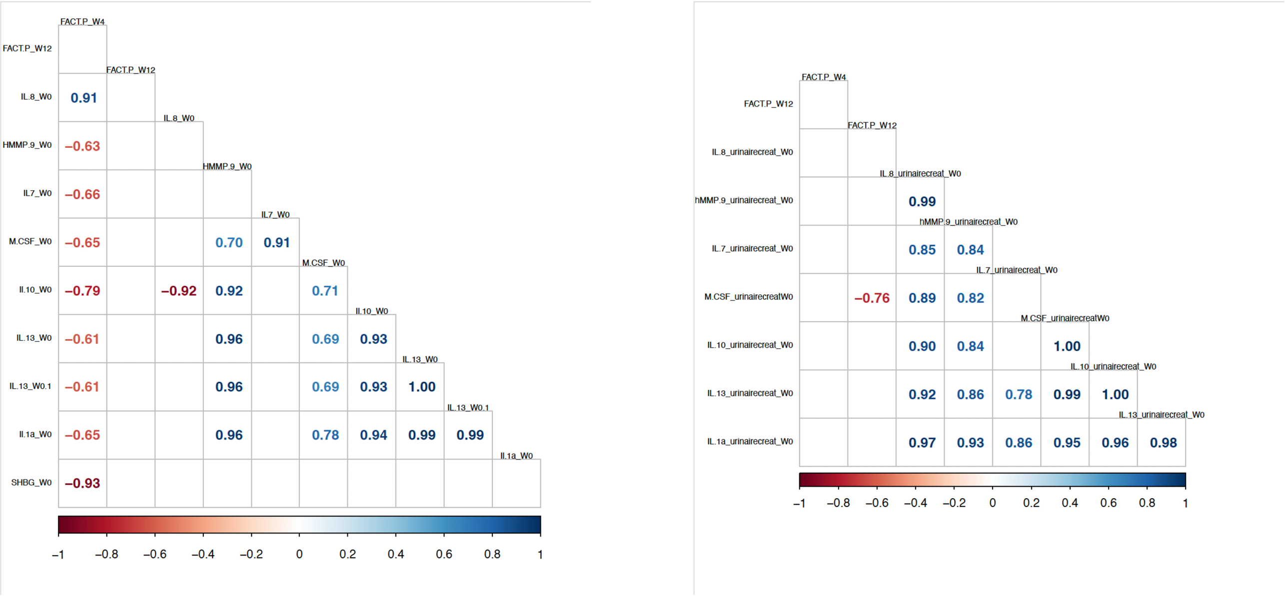


Correlation Between Genitourinary Toxicity Grade and HGF, SHBG, and IL8 Urine Concentrations

Possible correlations between maximum acute genitourinary toxicity grade and serum and urine concentrations in patients with prostate cancer treated with radiotherapy are presented in Figure 8.

Significant negative correlations with FACT-P scores were found at week 4 with respect to baseline serum M-CSF concentrations (r=−0.65, *P*=.04), and at week 12 with respect to baseline urine M-CSF concentrations (*r*=−0.76, *P*=.02).

Figure 8. Correlation matrices between FACT-P scores and cytokine concentrations in serum (**A**) and urine (**B**). Empty cells indicate a nonsignificant correlation (*P*>.05). When significant (*P*<.05), numbers correspond to *r* correlation coefficients, positive or negative (Pearson test). FACT-P: Functional Assessment of Cancer Therapy-Prostate.



	FACT.P_W4	FACT.P_W12	IL.8_W0	HMMP.9_W0	IL7_W0	M.CSF_W0	Il.10_W0	IL.13_W0	IL.13_W0.1	Il.1a_W0
FACT.P_W12										
IL.8_W0	0.91									
HMMP.9_W0	−0.63									
IL7_W0	−0.66									
M.CSF_W0	−0.65			0.70	0.91					
Il.10_W0	−0.79		−0.92	0.92		0.71				
IL.13_W0	−0.61			0.96		0.69	0.93			
IL.13_W0.1	−0.61			0.96		0.69	0.93	1.00		
Il.1a_W0	−0.65			0.96		0.78	0.94	0.99	0.99	
SHBG_W0	−0.93									

	FACT.P_W4	FACT.P_W12	IL.8_urinairecreat_W0	hMMP.9_urinairecreat_W0	IL.7_urinairecreat_W0	M.CSF_urinairecreatW0	IL.10_urinairecreat_W0	IL.13_urinairecreat_W0
FACT.P_W12								
IL.8_urinairecreat_W0								
hMMP.9_urinairecreat_W0			0.99					
IL.7_urinairecreat_W0			0.85	0.84				
M.CSF_urinairecreatW0		−0.76	0.89	0.82				
IL.10_urinairecreat_W0			0.90	0.84		1.00		
IL.13_urinairecreat_W0			0.92	0.86	0.78	0.99	1.00	
IL.1a_urinairecreat_W0			0.97	0.93	0.86	0.95	0.96	0.98

Discussion

Principal Findings

This prospective study is the first to explore the overexpression of inflammatory proteins in the blood and urine of patients with symptoms of acute RC and to assess the correlation between electronic patient‐reported outcomes and biomarkers. Our principal findings include (1) significant overexpression of inflammatory proteins such as M2 macrophages, HGF, M-CSF, and MIP-1 in patients with RC, suggesting their involvement in the pathophysiology of the condition, and (2) a demonstrated correlation between higher levels of urinary M-CSF and increased bladder toxicity, indicating that urinary M-CSF could serve as a predictive biomarker for radiation-induced bladder damage. These results provide new insights into the molecular mechanisms underlying RC and highlight potential biomarkers for the early detection and management of this condition.

Radiotherapy is a powerful tool in the management of localized prostate cancer. Hamdy et al [28] reported the results of the PROTECT study after 15 years of follow-up. This study assessed the effectiveness of conventional treatments in clinically localized prostate cancer. A total of 545 patients underwent radiotherapy. After median follow-up of 15 years, 16 (2.9%) patients had died of prostate cancer in the radiotherapy group. No significant difference in prostate cancer mortality was found between the trial groups (monitoring, surgery, or radiotherapy; *P*=.53). This study confirmed the efficacy of radiation in the management of localized prostate cancer.

However, the incidence of RC is stable over time for all types of pelvic irradiation techniques. In the randomized phase 3 multicenter HYPRO trial, the cumulative incidence by 120 days after radiotherapy of grade 2 or worse acute genitourinary toxicity was 58% (95% CI 52.9% to 62.7%) in the standard fractionation group versus 60.5% (95% CI 55.8 to 65.3) in the hypofractionation group, a difference of 3% (95% CI −2.99% to 8.48%; odds ratio 1.12, 95% CI 0.84 to 1.49, *P*=.43). Approximately 22% of the patients reported grade 2 or worse genitourinary toxicity, and 2 patients (<1%) reported grade toxicity 4 in the 3 months after irradiation [29]. Dearnaley et al [30] also reported that more than 40% of patients presented Radiation Therapy Oncology Group grade 2 or worse bladder toxicity while acute Radiation Therapy Oncology Group bladder symptoms peaked at 4‐5 weeks in hypofractionated radiation schedules.

Moreover, this incidence is possibly underestimated considering the discrepancy between the clinician’s description of the severity of the symptom and the patient’s experience [31]. In a study assessing QoL and satisfaction with outcome in prostate cancer survivors, Sanda et al [32] reported that urinary symptoms had a significant impact on their QoL at 2 months after irradiation. In total, 30% of patients in the External Beam Radiation Therapy arm and 39% of patients in the brachytherapy arm reported urinary discomfort. Patients in the brachytherapy arm reported a significant decrease in urinary irritation or obstruction and incontinence compared to baseline (*P*<.001). At one year, 18% of patients in the brachytherapy group and 11% in the External Beam Radiation Therapy group reported moderate or worse distress related to overall urinary symptoms. Incontinence after brachytherapy was reported by 4%‐6% of patients 1 to 2 years after treatment, and was significantly related to worse QoL [32].

As a first step, our work reported patients’ experience during radiotherapy through telemonitoring, in order to have a picture as close as possible to reality and assess the impact of side effects on their QoL. Collecting data from patients (patient-reported outcomes) helps to correct the discrepancy in the severity of the side effects when reported by the clinician or by the patient [31]. Our results confirm the impact of urinary symptoms on patients’ QoL, which deteriorated at W4 due to an increase in urinary symptoms, with 53% classified as “minor” and 12% as “fragile.” The main symptoms were related to pollakiuria.

The second step involved analyzing the pathophysiology of acute RC, which is often the initial stage of late RC lesions with a risk of life-threatening chronic hemorrhagic cystitis. Our findings reveal an early polarization of M2 phenotype macrophages as early as W4 with a significant increase at W12.

Macrophages are immune cells that play a crucial role in the repair and remodeling of tissues after injury by infiltrating the irradiated area and releasing various factors that promote tissue repair and fibrosis. Macrophages can be classified into two main subsets: proinflammatory M1 macrophages, which are associated with tissue damage, and anti-inflammatory M2 macrophages which are involved in tissue repair and remodeling [33]. The balance between these two phenotypes ensures homeostasis, with M2 macrophages apparently involved in the pathophysiology of fibrosis and radiotoxicity [34].

The M2 macrophages produce a range of cytokines and growth factors, such as transforming growth factor-beta (TGF-β), platelet-derived growth factor, and fibroblast growth factor, which stimulate the proliferation and differentiation of fibroblasts and the deposition of extracellular matrix (ECM) proteins [34,35]. M2 macrophages have been shown to play a critical role in the initiation and progression of fibrotic diseases in various organs, including the liver, lung, and kidney [35-38]. M2 macrophages also inhibit the activity of proinflammatory T cells and promote the recruitment and activation of regulatory T cells, resulting in a shift toward an anti-inflammatory environment that favors fibrosis [39]. Furthermore, M2 macrophages can interact with other cell types, such as myofibroblasts and endothelial cells, to promote fibrogenesis [34,40]. The polarization of macrophages toward the M2 phenotype has been shown to play a critical role in the development of fibrosis following radiation-induced tissue damage. Irradiation has been shown to induce the recruitment of M2 macrophages which release various factors, such as TGF-β and platelet-derived growth factor. These factors promote the differentiation and activation of fibroblasts, which are the primary cells responsible for the production and deposition of ECM components, such as collagen and fibronectin, that form the fibrotic scar tissue [18,41].

The role of M2 macrophages in the development of radiation-induced fibrosis in various organs, including the lung, liver, and skin has been investigated in several studies. In a mouse model of radiation-induced lung fibrosis (RILF), the recruitment of M2 macrophages to the lung was found to be associated with the development of fibrosis, while depletion of macrophages or inhibition of M2 polarization reduced the extent of fibrosis [42,43]. Similarly, in a rat model of radiation-induced liver fibrosis, M2 macrophages were found to be the primary source of TGF-β, which promoted the differentiation of hepatic stellate cells into myofibroblasts, leading to the development of fibrosis [44]. In addition to promoting the differentiation and activation of fibroblasts, M2 macrophages can also contribute directly to the development of fibrosis by producing ECM components, such as collagen. In a study of radiation-induced skin fibrosis, M2 macrophages were shown to be a significant source of collagen in the irradiated skin, while depletion of macrophages or inhibition of M2 polarization reduced collagen deposition and the extent of fibrosis [34]. An early and maintained polarization of macrophages into the M2 phenotype could therefore be involved in the development of acute and late RC.

Second, we investigated blood and urine biomarkers. A significant irradiation-induced increase in HGF was observed in blood and urine. HGF is a pleiotropic cytokine implicated in various physiological and pathological processes, including tissue repair and fibrosis. HGF is a potent stimulator of epithelial cell growth, migration, and survival, and plays an important role in the regeneration and repair of various organs, including the liver, kidney, and lung [45]. Nonetheless, an elevated and persistent level is also involved in the pathophysiology of radiation-induced toxicity. Zwaans et al [14] analyzed urine samples from prostate cancer survivors who had undergone radiation therapy to identify changes in excreted urinary proteins involved in fibrosis, inflammation, and vascular biology. They reported that HGF concentration was significantly higher in patients with high symptom scores and positively associated with hematuria and a diagnosis of RC [14]. In our study, we have demonstrated that HGF secretion is induced by radiotherapy with a significant increase at W12. Initially this protein is involved in the repair process but over time continued secretion leads to the permanent recruitment of M2 macrophages and thus to the development of chronic RC.

Third, we observed a significant increase in urine levels of MIP-1α. MIP-1α, also known as CCL3, is a chemokine involved in the recruitment and activation of immune cells, including macrophages and T cells, in response to tissue injury or inflammation [46]. Recent studies have shown that MIP-1α may also play a role in the development of fibrosis. Heinrichs et al [26] demonstrated that MIP-1α promoted liver fibrosis in a mouse model, by recruiting immune cells. Deletion of MIP-1α reduced liver fibrosis [26]. Yang et al [47] reported that thoracic irradiation in in vitro and in vivo models increased MIP-1α levels, which was linked to inflammation and fibrosis, whereas irradiated mice lacking MIP-1α or its receptor, CCR1, did not develop lung inflammation or fibrosis [47].

Finally, our findings suggest that M-CSF levels could serve as a valuable prognostic factor for RC. M-CSF or colony stimulating factor 1 is a cytokine that plays an important role in the regulation of the immune system and tissue repair, more specifically in the differentiation, proliferation, and survival of monocytes and macrophages, and is critical for the maintenance of tissue homeostasis. M-CSF has also been linked to the pathogenesis of radiation-induced fibrosis and radiation toxicity. Baran et al [48] investigated the role of M-CSF in the pathogenesis of pulmonary fibrosis in a mouse model and human patients. They reported that patients with idiopathic pulmonary fibrosis had elevated levels of M-CSF in bronchoalveolar lavage fluid compared to normal volunteers. On the other hand, M-CSF-/- mice were protected from bleomycin-induced pulmonary fibrosis [48]. Meziani et al [43] reported an accumulation of pulmonary macrophages, particularly M2 macrophages, in RILF. Blocking the interaction between M-CSF and its receptor, however, leads to a depletion of M2 macrophages and blocks the development of RILF [43]. Kopčalić et al [23] reported a correlation between TGF-β1 and genitourinary toxicity in localized or locally advanced patients with prostate cancer treated with radiotherapy [23]. Although no such correlation was observed in our study, it is consistent with our findings concerning the polarization of macrophages toward the M2 phenotype which are responsible for TGF-β1 secretion.

Notwithstanding the promising results of the RABBIO study, several limitations should be taken into consideration. First, this study was conducted on a relatively small number of patients that may limit the generalizability of our findings. Second, this study is restricted to patients with intermediate-risk localized prostate cancer undergoing localized radiotherapy limiting its applicability to other pathological settings, such as the association of radiotherapy with hormonotherapy known to alter immunity. Despite these limitations, our study provides valuable insights into irradiation inducing immune changes and may inform on the development of future interventions to improve QoL for patients undergoing radiation therapy. We need to confirm these results in an independent validating cohort.

Our results reveal that pelvic irradiation for prostate cancer increases the secretion of HGF, M-SCF, and MIP-1α which act synergistically to induce macrophage polarization into the M2 phenotype, possibly favoring bladder toxicity and fibrosis. Inhibition of these molecules and in particular of M-CSF in patients with high levels could be taken as a therapeutic approach to prevent or mitigate RC incidence.

Conclusion

This prospective study is the first to explore the overexpression of inflammatory proteins in the blood and urine of patients with symptoms of acute RC. Our first results suggest a central role of serum and urine HGF, M-CSF, MIP-1α, and macrophage polarization in the pathophysiology of RC. Moreover, an elevated level of M-CSF in serum and urine at baseline was found to be associated in the deterioration of QoL for localized patients with prostate cancer during radiotherapy.

Though cystitis can have significant implications for the QoL of affected patients, there is currently no standard established to identify patients at risk. There is a need for more sensitive and specific markers. In this study, we looked at an extended set of biomarkers as potential indicators of RC. These markers offer an opportunity for significant improvement in the early detection and management of cystitis, which could help improve diagnostic accuracy, identify at-risk patients earlier, and implement preventive management strategies.

At present, the lack of in-depth discussion of therapeutic management, hospitalizations, and costs in relation to reported symptoms and the potential link with biological markers is a major limitation of this study. However, it is essential to stress that these complex and interconnected aspects require a detailed analysis that would go beyond the scope of the present investigation. These crucial elements will be addressed in future work dedicated specifically to the clinical management of identified cases, highlighting therapeutic implications, hospitalization requirements, and associated financial considerations. In-depth analysis of these aspects will contribute to a more comprehensive understanding of the disease, enabling more effective patient management. By focusing on quality of care, optimization of treatment protocols, and efficient management of medical resources, future work will aim to provide practical, informed recommendations for health care professionals and policy makers. In summary, although these issues were not addressed in this study, they represent a promising area of research that will be explored in depth in our future work.

The results of this study may allow us to develop strategies to limit radiation damage and improve patients’ QoL, as well as predictive or prognostic models of bladder toxicity from irradiation radiotherapy in patients with prostate cancer combining clinical parameters, individual patient characteristics, and M-CSF levels in urine and blood.

Data Availability

The datasets generated and analyzed during this study are available from the corresponding author on reasonable request.

Conflicts of Interest

CC received funding from Roche, TherAguiX, Ipsen, Merck, MSD, Eisai, and AstraZeneca for research, traveling or teaching.

Multimedia Appendix 1
Supplementary materials regarding flow cytometry and assays.
[DOCX File, 20 KB - cancer_v10i1e48225_app1.docx]

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Abbreviations

ECM: extracellular matrix
FACT-P: Functional Assessment of Cancer Therapy-Prostate
HGF: hepatocyte growth factor
IPSS: International Prostate Symptom Score
M-CSF: macrophage colony-stimulating factor
MAP: Multi-Analyte Profiling
MIP: macrophagic inflammatory protein
QoL: quality of life
RABBIO: Radiotoxicity Bladder Biomarkers
RC: radiation cystitis
RILF: radiation-induced lung fibrosis
TGF-β: transforming growth factor-beta

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Oral Cancer Incidence Among Adult Males With Current or Former Use of Cigarettes or Smokeless Tobacco: Population-Based Study

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Abstract

Background: Tobacco use has been identified as a risk factor for oral cancer worldwide. However, relative oral cancer incidence among adults who smoke cigarettes, use smokeless tobacco products (ST), have transitioned from cigarettes to ST, quit cigarettes and/or ST ("quitters"), or never used tobacco has not been well studied.

Objective: We aim to present population-based oral cancer incidence rates for adults who smoke cigarettes, use ST, are former smokers who now use ST, or quit.

Methods: We estimated cross-sectional incidence rates and incidence rate ratios (IRRs) using data from statewide cancer registries (Colorado, Florida, North Carolina, and Texas) and population counts derived from national surveys using combined data from 2014 - 2017. A random-effect meta-analysis approach was used to summarize estimates among these groups, based on multiple imputation-based IRR estimates by state and age group while considering potential heterogeneity.

Results: A total of 19,536 oral cancer cases were identified among adult males 35 years and older in the study geographies and period. The oral cancer incidence rate among adults who smoke was significantly higher than the ST group (2.6 times higher, 95% CI 2.0 - 3.3, *P*<.001), 3.6 (95% CI 3.2 - 4.1, *P*<.001) times higher than the never users, and 2.4 (95% CI 1.8 - 3.1, *P*<.001) times higher compared to former smokers who now use ST. The IRR among the ST group relative to never users was 1.4 (95% CI 1.1 - 1.9, *P*=.02). The IRR between former smokers who now use ST and those who quit was 1.4 (95% CI 1.0 - 2.1, *P*=.08).

Conclusions: Findings from this population-based study with a large number of oral cancer cases support significantly high oral cancer incidence among adults who smoke and a lower risk of oral cancer incidence among never users, quitters, users of ST, and former smokers who now use ST compared to cigarettes. Future studies with detailed control of tobacco history and other relevant confounders are needed to confirm these findings.

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KEYWORDS

tobacco harm reduction; oral cancer; smokeless tobacco; smoking; cancer epidemiology; cancer registry; population-based study; oral cancer incidence; cancer cases

Introduction

Oral cancer is one of the most common cancers worldwide, particularly among males [1]. Oral cancer comprises almost 3% of new cancers in the United States, with incidence rates rising in the last decade [2]. The global incidence of cancers of the lip and oral cavity is estimated at 4.1 cases per 100,000 people, however, there is wide variation across the globe [1]. In some Asian-Pacific countries, the incidence of oral cancer ranks among the 3 top cancers [3]. Oral cancer or mouth cancer includes cancers of the lip, oral cavity, and the pharynx (hence sometimes referred to as oropharyngeal cancer) [4]. Oral cancers most commonly develop on the tongue and other parts of the mouth [5]. Oral cancer is more common in men and in older people and varies strongly by socioeconomic condition. Tobacco, alcohol, and areca nut (betel quid) use are among the leading causes of oral cancer [6]. In North America and Europe, human papillomavirus (HPV) infections are responsible for a growing percentage of oral cancers [7,8].

The published evidence regarding the association of oral cancer with tobacco use has primarily focused on combustible cigarettes and smokeless tobacco (ST) products. Previous studies have shown a consistent association between cigarette use and elevated risks of oral cancer [9-12]. For example, a meta-analysis by Gandini et al found substantially elevated risk of oral cavity cancer (relative risk 3.43, 95% CI 2.37 - 4.94, based on 14 studies) and pharyngeal cancer (relative risk 6.76, 95% CI 2.86 - 15.98, based on 7 studies) among people who currently smoke cigarettes. With a focus on mortality from oral cancer, Rostron [13] reported 10.89 times higher risk of oral cancer mortality risk among males and 5.08 times higher mortality risk among females who smoke cigarettes compared to those who never smoke cigarettes. Similarly, Coleman identified a 4.84 times higher risk of oral and oropharyngeal cancer mortality among current smokers after adjusting for air pollution and other covariates [14]. Additionally, Fisher [15] reported a 6.33 (95% CI 1.46 - 27.38) times higher oral cancer mortality risk among people who currently smoke cigarettes (and have never used ST) compared to those who never used any tobacco products.

ST, a Group 1 carcinogen as classified by the International Agency for Research on Cancer [16], has also been associated with oral cancer, with notable regional differences. ST products vary widely in type and composition around the world, and there are marked regional differences in patterns of consumption. These differences may explain the substantial differences between the health risks of different ST products and their associated disease burden across different countries and regions [17-21]. Elevated health risks have been observed in the South Asian and eastern Mediterranean regions [20,22,23], where many common ST products (eg, gutkha, zarda, paan, khaini) contain high levels of carcinogens, notably tobacco-specific nitrosamines and heavy metals, compared to products commonly used in Sweden [24] and the United States [25-27]. For example, the total tobacco-specific nitrosamine levels are 5- to 25-fold higher in Southeast Asian zarda (mean 0.051 mg/g) [25] than in the ST products used in Sweden (mean 0.002 mg/g) and the United States (mean 0.01 mg/g) [28]. Recently, 2 meta-analyses concluded that there is a positive association between ST use and oral cancer worldwide; however, associations varied by geographic region such that studies in North America showed no associations with oral cancer [20,29]. Conversely, 3 US-focused meta-analyses identified a 1.39- [30], 1.65- [31], and 2.6-fold [32] increased oral cancer risk among US ST users compared to nonusers. Of note, these 3 meta-analyses included studies published over a wide time frame, and 2 noted a pattern of decreasing risk estimates over time [30,31]. Past commentary has identified varied definitions of oral cancer type, inconsistent control for smoking, and time frame of studies as contributing reasons for inconsistent results in commonly cited meta-analyses [33]. Importantly, there is sparse data comparing oral cancer incidence among individuals who have stopped smoking and use ST products relative to continued smokers or those who have quit both cigarettes and ST products. Further, many studies among ST users are hampered by small oral cancer case sizes [15,34-37].

The data for this study were collected by population-based cancer registries and provide detailed information on tobacco use and cancer incidence. All US states and many substate jurisdictions actively collect information on tumors that occur within the surveillance area with the goal of providing accurate and timely information on cancer incidence, treatment, and survivorship [38]. Information on cancer cases and treatment collected within hospitals and other medical facilities is consolidated by a state or local cancer registrar, then it is standardized and made available for study [39]. In 2011, some states began collecting enhanced information on tobacco use risk factors including past and current cigarette, ST, and other tobacco use [40]. These large population-based cancer registries allow the combination of oral cancer cases with a valid population base to estimate oral cancer incidence rates among various adult male tobacco use groups. This study is the first to leverage state-based cancer registries to estimate and compare the incidence of oral cancer among adult males who smoke cigarettes, use ST products, are former smokers who now use ST, quit cigarettes and/or ST ("quitters"), and are never users of tobacco products in select US states.

Methods

Data Source and Study Population

We used data from state cancer registries, which provided coverage of all cancer cases in the entire state, to identify oral cancer cases. We used data from the Tobacco Use Supplement to the Current Population Survey (TUS-CPS) to estimate the number of individuals in each state based on their tobacco use status. Incidence rates of oral cancer among tobacco use groups were calculated by dividing the number of oral cancer cases (from the state registries) by the population estimates (from TUS-CPS); see the Data Analysis section for additional details.

Cancer registry data were combined from the Colorado (CO), Florida (FL), North Carolina (NC), and Texas (TX) state cancer registries from the years 2014 through 2017. Although cancer registries provide robust data on cancers diagnosed in their jurisdiction, they often lack complete and accurate collection of data on cigarette and ST use. The registries selected for this study are different from other registries because during this time period, they gathered enhanced tobacco use information in addition to the regularly collected cancer incidence and demographic information. This enhanced tobacco use information includes current, never, or former use of cigarettes and/or ST, and some other tobacco use behaviors. Tobacco use risk behavior data was relatively more complete during the study period (>60% of records with tobacco data) than in prior years.

The population denominator in this study is from the available July 2014, January 2015, May 2015, and July 2018 administrations of the TUS-CPS, a nationally representative survey sponsored by the National Cancer Institute as a part of the US Census Bureau's Current Population Survey. We combined 4 years of case data and 4 years of population data to construct a reasonably accurate incidence rate using population data from the year closest to case data years. TUS-CPS data were weighted for selection probabilities and nonresponse; poststratification factors were applied to balance the sample against the population estimates for each state. Population size of tobacco use/nonuse groups were generated using the weighted counts. Behavioral Risk Factor Surveillance System (BRFSS) estimates were used to replace any zero denominator in the rare event that there was no individual in a state-specific tobacco use group in the TUS-CPS data.

In this study, we focused on the US male population ≥35 years of age because of the limited number of oral cancer cases among individuals younger than 35 years and limited numbers of female ST users, which precluded estimates with reasonable precision when stratified by state and age. Moreover, because >90% of ST users in the United States were males [41], we consider our results generalizable to the majority of the US population of ST users.

Oral Cancer Definition

We included the following invasive malignant oral tumors as oral cancers based on the International Classification of Diseases for Oncology, Third Edition: lip (codes C000-C009), tongue (C019-C029), salivary gland (C079-C089), floor of mouth (C040-C049), gum and other mouth (C030-C039, C050-C059, C060-C069), nasopharynx (C110-C119), tonsil (C090-C099), oropharynx (C100-C109), hypopharynx (C129, C130-C139), and other oral cavity and pharynx (C140, C142, C148). We excluded lymphoma and hematopoietic histology (9050 - 9055, 9140, 9590 - 9992) to meet the current Surveillance, Epidemiology, and End Results Program and World Health Organization definition.

Tobacco Use Status

The state cancer registry data contained variables coding never, current, and former cigarette smoking and ST use (including moist loose or pouched snuff, chewing tobacco, snus, dry snuff) status based on self-reported information when included in the medical records relevant to the cancer diagnosis. In TUS-CPS, information on tobacco use was collected via survey questions about cigarette smoking and ST use (including moist snuff, dip, spit, chew tobacco, or snus). The population data were coded into the same "never," "current," and "former" categories as case data. We defined never smokers as individuals who have never smoked at least 100 cigarettes in their lifetime and never ST users as individuals who have never used ST. We defined current users as ever users who responded "everyday" or "some days" when asked whether they smoked or used ST now. Actual survey questions were utilized from the TUS-CPS Questionnaires as described on the website [42].

Using the "never," "current," and "former" categories, we combined the cancer cases and the population denominator into the following tobacco use groups: the never cigarette never ST group (Never Cig/Never ST) included individuals who were never users of cigarettes and never users of ST; the cigarette smoking group (Current Cig/Never ST) included individuals who were current users of cigarettes but never users of ST; the ST group (Never Cig/Current ST) included individuals who currently used ST but never cigarettes; the dual user group (Current Cig/Current ST-Dual) included individuals who currently used cigarettes and ST; the former smokers who now use ST group (Former Cig/Current ST) included those who were former smokers (last used cigarettes over 12 months ago) and currently used ST; and the former smoker former ST group (Former Cig/Former ST), also referred to as "quitters," irrespective of other tobacco use. In this study, we considered the former smokers who now use ST group as individuals who smoked in the past, stopped smoking, and now currently use ST, although the temporal nature of the tobacco use transition was not precisely reported. Other tobacco states and possible transitions were not included in this analysis.

Data Analysis

Oral cancer incidence rates were calculated by dividing the number of oral cancer cases from the state cancer registry by weighted population counts estimated from TUS-CPS for each tobacco user group. Incidence rate ratios (IRRs) were calculated using Poisson regression for each age group (35 - 44, 45 - 54, 55 - 64, 65 - 74, and ≥75 years) and each state of residence at diagnosis. A random-effect meta-analysis approach was used to summarize state- and age-specific estimates while taking into account potential heterogeneity [43].

Missing data on cigarette and ST use in state cancer registries ranged from 21% in CO to 37% in TX. In order to account for missing values in tobacco use variables that would lead to unnaturally low rates, we assumed the rate of cancer incidence by state and age group was the same among the records with and without tobacco data. Using this assumption, we conservatively weighted the number of oral cancer cases among records with tobacco use data at a proportion equal to the amount of missing values in the tobacco use variable by state and age to allow for incidence rate comparisons between tobacco use groups.

Once rates were constructed, we took 2 approaches during data analysis and present results from each. First, as described above, we inflated the number of oral cancer cases at a proportion equal to the amount of missing values in the tobacco use variable by state and age to allow for incidence rate comparisons between tobacco use groups. This provided incidence rates for each tobacco use group adjusted for state and age. Second, we used a multiple imputation approach [44]. Multiple imputation was conducted to understand the potential impact of missing data on estimates. Variables used in multiple imputation for all states include cancer site, year of diagnosis, age at diagnosis, sex, and race/ethnicity. Other states shared additional information that could be used during multiple imputation. For example, the states of TX and CO included the degree of malignancy and spread in the body, which were also included in the multiple imputation. Additionally, TX provided county of residence, poverty level, and cancer grade. A total of 10 imputations were generated (seed number=212,215). Augmented regression was used to address any perfect prediction by adding a few observations with small weights to the data during estimation to avoid perfect prediction. Analysis was conducted using SAS 9.4 (SAS Institute) and Stata 16 (StataCorp LLC).

Ethical Considerations

This study was conducted in accordance with the Declaration of Helsinki and its amendments, and the data analysis protocol was approved by Advarra, an independent Institutional Review Board (Pro00042038). The written informed consent of the participants was waived by Advarra. Permission to use the data was obtained from individual state cancer registries and is governed by data use agreements. Privacy and confidentiality protections are in place and study data did not include personal identifiers.

Results

Sample Description

A total of 36,270 oral cancer cases among adults 35 years and older were included in this study, with 73.5% (n=26,666) of cases among males. Of these cases in the registries, almost three-quarters of cases, 73.3%, had tobacco use data, to yield a final sample of 19,536 oral cancer cases among males 35 years and older. The distribution among the groups identified were as follows: Never Cig/Never ST=32.4% (n=6325); Current Cig/Never ST=24.4% (n=4770); Never Cig/Current ST=1% (n=190); Current Cig/Current ST-Dual=0.8% (n=153); Former Cig/Current ST=0.7% (n=136); Former Cig/Former ST=2.3% (n=443). Other tobacco use combinations make up the remaining 38.5% (n=7519), with 96% (n=7218) of that remainder being former smokers who have not used ST. Case distribution by state, age, ethnicity, race, and tobacco group are included in Table 1. The cancer registries are located in geographically diverse areas of the United States, with FL and TX contributing the most cases to this analysis. The percentages of total cases were highest in the 55‑64 years age group. Case ethnicity and race varied across states at a level that generally reflected local population demographics. For example, TX and FL had a higher proportion reporting Hispanic or Latino origin than other study states and NC had a proportionally higher Black or African American population. Most cases were White, non-Hispanic.

Table . Demographics and oral cancer case description among males aged ≥35 years, 2014‑2017. Study case data are from respective state cancer registries and are abstracted from the patient medical record. “Never” tobacco use refers to evidence of never use of cigarettes and/or ST, “current” use refers to evidence of use at time of diagnosis, and “former” use refers to evidence of use in the past but nonuse at time of diagnosis. “Other” tobacco users are excluded from further analysis and tabulations.

Characteristic		Colorado, n (%)	Florida, n (%)	North Carolina, n (%)	Texas, n (%)	Overall, n (%)
Cases						
	Oral cancers	1897 (100)	11,525 (100)	4241 (100)	9003 (100)	26,666 (100)
	Oral cancers with tobacco data	1504 (79.3)	8779 (76.2)	3542 (83.5)	5711 (63.4)	19,536 (73.3)
Age group (years)						
	35‑44	71 (4.7)	275 (3.1)	148 (4.2)	269 (4.7)	763 (3.9)
	45‑54	258 (17.2)	1446 (16.5)	688 (19.4)	1053 (18.4)	3445 (17.6)
	55‑64	528 (35.1)	3000 (34.2)	1257 (35.5)	1952 (34.2)	6737 (34.5)
	65‑74	421 (28)	2548 (29)	952 (26.9)	1611 (28.2)	5532 (28.3)
	≥75	226 (15)	1510 (17.2)	497 (14)	826 (14.5)	3059 (15.7)
Ethnicity and race						
	Hispanic	107 (7.1)	999 (11.4)	69 (2)	713 (12.5)	1888 (9.7)
	White non-Hispanic	1316 (87.5)	7001 (79.8)	2899 (81.9)	4430 (77.6)	15,646 (80.1)
	Black non-Hispanic	47 (3.1)	586 (6.7)	493 (13.9)	382 (6.7)	1508 (7.7)
	Other/unknown	34 (2.3)	193 (2.2)	81 (2.3)	186 (3.3)	494 (2.5)
Tobacco group[a]						
	Never Cig/Never ST	503 (33.4)	2641 (30.1)	865 (24.4)	2316 (40.6)	6325 (32.4)
	Current Cig/Never ST	315 (20.9)	2167 (24.7)	1024 (28.9)	1264 (22.1)	4770 (24.4)
	Never Cig/Current ST	24 (1.6)	36 (0.4)	45 (1.3)	85 (1.5)	190 (1)
	Current Cig/Current ST-Dual	14 (0.9)	50 (0.6)	41 (1.2)	48 (0.8)	153 (0.8)
	Former Cig/Current ST	14 (0.9)	24 (0.3)	48 (1.4)	50 (0.9)	136 (0.7)
	Former Cig/Former ST	34 (2.3)	178 (2)	129 (3.6)	102 (1.8)	443 (2.3)
	Other	600 (39.9)	3683 (42)	1390 (39.2)	1846 (32.3)	7519 (38.5)

[a] Cig: cigarette; ST: smokeless tobacco. Group descriptions are as follows: Never Cig/Never ST were never users of cigarettes and never users of ST; Current Cig/Never ST were current users of cigarettes but never users of ST; Never Cig/Current ST currently used ST but never cigarettes; Current Cig/Current ST-Dual were current users of cigarettes and ST; Former Cig/Current ST were former smokers (last used cigarettes over 12 months ago) and currently used ST; Former Cig/Former ST stopped using both cigarettes and ST.

The population base was calculated for each state, age group, and tobacco user group combination using TUS-CPS. Seven of these estimates could not be calculated due to a lack of tobacco user respondents and they were replaced with BRFSS estimates, including 5 from the relatively smaller groups of Current Cig/Current ST-Dual users (2 in CO, 2 in FL, 1 in TX), 1 from Former Cig/Current ST users (CO), and 1 from Never Cig/Current ST users (CO).

Incidence Rates

Oral cancer incidence rates (Table 2) among males ≥35 years old were highest among the current smoking groups and lowest among current nonsmoking groups. The overall incidence rate in the Never Cig/Never ST group was 22.1 per 100,000 (95% CI 21.5 - 22.6). The overall incidence rate in the Never Cig/Current ST group (20.6 per 100,000, 95% CI 18.3 - 23.3) was not significantly different from never users (*P*=.29) and was significantly lower than the Current Cig/Never ST group (74.0 per 100,000, 95% CI 71.9 - 76.2; *P*<.001) and Current Cig/Current ST-Dual group (40.6 per 100,000, 95% CI 35.4 - 46.6; *P*<.001). The overall incidence rates among Former Cig/Current ST and Former Cig/Former ST (quitters) were not significantly different between the 2 groups, at 18.8 per 100,000 (95% CI 16.3 - 21.8) and 18.0 per 100,000 (95% CI 16.6 - 19.6; *P*=.60), respectively. Incidence rates were generally consistent between states, with limited differences being observed within the subgroups with smaller sample sizes (ie, Former Cig/Former ST, Former Cig/Current ST, Current Cig/Current ST-Dual).

Table . Oral cancer incidence rates per 100,000 among males aged ≥35 years by tobacco use status. Rates by state were calculated by Poisson regression. State-specific estimates were adjusted for age group and the overall estimate was adjusted by state and age group.

Group[a]	Colorado, rate (95% CI)	Florida, rate (95% CI)	North Carolina, rate (95% CI)	Texas, rate (95% CI)	Overall, rate (95% CI)
Never Cig/Never ST	22.7 (20.8 - 24.7)[c]	23.1 (22.2 - 24)[b,c]	18.9 (17.7 - 20.2)[c]	24.6 (23.7 - 25.5)[c]	22.1 (21.5 - 22.6)[c]
Current Cig/Never ST	81.6 (73.4 - 90.7)[b,c]	86.1 (82.6 - 89.8)[b,c]	83.0 (77.9 - 88.5)[b,c]	65.2 (62.1 - 68.4)[b,c]	74.0 (71.9 - 76.2)[b,c]
Never Cig/Current ST	22.7 (15.8 - 32.5)[c]	17.3 (12.9 - 23.1)[c]	16.8 (12.9 - 22.1)[c]	24.0 (20.2 - 28.5)[c]	20.6 (18.3 - 23.3)
Current Cig/Current ST-Dual	41.6 (26 - 66.6)[b,c]	73.3 (57.4 - 93.6)[b,c]	28.6 (21.6-37.9)[b]	36.7 (29.2 - 46.1)[b,c]	40.6 (35.4 - 46.6)[b,c]
Former Cig/Current ST	14.0 (8.8 - 22.3)[c]	12.7 (8.9 - 18)[c]	23.2 (17.9 - 30)	22.0 (17.6 - 27.4)[c]	18.8 (16.3 - 21.8)
Former Cig/Former ST	7.5 (5.5 - 10.1)[b]	29.7 (26.1-33.8)[b]	25.7 (21.9-30.1)[b]	12.6 (10.8 - 14.7)[b]	18.0 (16.6 - 19.6)

[a] Cig: cigarette; ST: smokeless tobacco. Group descriptions: Never Cig/Never ST - never used cigarettes or ST; Current Cig/Never ST - current cigarette users, never used ST; Never Cig/Current ST - current ST users, never used cigarettes; Current Cig/Current ST-Dual - current users of both; Former Cig/Current ST - former smokers (before 12 months) and current ST users; Former Cig/Former ST - former users of both

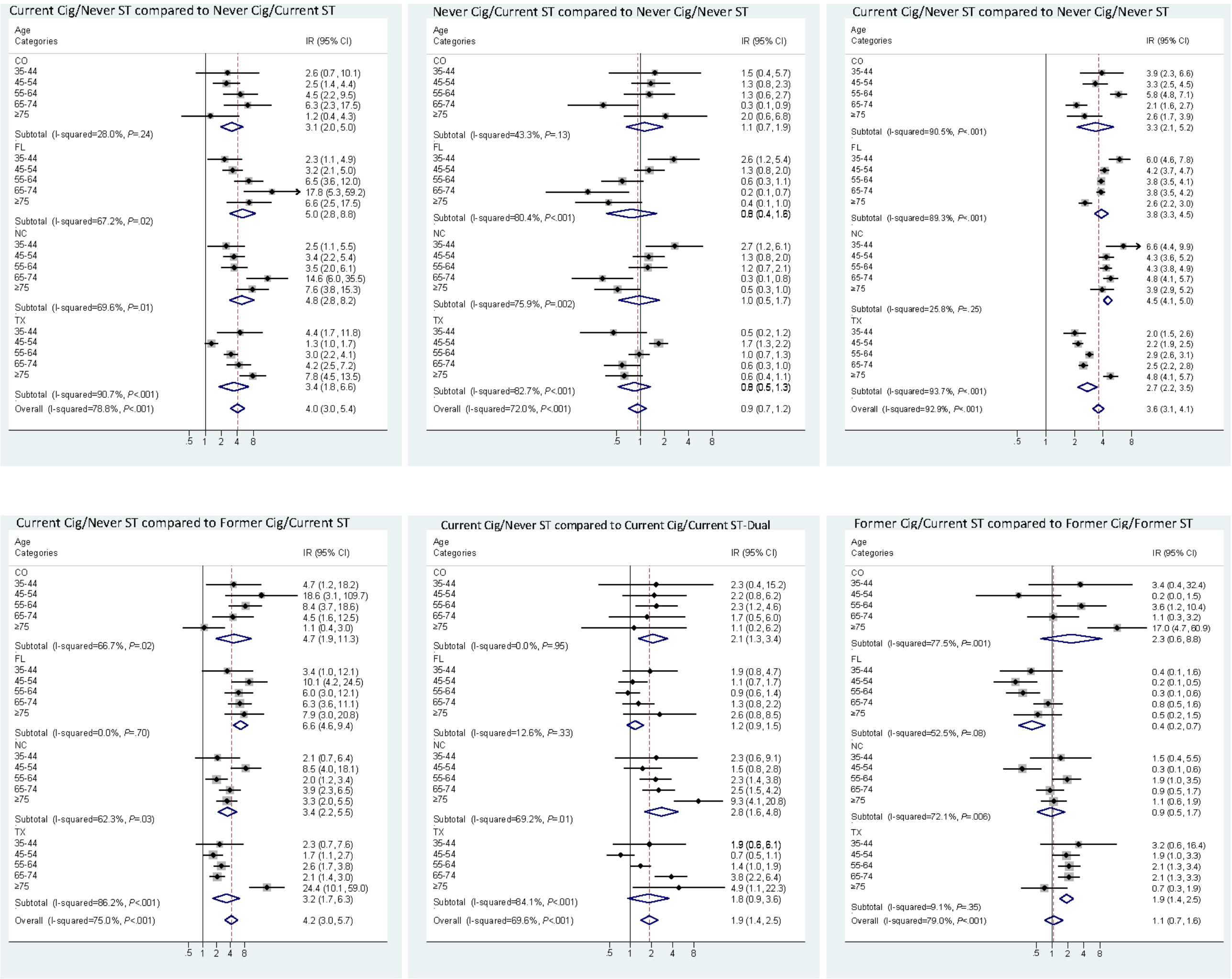
[b] Significantly different (*P*<.05) rates compared to the Never Cig/Current ST group.

[c] Significantly different rates (*P*<.05) compared to the Former Cig/Former ST group.

Incidence Rate Ratios

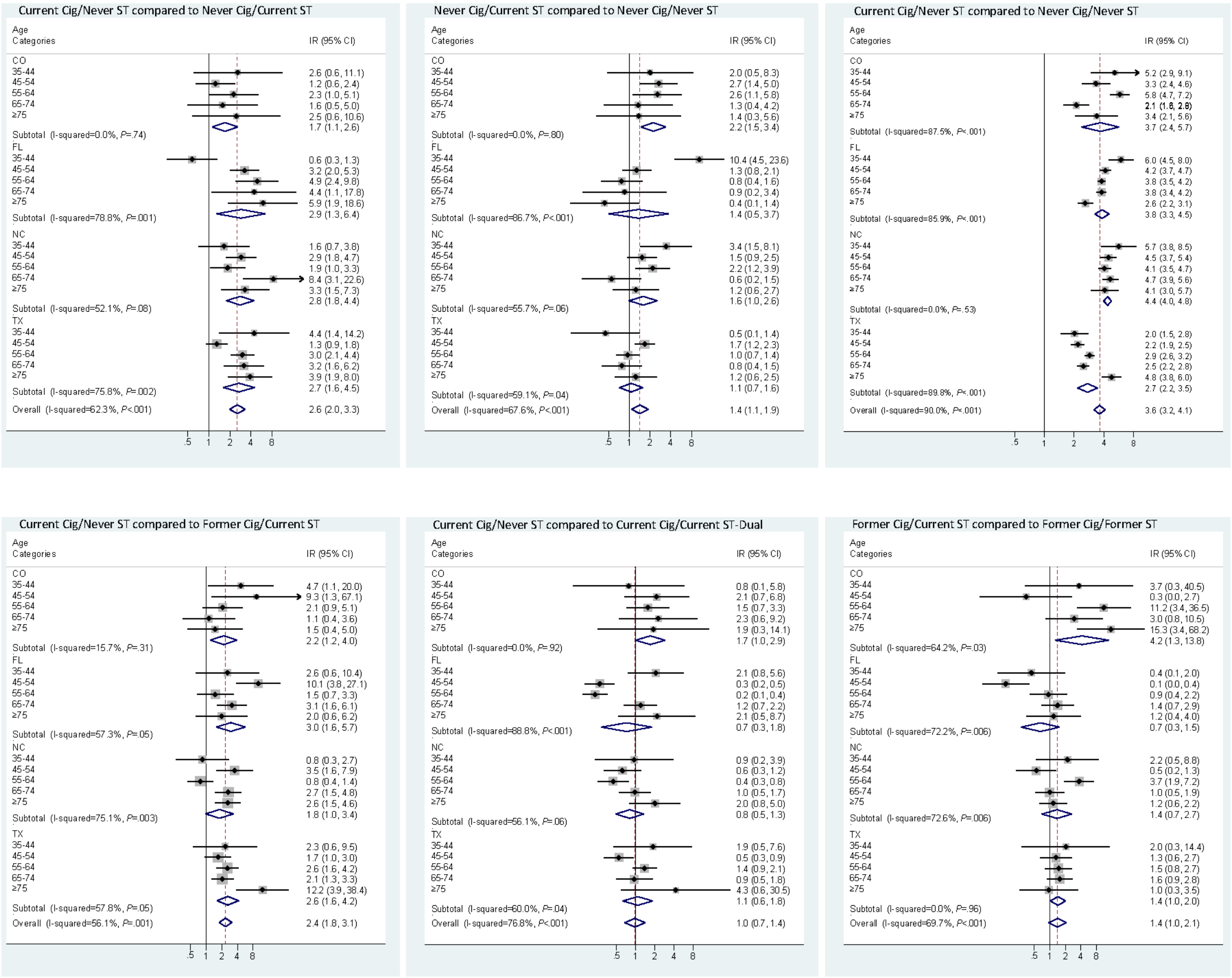
Using the first approach without multiple imputation (Figure 1), the combined oral cancer incidence rate for the Current Cig/Never ST group was significantly higher, 4.0 (95% CI 3.0-5.4) times, than the Never Cig/Current ST group and 3.6 (95% CI 3.1-4.1) times higher compared to the Never Cig/Never ST group. The incidence rate among the Current Cig/Never ST group was also significantly higher, 4.2 (95% CI 3.0-5.7) times, compared to the Former Cig/Current ST group. The oral cancer incidence rate for the Never Cig/Current ST group was comparable to the Never Cig/Never ST; the IRR estimate was 0.9 (95% CI 0.7-1.2). The estimated rate among the Current Cig/Never ST group was significantly higher, 1.9 (95% CI 1.4-2.5) times, compared to the Current Cig/Current ST-Dual group. Moreover, the comparable rates between the Former Cig/Current ST and Former Cig/Former ST groups yielded an IRR of 1.1 (95% CI 0.7-1.6).

Figure 1. Meta-analysis of incidence rate ratios based on tobacco use status. (A) Current Cig/Never ST group compared to Never Cig/Current ST. (B) Never Cig/Current ST group compared to Never Cig/Never ST. (C) Current Cig/Never ST group compared to Never Cig/Never ST. (D) Current Cig/Never ST group compared to Former Cig/Current ST. (E) Current Cig/Never ST group compared to Current Cig/Current ST-Dual. (F) Former Cig/Current ST compared to Former Cig/Former ST. A value of 1 indicates a null association; a value greater than 1 indicates a positive association; a value less than 1 indicates inverse association, and the horizontal line width reflects the confidence interval. The diamonds indicate the meta-analysis estimate by state and overall and the diamond width represents the confidence interval. The dashed red line indicates the overall estimate for reference. Group descriptions are as follows: Never Cig/Never ST were never users of cigarettes and never users of ST; Current Cig/Never ST were current users of cigarettes but never users of ST; Never Cig/Current ST currently used ST but never cigarettes; Current Cig/Current ST-Dual were current users of cigarettes and ST; Former Cig/Current ST were former smokers (last used cigarettes over 12 months ago) and currently used ST; Former Cig/Former ST stopped using both cigarettes and ST. Cig: cigarette; CO: Colorado; FL: Florida; IR: incidence ratio; NC: North Carolina; ST: smokeless tobacco; TX: Texas.



Results were largely similar when using the multiple imputation approach to address missing tobacco use data (Figure 2). The combined oral cancer incidence rate for the Current Cig/Never ST was significantly higher, 2.5 (95% CI 1.8-3.4) times, compared to Never Cig/Current ST group. Estimates were statistically significant across all states and overall. The combined point estimate for the IRR, when comparing the Never Cig/Current ST group to the Never Cig/Never ST group, was elevated but not statistically significant (combined estimate 1.4, 95% CI 0.97-1.9). The estimate from CO was statistically significant, but it was not for FL, NC, and TX. In contrast to ST, the Current Cig/Never ST group have statistically significant and more elevated risk compared to the Never Cig/Never ST group (combined estimate 3.4, 95% CI 2.9-3.9). Significantly higher oral cancer incidence (combined estimate 2.6, 95% CI 1.9-3.6) was observed for the Current Cig/Never ST group compared to the Former Cig/Current ST group. Oral cancer incidence was comparable between the Current Cig/Never ST and Current Cig/Current ST-Dual groups, with an estimated IRR of 1.0 (95% CI 0.7-1.4). The adjusted IRR for individuals in the Former Cig/Former ST ("quitters") group relative to the Former Cig/Current ST group was 1.4 (95% CI 0.95-2.1).

Figure 2. Meta-analysis of incidence rate ratios based on tobacco use status using multiple imputation for missing tobacco use status. (A) Current Cig/Never ST group compared to Never Cig/Current ST. (B) Never Cig/Current ST group compared to Never Cig/Never ST. (C) Current Cig/Never ST group compared to Never Cig/Never ST. (D) Current Cig/Never ST group compared to Former Cig/Current ST. (E) Current Cig/Never ST group compared to Current Cig/Current ST-Dual. (F) Former Cig/Current ST compared to Former Cig/Former ST (ie, quitters). Group descriptions are as follows: Never Cig/Never ST were never users of cigarettes and never users of ST; Current Cig/Never ST were current users of cigarettes but never users of ST; Never Cig/Current ST currently used ST but never cigarettes; Current Cig/Current ST-Dual were current users of cigarettes and ST; Former Cig/Current ST were former smokers (last used cigarettes over 12 months ago) and currently used ST; Former Cig/Former ST stopped using both cigarettes and ST. Cig: cigarette; CO: Colorado; FL: Florida; IR: incidence ratio; NC: North Carolina; ST: smokeless tobacco; TX: Texas.



Discussion

Principal Findings

In this study, we found consistent evidence that individuals who were current users of cigarettes who have never used ST have 2.6 times the oral cancer incidence compared to current users of ST products who have never smoked. In addition, those who used cigarettes in the past and now use ST have lower oral cancer incidence compared to current users of cigarettes. There was a clear oral cancer rate gradient among tobacco use behaviors, where current users of cigarettes have the highest rates, followed by current smokers and ST dual users, with users of ST, never users, and former smoking groups with comparable lower rates. A major strength of the study is the large number of oral cancer cases obtained from state cancer registries, which contained the vast majority, if not all, of oral cancer cases from 4 geographically diverse states across the United States (ie, >19,000 cases in this study), which allowed for robust estimation and enabled specific analysis by tobacco use status (eg, dual users, former smokers who now use ST, and quitters), age group, and state, compared to many previous studies (eg, [35,36,45,46]).

Findings from our analysis on incidence rates are generally consistent with previous reports, including studies from the United States reporting higher relative risks with smoking cigarettes [9,11-14] compared to estimates related to ST use [20,29-32]. For example, US studies consistently show a 3.4- to 10.9-fold elevated oral cancer incidence risk with cigarette smoking relative to never smoking [9,11-14]. In comparison, we note that oral cancer risk estimates for ST product use in the United States have been variable, with some showing nonsignificant associations and others showing an elevated risk; however, they do consistently show mouth cancer risk estimates that are lower than those of cigarette smoking [20,29-32]. Boffetta and colleagues [32] summarized estimates from 9 studies conducted in the United States and found a relative risk of 2.6 (95% CI 1.3-5.2) for oral cancer among ever users of ST compared to nonusers. In another meta-analysis (2009), Lee and Hamling reported a statistically significant risk of oral cancer among people who use ST compared to nonusers after adjusting for smoking (relative risk 1.65, 95% CI 1.22-2.25); however, the differences were not statistically significant when additionally adjusting for alcohol use (relative risk 1.04, 95% CI 0.80-1.35) [31]. Moreover, 2 meta-analyses of more recent epidemiological studies showed no difference in risk among ST product users compared to nonusers [20,29].

This study included recently diagnosed oral cancer cases in order to represent risks associated with more contemporary US tobacco use behaviors and used consistent methodology to construct and compare oral cancer incidence based on a large number of oral cancer cases and population counts from national surveys. These estimates provided a clear and direct comparison of average oral cancer risk between smokers, ST users, former smokers who now use ST, and cigarette and ST quitters. We further demonstrated the consistency of our results by stratifying across age group and state strata. The point estimates indicated a higher incidence of oral cancer in the current cigarette group compared to the ST group across all strata and most estimates were statistically significant at a $P<.05$ level. By using a random-effect meta-analytic approach, we were able to summarize incidence ratio estimates while taking into account any heterogeneity across strata (eg, differences in sample sizes); the meta-analytic incidence ratio estimate was highly robust. Therefore, when considering the overall published literature and our findings, the evidence consistently and clearly indicates that oral cancer risks are substantially higher among adults who smoke cigarettes than adults who use ST products or have quit cigarettes and ST.

This study provides updated population-based estimates of oral cancer risk among ST users based on contemporary ST use behaviors. Although ST products have been used in the US population for almost a century and oral cancer risks have been investigated by others (eg, [31,32,47]), ST products and use patterns have changed over time. For example, studies that included early ST products such as dry snuff use among women, from more than 40 years ago, tended to produce higher relative risk estimates [48] as compared to more recent studies when moist ST was the dominant ST product. Some studies were conducted in specific populations (eg, female Appalachian snuff users [48], agricultural workers [45]), which may not be generalizable to the larger US population; thus, the contemporary analysis presented here adds to the scientific evidence. Moreover, our study presents a unique analysis of more than 19,000 oral cancer cases, which further adds to the body of evidence.

In line with inconsistent evidence on the risk of oral cancer associated with use of ST in the existing literature (eg, [32,36,46]), we found variations in incidence ratio estimates across age groups and states in this study—some estimates were negative, some were positive, and many were null. This finding is not surprising given that the etiology of oral cancer is complex, and some potential confounders were not controlled for due to a lack of such information, including alcohol consumption and HPV infection. Previous studies have found that users of ST were more likely to be heavier alcohol drinkers [49,50]. To further assess potential differences in alcohol drinking, we compared the prevalence of heavy drinking and past 30-day binge drinking using 2018 BRFSS data of the 4 states included in this study and found no statistically significant differences between male smokers and ST users. Furthermore, the existing evidence points to a positive association between tobacco use and HPV [51]. These positive associations between use of ST and potential confounders might have biased the estimates against the null (ie, overestimation).

In this study, we found that males who used cigarettes in the past and now use ST have a substantial reduction in oral cancer risk (>50%) compared to current smokers. A previous study documented that individuals who were former smokers and current snus users tended to be less likely to have oral cancer compared to those who continued to smoke, although the estimate was of borderline statistical significance at the .05 level (odds ratio 0.43, 95% CI 0.18-1.02), possibly due to the moderate sample size of the study (n=139 snuff users) [52,53]. Results from this study extended findings from the previous study to use of ST with greater statistical precision.

Results from this study should be interpreted in the context of the following limitations. First, this study is observational in nature and cannot provide definitive evidence for causal relationships as information about some potential confounders was not available, including details about cigarette consumption, HPV infection, and alcohol consumption. Further, the ecological design of this study precludes individual level inferences. Future studies with detailed control of tobacco history and other relevant confounders, perhaps collected through surveys linked to medical history, could improve the ability to make inferences. Second, oral cancers take years to develop and are impacted by an interplay of various risk factors, which cannot be fully investigated with the cross-sectional approach of this study. The approach presented here may lay the foundation for future studies with the capability of taking a longitudinal approach (eg, retrospective cohort study design) to provide further insights. Third, cancer registry data contains missing tobacco use information and does not precisely characterize types of ST product used, which could lead to tobacco group misclassification. For example, in the United States, ST use includes moist loose or pouched snuff, chewing tobacco, snus, or dry snuff, and this information was not reported in the cancer registry records. However, given that moist loose or pouched snuff (~80% market share) and chewing tobacco (~18% market share) are the most prevalent ST type used in the United States [54,55], we can reasonably assume that these estimates apply to moist ST, the most predominant form of ST use. We applied "never," "current," and "former" use categories to all groups, so there is no differential treatment of numerator and denominator. In this study, we used multiple imputation to mitigate the potential impact of missing values and confounders. Inferences were largely consistent between the 2 approaches and showed elevated incidence of oral cancer in the current cigarette group compared to the never user, former smoker who now uses ST, and ST groups. Different statistical inference was drawn with and without using multiple imputation for 2 comparisons (ie, ST use versus never use and smoking versus dual use), which implies nonrandom missing patterns across tobacco use status. Nonetheless, both approaches produced robust estimates, supporting higher oral cancer incidence among current users of cigarettes when compared to users of ST and compared to former smokers who now use ST, respectively. Fourth, cancer registries do not contain information on frequency, intensity, or duration of tobacco use or detailed time since quitting, which precluded a more refined consideration of tobacco use history, particularly transitions from cigarettes to ST products. Nonetheless, despite the lack of this information, we identified higher oral cancer incidence among current users of cigarettes compared to several other tobacco use groups (eg, never smokers, users of ST, former smokers who now use ST) using a similar user definition as other recent studies that revealed comparable differences in risk [15,47]. Improvements to the medical record to include additional types, categories (such as electronic nicotine delivery systems or other novel tobacco products), volume, and duration of tobacco use can enhance future analyses. Fifth, the ST use prevalence is relatively low in the United States (2.3% of adults [56]), which may have contributed to the small sample size within some of the subgroups and imprecise estimates in some age by state strata. We combined multiple years and states to mitigate the impact of small sample size and note that future studies could combine age groups to calculate state-level oral cancer incidence estimates among females.

Despite these limitations, this study did provide comprehensive statewide coverage of cancer cases across 4 large geographically distant states. Here, we highlight the importance of cancer registries as a tool to gain insights into health outcomes related to tobacco use behavior. Our analysis provides evidence regarding the increase in risk of oral cancer among individuals who smoke and supports existing epidemiology demonstrating that these risks are lower among never and former tobacco users, current ST product users, and former smokers who now use ST products.

Conclusion

Based on our analysis of the data on >19,000 cases in the United States, we present 3 major conclusions. First, smoking cigarettes is linked to oral cancer risk. Second, quitting tobacco or use of ST products is associated with lower risks of oral cancer than cigarette smoking. Third, those who smoked in the past but now use ST products have lower oral cancer risk compared to those who continue to smoke.

These findings have important public health implications. The US Food and Drug Administration and many in the scientific, medical, and public health community [57-60] have concluded that a continuum of risk exists within tobacco products, combustible cigarettes being the highest and noncombustible products like ST products being far lower. Although quitting all tobacco products is the optimum outcome, according to the harm reduction framework [59], smoking-related morbidity and mortality can be reduced by encouraging adult smokers who are unable or unwilling to quit tobacco to switch to less harmful products. However, despite the evidence presented here and supported by other reports [9,11,20,31,32], millions of adults continue to smoke [56]. One of the reasons is that most (~90%) believe that use of ST products is equal to or more harmful than use of cigarettes [61-64]. The misperceptions regarding the risk differential between cigarettes and ST may be dissuading smokers who are unable or unwilling to quit tobacco from switching to lower risk products like ST [65]. Our findings support existing evidence of higher oral cancer risk among individuals who smoke compared to those who quit or used ST products. However, the vast majority of adult smokers are not aware of this evidence. Improved knowledge of the relative risks of ST and cigarettes could allow adult smokers to make informed decisions regarding the benefits of quitting or switching and successfully reduce the harm from smoking-related diseases.

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Data Availability

Colorado data were collected and provided, in part, by the Colorado Central Cancer Registry. The Colorado Central Cancer Registry and the Colorado Department of Public Health and Environment specifically disclaim responsibility for any analyses, interpretations, or conclusions they have not provided. The Florida cancer incidence data used in this report were collected by the Florida Cancer Data System, the statewide cancer registry funded by the Florida Department of Health and the Centers for Disease Control and Prevention's National Program of Cancer Registries. The views expressed herein are solely those of the authors and do not necessarily reflect those of the Florida Department of Health or Centers for Disease Control and Prevention's National Program of Cancer Registries. The findings and conclusions in this publication are those of the authors and do not necessarily represent the views of the North Carolina Department of Health and Human Services, Division of Public Health. Cancer incidence data have been provided by the Texas Cancer Registry, Cancer Epidemiology and Surveillance Branch, Texas Department of State Health Services, 1100 West 49th Street, Austin, TX 78756.

Authors' Contributions

BN and HC designed the study, conducted the analysis, and wrote the manuscript. BN applied for, collected, and managed study data. MS reviewed and edited the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

BN, HC, and MS are employees of Altria Client Services LLC. This study was funded by Altria Client Services LLC.

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Abbreviations

BRFSS: Behavioral Risk Factor Surveillance System
CO: Colorado
FL: Florida
HPV: human papillomavirus
IRR: incidence rate ratio
NC: North Carolina
NC: North Carolina

ST: smokeless tobacco
TUS-CPS: Tobacco Use Supplement to the Current Population Survey
TX: Texas

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Variation in Trust in Cancer Information Sources by Perceptions of Social Media Health Mis- and Disinformation and by Race and Ethnicity Among Adults in the United States: Cross-Sectional Study

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Abstract

Background: Mis- and disinformation on social media have become widespread, which can lead to a lack of trust in health information sources and, in turn, lead to negative health outcomes. Moreover, the effect of mis- and disinformation on trust in information sources may vary by racial and ethnic minoritized populations.

Objective: We evaluated how trust in multiple sources of cancer information varied by perceptions of health mis- and disinformation on social media and by race and ethnicity.

Methods: Cross-sectional, nationally representative survey data from noninstitutionalized adults in the United States from the 2022 Health Information National Trends Survey 6 (HINTS 6) were analyzed (N=4137). The dependent variable measured the level of trust in cancer information sources. The independent variables were perceptions about health mis- and disinformation on social media and race and ethnicity. Multivariable logistic regression models were adjusted for survey weight and design, age, birth gender, race and ethnicity, marital status, urban/rural designation, education, employment status, feelings about household income, frequency of social media visits, and personal and family history of cancer. We also tested the interaction effect between perceptions of social media health mis- and disinformation and participants’ self-reported race and ethnicity.

Results: Perception of “a lot of” health mis- and disinformation on social media, relative to perception of “less than a lot,” was associated with a lower likelihood of high levels of trusting cancer information from government health agencies (odds ratio [OR] 0.60, 95% CI 0.47-0.77), family or friends (OR 0.56, 95% CI 0.44-0.71), charitable organizations (OR 0.78, 95% CI 0.63-0.96), and religious organizations and leaders (OR 0.64, 95% CI 0.52-0.79). Among White participants, those who perceived a lot of health mis- and disinformation on social media were less likely to have high trust in cancer information from government health agencies (margin=61%, 95% CI 57%-66%) and family or friends (margin=49%, 95% CI 43%-55%) compared to those who perceived less than a lot of health mis- and disinformation on social media. Among Black participants, those who perceived a lot of health mis- and disinformation on social media were less likely to have high trust in cancer information from religious organizations and leaders (margin=20%, 95% CI 10%-30%) compared to participants who perceived no or a little health mis- and disinformation on social media.

Conclusions: Certain sources of cancer information may need enhanced support against the threat of mis- and disinformation, such as government health agencies, charitable organizations, religious organizations and leaders, and family or friends. Moreover, interventions should partner with racial and ethnically minoritized populations that are more likely to have low trust in certain cancer information sources associated with mis- and disinformation on social media.

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KEYWORDS

cancer; United States; cross-sectional study; trust; consumer health information; misinformation; disinformation; race; ethnicity; cancer information; source; sources; perception; perceptions; social media; health information; cross-sectional data; misleading

Introduction

Misinformation is unintentionally providing false or inaccurate information, while disinformation is intentionally spreading false or inaccurate information [1-3]. A recent systematic review found that more than 80% of adult social media users perceive "some" or "a lot of" false or misleading health information on social media, while nearly a fifth reported either "none" or "a little" [4]. Both mis- and disinformation have been linked to reductions in health-promoting behaviors. For example, people who perceive more misinformation in the media are associated with a lower likelihood of being vaccinated against COVID-19 and a greater likelihood of smoking more and having poorer nutrition than people who perceive less misinformation in the media [5-11]. According to the Comprehensive Model of Information Seeking, misinformation may be associated with a lack of trust in health information sources, which can, in turn, lead to changes in health behaviors [12,13].

There is limited research on misinformation and trust, with some mixed findings. Some cross-sectional studies have found that higher perceptions of misinformation are associated with lower trust in the media, while one study of multiple countries, including the United States, did not find a relationship between perceptions of misinformation and trust in news media [14-19]. A gap in the literature is that these studies were not drawn from representative samples and only measured trust in media. Furthermore, the effects of misinformation may be more pronounced among individuals with comorbidities, particularly cancer, that have complex clinical treatment plans and significant economic costs [20]. For example, cancer survivors are more likely to have a lot of trust in information from doctors compared to persons that have not been diagnosed with cancer [20]. Therefore, there is an evidence gap for the effects of social media mis- and disinformation on trust in different credible sources (eg, scientists, doctors, and government health agencies) of cancer information.

The effect of mis- and disinformation on trust may also vary by different population groups. In some studies, racial and ethnic minoritized populations were found to be less likely to perceive false or misleading health information on social media and to trust noncredible information sources compared to non-Latino White people [21,22]. The lack of trust may also extend to credible sources of cancer information because, for example, non-Latino Black and Latino people have reported lower trust in doctors compared to non-Latino White people [20,23]. A study of 10-year trends in trust in cancer information found that, compared to non-Latino White participants, non-Latino Black participants were more likely to trust cancer information from media, government, charitable organizations, and religious organizations. In contrast, that same study found that Latino participants were less likely to trust cancer information from doctors compared to non-Latino White people [24]. There may be differences within Latino populations in trust in cancer information. For example, Cuban Americans and Puerto Ricans were more than twice as likely to trust information about cancer from print media and religious organizations compared to Mexican Americans [25]. However, a recent study found that trust in cancer information from government health agencies and family or friends declined among non-Latino Black participants from 2018 to 2020 [26]. Given these mixed findings, there is a need to examine whether the effect of mis- and disinformation on trust in cancer information varies among racial and ethnic minoritized populations and therefore may be a mechanism to explain these variations and a possible target for interventions to improve trust in cancer information, at least from credible sources such as doctors and scientists [27].

Research Objective

The purpose of this study is to use recently released nationally representative data to estimate the association between perceptions of health information on social media and level of trust in multiple sources of information about cancer. We hypothesized that perception of a lot of health mis- and disinformation on social media would be associated with lower levels of trust in cancer information sources. By extension, this study evaluated the interaction effect between race and ethnicity of the participants, perceptions of social media health mis- and disinformation, and trust in cancer information. We hypothesized that the association between perceptions of a lot of mis- and disinformation on social media and trust in cancer information sources would vary by race and ethnicity. The results of this research have implications for effective communication about cancer in public health education campaigns, especially for racial and ethnic minoritized populations.

Methods

Data

This study used cross-sectional data from the Health Information National Trends Survey 6 (HINTS 6), which is a nationally representative survey of civilian, noninstitutionalized adults aged 18 years and older living in the United States. HINTS 6 provides data on adults' knowledge of cancer risk factors, attitudes toward cancer screening, and cancer prevention and screening behaviors. HINTS 6 used a 2-stage probability sample of residential addresses. Mail and online surveys were administered to household members from March 7 to November 8, 2022, with a response rate of 28.1% [28]. The data are publicly available and deidentified. Further details about the survey methodology and recruitment procedures are available from the HINTS 6 Methodology Report [28].

Given the focus of this study was perceptions of false or misleading health information on social media, persons that reported that they did not use social media were excluded. There were 4710 cases with complete data for the dependent and independent variables. After using listwise deletion for 573 cases with missing data for the control variables, the final analytical sample consisted of 4137 adult social media users.

Measures

Our dependent variables were measured by asking participants, "In general, how much would you trust information about cancer from..." Responses included the following: "a doctor," "family or friends," "religious organizations and leaders," "government health agencies," "charitable organizations," and "scientists." The response options were dichotomized into low levels of trust ("not at all" or "a little") versus high levels of trust ("some" or "a lot").

The primary independent variable was perceptions about health mis- and disinformation on social media, which was assessed by the following question: "How much of the health information that you see on social media do you think is false or misleading?" HINTS had not measured perceptions about social media mis- and disinformation in prior iterations of the survey. However, this measure did not differentiate between people's perceptions of mis- versus disinformation. The original response categories were "a lot," "some," "a little," and "none." We dichotomized this as "less than a lot" (including "some," "a little," and " none") versus "a lot." Race and ethnicity were self-reported by the participants in 5 categories: "non-Latino White," "non-Latino Black," "Asian American," "other," and "Latino."

Demographic control variables included age (18-34, 35-49, 50-64, and ≥65 years), sex (male and female), marital status (married or cohabiting, formerly married, and never married), residence in a metropolitan versus nonmetropolitan county as designated by the United States Department of Agriculture in 2013, education (high school or less, some college, and college degree or higher), full-time employment status, and feelings about household income (finding it very difficult on present income, getting by on present income, and living comfortably on present income). It should be noted that age was not collected as a continuous variable in HINTS 6, which limited the age categories that could be analyzed. In addition, we controlled for frequency of visiting social media sites (never, monthly/weekly, and daily) in the past 12 months and personal and family (first- or second-degree biological relatives) history of cancer.

Statistical Analysis

All analyses accounted for survey weights and design using jackknife replicate weights for variance estimation. Statistical significance was set at α<.05. The descriptive statistics for the study sample were calculated as survey-weighted percentages accompanied with the raw sample size for each variable. The bivariate relationship between level of trust in cancer information and perceptions of mis- and disinformation were calculated with cell percentages and adjusted Wald *P* values. Then, multivariable logistic regression models were calculated for each dichotomous outcome. In addition to the main effect, we also tested the interaction effect between perceptions of health mis- and disinformation on social media and participants' self-reported race and ethnicity. To facilitate interpretation of the interaction effect, we calculated predicted marginal effects from the multivariable logistic regression models.

For this study, the primary focus was perceptions of information on social media. Therefore, we conducted a sensitivity analysis in which we excluded 257 adults who had not visited a social media site in the past year or reported that they did not use social media (n=3880 were included). After excluding these participants, the results were similar, as shown in Multimedia Appendix 1, Table S1. In addition, we conducted a sensitivity analysis for an ordinal measurement of the dependent variables ("a lot," "some," "a little," and "not at all") using ordered logit regression, and we found that the results were replicated with this alternative measurement, as shown in Multimedia Appendix 1, Table S2. Another sensitivity analysis included participants that did not use social media (n=4986). After including participants that did not use social media, the results were similar, as shown in Multimedia Appendix 1, Table S3. In Multimedia Appendix 1, Table S4, we tested an alternative measurement of the independent variable in which perception of "a lot" of social media mis- and disinformation was compared with respondents that reported "some" and "none" or "a little." For this sensitivity analysis, we combined "none" and "a little" because only 108 participants chose "none" for this measure. We replicated the main result using this alternative measurement of the independent variable.

Ethical Considerations

The University of Texas Southwestern Medical Center institutional review board determined that the study was exempt from review because it used publicly available data without personal identifiers.

Results

Table 1 provides the survey-weighted percentages for the study variables. Most participants in the survey reported high trust in cancer information from doctors (95%), scientists (86%), and government health agencies (71%). About half reported high trust in cancer information from family or friends (54%) and charitable organizations (49%). About a quarter of participants reported high trust in cancer information from religious organizations and leaders (26%). When participants were asked about perceptions of false or misleading health information on social media, most reported "less than a lot" (63%) and 37% reported "a lot."

Table 1. Unadjusted sample size and survey-weighted percentages for study variables from the 2022 Health Information National Trends Survey 6 (N=4137).

Variables	Unadjusted sample size, n (weighted %)
Outcome variables	
In general, how much would you trust information about cancer from a doctor?	
Low	200 (5)
High	3937 (95)
In general, how much would you trust information about cancer from scientists?	
Low	525 (14)
High	3612 (86)
In general, how much would you trust information about cancer from government health agencies?	
Low	1077 (29)
High	3060 (71)
In general, how much would you trust information about cancer from family or friends?	
Low	1874 (46)
High	2263 (54)
In general, how much would you trust information about cancer from charitable organizations?	
Low	2050 (51)
High	2087 (49)
In general, how much would you trust information about cancer from religious organizations and leaders?	
Low	3034 (74)
High	1103 (26)
Independent variables	
How much of the health information that you see on social media do you think is false or misleading?	
Less than a lot	2643 (63)
A lot	1494 (37)
Race and ethnicity	
Non-Latino White	2381 (61)
Non-Latino Black	643 (11)
Latino	734 (17)
Non-Latino Asian American	230 (6)
Non-Latino other	149 (5)
Age group (years)	
18-34	771 (29)
35-49	1012 (29)
50-64	1222 (27)
≥65	1132 (15)
Birth gender	
Male	1586 (48)
Female	2551 (52)
Marital status	
Married/cohabiting	2290 (57)
Formerly married	994 (10)
Never married	853 (33)

Variables	Unadjusted sample size, n (weighted %)
United States Department of Agriculture 2013 rural/urban designation	
Nonmetropolitan	512 (12)
Metropolitan	3625 (88)
Education	
High school or less	812 (25)
Some college	1185 (39)
College graduate or higher	2140 (36)
Work full time (past 30 days)	
No	1878 (40)
Yes	2259 (60)
Feelings about household income	
Finding it very difficult on present income	811 (19)
Getting by on present income	1505 (36)
Living comfortably on present income	1821 (45)
Frequency of social media site visits	
Never	257 (6)
Monthly or weekly	1119 (25)
Daily	2761 (70)
Personal history of cancer	
No	3593 (91)
Yes	544 (9)
Family history of cancer	
No	1259 (35)
Yes	2878 (65)

Table 2 provides the bivariable relationship between the outcome variables and the independent variable. There was not a statistically significant relationship between perception of mis- and disinformation and trust in cancer information from doctors (*P*=.93) or scientists (*P*=.85). However, there was a statistically significant bivariable relationship between perception of mis- and disinformation and trust in cancer information from government health agencies (*P*<.001), family or friends (*P*<.001), charitable organizations (*P*=.007), and religious organizations and leaders (*P*<.001). About a quarter of participants (24%) that perceived a lot of mis- and disinformation on social media had a high level of trust in government health agencies. Nearly half of participants (47%) that perceived less than a lot of mis- and disinformation on social media had a high level of trust in government health agencies. Only 17% of participants that perceived a lot of mis- and disinformation on social media had a high level of trust in family or friends. In contrast, 37% of participants that perceived less than a lot of mis- and disinformation on social media had a high level of trust in family or friends. Only 16% of participants that perceived a lot of mis- and disinformation on social media had a high level of trust in charitable organizations. A third of participants (33%) that perceived less than a lot of mis- and disinformation on social media had a high level of trust in charitable organizations. Finally, only 7% of participants that perceived a lot of mis- and disinformation on social media had a high level of trust in religious organizations and leaders. Nearly 1 in 5 participants (19%) that perceived less than a lot of mis- and disinformation on social media had a high level of trust in religious organizations and leaders.

Table 2. Survey-weighted unadjusted bivariable relationship between trust in cancer information source (low vs high) and perception of health mis- and disinformation on social media ("less than a lot" vs "a lot") from the 2022 Health Information National Trends Survey 6 (N=4137).

Cancer information source	Trust in cancer information source and perception of health mis- and disinformation on social media				*P* value[a]
	Low trust		High trust		
	Less than a lot[b], %	A lot[c], %	Less than a lot[b], %	A lot[c], %	
Doctors	3	2	60	35	.93
Scientists	9	5	54	32	.85
Government health agencies	16	13	47	24	<.001
Family or friends	26	20	37	17	<.001
Charitable organizations	31	20	33	16	.007
Religious organizations and leaders	45	29	19	7	<.001

[a] *P* values were calculated with the adjusted Wald χ^2 test.

[b] Perception of "less than a lot" of health mis- and disinformation on social media.

[c] Perception of "a lot" of health mis- and disinformation on social media.

Table 3 provides the multivariable odds ratios (ORs) and 95% CIs calculated from logistic regression. Perception of a lot of health mis- and disinformation on social media, relative to perception of less than a lot, was associated with a lower likelihood of high levels of trusting cancer information from government health agencies (OR 0.60, 95% CI 0.47-0.77), family or friends (OR 0.56, 95% CI 0.44-0.71), charitable organizations (OR 0.78, 95% CI 0.63-0.96), and religious organizations and leaders (OR 0.64, 95% CI 0.52-0.79).There was not a statistically significant association between perception of social media health mis- and disinformation and level of trust in cancer information from doctors (OR 0.95, 95% CI 0.45-2.01) or scientists (OR 0.98, 95% CI 0.72-1.33).

Table 3. Multivariable odds ratios (ORs) and 95% CIs for perceptions of social media health mis- and disinformation and trust in cancer information sources from the 2022 Health Information National Trends Survey 6 (N=4137). Logistic regression models were adjusted for survey weight and design, age, birth gender, marital status, urban or rural designation, race and ethnicity, education, employment status, feelings about household income, frequency of social media visits, and personal and family history of cancer.

Cancer information source	Trust in cancer information source among participants with the perception that a lot of health information on social media is false or misleading, odds ratio[a] (95% CI)
Doctors	0.95 (0.45-2.01)
Scientists	0.98 (0.72-1.33)
Government health agencies	0.60 (0.47-0.77)
Family or friends	0.56 (0.44-0.71)
Charitable organizations	0.78 (0.63-0.96)
Religious organizations and leaders	0.64 (0.52-0.79)

[a] Reference: "less than a lot."

Table 4 provides the predicted marginal effects, interpreted as percentage points, calculated from the multivariable logistic regression–adjusted interaction effects between perceptions of health mis- and disinformation on social media and participants' self-reported race and ethnicity. There was not a statistically significant interaction effect between perception of mis- and disinformation, race and ethnicity, and trust in cancer information from doctors or scientists. Among White participants, those who perceived a lot of health misinformation and disinformation on social media were less likely to have high trust in cancer information from government health agencies (margin=61%, 95% CI 57%-66%) and family or friends (margin=49%, 95% CI 43%-55%) compared to those who perceived less than a lot of health mis- and disinformation on social media. Among Black participants, those who perceived a lot of health mis- and disinformation on social media were less likely to have high trust in cancer information from religious organizations and leaders (margin=20%, 95% CI 10%-30%) compared to participants who perceived less than a lot of health mis- and disinformation on social media.

Table 4. Multivariable-adjusted percentage points for trusting cancer information by source and the interaction effect between race and ethnicity and perceptions of health mis- and disinformation on social media from the 2022 Health Information National Trends Survey 6 (N=4137). Predicted marginal effects were calculated from multivariable logistic regression models that were adjusted for survey weight and design, age, birth gender, marital status, urban or rural designation, education, employment status, feelings about household income, frequency of social media visits, and personal and family history of cancer.

Race and ethnicity	Perception of false or misleading health information from cancer information source, percentage points (95% CI)					
	Doctors	Scientists	Government health agencies	Family or friends	Charitable organizations	Religious organizations and leaders
Non-Latino White						
Less than a lot	96 (93-98)	86 (83-90)	74 (71-78)	62 (57-68)	51 (46-56)	23 (20-26)
A lot	95 (93-97)	85 (82-89)	61 (57-66)	49 (43-55)	43 (38-49)	19 (15-22)
Non-Latino Black						
Less than a lot	96 (94-99)	80 (71-88)	75 (66-84)	62 (53-71)	57 (50-64)	49 (40-57)
A lot	96 (92-101)	86 (76-95)	71 (60-83)	47 (33-61)	58 (44-73)	20 (10-30)
Latino						
Less than a lot	93 (89-98)	87 (83-92)	77 (68-85)	48 (39-56)	50 (42-58)	40 (28-51)
A lot	96 (92-100)	87 (82-95)	72 (63-82)	37 (28-47)	57 (46-68)	29 (17-40)
Non-Latino Asian American						
Less than a lot	89 (61-117)	90 (82-98)	77 (58-96)	54 (41-67)	44 (30-58)	26 (12-40)
A lot	99 (93-105)	93 (80-104)	86 (68-103)	32 (14-50)	34 (9-59)	23 (4-42)
Non-Latino Other						
Less than a lot	96 (84-107)	89 (78-100)	82 (72-92)	68 (53-82)	58 (38-77)	33 (16-50)
A lot	85 (70-99)	86 (70-101)	56 (36-77)	46 (26-67)	28 (14-42)	13 (2-24)

Discussion

Principal Findings

We found that trust in cancer information from doctors or scientists did not vary based on perceptions of health mis- and disinformation on social media. This suggests that people view doctors and scientists as credible sources of cancer information. However, we found that perception of a lot of mis- and disinformation was associated with reduced levels of trust in cancer information from family or friends, government health agencies, charitable organizations, and religious organizations and leaders. This finding supports other studies that found that mis- and disinformation is associated with reductions in trust in media but extends this prior literature by finding an impact on trust in other sources of cancer information [14-19]. Moreover, this finding is consistent with the Comprehensive Model of Information Seeking, which identifies trust as a mechanism linking mis- and disinformation to health behaviors [12,13].

There were notable variations in the relationship between trust in cancer information sources, perceptions of false or misleading health information, and race and ethnicity. For instance, we found that Black participants who perceived a lot of health mis- and disinformation on social media were less likely to have high trust in cancer information from religious organizations and leaders compared to Black participants who perceived less than a lot of health mis- and disinformation on social media. Another contribution of our study is that White participants who perceived a lot of health mis- and disinformation on social media were less likely to have high trust in cancer information from government health agencies and family or friends compared to White participants who perceived less than a lot of health mis- and disinformation on social media. There have been mixed findings on trust in cancer information sources by race and ethnicity in the recent literature, with one study finding higher trust among Black participants for several sources of cancer information compared to White participants and lower trust in doctors among Latino participants compared to White participants [21-25]. However, another study found that trust in cancer information from government health agencies and family or friends declined among Black participants after the COVID-19 pandemic [26]. Our study adds to this literature by identifying that the effect of mis- and disinformation on trusting information sources may vary among racial and ethnic minoritized populations.

Limitations

We were able to replicate the findings of the study using several different sensitivity analyses, as shown in Multimedia Appendix 1. However, the results should be interpreted within the constraints of the cross-sectional data. First, this study cannot be used to determine the causal relationship between perceptions of mis- and disinformation and trust in social institutions. Second, the 2022 wave of the HINTS survey was the first time that the public's perceptions of mis- and disinformation were measured. If this measure is collected in subsequent iterations of HINTS, then analyses may be able to detect changes in the association between mis- and disinformation and trust in information sources over time. We note that perceptions of mis- and disinformation may not be an accurate measure of objective exposure to social media mis- and disinformation. Further, this measure does not differentiate between people’s perceptions of mis- versus disinformation. Another limitation is that the focus of this study was on social media mis- and disinformation rather than all media, such as traditional television and print, and therefore the results should be interpreted for this specific form of media. Finally, this study focused on trust in cancer information, and the findings might not apply to trust in other types of health information. By extension, levels of trust in government information may differ between federal and state government health agencies, which were not differentiated in our study [29,30].

Conclusion

Certain sources of cancer information may need enhanced support from the threat of mis- and disinformation, such as government health agencies, charitable organizations, religious organizations and leaders, and family or friends. Moreover, there were notable variations in the relationship between trust in cancer information sources (government health agencies, family or friends, and religious organizations and leaders), perceptions of false or misleading health information, and race and ethnicity. One positive finding is that perceptions of mis- and disinformation were not associated with levels of trust in credible sources of cancer information such as doctors or scientists overall or by race and ethnicity. In prior work, researchers have suggested that interventions should be focused on improving trust in science [1]. Although bolstering trust in science or doctors is important, our findings indicate that other sources of cancer information may be more susceptible to the threat of mis- and disinformation. Moreover, interventions should partner with racial and ethnically minoritized populations that are more likely to have low trust in certain cancer information sources associated with mis- and disinformation on social media.

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Data Availability

The data sets generated during and/or analyzed during this study are available in the National Cancer Institute repository [31].

Authors' Contributions

All authors contributed to the study conception and design. Data analysis was performed by JPS. The first draft of the manuscript was written by JPS. All authors contributed to subsequent drafts of the manuscript. All authors read and approved the final version of the manuscript.

Conflicts of Interest

JPS, SP, and ANO have no relevant financial or nonfinancial conflicts of interest to disclose. Unrelated to this work, SLP receives consulting fees from Pfizer and Gilead.

Multimedia Appendix 1
Supplemental analyses.
[DOCX File , 30 KB - cancer_v10i1e54162_app1.docx]

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Abbreviations

HINTS: Health Information National Trends Survey.
OR: odds ratio.

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Original Paper

Real-World Survival Comparisons Between Radiotherapy and Surgery for Metachronous Second Primary Lung Cancer and Predictions of Lung Cancer–Specific Outcomes Using Machine Learning: Population-Based Study

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Abstract

Background: Metachronous second primary lung cancer (MSPLC) is not that rare but is seldom studied.

Objective: We aim to compare real-world survival outcomes between different surgery strategies and radiotherapy for MSPLC.

Methods: This retrospective study analyzed data collected from patients with MSPLC between 1988 and 2012 in the Surveillance, Epidemiology, and End Results (SEER) database. Propensity score matching (PSM) analyses and machine learning were performed to compare variables between patients with MSPLC. Survival curves were plotted using the Kaplan-Meier method and were compared using log-rank tests.

Results: A total of 2451 MSPLC patients were categorized into the following treatment groups: 864 (35.3%) received radiotherapy, 759 (31%) underwent surgery, 89 (3.6%) had surgery plus radiotherapy, and 739 (30.2%) had neither treatment. After PSM, 470 pairs each for radiotherapy and surgery were generated. The surgery group had significantly better survival than the radiotherapy group (P<.001) and the untreated group (563 pairs; P<.001). Further analysis revealed that both wedge resection (85 pairs; P=.004) and lobectomy (71 pairs; P=.002) outperformed radiotherapy in overall survival for MSPLC patients. Machine learning models (extreme gradient boosting, random forest classifier, adaptive boosting) demonstrated high predictive performance based on area under the curve (AUC) values. Least absolute shrinkage and selection operator (LASSO) regression analysis identified 9 significant variables impacting cancer-specific survival, emphasizing surgery's consistent influence across 1 year to 10 years. These variables encompassed age at diagnosis, sex, year of diagnosis, radiotherapy of initial primary lung cancer (IPLC), primary site, histology, surgery, chemotherapy, and radiotherapy of MPSLC. Competing risk analysis highlighted lower mortality for female MPSLC patients (hazard ratio [HR]=0.79, 95% CI 0.71-0.87) and recent IPLC diagnoses (HR=0.79, 95% CI 0.73-0.85), while radiotherapy for IPLC increased mortality (HR=1.31, 95% CI 1.16-1.50). Surgery alone had the lowest cancer-specific mortality (HR=0.83, 95% CI 0.81-0.85), with sublevel resection having the lowest mortality rate among the surgical approaches (HR=0.26, 95% CI 0.21-0.31). The findings provide valuable insights into the factors that influence cumulative cancer-specific mortality.

Conclusions: Surgical resections such as wedge resection and lobectomy confer better survival than radiation therapy for MSPLC, but radiation can be a valid alternative for the treatment of MSPLC.

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KEYWORDS

metachronous second primary lung cancer; radiotherapy; surgical resection; propensity score matching analysis; machine learning

Introduction

Lung cancer has become a leading cause of cancer-related deaths worldwide [1]. With the rapid development of screening tools and therapeutic strategies, survival outcomes of lung cancer patients have encouragingly improved, especially for early-stage non-small cell lung cancer (NSCLC), which has a 5-year survival rate as high as 90% [2]. For cancer survivors, longer survival may well lead to a higher probability of developing a second primary cancer. In recent years, metachronous second primary lung cancer (MSPLC) has been commonly observed among survivors with previously treated lung cancer. Thakur et al [3] reported that MSPLC occurred in 2.95% of patients with initial primary lung cancer (IPLC) in the Surveillance, Epidemiology, and End Results (SEER) database. According to the study by Surapaneni et al [4], the risk of developing a second lung cancer is the highest in the first year and continues to be high at 10 years. The surveillance and management of patients with MSPLC have become an urgent issue.

For patients with an initial, early-stage lung cancer, surgical resection remains the most effective treatment. However, there is still a lack of guidelines to assess tumor resectability in patients with MSPLC. Several studies have confirmed the feasibility of surgery for MSPLC [5-9]. Remarkably, patients with MSPLC with previously resected lung cancer may be in poor physical condition and have insufficient lung function reserve, and another surgical procedure may not be appropriate. Thus, an alternative treatment is required for patients with inoperable MSPLC.

Radiation therapy is an effective treatment choice for patients with MSPLC and has fewer complications and impairments. Stereotactic body radiotherapy has recently been reported to have similar survival outcomes as surgery in patients with early-stage lung cancer [10,11]. Previous studies have shown that radiotherapy is a safe and feasible treatment for MSPLC, but whether it can compare with surgery in terms of survival outcomes remains debated [12,13]. Therefore, in this population-based study, the initial step involved conducting propensity score matching (PSM) analyses to compare the survival outcomes of patients who underwent surgical resection with those who received radiotherapy for multiple synchronous primary lung cancers. Furthermore, specific focus was placed on comparing the outcomes of common surgical methods, namely lobectomy and wedge resection, with those of radiotherapy for patients with MSPLC. To enhance the accuracy of the predictions, state-of-the-art machine learning (ML) techniques were used, and multiple algorithms were used to develop robust prediction models.

Methods

Data Source

Data for all patients diagnosed with MSPLC included in this retrospective study were sourced from the SEER database [14], covering approximately 30% of cancer patients in the United States. Data pertaining to these patients were extracted from 9 cancer registries and augmented with additional treatment information from regions including Atlanta, Connecticut, Detroit, Hawaii, Iowa, New Mexico, San Francisco–Oakland, Seattle–Puget Sound, and Utah. The data set's most recent follow-up information was updated in November 2018. This study aimed to prognosticate the outcomes for patients with MSPLC. In adherence to the established guidelines for the development and reporting of ML predictive models in biomedical research [15], we meticulously maintained precision and clarity throughout our research process.

Preparation of Data for Model Building

Patients aged ≥20 years who were diagnosed with MSPLC were identified from the SEER database. We defined MSPLC according to the criteria set by Martini and Melamed [16]. We only included patients with 2 primary lung tumors with a diagnostic interval between the tumors ≥4 years, because it is difficult to distinguish a primary lung tumor from relapse or metastasis when the interval is <4 years [17]. The initial inclusion criteria were as follows: (1) primary sites of the 2 tumors were the lung and bronchus (International Classification of Diseases for Oncology [ICD-O]-3/World Health Organization [WHO] 2008, Third Edition), (2) the time of diagnosis for the IPLC was from January 1988 to December 2012 (to ensure that all enrolled patients had been followed for enough time), and (3) age was ≥20 years. The exclusion criteria included (1) <4 years between the diagnosis of the 2 primary tumors, (2) distant metastasis, (3) histological type of small cell lung cancer for IPLC or MSPLC, and (4) incomplete follow-up information.

We collected the patients’ demographic features and clinical characteristics, such as age at diagnosis, sex, race (White, Black, other [American Indian/Alaska Native, Asian/Pacific Islander], and unknown), location relationship of the 2 primary tumors (ipsilateral and contralateral), diagnostic interval, year of diagnosis, SEER cancer stage (localized and regional), histological type (adenocarcinoma, squamous cell carcinoma, and other NSCLC), grade, surgical procedure, chemotherapy, and radiotherapy (beam radiation). Sublevel resection was regarded as an extent of resection that was less than lobectomy. For patients diagnosed with IPLC after 2004, additional clinical information such as TNM (tumor [T], extent of spread to the lymph nodes [N], and presence of metastasis [M]) stage (6th edition of the American Joint Committee on Cancer TNM system) and tumor size were available.

Predictive Models

We used 6 classical ML algorithms, namely extreme gradient boosting (XGB), random forest classifier (RFC), adaptive boosting (ADB), K nearest neighbor (KNN), artificial neural network (ANN), and gradient boosting decision tree (GBDT), to forecast long-term cancer-specific survival (CSS). To select the variables for modeling, the least absolute shrinkage and selection operator (LASSO) regression technique was used. An extensive method was used to determine the optimal combination of variables for each algorithm. The performance and predictive capabilities of over a dozen variables were individually assessed using the models, measured using the area under the receiver operating characteristic curves (AUC of ROCs), and decision curve analysis was conducted. The most effective variables were identified, and additional variables were combined iteratively until the best overall results were obtained. The selection of the optimal modeling approach for each algorithm was determined using 5-fold cross-validation. Furthermore, the contribution of each variable was calculated. Additionally, age-adjusted competing risk regression analysis was conducted using the “cmprsk” package in R to examine the cumulative risk of cancer-specific mortality. This comprehensive approach facilitated a thorough evaluation of the risk factors and outcomes associated with cancer-specific mortality in diverse patient populations.

Statistical Analyses

All statistical analyses were performed using SPSS 27.0 (IBM Corp) and R software version 4.3.1 [18]. SEER*Stat software version 8.4.2 was used to identify the study population from the SEER database. A 2-tailed *P* value <.05 was considered statistically significant. Continuous parameters such as patients’ age and diagnostic interval are expressed as mean (SD) and were compared between the different treatment groups using Mann-Whitney *U* tests. For categorical parameters, proportions were compared using Pearson chi-square tests. To balance the baseline characteristics between the different treatment groups, PSM analyses were used. Survival curves were plotted using the Kaplan-Meier method and compared using log-rank tests.

Ethical Considerations

The data used in this research were extracted from the publicly accessible, anonymized SEER database. Given the nature of the SEER database, which contains deidentified patient information and is widely used for epidemiological and clinical research purposes, our study fell within the category of research that is exempt from formal ethical approval and consent requirements. This exemption is consistent with established institutional and local policies regarding the use of publicly available, deidentified data for research purposes [19].

Results

Demographic Characteristics

According to our inclusion and exclusion criteria, a total of 2451 patients diagnosed with MSPLC were included in this study. All patients’ baseline characteristics are summarized in Table 1. There were 1137 men and 1314 women, with a mean age of 63.5 (SD 9.2) years. White people accounted for 84.1% (2062/2451) of the study population. The mean diagnostic interval between the 2 primary lung tumors was 101.0 (SD 47.6) months. The year of diagnosis of the IPLC ranged from 1988 to 2012. For IPLC, 264 (10.8%) of the 2451 patients did not undergo any surgical procedure, while 2447 underwent surgical resection, including 295 (295/2447, 12%) sublevel resections, 1786 (1786/2447, 72.9%) lobectomies, and 106 (106/2447, 4.3%) pneumonectomies. Additionally, 465 (465/2451, 19%) patients received chemotherapy, and 489 (489/2451, 20%) underwent radiation therapy for IPLC. Based on treatments for MSPLC, patients were divided into the following 4 subgroups: radiotherapy only (864/2451, 35.3%), surgery only (759/2451, 31%), surgery plus radiotherapy (89/2451, 3.6%), and no treatment (739/2451, 30.2%). The median follow-up time after MSPLC diagnosis was 18 (range: 1-273) months. For the entire study population, the 5-year overall survival (OS) was 34.7%.

Table 1. Demographic and clinical characteristics of 2451 patients diagnosed with second primary lung cancer.

Characteristic	Results
Age (years), mean (SD)	63.5 (9.2)
Race, n (%)	
White	2062 (84.1)
Black	240 (9.8)
Other	149 (6.1)
Sex, n (%)	
Male	1137 (46.4)
Female	1314 (53.6)
Relative location, n (%)	
Ipsilateral	815 (33.3)
Contralateral	1636 (66.7)
Diagnostic interval (months), mean (SD)	101.0 (47.6)
Initial primary lung cancer	
Year of diagnosis, n (%)	
1988-1995	763 (31.1)
1996-2003	919 (37.5)
2004-2012	769 (31.4)
SEER[a] stage, n (%)	
Localized	1538 (62.7)
Regional	913(37.3)
Histology, n (%)	
ADC[b]	1399 (57.1)
SCC[c]	690 (28.2)
Other NSCLC[d]	362 (14.8)
Grade, n (%)	
Well differentiated	277 (11.3)
Moderately differentiated	844 (34.3)
Poorly differentiated	792 (32.3)
Undifferentiated	115 (4.7)
Unknown	423 (17.3)
Surgery, n (%)	
No surgery	264 (10.8)
Sublevel resection	295 (12)
Lobectomy	1786 (72.9)
Pneumonectomy	106 (4.3)
Chemotherapy, n (%)	
Yes	465 (19)
No/unknown	1986 (81)
Radiotherapy, n (%)	
Yes	489 (20)
No/unknown	1962 (80)

Characteristic	Results
Second primary lung cancer	
Surgery, n (%)	
No surgery	1603 (65.4)
Wedge resection	295 (12)
Segmentectomy	61 (2.5)
Other/inseparable sublevel resection	87 (3.5)
Lobectomy	352 (14.4)
Pneumonectomy	53 (2.2)
Chemotherapy, n (%)	
Yes	694 (28.3)
No/Unknown	1757 (71.7)
Radiotherapy, n (%)	
Yes	953 (38.9)
No/Unknown	1498 (61.1)
Treatment, n (%)	
Only radiotherapy	964 (35.3)
Only surgery	759 (31.0)
Surgery + radiotherapy	89 (3.6)
None	739 (30.2)

[a] SEER: Surveillance, Epidemiology, and End Results.

[b] ADC: adenocarcinoma.

[c] SCC: squamous cell carcinoma.

[d] NSCLC: non-small cell lung cancer.

Radiotherapy Versus Surgery

Before PSM, the distributions of several baseline characteristics were significantly different between the radiotherapy and surgery groups. These included age (*P*<.001); sex (*P*=.005); relative location of the 2 primary tumors (*P*<.001); diagnostic interval (*P*<.001); and IPLC characteristics such as year of diagnosis (*P*=.004), histology (*P*<.001), surgical procedure (*P*<.001), radiotherapy (*P*=.04), and chemotherapy for MSPLC (*P*<.001; Table 2). Figure 1A shows the survival outcomes among the 4 treatment groups (*P*<.001). Patients who only received radiotherapy had worse survival than those who underwent surgical resection but better survival than the no treatment group.

To evaluate the role of radiotherapy in terms of treatment for MSPLC, multiple PSM analyses were performed to compare radiotherapy with no treatment, surgery, and surgery plus radiotherapy. After PSM (ratio: 1:1; caliper=0.01), all baseline characteristics were matched well between the corresponding comparison groups (Table 2 and Tables S1 and S2 in Multimedia Appendix 1). As shown in Figure 1, the radiotherapy group had significantly better survival outcomes than the no treatment group (*P*<.001; Figure 1B) but significantly worse survival outcomes than the surgery group (*P*<.001; Figure 1C). However, radiotherapy seemed to not improve the survival outcome among patients who received surgery for MSPLC (*P*=.26; Figure 1D).

Table 2. Comparison of baseline characteristics between surgery and radiotherapy for second primary lung cancer before and after propensity score matching (PSM).

Characteristic	Before PSM			After PSM		
	Radiation (n=864)	Surgery (n=759)	*P* value	Radiation (n=470)	Surgery (n=470)	*P* value
Age (years), mean (SD)	63.9 (8.9)	62.1 (9.0)	<.001	63.0 (8.8)	62.7 (9.1)	.55
Race, n (%)			.10			.75
White	737 (85.3)	642 (84.6)		401 (85.3)	393 (83.6)	
Black	85 (9.8)	63 (8.3)		39 (8.3)	45 (9.6)	
Other	42 (4.9)	54 (7.1)		30 (6.4)	32 (6.8)	
Sex, n (%)			.005			.95
Male	417 (48.3)	313 (41.2)		201 (42.8)	203 (43.2)	
Female	447 (51.7)	446 (58.8)		269 (57.2)	267 (56.8)	
Relative location, n (%)			<.001			.73
Ipsilateral	321 (37.2)	208 (27.4)		152 (32.3)	146 (31.1)	
Contralateral	543 (62.8)	551 (72.6)		318 (67.7)	324 (68.9)	
Diagnostic interval (months), mean (SD)	104.4 (48.7)	95.8 (45.3)	<.001	99.1 (43.5)	100.9 (50.5)	.56
IPLC[a]						
Year of diagnosis			.004			.93
1988-1995	242 (28)	256 (33.7)		135 (28.7)	135 (28.7)	
1996-2003	313 (36.2)	286 (37.7)		174 (37)	169 (36)	
2004-2012	309 (35.8)	217 (28.6)		161 (34.3)	166 (35.3)	
SEER[b] **stage**			.499			.73
Localized	560 (64.8)	505 (66.5)		300 (63.8)	306 (65.1)	
Regional	304 (35.2)	254 (33.5)		170 (36.2)	164 (34.9)	
Histology			<.001			.82
ADC[c]	451 (52.2)	495 (65.2)		275 (58.5)	275 (58.5)	
SCC[d]	280 (32.4)	173 (22.8)		125 (26.6)	131 (27.9)	
Other NSCLC[e]	133 (15.4)	91 (12)		70 (14.9)	64 (13.6)	
Grade			.06			≥.99
Well differentiated	82 (9.5)	106 (14)		50 (10.6)	52 (11.1)	
Moderately differentiated	295 (34.1)	259 (34.1)		167 (35.5)	168 (35.7)	
Poorly differentiated	295 (34.1)	231 (30.4)		149 (31.7)	148 (31.5)	
Undifferentiated	42 (4.9)	33 (4.3)		22 (4.7)	23 (4.9)	
Unknown	150 (17.4)	130 (17.1)		82 (17.4)	79 (16.8)	
Surgery			<.001			.98
No surgery	102 (11.8)	47 (6.2)		45 (9.6)	42 (8.9)	
Sublevel resection	100 (11.6)	105 (13.8)		59 (12.6)	61 (13)	
Lobectomy	616 (71.3)	591 (77.9)		353 (75.1)	355 (75.5)	
Pneumonectomy	46 (5.3)	16 (2.1)		13 (2.8)	12 (2.6)	
Chemotherapy			.77			.87
Yes	155 (17.9)	131 (17.3)		91 (19.4)	88 (18.7)	
No/unknown	709 (82.1)	628 (82.7)		379 (80.6)	382 (81.3)	
Radiotherapy			.04			.93

Characteristic	Before PSM			After PSM		
	Radiation (n=864)	Surgery (n=759)	*P* value	Radiation (n=470)	Surgery (n=470)	*P* value
Yes	176 (20.4)	123 (16.2)		86 (18.3)	88 (18.7)	
No/unknown	688 (79.6)	636 (83.8)		384 (81.7)	382 (81.3)	
SPLC[f]						
Chemotherapy			<.001			≥.99
Yes	318 (36.8)	91 (12)		88 (18.7)	87 (18.5)	
No/unknown	546 (63.2)	668 (88)		382 (81.3)	383 (81.5)	

[a] IPLC: initial primary lung cancer.

[b] SEER: Surveillance, Epidemiology, and End Results.

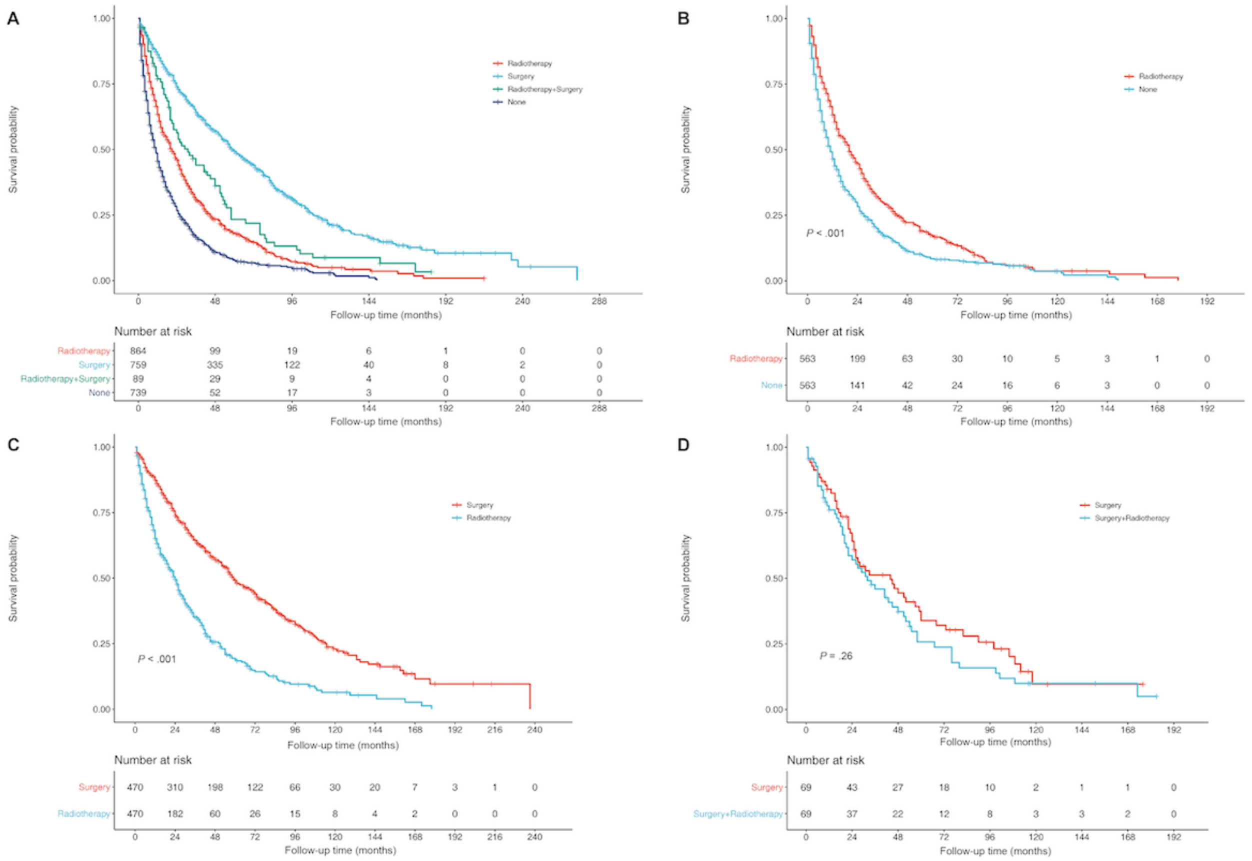
[c] ADC: adenocarcinoma.

[d] SCC: squamous cell carcinoma.

[e] NSCLC: non-small cell lung cancer.

[f] SPLC: second primary lung cancer.

Figure 1. (a) Overall survival of 2451 patients with MSPLC between 1988 and 2012 in different treatment groups before propensity score matching (PSM). (b) Overall survival of radio-therapy and none-treatment after PSM. (c) Overall survival of radiotherapy and surgery after PSM. (d) Overall survival of surgery and surgery plus radiotherapy after PSM.



Radiotherapy Versus Wedge Resection or Lobectomy

To further compare survival between radiotherapy and specific surgical procedures, patients with MSPLC diagnosed with IPLC after 2004 were selected. Those who underwent unknown or indefinite sublevel resection, segmentectomy (very few patients) and pneumonectomy for MSPLC were excluded. There were 716 patients included for further analyses. The demographic characteristics are described in Table 3. Before PSM, Figure 2A shows that patients who underwent wedge resection or lobectomy had significantly better OS than those who received radiotherapy, and all of them had significantly better OS than the no treatment group. More clinical parameters such as T and N stage for IPLC and tumor size for MSPLC were matched by PSM, and all parameters were matched well (Tables S3-S5 in Multimedia Appendix 1). Similarly, after PSM, both wedge resection (*P*=.004; Figure 2C) and lobectomy (*P*=.002; Figure 2D) had significantly better OS than radiotherapy. Furthermore, radiotherapy also had greater survival benefits than no treatment (*P*<.001; Figure 2B).

Table 3. Demographic and clinical characteristics of 716 patients diagnosed with second primary lung cancer after 2004.

Characteristic	Results
Age (years), mean (SD)	65.8 (9.0)
Race, n (%)	
White	608 (84.9)
Black	65 (9.1)
Other	43 (6)
Sex, n (%)	
Male	310 (43.3)
Female	406 (56.7)
Relative location, n (%)	
Ipsilateral	279 (39)
Contralateral	437 (61)
Interval, mean (SD)	74.2 (21.4)
Initial primary lung cancer	
T stage, n (%)	
T1	315 (44)
T2	277 (38.7)
T3	35 (4.9)
T4	66 (9.2)
Unknown	23 (3.2)
N stage, n (%)	
N0	528 (73.7)
N1	80 (11.2)
N2	97 (13.5)
Unknown	11 (1.5)
Histology, n (%)	
ADC[a]	406 (56.7)
SCC[b]	206 (28.8)
Other NSCLC[c]	104 (14.5)
Grade, n (%)	
Well differentiated	94 (13.1)
Moderately differentiated	275 (38.4)
Poorly differentiated	211 (29.5)
Undifferentiated	18 (2.5)
Unknown	118 (16.5)
Surgery, n (%)	
No surgery	131 (18.3)
Sublevel resection	106 (14.8)
Lobectomy	455 (63.5)
Pneumonectomy	24 (3.4)
Chemotherapy, n (%)	
Yes	237 (33.1)

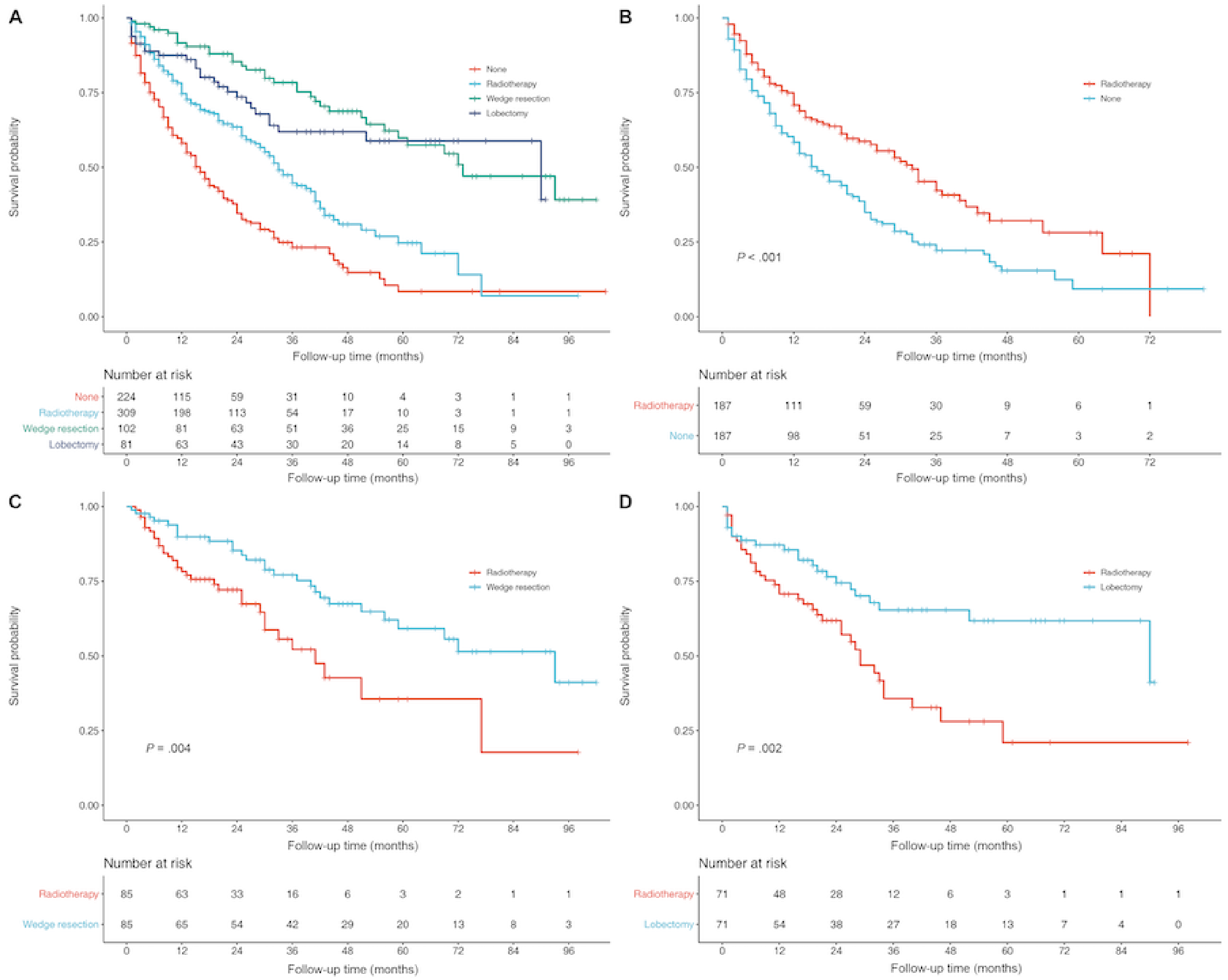
Characteristic	Results
No/unknown	479 (66.9)
Radiotherapy, n (%)	
Yes	174 (24.3)
No/unknown	542 (75.7)
Second primary lung cancer	
Size (cm), n (%)	
0-3	385 (53.8)
3-5	71 (9.9)
>5	56 (7.8)
Unknown	204 (28.5)
Surgery, n (%)	
No surgery	533 (74.4)
Wedge resection	102 (14.2)
Lobectomy	81 (11.3)
Chemotherapy, n (%)	
Yes	201 (28.1)
No/unknown	515 (71.9)
Radiotherapy, n (%)	
Yes	309 (43.2)
No/unknown	407 (56.8)
Treatment, n (%)	
None	224 (31.3)
Only radiation	309 (43.2)
Only wedge	102 (14.2)
Only lobectomy	81(11.3)

[a] ADC: adenocarcinoma.

[b] SCC: squamous cell carcinoma.

[c] NSCLC: non-small cell lung cancer.

Figure 2. Overall survival of (A) 716 patients with metachronous second primary lung cancer (MSPLC) after 2004 in different treatment groups before propensity score matching (PSM); (B) patients who received radiotherapy or no treatment, after PSM; (C) patients who received radiotherapy or underwent wedge resection, after PSM; (D) patients who received radiotherapy or underwent lobectomy, after PSM.



ML-Based Cancer-Specific Death Risk Prediction

Using LASSO regression, we identified 9 variables that made significant contributions to CSS (Figure 3). These variables encompassed age at diagnosis, sex, year of diagnosis, radiotherapy of IPLC, primary site, histology, surgery, chemotherapy, and radiotherapy of MPSLC. The ML models displayed outstanding performance, as indicated by high AUC values, highlighting the superiority of artificial intelligence in prognostic prediction (Figure 4). The decision curve analyses are depicted in Figure 5. Additionally, we assessed the sensitivity and specificity of each ML model using the maximal Youden index, which represents an optimal balance between true positives and true negatives (Table 4). Through 5-fold cross-validation, the XGB, RFC, and ADB models demonstrated superior performance. In order to gain deeper insights into the relationships between demographic characteristics and long-term outcomes for MSPLC patients, we used these ML algorithms to develop predictive models to assess the 1-year, 3-year, 5-year, and 10-year risks of cumulative cancer-specific mortality based on the aforementioned variables. Consequently, we calculated the contribution of each variable. Notably, we identified the variables associated with CSS at different time intervals (Figure 6). Surgery for MPSLC predominantly and substantially influenced 1-year, 3-year, 5-year, and 10-year CSS. Radiotherapy for MPSLC also had an impact on 1-year, 3-year, 5-year, and 10-year survival, but its effect was comparatively less than that of surgery. The primary site and histology of MPSLC affected 1-year, 3-year, and 5-year CSS, but it had no impact on 10-year CSS. Additionally, radiotherapy for IPLC had an impact on 1-year and 3-year CSS but had minimal influence on 5-year and 10-year survival.

Figure 3. Machine learning model using least absolute shrinkage and selection operator (LASSO) regression analysis for risk prediction of cumulative cancer-specific mortality in patients with metachronous second primary lung cancer (MSPLC): (A) 5-fold cross-validation results and (B) model regression coefficient profile.

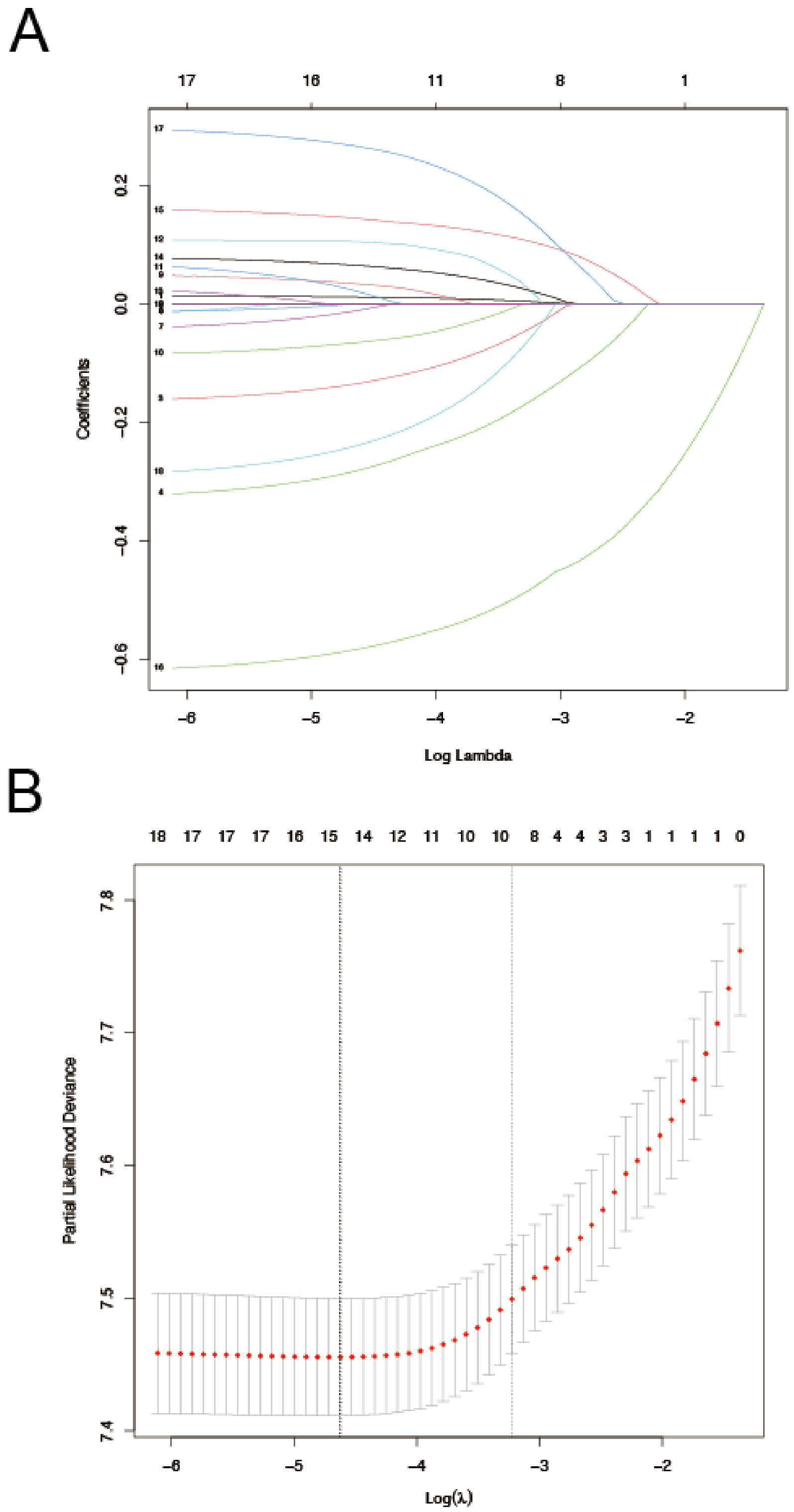


Figure 4. Receiver operating characteristic (ROC) curves for machine learning models for risk prediction of cumulative cancer-specific mortality in patients with metachronous second primary lung cancer (MSPLC): (A) 1-year lymphoma-specific mortality; (B) 3-year lymphoma-specific mortality; (C) 5-year lymphoma-specific mortality; (D) 10-year lymphoma-specific mortality. ADB: adaptive boosting; ANN: artificial neural network; AUC: area under the curve; GBDT: gradient boosting decision tree; KNN: K nearest neighbor; RFC: random forest classifier; ROC: receiver operating characteristic; XGB: extreme gradient boosting.

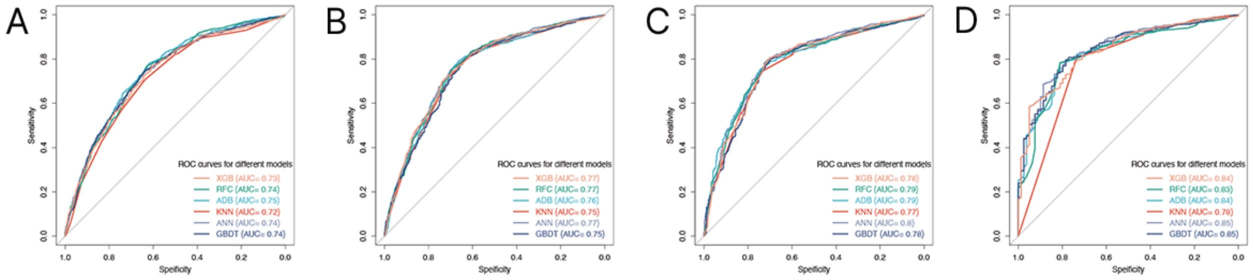


Figure 5. Decision curve analysis for 6 classical machine learning–based models for risk prediction of cumulative cancer-specific mortality in patients with metachronous second primary lung cancer (MSPLC): (A) 1-year lymphoma-specific mortality; (B) 3-year lymphoma-specific mortality; (C) 5-year lymphoma-specific mortality; (D) 10-year lymphoma-specific mortality.

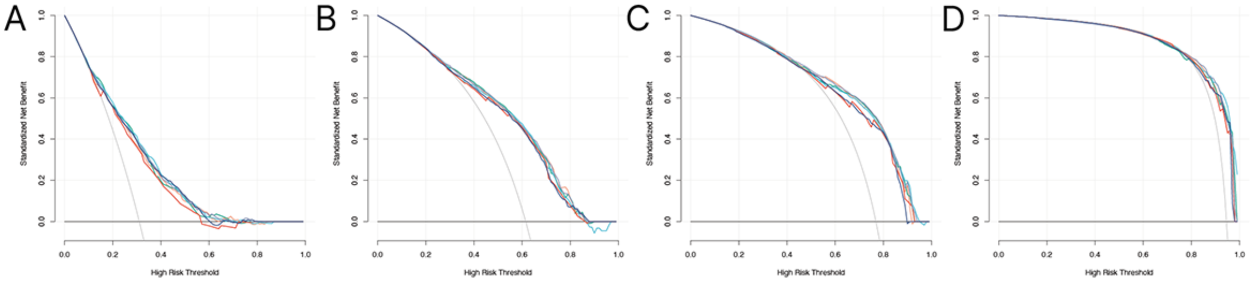


Table 4. Performance of machine learning models for risk prediction of long-term cancer-specific survival of patients with second primary lung cancer after 2004.

Model	Sensitivity, %	Specificity, %	AUC[a] (95% CI)
1-year cancer-specific survival			
XGB[b]	77	60.2	0.73 (0.71-0.75)
RFC[c]	76.7	63	0.74 (0.72-0.76)
ADB[d]	83.1	54.4	0.75 (0.73-0.77)
KNN[e]	70.9	63.6	0.72 (0.70-0.74)
ANN[f]	88.2	41.9	0.74 (0.72-0.76)
GBDT[g]	90.6	36	0.74 (0.72-0.76)
3-year cancer-specific survival			
XGB	69.9	73.8	0.77 (0.75-0.79)
RFC	75.6	69.2	0.77 (0.75-0.79)
ADB	79.3	66.4	0.76 (0.74-0.78)
KNN	79.6	64	0.75 (0.73-0.77)
ANN	83.6	59.9	0.77 (0.75-0.79)
GBDT	84.4	57.6	0.75 (0.73-0.77)
5-year cancer-specific survival			
XGB	79.6	71.3	0.78 (0.75-0.81)
RFC	79.2	71.5	0.79 (0.76-0.82)
ADB	75.3	74.7	0.79 (0.76-0.82)
KNN	74.3	73.9	0.77 (0.74-0.80)
ANN	79.3	71.5	0.80 (0.77-0.83)
GBDT	80.1	69.5	0.78 (0.75-0.81)
10-year cancer-specific survival			
XGB	78.8	74.7	0.84 (0.80-0.88)
RFC	78.3	40.7	0.83 (0.79-0.87)
ADB	78.4	81	0.84 (0.80-0.88)
KNN	80.7	73.4	0.78 (0.72-0.84)
ANN	68.8	88.6	0.85 (0.81-0.89)
GBDT	79.7	78.5	0.85 (0.81-0.89)

[a] AUC: area under the curve.

[b] XGB: extreme gradient boosting.

[c] RFC: random forest classifier.

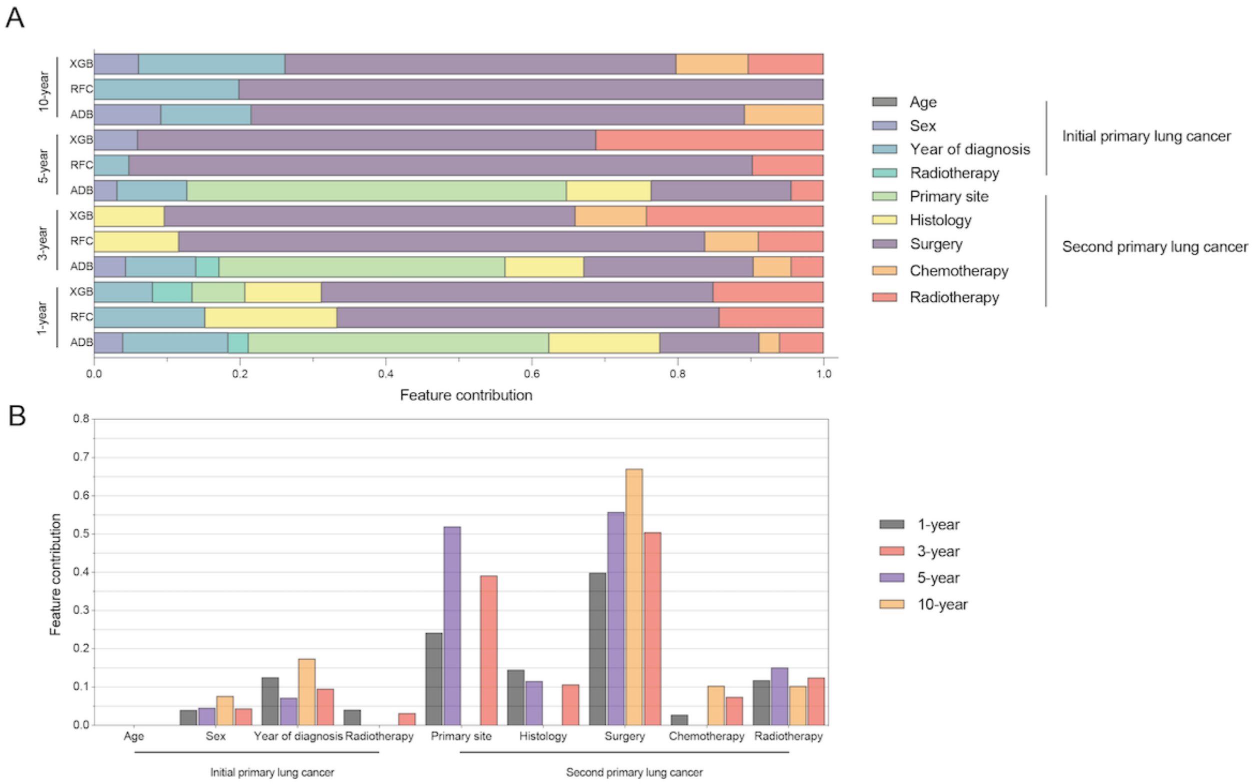
[d] ADB: adaptive boosting.

[e] KNN: K nearest neighbor.

[f] ANN: artificial neural network.

[g] GBDT: gradient boosting decision tree.

Figure 6. Machine learning model for risk prediction of cumulative cancer-specific mortality in patients with metachronous second primary lung cancer (MSPLC) showing the feature contribution (A) to survival and (B) by cancer characteristics. ADB: adaptive boosting; RFC: random forest classifier; XGB: extreme gradient boosting.



Age-Adjusted Competing Risk Analysis

To gain further insights into the cumulative incidence associated with each variable, we conducted competing risk analyses (Figure 7). Female MPSLC patients had lower cumulative cancer-specific mortality (hazard ratio [HR]=0.79, 95% CI 0.71-0.87; *P*<.001). Patients diagnosed with IPLC in more recent years also had lower cumulative cancer-specific mortality: 1996-2003 (HR=0.85, 95% CI 0.76-0.96; *P*<.001); 2004-2012 (HR=0.79, 95% CI 0.73-0.85; *P*<.001). However, patients who received radiotherapy for their IPLC had increased mortality (HR=1.31, 95% CI 1.16-1.50; *P*<.001). The histology of the second primary lung cancer played a significant role, with higher mortality rates for squamous carcinoma than adenocarcinoma (HR=1.28, 95% CI 1.12-1.46; *P*<.001). Moreover, the use of surgery for the second primary lung cancer was associated with lower mortality rates. This was particularly true for sublevel resection (HR=0.37, 95% CI 0.32-0.43; *P*<.001), lobectomy (HR=0.56, 95% CI 0.51-0.61; *P*<.001), and pneumonectomy (HR=0.80, 95% CI 0.71-0.89; *P*<.001). Conversely, the use of chemotherapy or radiotherapy for the second primary lung cancer was associated with increased mortality rates, potentially due to the severity of the patients' initial condition (chemotherapy: HR=1.64, 95% CI 1.47-1.83; *P*<.001; radiotherapy: HR=1.19, 95% CI 1.07-1.33; *P*<.001).

Therefore, we performed additional analyses for the different treatment modalities, as shown in Figure 8. Surgery alone (HR=0.83, 95% CI 0.81-0.85; *P*<.001) had the lowest cancer-specific mortality, followed by surgery and chemotherapy (HR=0.76, 95% CI 0.71-0.82, *P*<.001) and surgery and radiotherapy (HR=0.79, 95% CI 0.71-0.88, *P*<.001). Among different surgical approaches, sublevel resection alone (HR=0.26, 95% CI 0.21-0.31, *P*<.001) had the lowest mortality rate, followed by pneumonectomy alone (HR=0.72, 95% CI 0.63-0.82, *P*<.001) and lobectomy alone (HR=0.92, 95% CI 0.78-1.09, *P*<.001).

Figure 7. Cumulative cancer-specific mortality per age-adjusted competing risk analysis in subgroup analysis by (A) age, (B) sex, (C) year of diagnosis of the initial primary lung cancer, (D) radiotherapy of the initial primary lung cancer, (E) primary site of the second primary lung cancer, (F) histology of the second primary lung cancer, (G) surgery for the second primary lung cancer, (H) chemotherapy of the second primary lung cancer, (I) radiotherapy of the second primary lung cancer. HR: hazard ratio.

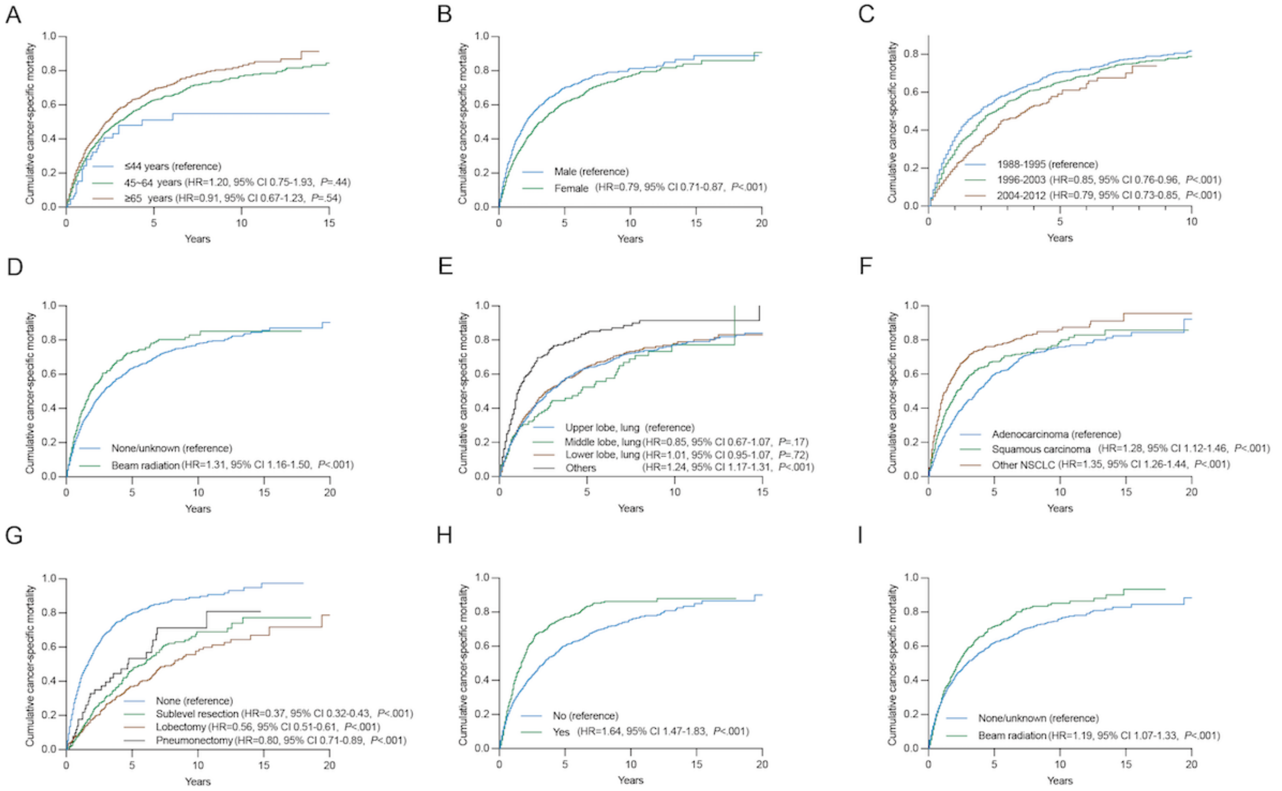
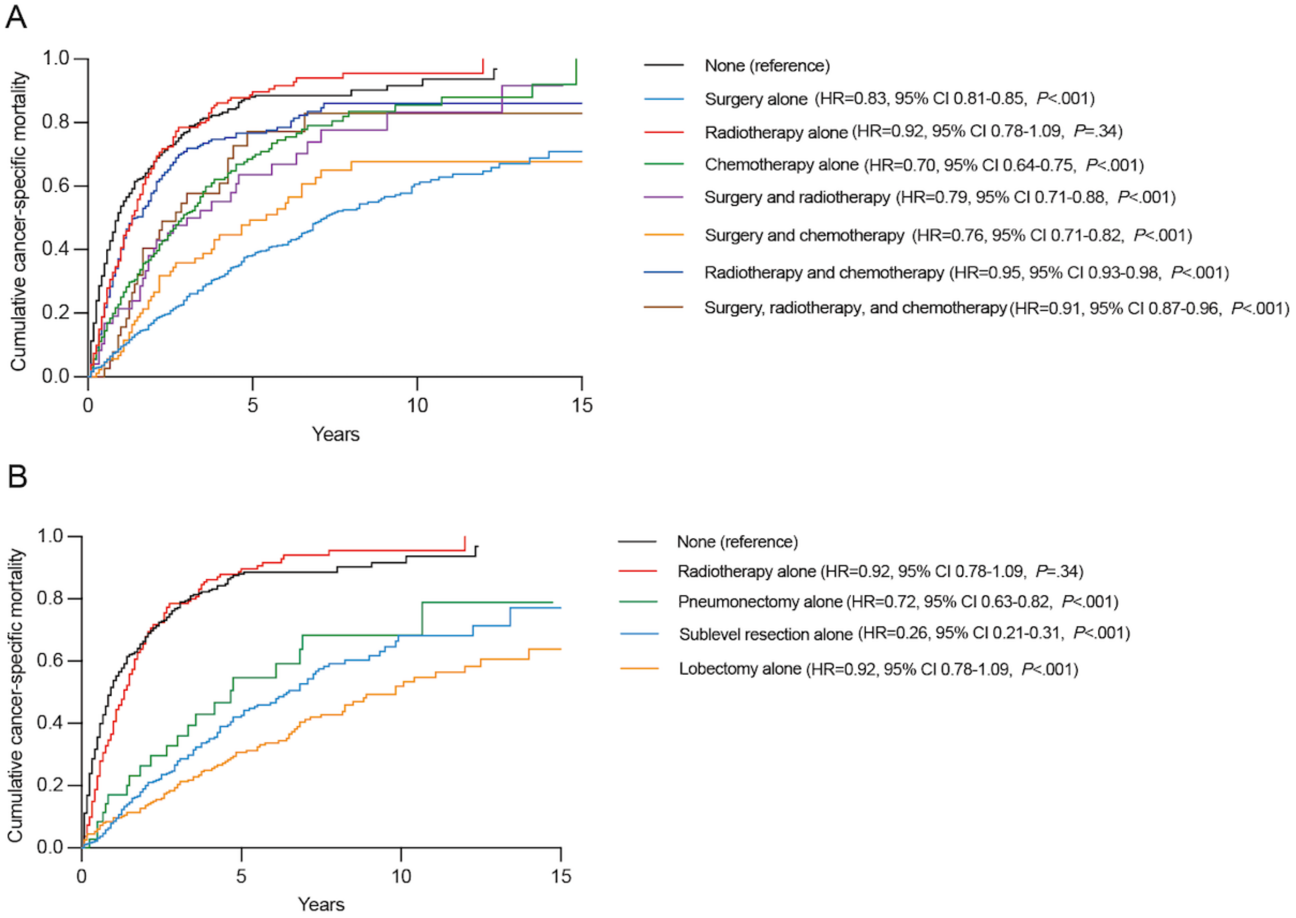


Figure 8. Age-adjusted competing risk analysis to estimate the cumulative cancer-specific mortality with different treatment modalities: (A) treatment for second primary lung cancer, (B) radiotherapy alone versus surgery alone. HR: hazard ratio.



Discussion

Principal Findings

With the rapid advancement and wide application of low-dose computed tomography for screening of pulmonary nodules, more patients are being diagnosed with MSPLC. Multiple primary lung cancer (MPLC) is a special kind of lung carcinoma that can be categorized into synchronous MPLC and metachronous MPLC. Among these, MSPLC is the most common form of MPLC that can be expected to receive curable management. However, limited progress has been made so far on accurate diagnoses, optimal medical interventions, and prognostic outcomes. In this study, our findings suggest that surgical resections, including wedge resection and lobectomy, contribute to better survival rates than radiation therapy in the context of MSPLC. However, it is important to note that radiation therapy remains a viable and valid alternative for the treatment of MSPLC.

Surgical resection is reportedly feasible for MSPLC and could significantly improve the prognosis [5-9], but the role of radiation therapy in the treatment of MSPLC remains unclear. Considering that patients who previously underwent surgery for IPLC may not tolerate another pulmonary resection, finding optimal alternative treatments is important. Therefore, using the population-based SEER database, this study used PSM analyses and ML techniques to first compare survival outcomes between patients who received radiotherapy or underwent surgical resection for MSPLC.

Of all enrolled patients, most (2187/2451, 89.2%) had undergone surgery for IPLC before (Table 1). However, 65.4% (1603/2451) of the patients with MSPLC did not undergo surgical resection for MSPLC, and 35.3% (864/2451) of them received radiation therapy (Table 1). It could be inferred that a considerable proportion of patients with MSPLC could not tolerate another surgical resection, and radiotherapy might be the predominant alternative treatment for them. Although surgical resection was first recommended for patients with MSPLC, radiation therapy is also important, especially for inoperable cancers. Given that very few studies have focused on long-term survival outcomes after radiotherapy versus surgery, this study may provide a more solid indication in terms of the use of radiotherapy for patients with MSPLC.

Previous studies reported that 5-year OS rates for patients with MSPLC varied, ranging from 26% to 38% [20-22]; these rates are similar to that of our study (34.7% for the entire cohort). The 5-year survival rates were 18.0% for radiotherapy, 49.3% for surgery, 38.8% for surgery plus radiotherapy, and 7.7% for no treatment. Ono et al [13] reported on 19 patients who were diagnosed with MSPLC after lung resection for IPLC and underwent proton beam therapy. Their research showed a 3-year survival rate of 63.2% and a 3-year local control rate of 84.2%, which indicated the safety and feasibility of proton beam therapy for patients with MSPLC. Miyazaki et al [23] compared survival outcomes among metachronous MPLC patients after stereotactic body radiotherapy (N=26) and surgery (N=51) and found no significant differences. The study by Taioli et al [24] included 494 cases from the SEER database and showed that OS was better with surgery than with radiation therapy after the treatment of MSPLC [24]. However, their inclusion criteria were not rigorous enough; the diagnostic interval between the 2 primary lung tumors was too short (6 months), which could fail to exclude patients with relapse or metastasis. Additionally, the analyses were not adjusted for confounding factors, and this might have caused significant bias. In our study, multiple PSM analyses were performed to control for confounding effects. The surgery group had significantly better survival than the radiotherapy group ($P<.001$), and the radiotherapy group had greater survival than the no treatment group ($P<.001$; Figure 1). Therefore, surgical resection should be considered first for patients with MSPLC if their physical condition and pulmonary function reserve permit. For those with an inoperable cancer or who are not willing to undergo another surgery, radiation therapy may be an alternative. Additionally, after PSM, there was no significant difference between the surgery and surgery plus radiotherapy groups ($P=.26$), which indicated that preoperative or postoperative radiotherapy might not increase survival benefits for patients with MSPLC.

Lobectomy remains the commonly accepted standard treatment for resectable NSCLC. In recent years, sublobar resections have been widely reported to be adequate in early-stage NSCLC, resulting in less impairment and greater respiratory function reserve [1,25,26]. However, the prognostic role of sublobar resection among patients with MSPLC has not been clearly clarified. Yang et al [8] identified 454 matched pairs of patients with MSPLC receiving lobectomy or sublobar resection from the SEER database and found that the lobectomy group had significantly better survival than the sublobar resection group. Lee et al [27] concluded that MSPLC had similar survival outcomes with wedge resection and lobectomy by analyzing 625 patients with a diagnostic interval ≥6 months. There have been few studies that have focused on survival outcomes after radiotherapy compared with wedge resection or lobectomy. Thus, to further verify the rigorousness of our study, patients diagnosed after 2004 and with definite therapeutic information (only including no treatment, radiotherapy, wedge resection, and lobectomy) were selected to compare survival outcomes between those undergoing radiotherapy or specific surgical resections. Very few cases underwent segmentectomy (n=16) or surgery plus radiotherapy (n=11) for MSPLC and were excluded. Additionally, T and N stage (American Joint Committee on Cancer, 6th edition) for IPLC and tumor size were also adjusted using PSM analyses. Of the 716 patients diagnosed after 2004, 53.8% had MSPLC with a tumor size ≤3 cm, while a limited number of patients (127/716, 17.3%; Table 2) had a tumor larger than 3 cm, though some patients' MSPLC tumor sizes were unknown (204/716, 28.5%). This implied that most of the patients with MSPLC could be categorized as "early-stage" NSCLC if their tumors were recorded as initial lung cancer, which is a strong indication for sublobar resection and radiation therapy. There were actually only a few patients that underwent lobectomy for MSPLC (entire sample: 352/2451, 14.4%; diagnosed after 2004: 81/716, 11.3%). Radiotherapy seemed to be the most common treatment for MSPLC (entire sample: 864/2451, 35.3%; diagnosed after 2004: 309/716, 43.2%). All the aforementioned facts indicate that most patients with MSPLC might not tolerate another surgical resection, especially lobectomy, or be more willing to receive noninvasive radiation therapy. Therefore, comparing survival outcomes between radiotherapy and wedge resection or lobectomy is highly necessary. As shown in Figure 2, the radiotherapy group also had significantly greater OS than the no treatment group ($P<.001$) but poorer OS than both the lobectomy ($P=.002$) and wedge resection ($P=.004$) groups. When patients' physical condition and pulmonary function reserve permit, whether choosing lobectomy or wedge resection, patients undergoing surgical resection may gain greater survival benefits than those receiving radiation therapy.

The development of long-term outcome prediction models using ML techniques represents a significant breakthrough in the field of MSPLC. This paper convincingly demonstrates the utility of ML algorithms for accurately predicting cumulative cancer-specific mortality at various time intervals. The exceptional performance of these predictive models emphasizes the superiority of artificial intelligence in prognostic prediction, offering precise and reliable predictions for individual patients. Integrating such models into routine clinical practice has the potential to optimize treatment strategies and improve patient outcomes in MSPLC. Furthermore, the study uses competing risk analysis to delve into the impact of different factors on CSS among MSPLC patients across distinct time intervals. The findings provide valuable insights into the factors influencing both short-term (1-year and 3-year) and long-term (5-year and 10-year) survival outcomes. This enhanced understanding of the factors affecting patient outcomes contributes to improved prognostic assessments and facilitates informed treatment decision-making by clinicians.

Generally, patients with MPLC had better survival outcomes than those with intrapulmonary metastases from IPLC after surgery [22,28]. However, effective methods to accurately identify MPLC patients have not existed until now. Previous studies identified patients with MSPLC using inclusion and exclusion criteria that lacked rigor [8,24,27]. In this study, to avoid the potential confounding effect of metastases, we only included patients with a diagnostic interval greater than 4 years, which indicated a thoroughly representative group of patients with MSPLC [16].

To the best of our knowledge, using PSM analyses and ML techniques on the largest cohort of patients with MSPLC, this study is the first to compare the survival outcomes after radiotherapy with those after surgical resection for MSPLC. Nevertheless, limitations in some aspects of the study still exist. First, this is a retrospective study based on the study population from the SEER database. A certain degree of data bias could not be totally avoided. Second, there might have been an inclination for treatment regarding the patients who received radiotherapy, because they were usually ineligible for surgery due to poorer physical condition and insufficient pulmonary function reserve. Thus, though we tried to control for the confounding effects using PSM, patient bias between different treatment groups also existed because details on physical condition and lung function were unknown. Further evaluation should be performed by prospective studies in the future. Third, since very few patients underwent a pneumonectomy and were thus excluded from our study, the prognostic role of pneumonectomy for patients with MSPLC requires a large cohort to verify. Additionally, we acknowledge the limitations inherent in the SEER database, which lacks comprehensive information, including details on immunotherapy and targeted therapy and the specifics of radiotherapy such as the target volume, treatment dose, and radiation technology. We hope that future cohort studies will incorporate these specifics to provide a more comprehensive understanding of the treatment landscape for MSPLC.

Conclusions

Overall, this study indicated that surgical resections such as wedge resection and lobectomy performed better than radiation therapy in terms of survival of patients with MSPLC. However, many patients with MSPLC may not tolerate surgery because of previously treated initial lung cancer. Among the treatment options, radiation therapy confers great survival outcomes and can be a valid alternative for surgery. Future prospective studies can be designed to further confirm the effectiveness of radiation therapy for MSPLC.

Acknowledgments

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Data Availability

The data sets generated and analyzed during the current study are available in the SEER database [14].

Authors' Contributions

YW conceptualized and supervised the study, acquired the funding, validated the data, and reviewed and edited the manuscript draft. YZ curated the data. YZ, AZ, and YY performed the methodology and wrote the original manuscript draft. All authors have read and agreed to the published version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Supplemental tables.
[DOCX File , 57 KB - cancer_v10i1e53354_app1.docx]

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Abbreviations

ADB: adaptive boosting
ANN: artificial neural network
AUC of ROCs: area under the receiver operating characteristic curves
CSS: cancer-specific survival
GBDT: gradient boosting decision tree
HR: hazard ratio
ICD-O: International Classification of Diseases for Oncology
IPLC: initial primary lung cancer
KNN: K nearest neighbor
LASSO: least absolute shrinkage and selection operator
ML: machine learning
MPLC: multiple primary lung cancer
MSPLC: metachronous second primary lung cancer
NSCLC: non-small cell lung cancer
OS: overall survival
PSM: propensity score matching
RFC: random forest classifier
SEER: Surveillance, Epidemiology, and End Results
WHO: World Health Organization
XGB: extreme gradient boosting

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Original Paper

Crowdfunding for Complementary and Alternative Cancer Treatments in Tijuana, Mexico: Content Analysis

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Abstract

Background: Complementary and alternative (CAM) cancer treatment is often expensive and not covered by insurance. As a result, many people turn to crowdfunding to access this treatment.

Objective: The aim of this study is to identify the rationales of patients with cancer seeking CAM treatment abroad by looking specifically at crowdfunding campaigns to support CAM cancer treatment in Tijuana, Mexico.

Methods: We scraped the GoFundMe.com and GiveSendGo.com crowdfunding platforms for campaigns referencing CAM cancer clinics in Tijuana, initiated between January 1, 2022, and February 28, 2023. The authors created a coding framework to identify rationales for seeking CAM treatment in Tijuana. To supplement campaign metadata, we coded the beneficiary's cancer stage, type, age, specific treatment sought, whether the beneficiary died, gender, and race.

Results: Patients sought CAM cancer treatment in Tijuana because the (1) treatment offers the greatest efficacy (29.9%); (2) treatment offered domestically was not curative (23.2%); (3) the clinic treats the whole person, and addresses the spiritual dimension of the person (20.1%); (4) treatments are nontoxic, natural, or less invasive (18.2%); and (5) clinic offers the newest technology (8.5%). Campaigns raised US $5,275,268.37 and most campaign beneficiaries were women (69.7%) or White individuals (71.1%).

Conclusions: These campaigns spread problematic misinformation about the likely efficacy of CAM treatments, funnel money and endorsements to CAM clinics in Tijuana, and leave many campaigners short of the money needed to pay for CAM treatments while costing beneficiaries and their loved one's time, privacy, and dignity. This study affirms that Tijuana, Mexico, is a very popular destination for CAM cancer treatment.

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KEYWORDS

cancer; crowdfunding; Tijuana; CAM; patient; patients; insurance; crowdfunding platforms; GoFundMe; GiveSendGo; cancer clinic; Mexico; campaigns; cancer treatment; medical intervention; CAM cancer treatments; misinformation; alternate care; women's health; internet research; international medical tourism; alternative cancer therapy; financial toxicity

Introduction

Traveling abroad for complementary and alternative (CAM) cancer treatments—understood as medical interventions that are outside of standard medical care—is common in North America and Europe [1,2]. Motivations for seeking CAM cancer treatments include the belief that alternative care alone is curative, desire for control over one's care, addressing the side effects of conventional treatment, attending to the needs of the whole person (including their emotional and spiritual well-being), and preservation of hope for better health [3-5]. For people seeking CAM cancer care abroad, private and public insurance typically does not reimburse any or all costs of this treatment. In these cases, crowdfunding can serve as a means of accessing CAM cancer care through helping the beneficiary not only to afford the treatment itself but also to pay for indirect expenses like travel, accommodation, and time off work [6].

Previous scholarship on crowdfunding for CAM cancer treatments has identified several concerns with this practice. These campaigns can spread misinformation about the safety and efficacy of CAM cancer treatments, potentially reaching large audiences through social media [7]. People with cancer who forgo conventional treatment in favor of alternative modalities may have poorer health outcomes [8]. Campaign beneficiaries are generally very ill and have a late-stage cancer diagnosis. The preservation of hope for a cure or extended life may come at financial costs and divert time from palliative care and other activities [9,10].

Prior analyses of crowdfunding campaigns for CAM cancer treatments have identified Mexico as a common destination. Peterson et al [7] found that 81.9% (N=194) of US-based campaigners on the GoFundMe crowdfunding platform who sought CAM cancer treatment abroad intended to travel to Mexico. Within Mexico, the Tijuana region on the US border is especially popular. The 5 most commonly named facilities in 1 study of crowdfunding for CAM cancer treatments were all located in Tijuana, Mexico [9]. These connections may be further reinforced by clinics in Tijuana encouraging potential clients to use crowdfunding to pay for their services [11].

The aim of this study is to build on this previous scholarship on crowdfunding for CAM cancer care by looking specifically at crowdfunding campaigns to support CAM cancer treatment in Tijuana, Mexico. Our aims in doing so are to revisit analyses of crowdfunding for CAM cancer treatments following the removal of COVID-19–related travel restrictions. We also seek to better understand the demographics of and rationales for people seeking CAM treatment in a specific, highly popular destination catering to patients from abroad.

Methods

Overview

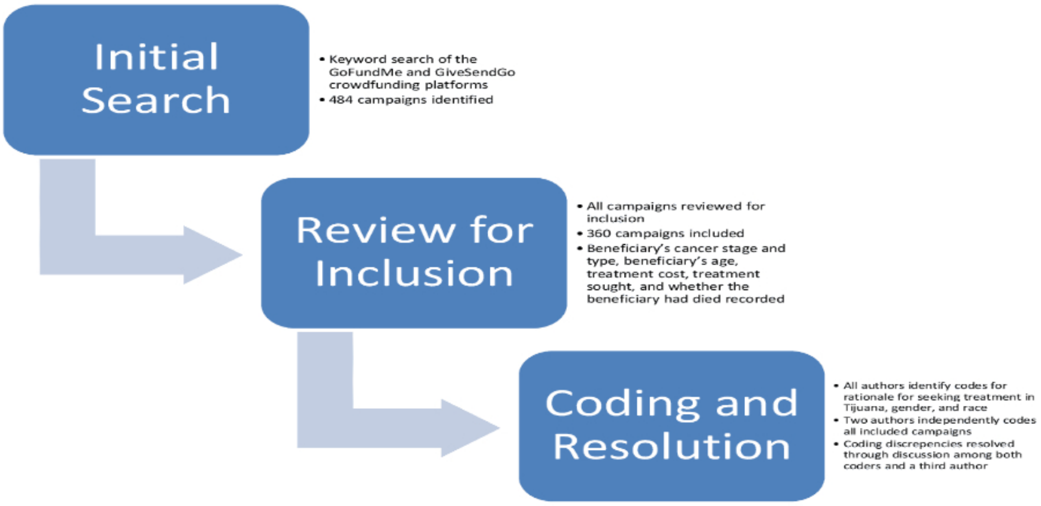
We searched the GoFundMe and GiveSendGo crowdfunding platforms from March 1, 2023, to March 7, 2023. These 2 crowdfunding platforms were selected because GoFundMe is the largest host of health-related crowdfunding campaigns in North America, while GiveSendGo has emerged in North America as a home for Christian and politically conservative campaigners, often as an alternative to GoFundMe [12,13]. The search was conducted using the clinic's name or the locations "Tijuana" or "Baja" with "cancer" and "alternative." Provider names were compiled from publications on alternative cancer providers in the scholarly [9,14] and gray [15,16] literature. This list was expanded as additional facilities were identified during the review of resulting crowdfunding campaigns. The search was carried out using a database of scraped campaign data from both platforms and the platforms' internal search engines. Campaigns initiated between January 1, 2022, and February 28, 2023, were then selected. This process identified 484 campaigns (GoFundMe n=432, GiveSendGo n=52).

The scraped data for these campaigns included the campaign URL, title, text, updates, funding requested, funding pledged, number of donations and online shares, creation date, and currency type. GoFundMe campaigns also included the campaigner's city and country location. These campaigns were reviewed for inclusion as seeking funding to access CAM cancer treatment in Tijuana, Mexico. This process removed 124 campaigns, leaving 360 campaigns that met our inclusion criteria. One clinic, Hope4Cancer, also operates facilities in Cancun, Mexico. Campaigns for treatment at this clinic were included regardless of the intended location as the specific location was often unclear and they captured a similar practice. During this review, we confirmed the clinic name where possible and recorded information about the beneficiary's cancer stage and type, the beneficiary's age, the treatment cost, the treatment sought, and whether the beneficiary had died. Funding requested and pledged were converted to US dollars for non-US currencies using the exchange rate for the date the campaign was created.

We independently reviewed 10% of included campaigns with a focus on campaigners' stated reasons for selecting Tijuana, Mexico, as a destination for CAM cancer care. Based on this review and after discussion among all authors, we identified five rationales for seeking alternative cancer care in Tijuana. (1) Treatment in Tijuana offers the greatest efficacy in terms of cancer treatment. Campaigners could support this rationale with appeals to specific and comparative success rates, patient testimonials positively discussing the efficacy of the treatment they received, and claims that these treatments improved success rates by supplementing treatment available domestically. (2) Treatment offered domestically was not curative. Campaigns with this rationale could include statements that the recipient was previously offered a poor prognosis, directed toward hospice or palliative care, or variations on the theme that trying some form of care was better than having no potentially curative care. (3) The facility in Tijuana is caring, treats the whole person, and addresses the spiritual dimension of the person. This rationale included depictions of specific, caring interactions with staff in Tijuana, references to the spiritual and religious convictions of staff in Tijuana, or references to a "whole person" approach. (4) Treatment in Tijuana is nontoxic, natural, or less invasive. Campaigns with this rationale could point to the perceived toxicity of conventional care, particularly chemotherapy, and suggest that CAM care in Tijuana used gentler and more natural modalities. (5) Treatment in Tijuana offers the newest or most advanced technology and treatment types. These campaigns could include statements that the regulatory system in the recipient's home country was too restrictive and made these treatments unavailable domestically, discussion of perceived "cutting edge" technologies, or appeals to the training and credentials of staff at the preferred provider. We then applied these codes to each campaign, allowing for multiple rationale codes per campaign. All of these codes were independently confirmed by 2 authors. Discrepancies were discussed among the first 3 authors and coding was refined until consensus was reached.

We reviewed all campaigns and assigned a gender and racial category to each beneficiary. Gender categories included women, men, nonbinary, and undetermined. Gender identification was based on campaign photos, pronoun usage in the campaign text, and other textual cues. Racial categories were identified in consultation with publications on racial characteristics in crowdfunding in order to identify commonly used categories within this area of scholarship [17-20] and further refined through discussion among the reviewers. These categories were then assigned based on campaign images, the beneficiary's and family members' names, non–English language campaign text, and other textual cues as informed by the reviewers' experience and prior publications using racial data in crowdfunding campaigns. Two authors each independently assigned a gender and racial category for each campaign or noted uncertainty regarding categorization. Discrepancies in these codes were discussed among each reviewer and a third author, and they were resolved where possible after exchanging rationales for assigning discrepant codes. Where consensus was not achieved or there was not enough information in the campaign to decide, the relevant category was assigned as undetermined. While challenging, collecting and analyzing gender and racial data can yield important insight around medical access and health equity (see Figure 1) [21].

Figure 1. Workflow.



Ethical Considerations

Ethics approval was not required for this study as per the Tri Council Policy Statement (TCPS2; Article 2.2) [22], as all data were posted in the public domain and the individuals to whom the information refers have no reasonable expectation of privacy.

Results

This process identified 360 crowdfunding campaigns (GoFundMe, n=311; GiveSendGo, n=49). These campaigns raised US $5,275,268.37 (median US $7685) with a range of US $0-$220,812. They requested US $17,032,458.06 (median US $45,000) with a range of US $0-$250,000. Contributions were received from 38,212 (median 46) donations with a range of 0-1495. In total, 352 (97.8%) of the campaigns received some funding and 22 (6.1%) reached or exceeded their fundraising goals. These campaigns were shared online 86,907 (median 124) times on social media with a range of 0-2600 shares. Table 1 presents these data by crowdfunding platform, and Table 2 presents this information by quartile.

Table 1. Fundraising by crowdfunding platform.

	US $ raised	Median raised	US $ requested	Median requested	Total donations, n	Median donations	Total shares, n	Median shares	Receiving funding, %	Meeting funding goal, %
GiveSendGo	809,428.50	8250.00	2,326,394.86	45,000	2607	32	1229	15	83.7	14.3
GoFundMe	4,465,839.87	7525	14,706,063.20	45,000	35,605	49	85,678	150	100	4.8
Both platforms	5,275,268.37	7685	17,032,458.06	45,000	38,212	46	86,907	124	97.8	6.1

Table 2. Fundraising by quartile.

	First quartile	Second quartile	Third quartile	Fourth quartile
Funding received (US $)	0-2620	2640-7605	7765-18,750	18,895-220,812
Funding requested (US $)	0-25,689.80	25,900-45,000	45,000-55,000	55,867-250,000
Donations, n	0-18	19-50	51-105	107-1495
Shares, n	0-23	23-128	130-331	332-2600

Beneficiary and Provider Characteristics

In total, 251 (69.7%) campaign beneficiaries were women and 109 (30.3%) were men (no beneficiaries identified as nonbinary). The GiveSendGo platform skewed more heavily toward women (n=39, 79.6%) compared to the GoFundMe platform (n=212, 68.2%). The beneficiary's age was identified in 105 campaigns. Ages ranged from 18 to 71 years with a median age of 44 years. Most beneficiaries were White (n=256, 71.1%) followed by Latino (n=39, 10.8%), Black (n=38, 10.6%), East Asian (n=10, 3.1%), Middle Eastern and South Asian (n=5, 1.4%), and Indigenous (n=2, 0.6%) beneficiaries with 7 (2.5%) campaigners not identified (see Table 3). White and women beneficiaries outraised other groups (see Table 4). Campaigners were most commonly located in the United States (85%), followed by Canada (6.4%) and the United Kingdom (3.6%). Over 75% of campaigns sought treatment at 3 clinics: Hope4Cancer (n=146, 40.6%), Centro Hospitalario Internacional Pacifico (CHIPSA; n=81, 22.5%), and Oasis of Hope (n=44, 12.2%; see Table 5).

Table 3. Beneficiary race.

Race	GoFundMe, n (%)	GiveSendGo, n (%)	Total, n (%)
White	211 (67.8)	45 (91.8)	256 (71.1)
Latino	38 (12.2)	1 (2.0)	39 (10.8)
Black	38 (12.2)	0 (0.0)	38 (10.6)
East Asian	10 (3.2)	1 (2.0)	11 (3.1)
Middle Eastern and South Asian	5 (1.6)	0 (0.0)	5 (1.4)
Indigenous	2 (0.6)	0 (0.0)	2 (0.6)
Uncertain	7 (2.3)	2 (4.1)	9 (2.5)

Table 4. Outcomes by gender and race.

	Median donations	Median raised (US $)	Median requested (US $)
Women	49.5	7959	45,000
Men	41	7085	45,000
White	50	8516	47,770.56
Latino	41	4060	30,000
Black	48	4439	45,000
East Asian	44	7144.21	40,000
Middle Eastern or South Asian	370	25,357.30	44,933.80
Indigenous	104.5	20,051	37,500
Uncertain	17	3610	37,500

Table 5. Intended provider.

Clinic Name	Value, n (%)
Hope4Cancer	146 (40.6)
CHIPSA[a]	81 (22.5)
Oasis of Hope	44 (12.2)
ITC[b]	24 (6.7)
Sanoviv	11 (3.1)
Immunotherapy Institute	6 (1.7)
Gerson Institute	5 (1.4)
Hoxsey	4 (1.1)
Advanced Gerson	3 (0.8)
Health Institute de Tijuana	2 (0.6)
Integrative Cancer Centers of America	1 (0.3)
Medgate Baja	1 (0.3)
Northern Baja Gerson Center	1 (0.3)
Stella Maris Clinic	1 (0.3)
Unidentified	30 (8.3)

[a] CHIPSA: Centro Hospitalario Internacional Pacifico.

[b] ITC: Immunity Therapy Center.

A total of 125 campaigners stated the cost of the treatments they sought in Tijuana, which ranged from US $11,000 to US $100,000 (median US $45,000). The most common cancer types or locations disclosed in these campaigns were breast (26.9%), colorectal (14.2%), and pancreatic (7.2%) cancers. Of the 205 campaigns that stated the beneficiary's cancer stage, these skewed toward later stages with 161 (78.6%) at stage 4 followed by 35 (17.1%) stage 3, 6 (2.9%) stage 2, and 3 (1.5%) stage 1. A total of 67 (18.6%) beneficiaries were identified as having died after the start of the campaign. Common treatments sought included immunotherapy (n=94), dietary supplements (n=44), detoxification (n=36), Gerson therapy (n=31), ozone and oxygenation therapies (n=32), hyperbaric oxygen therapy (n=27), hyperthermia (n=26), vitamin C (n=26), dendritic cell therapy (n=20), light-based (infrared, laser, photodynamic) treatments (n=16), vitamin B17 (n=14), low dose chemotherapy (n=12), sono-photodynamic therapy (n=10), Coley's therapy (n=8), insulin potentiation therapy (n=8), cryotherapy (n=7), curcumin (n=7), and pulsed electromagnetic therapy (n=7).

Rationales for Seeking Treatment in Tijuana

These campaigns offered a variety of rationales for seeking alternative cancer treatment in Tijuana, including multiple rationales in the same campaign. The most common rationale (30.9%) was that this treatment was perceived as offering the greatest possible efficacy in terms of curing the beneficiary's cancer or extending their lifespan. Campaigns included both general claims about the success of treatments at the facility and highly specific numbers such as "a high success rate of over 90 percent." These claims were bolstered by the providers ("they claim that they can both stop the cancer he has") and patient testimonials ("success stories at this centre have been incredible to read").

The second most common rationale (23.6%) for seeking treatment in Tijuana was that the care offered domestically was not curative and so they desired to continue seeking curative treatment. These campaigns frequently described an experience where domestic practitioners stated a low survival rate or duration for the beneficiary and suggested they explore hospice or palliative care. Accepting a lack of curative treatment options was often rejected, positioning the recipient as a "fighter" who does not "give up as easily" or explaining that they had others who needed them to survive ("I NEED to be here to see my wee babies grow up and to be their mummy").

Beneficiaries also sought treatment in Mexico (19.3%) because these facilities were seen as treating the whole person in a caring way. These campaigns often referred to the alternative care they sought as "holistic" or targeting the "whole person" including their "mind, spirit and emotions." Others described the caring approach of the clinic staff and personalized nature of their care: "the doctors are so kind, warm, attentive and the treatment plan is truly individualized!". Some of these campaigns particularly flagged the spiritual or religious dimension of the providers in Tijuana, including describing one clinic as "run by doctors and staff that are all Spirit-filled believers."

These clinics were also seen as offering less toxic and less invasive, natural treatment options (17.6%). Campaigners sought "non-toxic cancer therapies" that "target only cancer cells," leaving the rest of the person intact. Chemotherapy and radiation treatments were seen as "harsh" based on the beneficiary's past experience or witnessing the treatment of loved ones. Instead, the "natural" treatments offered in Tijuana could particularly "rebuild" the recipient's immune system. Other campaigners objected to surgery, including the removal of reproductive organs or other life-altering changes. Alternative care offered "less invasive treatments" that avoided these outcomes.

Least commonly (8.6%), these campaigns were motivated by the perceived technological superiority of the treatments offered in Tijuana. These treatments were frequently described as being "experimental," "cutting edge," or "state of the art." Specific clinics were flagged as having a reputation as global leaders in "advanced" cancer treatments or being "known for being on the forefront" of cancer care. In some cases, campaigners noted that the clinics were free from regulatory limits on new treatments domestically, and therefore, "able to do certain treatments that are not FDA approved here in the US" (See Table 6).

Table 6. Alternative treatment rationales.

Rationale	GoFundMe, n (%)	GiveSendGo, n (%)	Total, n (%)
Efficacy	166 (30.6)	29 (32.6)	195 (30.9)
Domestic not curative	137 (25.3)	12 (13.5)	149 (23.6)
Whole person	98 (18.1)	24 (27.0)	122 (19.3)
Natural	94 (17.3)	17 (19.1)	111 (17.6)
Newest technology	47 (8.7)	7 (7.9)	54 (8.6)

Discussion

The findings from this study affirm earlier studies of crowdfunding for CAM cancer treatment. Crowdfunding beneficiaries seeking CAM cancer treatments in this study most commonly experienced breast and colorectal cancers, as has been seen in previous studies [10,23,24]. The beneficiaries in this study were most commonly women (69.7%). This closely matches previous findings of 64.3% and 70% of beneficiaries as female [10,24]. As with the previous studies, most beneficiaries were described as having stage 4 cancer [6,10].

Campaigns in this study generally had higher median fundraising goals (US $45,000) and donations (US $7685) than in previous studies. Holler et al found that crowdfunding campaigns for US beneficiaries for conventional and alternative treatments raised median US $1610 of US $9000 requested and Song et al [10] found of a median goal of US $15,000 for CAM cancer treatments with US $2870 raised [10,23]. Another study that included non-US GoFundMe campaigns found median US $19,880 requested and US $5055.50 raised [9]. Only one study of US-based campaigns for alternative treatment abroad found higher median donations. These campaigns raised median US $7833 of US $35,000 requested [6]. As the campaigners generally lived in the United States, Canada, and the United Kingdom, travel costs likely influenced higher fundraising goals, which may have in turn encouraged more giving. Moreover, the median stated direct cost of treatment (US $45,000) suggests that treatment costs in the providers included in this study were higher than those in previous studies.

Previous studies of crowdfunding for CAM cancer treatments have not examined racial characteristics of campaign beneficiaries. Among a sample of 2618 US-based medical campaigns on the GoFundMe platform, White beneficiaries were found to be most common (73.7%), followed by Latino (12.3%) and Black (9.4%) beneficiaries [20]. This and other studies have also shown that White campaigners tend to raise more money than Black beneficiaries [17,18]. Our study findings are consistent with these observations.

These campaigns conferred many benefits to clinics in Tijuana. Most directly, these campaigns supplied these clinics with a potential new source of revenue. Not all of the over US $5 million raised through these campaigns will go to these clinics as it was also used for indirect costs like travel and time off work and some beneficiaries were unable to travel to Tijuana for treatment. Nonetheless, the funding raised through these campaigns supplemented campaigners' insurance, savings, and other financial resources and, as a result, these clinics may have received more paying clients. Moreover, these campaigns serve as highly effective advertising about the clinics' perceived merits to people viewing and contributing to them. Campaign claims about the efficacy of these clinics and their superiority to domestic providers are presented in the form of patient testimonials; as such, they are likely to be highly effective forms of advertisements, reaching a wide audience via social media. In this way, crowdfunding campaigns create a positive feedback loop for targeted clinics where customers using crowdfunding generate highly positive social media about the clinics, which in turn generates new potential customers, some of whom likely turn to crowdfunding themselves.

While these campaigns raised a great deal of money collectively, they typically fell short of their individual fundraising goals; the median US $7685 raised was well short of the median US $45,000 requested and only 6.1% of the campaigns reached or exceeded their fundraising goals. These fundraising goals were likely driven by the substantial cost of treatment in Tijuana as the campaigns indicated a median treatment cost of US $45,000. Many campaigners were unable to afford their desired treatments and others likely drained savings or went into debt to do so. This issue was particularly acute for Black and Latino beneficiaries who raised median US $4439 and US $4060, respectively, compared to US $8516 for White beneficiaries. Outside of these financial implications, these campaigns entail the loss of privacy for campaign beneficiaries and their families through public exposure of their medical, financial, and other details. Other campaigners for cancer care have described feeling uncomfortable or humiliated from having to ask others for financial support for their care [25].

Previous studies have flagged the use of markers of legitimacy among providers of alternative medical treatments. These markers include scientific and research-based language that helps build trust in potential clients [9]. The rationales for seeking CAM treatment in these campaigns tended to emphasize the efficacy of the interventions they sought and, to a lesser extent, how it was cutting-edge technology and not available domestically. By comparison, campaigns emphasizing the natural dimensions of the treatment or caring and spiritual nature of the facility's staff were less common. Specific treatments like immunotherapy borrow from language used in more conventional and evidence-based treatments such as Chimeric Antigen Receptor T-cell therapy. Thus, patients may be unclear about the actual nature of and evidence for the treatments they seek abroad [26]. This may mark a divergence from previous studies that have found interest in combatting cancer through immune boosting modalities that focus primarily on "natural" products to do so [24].

Campaigns on both the GoFundMe and GiveSendGo crowdfunding platforms had the same median fundraising goal. While campaigns on GoFundMe had a larger median number of donations and shares, GiveSendGo campaigns had a larger median amount raised and relatively more campaigns reach their goal. These differences could be due to the higher ratio of White beneficiaries using GiveSendGo or other factors that lead to higher amounts given per donor on that platform. GiveSendGo campaigns put relative emphasis on caring for the whole person, including the spiritual dimensions of care, as a motivation for seeking treatment in Tijuana. These differences display how the populations using crowdfunding platforms can differ despite seeking the same treatments in the same location. Additional study of these differences is needed, particularly given the growth of the GiveSendGo.

This study had several limitations. Coding for the beneficiary's gender and race typically relies on the perceptions of the coders and may be inaccurate. Some campaigns may have been removed prior to data collection, particularly campaigns from earlier in the inclusion period. Campaigns that met our inclusion criteria but did not mention a clinic name or specify seeking alternative cancer treatment in Tijuana or Baja, Mexico, would not have been identified. Additionally, some campaigns may have continued to raise money after the end of data collection. Thus, this study likely understates the number and fundraising total of campaigns for CAM cancer treatment in Tijuana, Mexico.

As has been previously established, crowdfunding is actively used to raise money to access CAM cancer treatments. These campaigns spread problematic misinformation about the likely efficacy of these treatments, funnel money and endorsements to these clinics, and leave many campaigners short of the money needed to pay for them while costing beneficiaries and their loved ones time, privacy, and dignity. This study affirms that Tijuana, Mexico, is a popular destination for these campaigners and that this interest persists following the COVID-19 pandemic. While most of these campaigns fell well short of their goals, Black and Latino beneficiaries were particularly unsuccessful. This study also demonstrates an evolving landscape of CAM cancer treatments generally, and in Tijuana specifically, with increased marketing of immunotherapy as a form of treatment. This study demonstrates both the value of close examination of specific destinations for CAM cancer treatments and for how distinct populations may be drawn to different crowdfunding platforms.

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Data Availability

The data are available on request from the corresponding author.

Conflicts of Interest

None declared.

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Abbreviations

CAM: complementary and alternative
CHIPSA: Centro Hospitalario Internacional Pacifico

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Original Paper

Predictive Models for Long Term Survival of AML Patients Treated with Venetoclax and Azacitidine or 7+3 Based on Post Treatment Events and Responses: Retrospective Cohort Study

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Abstract

Background: The treatment of acute myeloid leukemia (AML) in older or unfit patients typically involves a regimen of venetoclax plus azacitidine (ven/aza). Toxicity and treatment responses are highly variable following treatment initiation and clinical decision-making continually evolves in response to these as treatment progresses. To improve clinical decision support (CDS) following treatment initiation, predictive models based on evolving and dynamic toxicities, disease responses, and other features should be developed.

Objective: This study aims to generate machine learning (ML)–based predictive models that incorporate individual predictors of overall survival (OS) for patients with AML, based on clinical events occurring after the initiation of ven/aza or 7+3 regimen.

Methods: Data from 221 patients with AML, who received either the ven/aza (n=101 patients) or 7+3 regimen (n=120 patients) as their initial induction therapy, were retrospectively analyzed. We performed stratified univariate and multivariate analyses to quantify the association between toxicities, hospital events, and short-term disease responses and OS for the 7+3 and ven/aza subgroups separately. We compared the estimates of confounders to assess potential effect modifications by treatment. 17 ML-based predictive models were developed. The optimal predictive models were selected based on their predictability and discriminability using cross-validation. Uncertainty in the estimation was assessed through bootstrapping.

Results: The cumulative incidence of posttreatment toxicities varies between the ven/aza and 7+3 regimen. A variety of laboratory features and clinical events during the first 30 days were differentially associated with OS for the two treatments. An initial transfer to intensive care unit (ICU) worsened OS for 7+3 patients (aHR 1.18, 95% CI 1.10-1.28), while ICU readmission adversely affected OS for those on ven/aza (aHR 1.24, 95% CI 1.12-1.37). At the initial follow-up, achieving a morphologic leukemia free state (MLFS) did not affect OS for ven/aza (aHR 0.99, 95% CI 0.94-1.05), but worsened OS following 7+3 (aHR 1.16, 95% CI 1.01-1.31) compared to that of complete remission (CR). Having blasts over 5% at the initial follow-up negatively impacted OS for both 7+3 (*P*<.001) and ven/aza (*P*<.001) treated patients. A best response of CR and CR with incomplete recovery (CRi) was superior to MLFS and refractory disease after ven/aza (*P*<.001), whereas for 7+3, CR was superior to CRi, MLFS, and refractory disease (*P*<.001), indicating unequal outcomes. Treatment-specific predictive models, trained on 120 7+3 and 101 ven/aza patients using over 114 features, achieved survival AUCs over 0.70.

Conclusions: Our findings indicate that toxicities, clinical events, and responses evolve differently in patients receiving ven/aza compared with that of 7+3 regimen. ML-based predictive models were shown to be a feasible strategy for CDS in both forms of AML treatment. If validated with larger and more diverse data sets, these findings could offer valuable insights for developing AML-CDS tools that leverage posttreatment clinical data.

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KEYWORDS

Leukemia, Myeloid, Acute; Venetoclax; Azacitidine; Anthracycline; Arabinoside, Cytosine; Clinical Decision Support; Clinical Informatics; Machine Learning; Predictive Model; Overall Survival

Introduction

Acute myeloid leukemia (AML) is an aggressive malignancy of the myeloid cells in the hematopoietic system [1]. Without treatment, patients can die within days to months due to infection, bleeding, organ damage, or other complications. The treatment approaches for AML vary significantly based on the patient's ability or willingness to tolerate intensive therapy [1,2]. For young and fit patients, a typical intensive therapy approach involves induction treatment with anthracycline and cytosine arabinoside, commonly known as 7+3 therapy. This is followed by additional consolidative chemotherapy or an allogeneic stem cell transplantation (alloSCT), depending on the genetic features of the AML at diagnosis, as well as the clinical status of the patient and the AML after induction therapy [3,4]. This intensive approach is potentially curative but is associated with high morbidity, mortality, cost, and prolonged hospital stays. For patients who are not suitable for, or choose to decline, this intensive approach due to age, fitness, or personal preference at diagnosis, the Bcl-2 inhibitor venetoclax, in combination with a hypomethylating agent such as azacitidine or decitabine, has become a new standard of care [5-7]. This strategy is typically aimed at prolonging life rather than achieving a cure and is associated with less morbidity, treatment-related mortality, and time spent in the hospital compared with intensive approaches [8].

We and others have described a variety of features of both patients and AML at diagnosis that are associated with long-term survival and other outcomes following treatment with either intensive approaches or venetoclax plus azacitidine (ven/aza)–based treatments [9-11]. However, the treatment course for patients with AML is highly variable, and factors such as "fitness" can change significantly, for better or worse, during treatment. Additionally, there is significant variability in AML responses to therapy during treatment, which are difficult to predict at diagnosis. As a result, prognosis and clinical decision-making can evolve significantly based on events and responses occurring after the initiation of treatment. Therefore, identifying key prognostic features that develop following treatment and are associated with long-term disease behavior and survival is essential for refining clinical decision-making over time. For intensive treatment approaches, events such as the achievement of a morphologic complete remission (CR), the presence or absence of minimal residual disease (MRD) detected by flow cytometry or next-generation sequencing, and other AML-related assessments that occur following the initiation of therapy are predictive of long-term outcomes [12-28]. Many of these early response indicators are useful for guiding subsequent therapeutic decisions. For example, the presence of MRD after induction therapy with 7+3 or other intensive treatments can predict the success of alloSCT, guide the choice of transplant type, and identify high-risk patients who may benefit from post-transplant maintenance therapy [16,18-20,29-33]. In ven/aza treatment, achieving MRD negativity is associated with improved event-free survival and overall survival (OS) [34]. However, in contrast to intensive approaches, there is limited knowledge about how toxicities, early clinical events, and short-term treatment responses are associated with disease behavior and long-term patient outcomes with this therapy.

To address this gap, we evaluated clinical events, toxicities, short-term outcomes, biomarkers, and other features occurring after the initiation of treatment with either 7+3 or ven/aza to understand their association with OS. Additionally, we developed models to assess the long-term dynamic behavior of responses to 7+3 and ven/aza based on short-term disease responses. These studies reveal substantial differences in the clinical and AML features that evolve with the 2 different treatments and highlight how these differences impact prognosis and clinical decision-making.

Methods

Patient Populations

Adult, newly diagnosed AML patients who received initial induction therapy with either the ven/aza regimen or the 7+3 regimen at the University of Colorado Hospital (UCH) between January 1, 2013, and December 31, 2020, were included in the study. Patients with acute promyelocytic leukemia and those who voluntarily withdrew within less than 28 days of treatment were excluded. Patient baseline characteristics are summarized in Table S1 in Multimedia Appendix 1. Note that this patient cohort is a subset of the analytical data set as previously described [10]. For exploratory analyses, 120 patients treated with 7+3 and 101 patients treated with ven/aza were included (Figure S1 in Multimedia Appendix 1). Best response analyses were based on 118 out of 120 (98.3%) of the 7+3 patients and all (101/101, 100%) of the ven/aza patients (including those who died before response assessment). For the multistate transition analyses, 115 out of 120 (95.8%) of the 7+3 patients and 98 out of 101 (97.0%) of the ven/aza patients had sufficient data after excluding those without at least one response assessment or who died before their first response assessment. Additionally, 111 out of 120 (92.5%) of the 7+3 patients and 91 out of 101 (90.1%) of the ven/aza patients had 30-day follow-up data adequate for developing machine learning (ML) models.

Ethical Considerations

This study was a retrospective analysis utilizing a limited data set. A full waiver of consent and a full waiver of Health Insurance Portability and Accountability Act (HIPAA) authorization were granted by the Colorado Multiple Institutional Review Board (approval number 18-1861). The limited data set was securely stored on a HIPAA-compliant, cloud-based data platform, and accessible only to members of the study team.

Outcome Definitions

Treatment responses, including CR, CR with incomplete hematologic recovery (CRi), morphologic leukemia-free state (MLFS), progressive disease, and stable disease, were defined according to the standard 2017 European LeukemiaNet (ELN) criteria [35]. A patient was classified as “refractory” if the disease persisted after 90 days from the start of treatment or if the disease worsened or showed no improvement at any point during the treatment cycle. Toxicity variables were graded according to the National Comprehensive Cancer Network (NCCN) Common Terminology Criteria for Adverse Events (CTCAE) guidelines [35-37]. Ejection fraction toxicity was defined as detailed in Table S10 in Multimedia Appendix 1. “Induction events” occurred during the initial treatment hospitalization. The “$\text{Day}_{15\text{-}55}$” disease assessment refers to patient examinations, laboratory analyses, and bone marrow biopsy (BMB) analyses performed closest to day 30 after the initiation of treatment, but within days 15-55 to accommodate variations in assessment timing. “Day 30 readmission events” were defined as clinical events that occurred at least one day after a patient’s discharge from the initial treatment hospitalization and at least one day before the “$\text{Day}_{15\text{-}55}$” BMB.

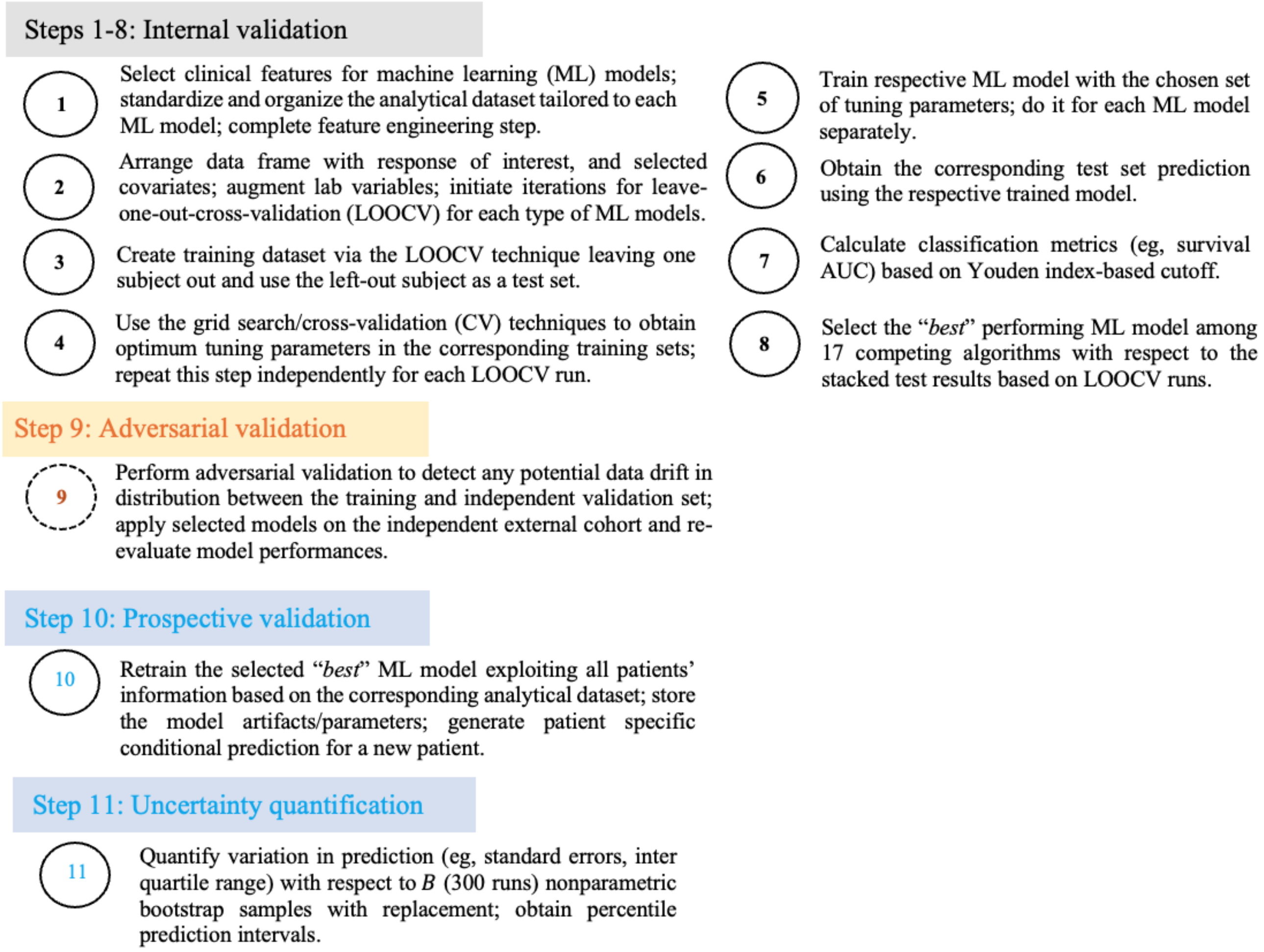
Statistical Learning

Structured and unstructured electronic medical record data were integrated into a heme data mart on the Google Cloud Platform (Alphabet Inc.), as previously described [10]. Descriptive summary statistics of confounders were provided for both 7+3 and ven/aza treatments. Systematic differences between treatments were compared using the Mann-Whitney *U* test, Fisher exact test (for small sample sizes), chi-square test, and standardized mean differences (SMDs). Kaplan-Meier analyses were performed for OS with 95% CIs, assuming right censoring. *P* values for testing the equality of survival curves were reported using log-rank (LR), Tarone-Ware (TW), and Fleming-Harrington (FH) methods. All hypotheses were 2-sided. Cumulative incidence functions (CIFs) for hazards were reported for toxicity along with 95% CIs, LR-based *P* values, and median time to reach the worst toxicity grading from baseline. Multistate survival analyses were conducted using follow-up BMB responses. Occupation probabilities of disease states were estimated using the Aalen-Johansen estimation technique [38-40]. Transition probabilities for moving from one disease state to another over time were estimated assuming a Markov process, with standard errors reported using bootstrap methods across 300 runs [41]. Multivariable Cox proportional hazards (Cox-PH) models with a ridge penalty (ie, L2 norm penalty) were fitted to adjust for multicollinearity, and estimates of adjusted hazard ratios (aHRs) were reported [42]. Before fitting multivariable models, numeric variables were categorized based on clinically meaningful thresholds to enhance interpretability. Noise variables were filtered out using a univariate approach based on accelerated failure time (AFT) models. Tuning parameters for the ridge penalty were selected using the 10-fold cross-validation (CV) approach. Bias-corrected 95% CIs for aHRs were constructed using the fractional random weight bootstrap method with 2000 runs, where weights were computed from a univariate Dirichlet distribution [43].

Development and Validation of Prognosis Models

The steps for training and evaluating ML models are depicted in Figures 1 and 2. The process consists of 2 stages. First, internal validation based on CV (steps 1-8) was conducted to select the appropriate ML model for each treatment separately. Second, subject-specific OS predictions, conditional on observed covariates, and the corresponding uncertainty quantification were performed using the selected treatment-specific ML models (steps 10-11). A total of 17 different models ranging from statistical learning-, ML-, and deep learning (DL)–based survival models were used to assess long-term outcomes. These included ensemble-based methods such as the random survival forest (RSF) [44], survival forest with bagging, and conditional inference survival forest [45], as well as Cox-PH models with boosting, penalized Cox-PH models, and parametric AFT models [46] with exponential, Weibull, and log-logistic error structures. These models generated OS probabilities by leveraging over 114 features, as highlighted in Table S12 in Multimedia Appendix 1. The prognostic variable list was further enhanced by creating binary variables based on the first and fifth quintiles of numeric laboratory variables. Regularization penalties [42,47-50] were applied to reduce the risk of overfitting. The penalty terms included ridge, LASSO, elastic-net (eNet), smoothly clipped absolute deviation (SCAD), minimax concave penalty (MCP), adaptive SCAD, adaptive MCP, adaptive eNet, adaptive MCP with L2 norm penalty (mNet), and adaptive SCAD with L2 norm penalty (sNet) [47]. Adaptive models were fitted in 2 stages: in the first stage, models were fitted with ridge penalties, and in the second stage, models were refitted with covariate weights calculated as the reciprocal of parameter estimates from the first stage. Additionally, DL-based survival models (Deep-Surv [51], Deep-LogHaz [52], and Deep-Hit [53]) with 2 hidden layers exploiting neural network structures were used. Tuning parameters for the ensemble-based approaches and DL models were selected using a combination of grid search and CV. For Cox-PH models, regularization penalties were selected using 10-fold CV. Parametric AFT models were fitted with a reduced set of variables. To minimize dimensionality and avoid collinearity in AFT models, a univariate filtering approach was applied, where only variables with Bonferroni-corrected *P* values below a prespecified threshold of 0.20 were included in the final multivariable AFT models. For additional technical details, please refer to Multimedia Appendix 1.

Figure 1. ML architecture. Notation and description of 11 steps for the development of ML models, optimum model selection, validation, prediction, and uncertainty quantification for a newly diagnosed patient with AML. AML: acute myeloid leukemia; AUC: area under the curve.



Steps 1-8: Internal validation

1 Select clinical features for machine learning (ML) models; standardize and organize the analytical dataset tailored to each ML model; complete feature engineering step.

2 Arrange data frame with response of interest, and selected covariates; augment lab variables; initiate iterations for leave-one-out-cross-validation (LOOCV) for each type of ML models.

3 Create training dataset via the LOOCV technique leaving one subject out and use the left-out subject as a test set.

4 Use the grid search/cross-validation (CV) techniques to obtain optimum tuning parameters in the corresponding training sets; repeat this step independently for each LOOCV run.

5 Train respective ML model with the chosen set of tuning parameters; do it for each ML model separately.

6 Obtain the corresponding test set prediction using the respective trained model.

7 Calculate classification metrics (eg, survival AUC) based on Youden index-based cutoff.

8 Select the "*best*" performing ML model among 17 competing algorithms with respect to the stacked test results based on LOOCV runs.

Step 9: Adversarial validation

9 Perform adversarial validation to detect any potential data drift in distribution between the training and independent validation set; apply selected models on the independent external cohort and re-evaluate model performances.

Step 10: Prospective validation

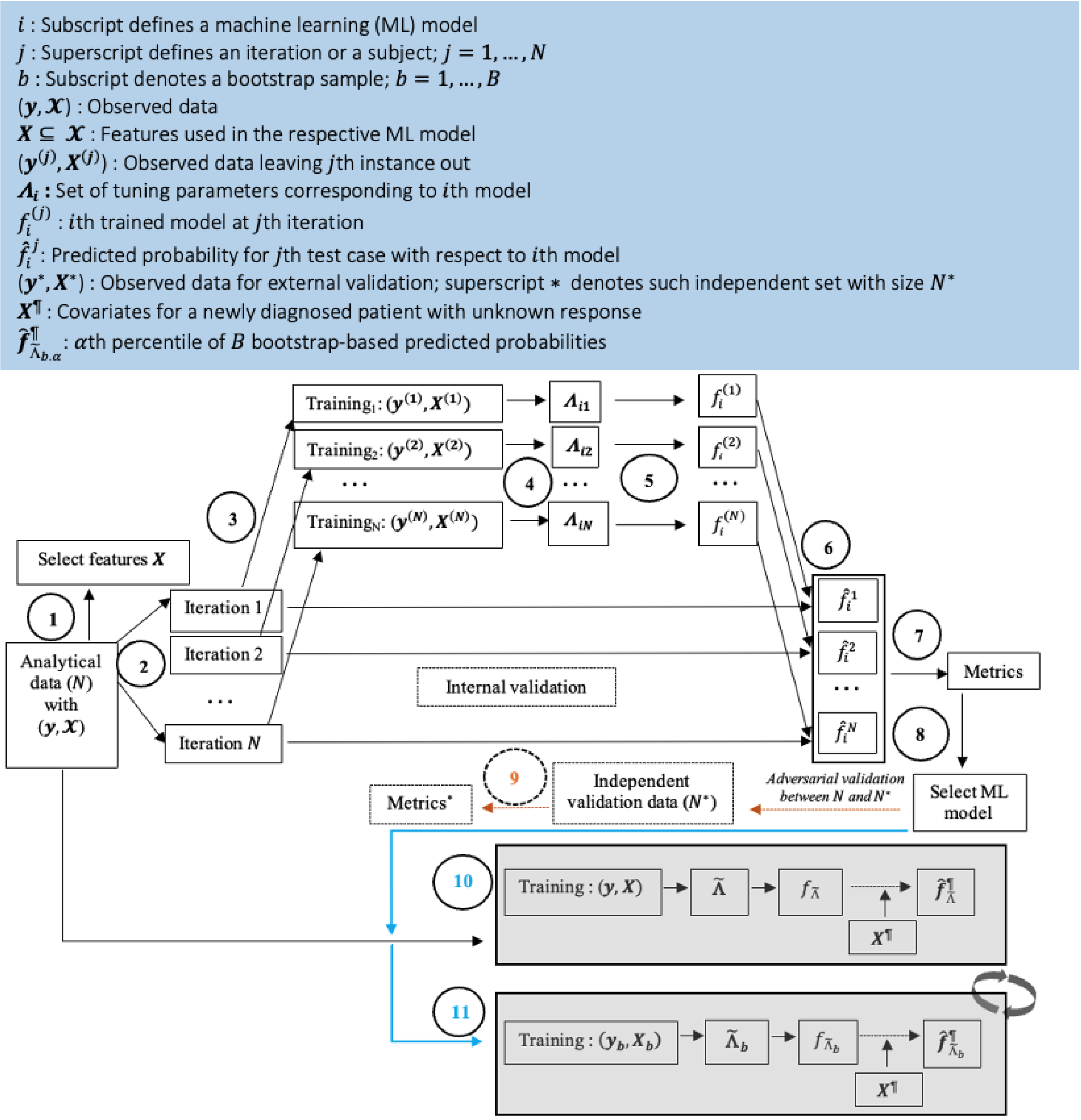
10 Retrain the selected "*best*" ML model exploiting all patients' information based on the corresponding analytical dataset; store the model artifacts/parameters; generate patient specific conditional prediction for a new patient.

Step 11: Uncertainty quantification

11 Quantify variation in prediction (eg, standard errors, inter quartile range) with respect to *B* (300 runs) nonparametric bootstrap samples with replacement; obtain percentile prediction intervals.

Internal validation was conducted using leave-one-out cross-validation, focusing on several metrics: dynamic area under the curve (AUC) of cumulative case dynamic control of receiver operative characteristics (ROC) curves (cAUC), incident case dynamic control ROC (iAUC) curves, integrated Brier scores, and time-dependent concordance (C) index and Brier score at 1-year survival (denoted by C_t and Brier$_t$, respectively). The median (M) of cAUCs and iAUCs over event times within 2 years were reported. The model demonstrating the best numerical performance during the internal validation step was retrained using the full data set with appropriately selected tuning parameters. These models were then further evaluated on 2 independent validation sets: 1 for each treatment arm (7+3, n_1=14; ven/aza, n_2=30 patients with AML) treated at the University of Colorado Hospital. Adversarial validation, utilizing a generalized linear model with a logit link function, was used to assess potential data drift between the training and validation sets. SMDs were computed, and the predictive performance of the models on the validation sets was reported. For out-of-sample patients, predicted probabilities were reported along with 95% percentile-based confidence bands, derived from 300 nonparametric bootstrap runs. As the primary aim of the study was to develop treatment-specific prognostic models, we did not apply multiple testing corrections for type I errors.

Figure 2. The processes for development of models, optimum model selection, validation, prediction, and uncertainty quantification for a newly diagnosed patient with AML. AML: acute myeloid leukemia; ML: machine learning.



i : Subscript defines a machine learning (ML) model
j : Superscript defines an iteration or a subject; $j = 1, \dots, N$
b : Subscript denotes a bootstrap sample; $b = 1, \dots, B$
$(\boldsymbol{y}, \boldsymbol{\mathcal{X}})$: Observed data
$\boldsymbol{X} \subseteq \boldsymbol{\mathcal{X}}$: Features used in the respective ML model
$(\boldsymbol{y}^{(j)}, \boldsymbol{X}^{(j)})$: Observed data leaving jth instance out
$\boldsymbol{\Lambda}_i$ **:** Set of tuning parameters corresponding to ith model
$f_i^{(j)}$: ith trained model at jth iteration
$\hat{f}_i^{j}$: Predicted probability for jth test case with respect to ith model
$(\boldsymbol{y}^*, \boldsymbol{X}^*)$: Observed data for external validation; superscript $*$ denotes such independent set with size N^*
$\boldsymbol{X}^{\P}$: Covariates for a newly diagnosed patient with unknown response
$\hat{\boldsymbol{f}}^{\P}_{\bar{\Lambda}_{b,\alpha}}$: αth percentile of B bootstrap-based predicted probabilities

Results

Statistical Learning–Based Comparison of Ven/Aza and 7+3 During the First 30 Days of Treatment

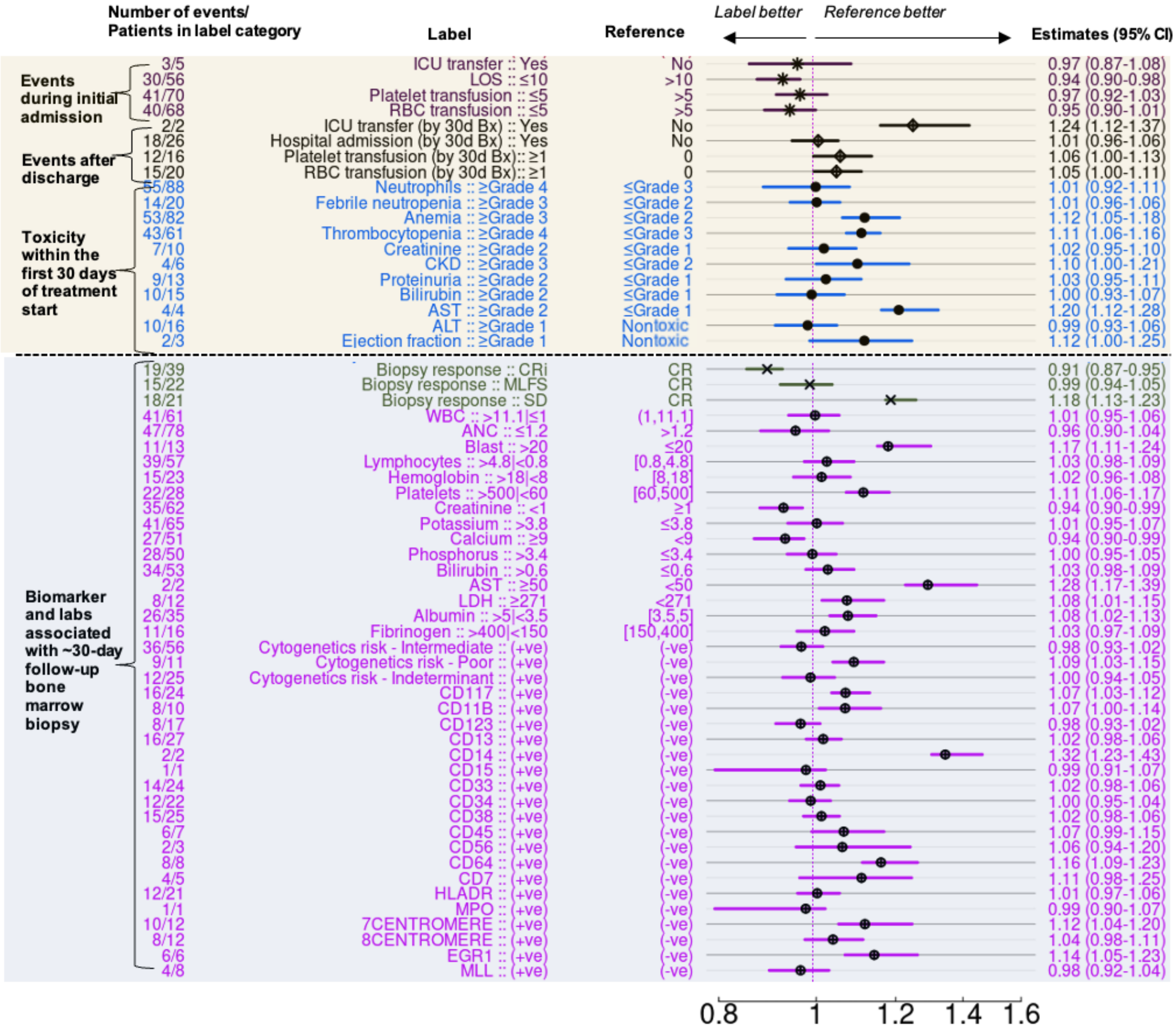
Summary statistics for the 7+3 and ven/aza cohorts are presented in Tables S1-S5 in Multimedia Appendix 1. Ven/aza patients were older (median age 72 years, IQR 66-78 years; range 22-90 years) and had more comorbidities and high-risk AML features compared with 7+3 patients (median age 53 years, IQR 41-59 years; range 20-75 years), as previously described [54]. The ven/aza cohort had a higher prevalence of patients with an Eastern Cooperative Oncology Group score of 2 (15/59, 25%) compared with the 7+3 cohort (1/31, 3%). Various diagnostic criteria, including demographic features, comorbidities, laboratory values, and AML pathology characteristics, were associated with OS for both the ven/aza cohort (Figure S2 in Multimedia Appendix 1) and the 7+3 cohort (Figure S4 in Multimedia Appendix 1, “Diagnostic criteria”), consistent with findings described previously [10]. Specific covariates showing notable negative associations (aHR>1) for the ven/aza cohort included prior myelodysplastic syndrome (aHR 1.09, 95% CI 1.03-1.16), prior coagulopathy (aHR 1.12, 95% CI 1.05-1.20), abnormal white blood cell (WBC) count (aHR 1.05, 95% CI 1.00-1.10), blasts >20% (aHR 1.13, 95% CI 1.06-1.22), abnormal platelet count (aHR 1.09, 95% CI 1.04-1.14), elevated uric acid (aHR 1.10, 95% CI 1.03-1.18), high lactate dehydrogenase (aHR 1.14, 95% CI 1.09-1.19), poor cytogenetic risk (aHR 1.12, 95% CI 1.07-1.17), flow cytometry–based CD7 expression (aHR 1.21, 95% CI 1.14-1.28), CD34 expression (aHR 1.06, 95% CI 1.01-1.11), CD38 expression (aHR 1.08, 95% CI 1.02-1.14), and CD11b expression (aHR 1.07, 95% CI 1.01-1.12). Multivariable analyses for the 7+3 cohort revealed similar effects in terms of direction for abnormal WBC, platelet count, uric acid, creatinine, lactate dehydrogenase, poor cytogenetic risk, myeloperoxidase (MPO), and isocitrate dehydrogenase 2 (IDH2). However, more pronounced adverse effects were observed for the ELN-2017–based adverse risk subgroup (aHR 1.06, 95% CI 1.01-1.12), *EGR1* mutation (aHR 1.14, 95% CI 1.07-1.22), and runt-related transcription factor (RUNX; aHR 1.07, 95% CI 1.01-1.13). For more details, see Figures S2 and S4 in Multimedia Appendix 1. The direction of effects was reversed for *CBFB* and *NPM1* between the ven/aza and 7+3 treatment cohorts (Table S13 in Multimedia Appendix 1). Variables indicating genetic abnormalities are detailed in Table S11 in Multimedia Appendix 1.

To determine whether features occurring after diagnosis and the initiation of treatment influenced long-term outcomes, we evaluated the associations between OS and factors such as toxicities, hospital events, transfusions, and short-term disease responses for both treatments separately. A summary of CTCAE toxicities, transfusions, and hospital events, including intensive care unit (ICU) transfers and readmission instances for the 2 treatment cohorts, is provided in Table S2 in Multimedia Appendix 1.

For toxicities occurring after the initiation of treatment, grade ≥3 anemia (aHR 1.12, 95% CI 1.05-1.18) and grade ≥4 thrombocytopenia (aHR 1.11, 95% CI 1.06-1.16) were associated with worse OS in the ven/aza group, as observed in both multivariable and univariate analyses (Figure 3, “Toxicity within the first 30 days of treatment”; Figure S3 in Multimedia Appendix 1). Elevated aspartate aminotransferase was also linked to worse OS (aHR 1.20, 95% CI 1.12-1.28) in the ven/aza group (Figure 3), but this association was not found in the 7+3 group, according to both univariate and multivariable analyses (Figures S4 and 5A in Multimedia Appendix 1). Creatinine grade ≥2 in the first 30 days of treatment was associated with worse OS in the 7+3 group, with an aHR of 1.10 (95% CI 1.01-1.20), as seen in both multivariable (Figure S4 in Multimedia Appendix 1, “Toxicity within the first 30 days of treatment start”) and univariate analyses (Figure S5B in Multimedia Appendix 1). By contrast, this association appeared weaker in the ven/aza group (Figure 3, “Toxicity within the first 30 days of treatment start”; Figure S5B in Multimedia Appendix 1). Despite this, worse OS was linked to chronic kidney disease (CKD) grade ≥3 in the ven/aza group, with a multivariable model–based aHR of 1.10 (95% CI 1.00-1.21; Figure 3, “Toxicity within the first 30 days of treatment start”). A similar trend was observed in the 7+3 group (Figure S4 in Multimedia Appendix 1, “Toxicity within the first 30 days of treatment start”). The kinetics of developing CKD differed significantly between ven/aza and 7+3 treatments (Figure S5C in Multimedia Appendix 1). In the ven/aza cohort, CKD was present at diagnosis or developed quickly, with a CIF of approximately 68% at 50 days. By contrast, CKD developed more gradually within the 7+3 cohort, showing a CIF of about 28% at 50 days. There was a trend toward worse outcomes associated with developing ejection fraction toxicity of grade ≥1 for the ven/aza group, although the patient numbers were small (Figure 3, “Toxicity within the first 30 days of treatment start”). For the 7+3 group, no significant association was found between ejection fraction grade ≥1 and OS (aHR 1.02, 95% CI 0.95-1.09; Figure S4 in Multimedia Appendix 1, “Toxicity within the first 30 days of treatment start”). However, both treatment groups developed progressively higher proportions of patients with ejection fraction toxicity grade >1 during the first 30 days of treatment and beyond, at roughly equal rates (Figure S5D in Multimedia Appendix 1). Febrile neutropenia, a common complication of AML therapy, did not show a clear association with OS in either treatment cohort. The aHRs were 1.01 (95% CI 0.96-1.06) for the ven/aza group and 1.02 (95% CI 0.95-1.09) for the 7+3 cohort, indicating no significant effect either by multivariable analysis (Figure 3, “Toxicity within the first 30 days of treatment start” and Figure S4 in Multimedia Appendix 1, “Toxicity within the first 30 days of treatment start”), or by univariate analysis (Figure S5E in Multimedia Appendix 1). Interestingly, for the 7+3 regimen, grade ≥4 neutrophils (CIF ~100% at 50 days) and grade ≥3 febrile neutropenia (CIF ~75% at 50 days) occurred at high levels. By contrast, for the ven/aza cohort, there was a much lower rate of febrile neutropenia (CIF ~25% at 50 days) over time, despite a nearly universal incidence of neurophils (Figure S5F in Multimedia Appendix 1).

For transfusions occurring after the initiation of treatment, Kaplan-Meier analysis revealed that a higher number of platelet and red blood cell transfusions were associated with poorer outcomes in the 7+3 group. This association was evident in both univariate (Figure S5G and S5H in Multimedia Appendix 1) and multivariable analyses (Figure S4 in Multimedia Appendix 1, “Toxicity within the first 30 days of treatment start” and Figure 3, “Toxicity within the first 30 days of treatment start”). Specifically, in the 7+3 cohort, the corresponding aHR indicated negative association with more than 5 platelet transfusions (aHR 1.11, 95% CI 1.06-1.18). This association was less pronounced in the ven/aza group. For hospital events occurring after the initiation of treatment, ICU transfer during the induction period was a particularly poor prognostic feature for patients receiving the 7+3 treatment, with an aHR of 1.18 (95% CI 1.10-1.28) indicating worse outcomes (Figure S4 in Multimedia Appendix 1, “Events during initial admission,” and Figure S5I in Multimedia Appendix 1). By contrast, there was no significant association between ICU transfer following ven/aza treatment and OS during the initial admission (Figure 3, “Events during initial admission”). However, if a patient was discharged and then readmitted to the hospital within the first month of treatment, ICU admission during the readmission was a poor prognostic feature for those treated with ven/aza, with an aHR of 1.24 (95% CI 1.12-1.37; Figure 3, “events after discharge”). For the 7+3 group, initial admissions lasting more than 35 days were associated with worse outcomes (aHR 1.11, 95% CI 1.04-1.18; Figure S4 in Multimedia Appendix 1, “Events during initial admission”). Similarly, for the ven/aza cohort, admissions lasting more than 10 days were associated with poorer outcomes (aHR 1.06, 95% CI 1.02-1.11; Figure 3, “Events during initial admission”).

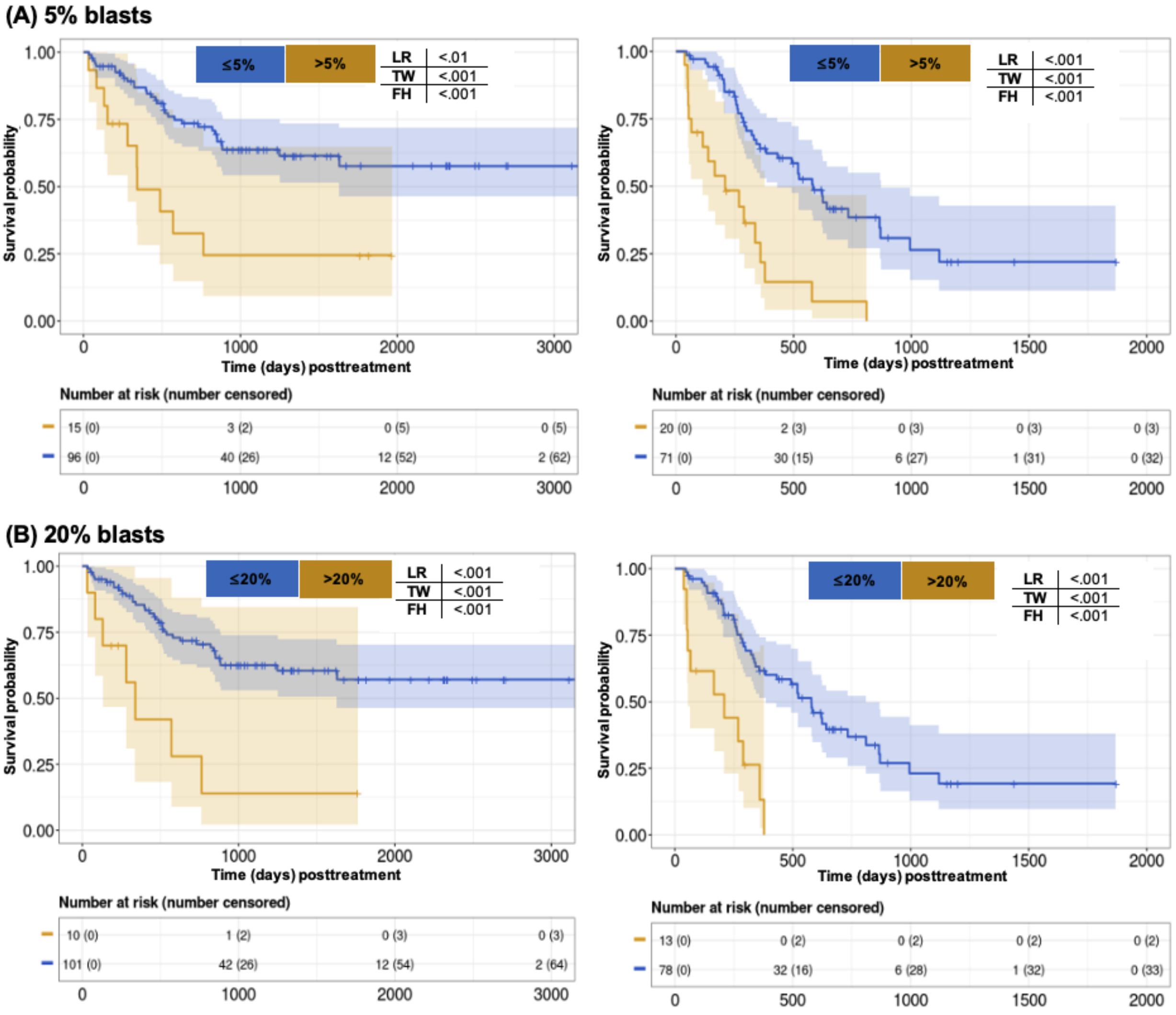
Figure 3. Adjusted hazard ratios (aHRs) for predictors of overall survival for the ven/aza cohort corresponding to events occurring during the first ~30 days of therapy. Reported are the aHRs (vertical tick) and bootstrap-based 95% CIs (horizontal line). “Reference features” correlating with a better outcome are to the right and “Label features” with a better outcome are to the left. The number of patients who died relative to the subset of patients with each feature is summarized at the far left. The table includes findings during the first 30 days and outcomes at the $\text{Day}_{15\text{-}55}$ bone marrow biopsy assessment at the bottom. $\text{Day}_{15\text{-}55}$ is defined as the day (or days) between 15 and 55 days from the initiation of treatment when bone marrow biopsy, blood test, and clinical evaluation are conducted to assess response. Different symbols for aHRs were used to differentiate the values between different types of variables. ALT: alkaline phosphatase; ANC: absolute neutrophil count; AST: aspartate transaminase; CKD: chronic kidney disease; CR: complete remission; CRi: complete remission with incomplete hematologic recovery; ICU: intensive care unit; LDH: lactate dehydrogenase; LOS: length of stay; MLFS: morphologic leukemia-free state; RBC: red blood cell; SD: stable disease; ven/aza: venetoclax plus azacitidine; WBC: white blood cell.



Next, associations between OS and patient assessments around day 30 (ie, $\text{Day}_{15\text{-}55}$) after treatment initiation were analyzed. Tables S3-S5 in Multimedia Appendix 1 provide a summary of follow-up patient laboratory values, biomarkers, and AML responses assessed at $\text{Day}_{15\text{-}55}$ for both ven/aza- and 7+3-treated patients, respectively. At the $\text{Day}_{15\text{-}55}$ assessment, the ven/aza cohort exhibited lower levels of alanine aminotransferase, aspartate aminotransferase, neutrophils, fibrinogen, lymphocytes, and WBC compared with that of the 7+3 cohort, with SMDs greater than 0.40 (Table S3 in Multimedia Appendix 1). Platelets and hemoglobin levels were also lower in the ven/aza cohort at the $\text{Day}_{15\text{-}55}$ assessment, but these differences were clinically inconsequential. Summary statistics for AML-related responses are provided in Table S5 in Multimedia Appendix 1. Notably, a lower proportion of ven/aza patients achieved CR at $\text{Day}_{15\text{-}55}$ (61/111, 55% for 7+3 vs 9/91, 10% for ven/aza). Conversely, a higher proportion of ven/aza patients were in CRi and MLFS compared with those treated with 7+3 (Figure S3 in Multimedia Appendix 1). Patients who achieved CR or CRi at $\text{Day}_{15\text{-}55}$ had better outcomes compared with those who did not, with an LR-based *P* value of <.001 (Figure S3 in Multimedia Appendix 1, top panel). This was also true for patients who proceeded to receive an alloSCT, with an LR-based *P* value of <.01 (Figure S3 in Multimedia Appendix 1, middle panel). Ven/aza-treated patients who achieved MLFS at $\text{Day}_{15\text{-}55}$ did not have worse OS compared with those who achieved CR, with an aHR of 0.99 (95% CI 0.94-1.05). By contrast, MLFS at this time point for patients treated with 7+3 was associated with worse outcomes than CR, with an aHR of 1.16 (95% CI 1.01-1.31). This difference was observed in both univariate (Figure S3 in Multimedia Appendix 1, bottom panel) and multivariable analyses (Figure 3, “Biomarker and labs associated with ~30-day follow-up bone marrow biopsy”, and Figure S4 in Multimedia Appendix 1, “Biomarker and labs associated with ~30-day follow-up bone marrow biopsy”). Findings of persistent leukemia in the marrow as detected by flow cytometry, cytogenetics, or fluorescence in situ hybridization were associated with worse outcomes for both treatment groups according to multivariable analysis (Figure S4 in Multimedia Appendix 1, “Biomarker and labs associated with ~30-day follow-up bone marrow biopsy,” and Figure 3, “Biomarker and labs associated with ~30-day follow-up bone marrow biopsy”). Summary statistics for genetics and phenotypic features are provided in Table S4 in Multimedia Appendix 1. Specific posttreatment covariates in the ven/aza cohort demonstrated substantial negative associations, with aHRs exceeding 1, including CD117 (aHR 1.07, 95% CI 1.03-1.12), CD11B (aHR 1.07, 95% CI 1.00-1.14), CD64 (aHR 1.16, 95% CI 1.09-1.23), 7 centromere (aHR 1.12, 95% CI 1.04-1.20), and EGR1 (aHR 1.14, 95% CI 1.05-1.23; Figure 3). Similarly, for the 7+3 patients’ cohort, posttreatment covariates demonstrated inverse associations with OS, with aHRs exceeding 1. Significant negative associations were observed for cytogenetic poor risk (aHR 1.20, 95% CI 1.10-1.31), indeterminant risk (aHR 1.10, 95% CI 1.03-1.17), 8 centromere (aHR 1.22, 95% CI 1.11-1.35), EGR1 (aHR 1.14, 95% CI 1.06-1.22), and FLT3 (aHR 1.22, 95% CI 1.10-1.34; Figure S4 in Multimedia Appendix 1).

For both treatments, the presence of >20% bone marrow blasts and >5% bone marrow blasts at the Day$_{15-55}$ time point were associated with very poor OS by univariate analysis (Figure 4). The corresponding aHRs of >20% blasts were 1.17 (95% CI 1.11-1.24) for the patients treated with ven/aza and 1.11 (95% CI 1.04-1.20) for the patients treated with 7+3. These findings highlight that early toxicities, treatment events, and short-term responses occurring within the first month after treatment initiation are associated with OS for both 7+3 and ven/aza. However, the impact and relevance of these features vary between the 2 treatment regimens.

Figure 4. Univariate analysis of blasts recorded at Day$_{15-55}$ response assessment and long-term outcomes (7+3 left, ven/aza right). (A) >5% blasts and outcomes and (B) >20% blasts and outcomes. As described in the "Methods" section, Day$_{15-55}$ is defined as a bone marrow biopsy and other clinical evaluation done within 15-55 days from the initiation of treatment and closest to day 30. *P* values are based on log-rank (LR), Tarone-Ware (TW), and Fleming-Harington (FH) tests. ven/aza: venetoclax plus azacitidine.



Prospective Machine Learning Predictors of OS

To translate the statistical associations between events and responses occurring after the initiation of therapy into predictions that could be potentially applied to individual patients, we developed ML-based predictive models for OS utilizing 17 different ML algorithms based on these baseline and early posttreatment features (Table 1 and Table S12 in Multimedia Appendix 1). The modeling steps are illustrated in Figure 1, and an example of the model development process is shown in Figure 2. Detailed information on feature engineering, model specification, optimization, and final model selection is provided in the section titled "Technical Details" in Multimedia Appendix 1.

Table 1. List of machine learning models.

Model abbreviation	Method definition
RSF	Ensemble survival forest—random
RSB	Ensemble survival forest—bagging
Cox-Ridge	Cox regression with ridge penalty
Cox-LASSO	Cox regression with lasso penalty
Cox-Relaxed	Cox regression with relaxed lasso penalty
Cox-Elastic	Cox regression with elastic net penalty
Cox-adElastic	Cox regression with adaptive elastic net penalty
Cox-adSCAD	Cox regression with adaptive smoothly clipped absolute deviation (SCAD) penalty
Cox-adSNET	Cox regression with adaptive SCAD coupled with L2 penalty
Cox-adMCP	Cox regression with adaptive minimax concave penalty (MCP)
Cox-adMNET	Cox regression with adaptive MCP coupled with L2 penalty
Cox-Boost	Boosted Cox regression
AFT	Accelerated failure time with exponential, Weibull, and log-logistic error
CISF	Conditional inference survival forest
Deep-Surv	Cox regression with deep neural net
Deep-LogHaz	Discrete-time survival estimates by log hazard with neural net
Deep-Hit	Deep learning–based survival analysis relaxing distributional assumptions

Among all the models, Cox-Boost (Boosted Cox regression) and RSF achieved median cAUCs of 0.85 (90% CI 0.78-0.88) and 0.80 (90% CI 0.76-0.84) for the ven/aza and 7+3 cohorts, respectively (Tables 2 and 3). In an independent validation set consisting of 16 7+3 and 30 ven/aza patients, median cAUCs of 0.71 and 0.68 were observed for the ven/aza and 7+3 cohorts, respectively (Table 4). DL models resulted in less optimal performance, primarily due to the small sample size and their susceptibility to noise variables. A comparative analysis highlighting the drift between the training and validation cohorts was conducted, with details provided in Tables S6-S9 in Multimedia Appendix 1. These tables cover laboratory values (Table S6 in Multimedia Appendix 1), phenotypic features (Table S7 in Multimedia Appendix 1), genetic biomarkers (Table S8 in Multimedia Appendix 1), and clinical events (Table S9 in Multimedia Appendix 1). For a test patient, the selected ML models were used to generate patient-specific survival probabilities. Figure 5 illustrates the features (top panel) and predicted survival (bottom panel) probabilities for a representative patient randomly selected from the independent validation set. Similarly, subject-specific analyses were conducted for 2 additional patients randomly selected from the internal validation cohorts: 1 treated with ven/aza (Figure S6 in Multimedia Appendix 1) and 1 treated with 7+3 (Figure S7 in Multimedia Appendix 1). The selected models were retrained with 120 7+3 and 100 ven/aza patients for the ven/aza test subject and with 119 7+3 and 101 ven/aza patients for the 7+3 test subject. Although exploratory and limited by sample size, these analyses illustrate that ML predictors of OS can potentially be developed based on clinical events, early disease responses, and biomarkers for both ven/aza and 7+3 treatments. However, as with the statistical analyses, the models that perform optimally are likely to vary between ven/aza and 7+3 treatments. Therefore, they should be developed and validated on a treatment-specific basis.

Table 2. Machine learning models of overall survival for ven/aza-treated patients based on events occurring in the first 30 days of treatment and the Day15-55 follow-up assessment.[a]

Overall survival (2 years) prognostic models[b]	Median cAUC[c] (5th-95th)[d]	Median iAUC[e] (5th-95th)[d]	C_t[d]	$Brier_t$[f]	iBrier[f]
RSF	0.79 (0.71-0.86)	0.68 (0.66-0.76)	0.72	0.20	0.17
RSB	0.73 (0.64-0.82)	0.61 (0.60-0.63)	0.67	0.23	0.19
Cox-Ridge	0.82 (0.79-0.89)	0.66 (0.62-0.75)	0.72	0.20	0.17
Cox-LASSO	0.85 (0.78-0.89)	0.69 (0.60-0.72)	0.73	0.20	0.16
Cox-Relaxed	0.83 (0.77-0.88)	0.61 (0.59-0.68)	0.72	0.20	0.17
Cox-Elastic	0.83 (0.78-0.86)	0.63 (0.60-0.70)	0.72	0.20	0.17
Cox-adElastic	0.80 (0.76-0.89)	0.64 (0.60-0.72)	0.66	0.24	0.19
Cox-adSCAD	0.62 (0.58-0.72)	0.52 (0.52-0.53)	0.52	0.29	0.23
Cox-adSNET	0.78 (0.73-0.85)	0.65 (0.62-0.69)	0.66	0.23	0.19
Cox-adMCP	0.62 (0.51-0.66)	0.55 (0.54-0.56)	0.55	0.26	0.22
Cox-adMNET	0.78 (0.73-0.85)	0.65 (0.62-0.69)	0.66	0.23	0.20
Cox-Boost[g]	0.85 (0.78-0.88)	0.66 (0.61-0.74)	0.76	0.19	0.16
AFT-Exponential	≤0.50	0.62 (0.60-0.64)	0.73	0.19	0.16
AFT-Weibull	≤0.50	0.65 (0.64-0.66)	0.72	0.22	0.17
AFT-log-logistic	≤0.50	0.65 (0.64-0.66)	0.75	0.21	0.17
CISF	≤0.50	0.64 (0.61-0.65)	0.58	0.22	0.21
Deep-Surv	≤0.50	0.52 (0.52-0.53)	0.46	0.25	0.44
Deep-Hit	0.52 (≤0.50-0.55)	0.52 (0.51-0.52)	0.38	0.32	0.34
Deep-LogHaz	≤0.50	0.53 (0.53-0.54)	0.46	0.43	0.74

[a] Time-dependent AUCs (ie, median cAUC and iAUC), time-dependent concordance (C) index and Brier score at 1 year, and integrated Brier score were reported. As described in the “Methods” section, Day_{15-55} is defined as a bone marrow biopsy and other clinical evaluation done within 15-55 days from the initiation of treatment.

[b] See Table 1 for models and method definitions.

[c] cAUC: cumulative case dynamic control of receiver operative characteristics.

[d] The higher value (ie, close to 1) means better numerical performance.

[e] iAUC: incident case dynamic control of receiver operative characteristics.

[f] The lower value (ie, close to 0) means better numerical performance.

[g] The selected final model for ven/aza.

Table 3. Machine learning models of overall survival for 7+3-treated patients based on events occurring in the first 30 days of treatment and the Day15-55 follow-up assessment.[a]

Overall survival (2 years) prognostic models[b]	Median cAUC[c] (5th-95th)[d]	Median iAUC[e] (5th-95th)[d]	C_t[d]	Brier_t[f]	iBrier[f]
RSF[g]	0.80 (0.76-0.84)	0.71 (0.70-0.73)	0.74	0.12	0.16
RSB	0.78 (0.75-0.84)	0.71 (0.71-0.72)	0.73	0.13	0.15
Cox-Ridge	0.80 (0.75-0.86)	0.70 (0.69-0.73)	0.71	0.11	0.17
Cox-LASSO	0.71 (0.67-0.83)	0.64 (0.63-0.65)	0.65	0.13	0.18
Cox-Relaxed	0.68 (0.61-0.73)	0.64 (0.63-0.65)	0.65	0.13	0.19
Cox-Elastic	0.73 (0.69-0.83)	0.65 (0.65-0.66)	0.67	0.12	0.18
Cox-adElastic	0.76 (0.70-0.79)	0.68 (0.67-0.68)	0.70	0.13	0.17
Cox-adSCAD	0.70 (0.44-0.73)	0.66 (0.66-0.67)	0.68	0.14	0.18
Cox-adSNET	0.71 (0.64-0.72)	0.66 (0.66-0.67)	0.68	0.13	0.17
Cox-adMCP	0.61 (0.47-0.65)	0.62 (0.61-0.62)	0.64	0.13	0.18
Cox-adMNET	0.71 (0.65-0.73)	0.66 (0.66-0.67)	0.68	0.13	0.17
Cox-Boost	0.70 (0.61-0.79)	0.63 (0.63-0.64)	0.64	0.13	0.18
AFT-Exponential	≤0.50	0.51 (0.50-0.51)	0.60	0.13	0.20
AFT-Weibull	≤0.50	0.53 (0.53-0.54)	0.57	0.14	0.20
AFT-log-logistic	≤0.50	0.57 (0.56-0.57)	0.60	0.14	0.20
CISF	≤0.50	0.63 (0.62-0.64)	0.61	0.13	0.23
Deep-Surv	≤0.50	0.58 (0.58-0.59)	0.39	0.15	0.44
Deep-Hit	0.55 (≤0.50-0.64)	≤0.50	0.53	0.14	0.59
Deep-LogHaz	≤0.50	0.61(0.60,0.61)	0.45	0.48	≥1.00

[a] Time-dependent AUCs (ie, median cAUC and iAUC), time-dependent concordance (C) index and Brier score at 1 year, and integrated Brier score were reported. As described in the “Methods” section, $\text{Day}_{15\text{-}55}$ is defined as a bone marrow biopsy and other clinical evaluation done within 15-55 days from the initiation of treatment.

[b] See Table 1 for models and method definitions.

[c] cAUC: cumulative case dynamic control of receiver operative characteristics.

[d] The higher value (ie, close to 1) means better numerical performance.

[e] iAUC: incident case dynamic control of receiver operative characteristics.

[f] The lower value (ie, close to 0) means better numerical performance.

[g] Selected model for 7+3.

Table 4. Numerical performances of the chosen machine learning models for ven/aza[a] and 7+3 on independent validation cohorts with respect to overall survival (≤2 years).

Treatment	Machine learning models	Median cAUC[b,c]	Median iAUC[b,d]	C_t[b]	Brier_t[e]	iBrier[e]
7+3 (n=14)	RSF[f]	0.71	0.69	0.66	0.19	0.21
ven/aza (n=30)	Cox-Boost[f]	0.68	0.64	0.66	0.29	0.23

[a] ven/aza: venetoclax plus azacitidine.

[b] The higher value (ie, close to 1) means better numerical performance.

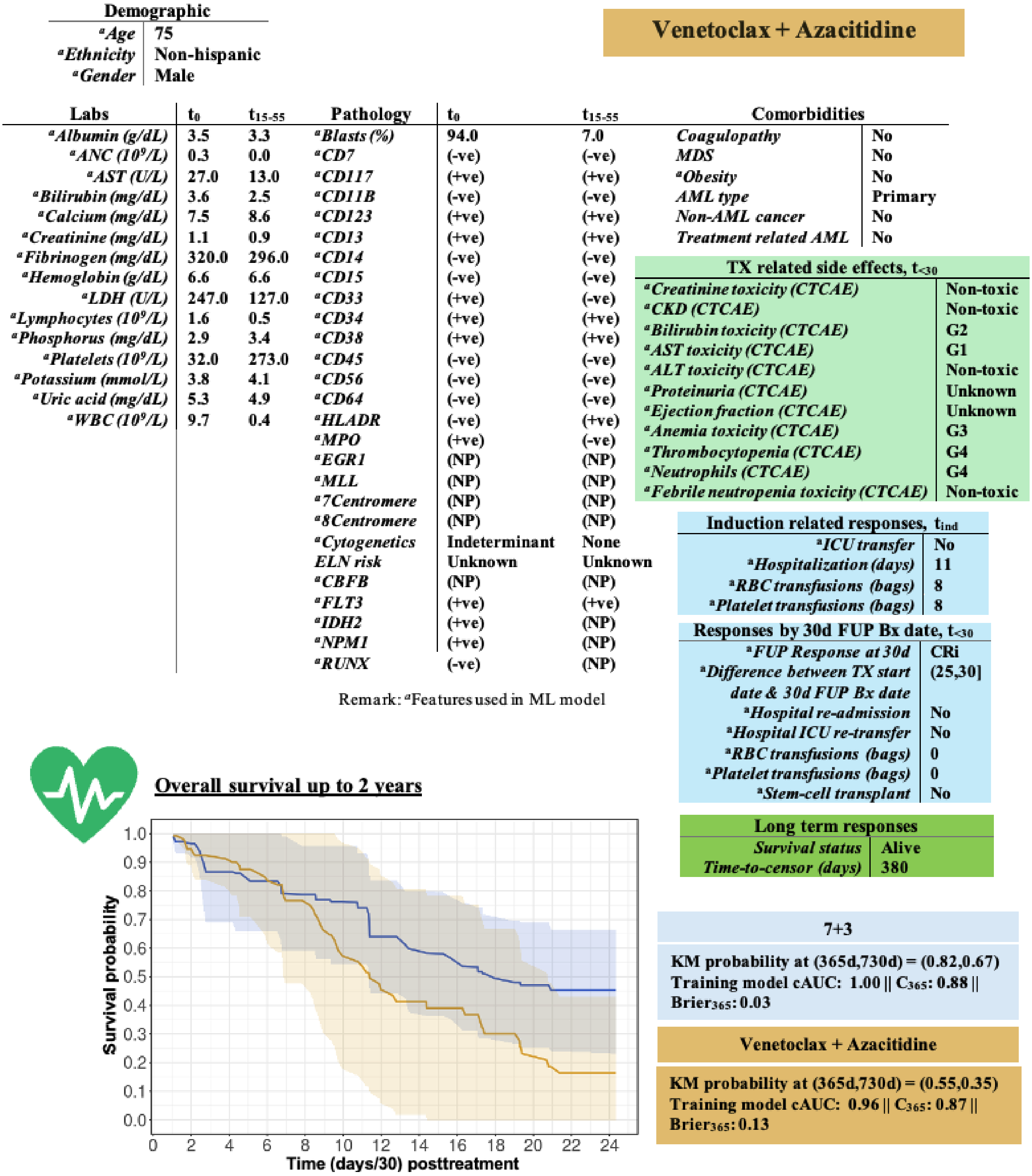
[c] cAUC: cumulative case dynamic control of receiver operative characteristics.

[d] iAUC: incident case dynamic control of receiver operative characteristics.

[e] The lower value (ie, close to 0) means better numerical performance.

[f] See Table 1 for models and method definitions.

Figure 5. Representative machine learning (ML)-based predictions for a patient chosen randomly from the validation cohort treated with ven/aza. Actual patient values are in the top boxes and the predicted overall survival probabilities along with 95% confidence bands based on the optimal ML models are depicted at the bottom. ALT: alkaline phosphatase; AML: acute myeloid leukemia; ANC: absolute neutrophil count; AST: aspartate transaminase; CKD: chronic kidney disease; CTCAE: Common Terminology Criteria for Adverse Events; FUP: follow-up; ICU: intensive care unit; LDH: lactate dehydrogenase; MDS: myelodysplastic syndrome; RBC: red blood cell; TX: treatment; ven/aza: venetoclax plus azacitidine; WBC: white blood cell.



Venetoclax + Azacitidine

Demographic	
[a]*Age*	75
[a]*Ethnicity*	Non-hispanic
[a]*Gender*	Male

Labs	t_0	$t_{15\text{-}55}$	Pathology	t_0	$t_{15\text{-}55}$
[a]*Albumin (g/dL)*	3.5	3.3	[a]*Blasts (%)*	94.0	7.0
[a]*ANC (10^9/L)*	0.3	0.0	[a]*CD7*	(-ve)	(-ve)
[a]*AST (U/L)*	27.0	13.0	[a]*CD117*	(+ve)	(+ve)
[a]*Bilirubin (mg/dL)*	3.6	2.5	[a]*CD11B*	(-ve)	(-ve)
[a]*Calcium (mg/dL)*	7.5	8.6	[a]*CD123*	(+ve)	(+ve)
[a]*Creatinine (mg/dL)*	1.1	0.9	[a]*CD13*	(+ve)	(+ve)
[a]*Fibrinogen (mg/dL)*	320.0	296.0	[a]*CD14*	(-ve)	(-ve)
[a]*Hemoglobin (g/dL)*	6.6	6.6	[a]*CD15*	(-ve)	(-ve)
[a]*LDH (U/L)*	247.0	127.0	[a]*CD33*	(+ve)	(-ve)
[a]*Lymphocytes (10^9/L)*	1.6	0.5	[a]*CD34*	(+ve)	(+ve)
[a]*Phosphorus (mg/dL)*	2.9	3.4	[a]*CD38*	(+ve)	(+ve)
[a]*Platelets (10^9/L)*	32.0	273.0	[a]*CD45*	(-ve)	(-ve)
[a]*Potassium (mmol/L)*	3.8	4.1	[a]*CD56*	(-ve)	(-ve)
[a]*Uric acid (mg/dL)*	5.3	4.9	[a]*CD64*	(-ve)	(-ve)
[a]*WBC (10^9/L)*	9.7	0.4	[a]*HLADR*	(-ve)	(+ve)
			[a]*MPO*	(+ve)	(-ve)
			[a]*EGR1*	(NP)	(NP)
			[a]*MLL*	(NP)	(NP)
			[a]*7Centromere*	(NP)	(NP)
			[a]*8Centromere*	(NP)	(NP)
			[a]*Cytogenetics*	Indeterminant	None
			ELN risk	Unknown	Unknown
			[a]*CBFB*	(NP)	(NP)
			[a]*FLT3*	(+ve)	(+ve)
			[a]*IDH2*	(+ve)	(NP)
			[a]*NPM1*	(+ve)	(NP)
			[a]*RUNX*	(-ve)	(NP)

Comorbidities	
Coagulopathy	No
MDS	No
[a]*Obesity*	No
AML type	Primary
Non-AML cancer	No
Treatment related AML	No

TX related side effects, $t_{<30}$	
[a]*Creatinine toxicity (CTCAE)*	Non-toxic
[a]*CKD (CTCAE)*	Non-toxic
[a]*Bilirubin toxicity (CTCAE)*	G2
[a]*AST toxicity (CTCAE)*	G1
[a]*ALT toxicity (CTCAE)*	Non-toxic
[a]*Proteinuria (CTCAE)*	Unknown
[a]*Ejection fraction (CTCAE)*	Unknown
[a]*Anemia toxicity (CTCAE)*	G3
[a]*Thrombocytopenia (CTCAE)*	G4
[a]*Neutrophils (CTCAE)*	G4
[a]*Febrile neutropenia toxicity (CTCAE)*	Non-toxic

Induction related responses, t_{ind}	
[a]*ICU transfer*	No
[a]*Hospitalization (days)*	11
[a]*RBC transfusions (bags)*	8
[a]*Platelet transfusions (bags)*	8

Responses by 30d FUP Bx date, $t_{<30}$	
[a]*FUP Response at 30d*	CRi
[a]*Difference between TX start date & 30d FUP Bx date*	(25,30]
[a]*Hospital re-admission*	No
[a]*Hospital ICU re-transfer*	No
[a]*RBC transfusions (bags)*	0
[a]*Platelet transfusions (bags)*	0
[a]*Stem-cell transplant*	No

Remark: [a]Features used in ML model

Long term responses	
Survival status	Alive
Time-to-censor (days)	380

Overall survival up to 2 years

7+3

KM probability at (365d,730d) = (0.82,0.67)
Training model cAUC: 1.00 || C_{365}: 0.88 ||
$Brier_{365}$: 0.03

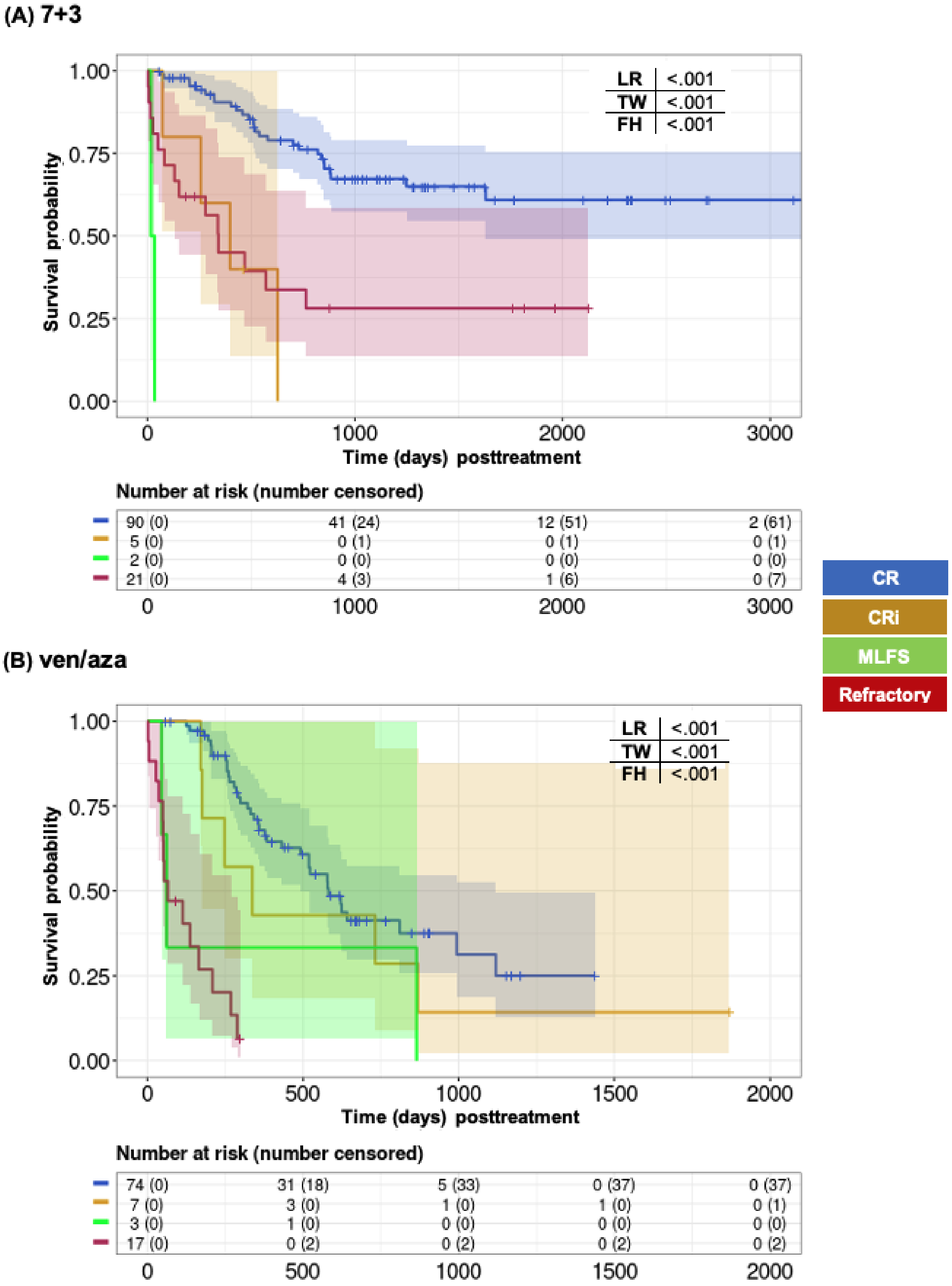
Venetoclax + Azacitidine

KM probability at (365d,730d) = (0.55,0.35)
Training model cAUC: 0.96 || C_{365}: 0.87 ||
$Brier_{365}$: 0.13

Association Between Events Occurring During the First Year of Therapy and Overall Survival

As treatment events and responses in AML can evolve beyond the first month of treatment, we investigated associations between later disease responses and OS. Initially, we examined the association between the best response after the treatment initiation and long-term OS. Among patients treated with 7+3, achieving CR as the best response correlated with a 4-year OS rate of approximately 60%. Conversely, achieving CRi, MLFS, or being nonresponsive (refractory) as the best responses correlated with an OS rate of approximately 25% or less. An LR–based *P* value <.001 indicated significant differences between survival curves (Figure 6A). In the ven/aza-treated cohort, both CR and CRi were similarly associated with OS, whereas MLFS and nonresponses correlated with lower OS (Figure 6B). It is important to note that Kaplan-Meier survival curves might be influenced by alloSCT. For instance, out of 21 refractory 7+3 patients, 10 (48%) underwent alloSCT, potentially leading to an overestimation of the corresponding survival curve. By contrast, only 3 (18%) out of 17 refractory ven/aza patients underwent alloSCT.

Figure 6. Univariate Kaplan-Meier analysis of best response during the first 180 days' assessment and long-term outcomes with (A) 7+3 and (B) ven/aza.*P* values are based on log-rank (LR), Tarone-Ware (TW), and Fleming-Harington (FH) tests. CR: complete remission; CRi: complete remission with incomplete hematologic recovery; MLFS: morphologic leukemia-free state; ven/aza: venetoclax plus azacitidine.



Next, we examined the kinetics of achieving the best response in the 2 treatment groups. The pattern of reaching the best responses differed between the 7+3 and ven/aza groups (Figure 7), as did the overall frequencies of various treatment response outcomes (Figure S8 in Multimedia Appendix 1). At the population level, the 7+3 cohort quickly reached a relatively stable state by day 30 (Figure 7A). By contrast, the ven/aza cohort showed a continual evolution with conversions from CRi and MLFS to either CR or death (Figure 7B). The disease-state transition probabilities between days 30 and 365 also differed significantly between 7+3 (Figure 8A) and ven/aza (Figure 8B). Achieving CR (0.28; SE 0.05), CRi (0.37; SE 0.06), or MLFS (0.42; SE 0.07) around day 30 after ven/aza treatment showed similar probabilities of transitioning to mortality within a year. By contrast, CR (0.13; SE 0.03) and CRi (0.20; SE 0.05) had comparable transitioning rates to mortality for 7+3. Ven/aza patients with stable disease and progressive disease around day 30 had poorer OS, with 1-year mortality rates of 0.61 (SE 0.08) and 0.75 (SE 0.18), respectively. These observations contrast with that of 7+3, presumably because 7+3 patients were generally fit enough to undergo additional therapies aimed at disease control during this period. Similar observations were noted in disease-state transition probabilities between days 90-365 (Figure S9 in Multimedia Appendix 1) and days 180-365 (Figure S10 in Multimedia Appendix 1). Unlike the 7+3 subgroup, patients treated with ven/aza who achieved any disease state around 180 days had a higher likelihood of transitioning to mortality, with the highest probability observed for the relapse state (0.73; SE 0.16 for ven/aza and 0.54; SE 0.33 for 7+3). Specifically, patients in the MLFS disease state around 180 days transitioned more rapidly to mortality with ven/aza (0.37; SE 0.08) compared with 7+3 (0.14; SE 0.07; refer to Figure S10 in Multimedia Appendix 1). These results further confirm that associations with short- and long-term outcomes differ following ven/aza and 7+3 treatments. The kinetics of responses with ven/aza are notably more dynamic and occur over different time frames compared with those with 7+3. These observations underscore the necessity for distinct response criteria, maintenance strategies, and timing of measurements tailored to each therapy.

Figure 7. Overall trends in disease state changes during first year of treatment for (A) 7+3 and (B) ven/aza. CR: complete remission; CRi: complete remission with incomplete hematologic recovery; MLFS: morphologic leukemia-free state; PD: progressive disease; SD: stable disease; ven/aza: venetoclax plus azacitidine.

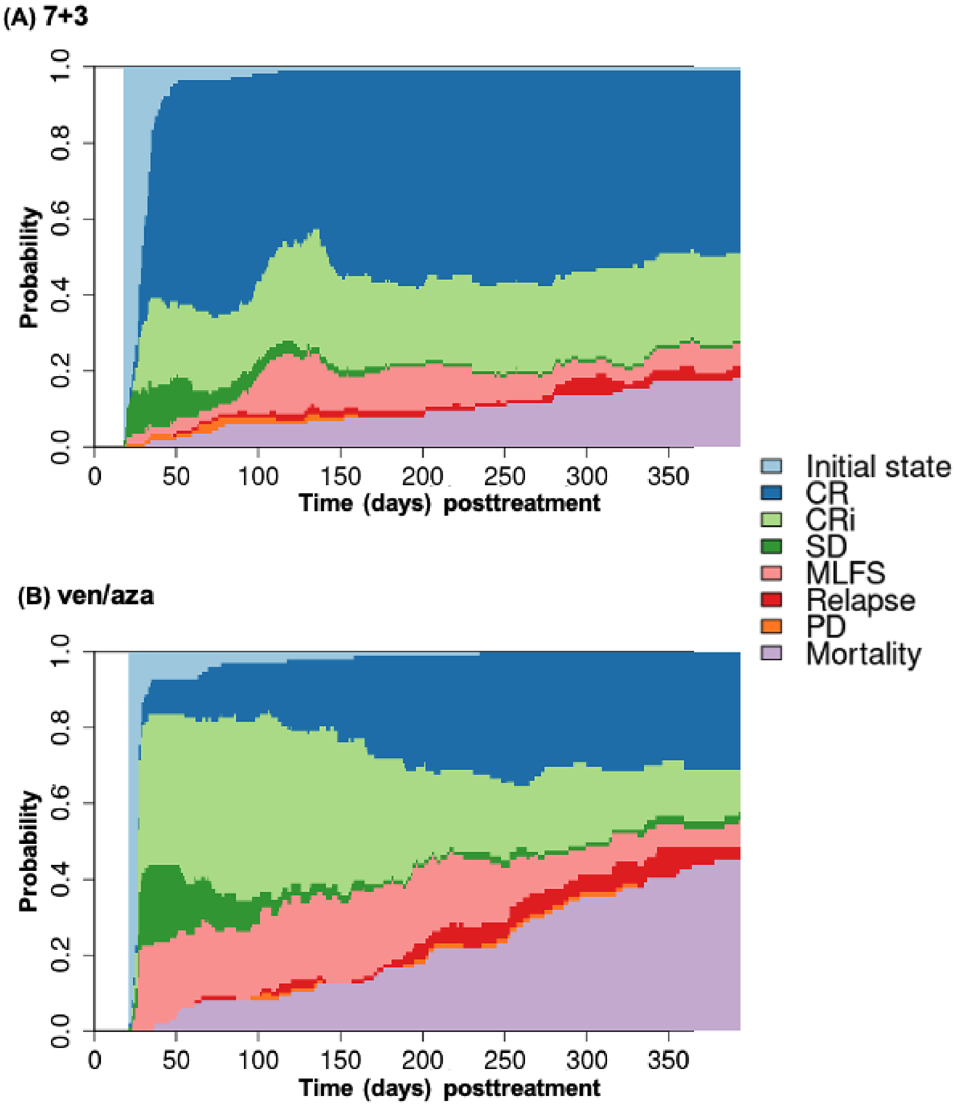
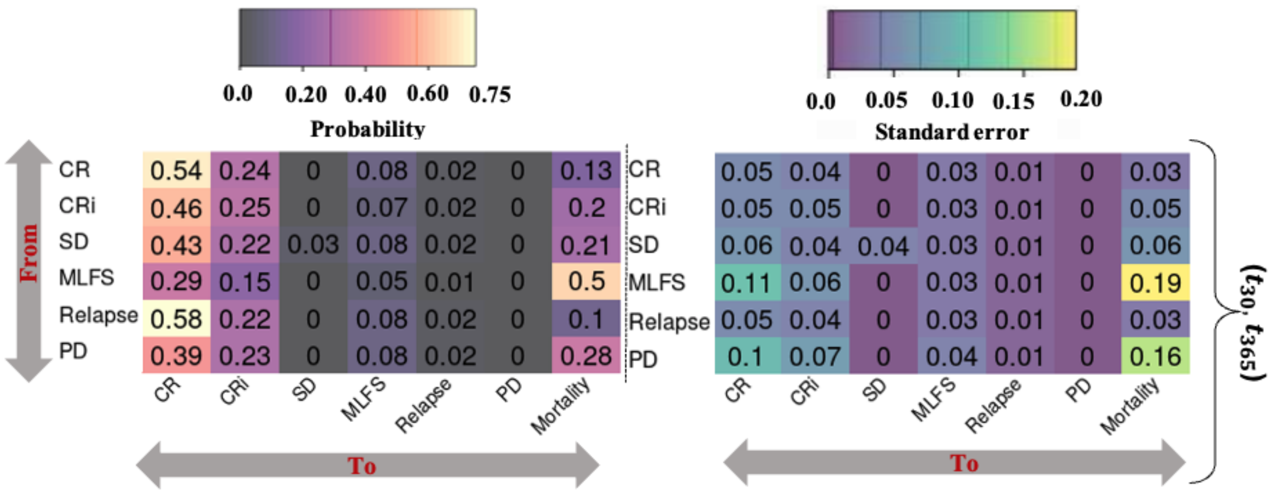


Figure 8. Probabilities of transitions from treatment responses (y-axis) achieved by day 30 of treatment to states (x-axis) within 365 days following treatment for (A) 7+3-treated patients and (B) ven/aza-treated patients. The state transition probabilities are on the left panels and SEs are on the right. CR: complete remission; CRi: complete remission with incomplete hematologic recovery; MLFS: morphologic leukemia-free state; PD: progressive disease; SD: stable disease; ven/aza: venetoclax plus azacitidine.

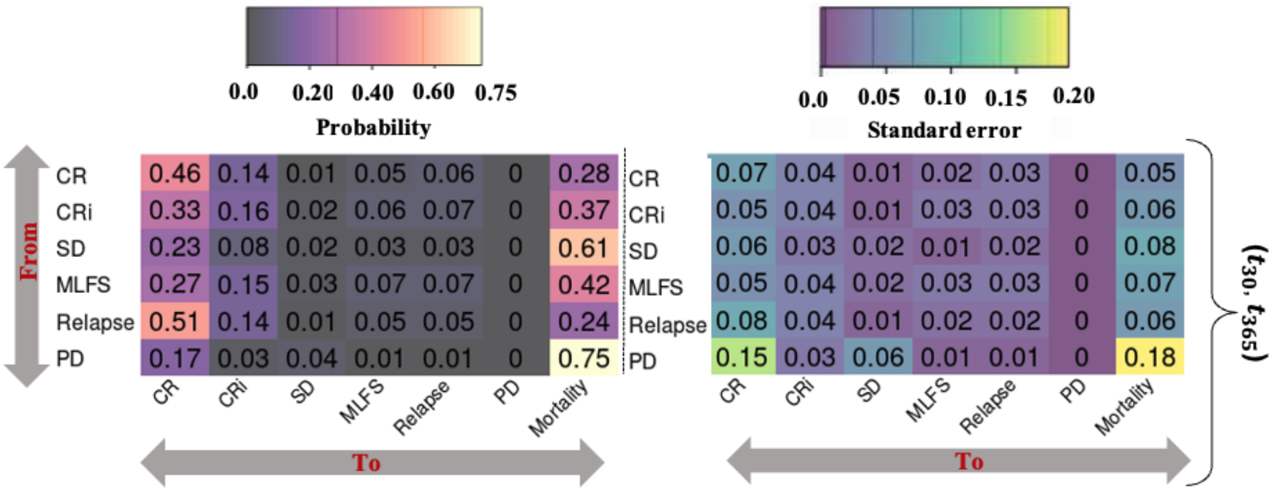
(A) 7+3



	CR	CRi	SD	MLFS	Relapse	PD	Mortality
CR	0.54	0.24	0	0.08	0.02	0	0.13
CRi	0.46	0.25	0	0.07	0.02	0	0.2
SD	0.43	0.22	0.03	0.08	0.02	0	0.21
MLFS	0.29	0.15	0	0.05	0.01	0	0.5
Relapse	0.58	0.22	0	0.08	0.02	0	0.1
PD	0.39	0.23	0	0.08	0.02	0	0.28

	CR	CRi	SD	MLFS	Relapse	PD	Mortality
CR	0.05	0.04	0	0.03	0.01	0	0.03
CRi	0.05	0.05	0	0.03	0.01	0	0.05
SD	0.06	0.04	0.04	0.03	0.01	0	0.06
MLFS	0.11	0.06	0	0.03	0.01	0	0.19
Relapse	0.05	0.04	0	0.03	0.01	0	0.03
PD	0.1	0.07	0	0.04	0.01	0	0.16

(B) ven/aza



	CR	CRi	SD	MLFS	Relapse	PD	Mortality
CR	0.46	0.14	0.01	0.05	0.06	0	0.28
CRi	0.33	0.16	0.02	0.06	0.07	0	0.37
SD	0.23	0.08	0.02	0.03	0.03	0	0.61
MLFS	0.27	0.15	0.03	0.07	0.07	0	0.42
Relapse	0.51	0.14	0.01	0.05	0.05	0	0.24
PD	0.17	0.03	0.04	0.01	0.01	0	0.75

	CR	CRi	SD	MLFS	Relapse	PD	Mortality
CR	0.07	0.04	0.01	0.02	0.03	0	0.05
CRi	0.05	0.04	0.01	0.03	0.03	0	0.06
SD	0.06	0.03	0.02	0.01	0.02	0	0.08
MLFS	0.05	0.04	0.02	0.03	0.03	0	0.07
Relapse	0.08	0.04	0.01	0.02	0.02	0	0.06
PD	0.15	0.03	0.06	0.01	0.01	0	0.18

Discussion

Principal Findings

The main findings of this study indicate that various clinical events occurring during the first month of ven/aza treatment correlate with OS, distinct from outcomes following the 7+3 treatment. Achieving CR/CRi or MLFS around day 30 (ie, Day$_{15-55}$) after ven/aza treatment has a similar long-term prognostic impact, while failure to achieve MLFS around day 30 with 7+3 indicates poorer outcomes. We also identified clinical features such as bone marrow blasts >5%, flow cytometric and genetic detection of AML, and AML-related cytogenetic factors at reassessment as having negative prognostic impacts on OS. Based on these observations, detection of persistent leukemia in the bone marrow around day 30 following ven/aza treatment suggests consideration of alternative therapies. By contrast, achieving CR/CRi/MLFS around day 30 with minimal evidence of persistent leukemia following ven/aza is associated with improved OS, indicating the benefit of continuing this treatment. However, we also found that failure to achieve CR/CRi by approximately day 180 after ven/aza initiation has negative implications for OS. This suggests that alternative therapies should be considered if the milestone of achieving CR/CRi by this time point is not met.

We also found that certain hospital events and toxicities occurring after the initiation of ven/aza treatment have prognostic implications, which differ from those seen with the 7+3 treatment. For instance, ICU admission during the initial ven/aza treatment was not associated with worse outcomes, whereas ICU transfer during the initial hospitalization for 7+3 was a poor prognostic factor. Additionally, grade ≥4 thrombocytopenia and grade ≥3 anemia were more pronounced as poor prognostic indicators for ven/aza compared with 7+3. The incidence of renal impairment was similar for both treatments; however, elevated creatinine, proteinuria, and CKD were associated with worse OS among patients treated with

7+3, but less so among those treated with ven/aza. The progression of grade ≥1 ejection fraction toxicity over time was comparable between both treatment arms. While there is a well-known association between anthracyclines in the 7+3 regimen and cardiac toxicity, such an association has not been previously described for ven/aza. These associative findings, albeit based on small sample sizes, may warrant further investigation.

Prospective Predictive Models for AML Clinical Decision Support

To translate the statistical associations between events and outcomes following the initiation of AML therapy into patient-specific prognostic models, we developed predictive ML models independently for OS with ven/aza and 7+3 treatments. These models utilized baseline and early disease responses, biomarkers, and clinical events. Several models achieved relatively high AUCs of 0.80 and 0.85 in the internal validation step. However, in the independent validation phase, AUCs were lower at 0.71 and 0.68 for the 7+3 and ven/aza cohorts, respectively. This predictive discrepancy may stem from data drift, yet we tested the models to evaluate their performance on nonhomogeneous data. Although not ideal, we contend that such drifts are typical in real-world data sets. Nevertheless, these findings illustrate the feasibility of developing ML-based individual predictors using patient data that evolve. This capability allows clinical decision-making to adapt to individual changes in treatment side effects and responses. This effort contributes to an expanding body of research utilizing ML to predict outcomes in the treatment of AML and other hematologic malignancies [55-58]. For instance, Park et al [55] evaluated the prognostic performance of ELN genetic risk stratification models using unsupervised ML techniques and found suboptimal predictions for OS in older patients with AML, indicating a need for new risk models in this demographic. Karami et al [56] identified novel prognostic factors for survival in patients with AML, incorporating demographic and AML-specific features through ML approaches. Shaikh et al [57] developed a novel risk stratification model for patients with AML and RUNX1-RUNX1T1 using supervised machine learning models. This model assesses risk based on somatic mutations in *Flt3*, *NRAS*, and other genes. Lastly, Eckardt et al [58] conducted a review of various ML approaches for AML diagnosis, prognosis, and risk stratification, emphasizing their evolving and potentially impactful role in this specific disease area. To our knowledge, no prior predictive ML-based survival models with uncertainty quantification have been developed in the AML literature by exploiting both patient- and event-specific long-term dynamic features at this level of detail.

Limitations

Our study is limited by relatively small data sets, and our results require validation on larger data sets from diverse centers ensuring heterogeneity. Although we adjusted for high collinearity among variables, missingness, and overfitting, these issues need further careful consideration in larger external data sets. Additionally, our single-center data set consists of half real-world and half clinical trial data, which may potentially bias the results compared with more diverse population-based data sets. Lastly, any comparison between the 2 primary treatments, ven/aza and 7+3, is influenced by differences in patient demographics, comorbidities, and other inherent features. Ven/aza is currently approved only for older and unfit patients, whereas 7+3 is primarily used in younger and fitter patients. Additionally, 24 out of 101 ven/aza patients (23.8%) underwent at least one alloSCT after the initiation of treatment, whereas 79 out of 120 7+3 patients (65.8%) underwent at least one alloSCT. Survival curves in AML are affected by alloSCT, which can significantly impact OS and necessitate adjustments and modifications in ML modeling, a direction we plan to explore in future studies. Because of these complexities, the extent and direction of association with OS for confounding factors vary across the treatments we evaluated. However, our primary objective was not to establish causal treatment effectiveness by treating ven/aza as the treatment group and 7+3 as the control for which a classical propensity score–based or weighted method is recommended to ensure balances in data distributions between the 2 treatment arms. Instead, our primary objective was to separately explore the variations in data to assess whether treatment modifies the effects (ie, directions) of confounders on OS. Therefore, we treated 7+3 and ven/aza as effect modifiers and conducted “stratified” multivariable analyses, creating subgroups of patients treated with 7+3 and ven/aza [59]. This stratification approach minimizes the variation attributed to treatment differences significantly, and by accounting for the same set of potential confounders in both models, it enhances the comparability of results.

Conclusions

Despite these considerations, our results have highlighted significant clinical implications of posttreatment outcomes, clinical events, and toxicities on long-term outcomes and treatment decisions in AML, demonstrating differences between ven/aza and 7+3. Additionally, these observations suggest strong potential to develop ML-based predictive models which could ultimately offer crucial ongoing clinical decision support for patients and providers as toxicities, responses, and other events evolve dynamically throughout treatment cycles.

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Data Availability

The raw, individual patient data are protected and not available due to data privacy laws. The processed data are available at reasonable request to the corresponding author.

Authors' Contributions

CS and NI designed the study and drafted the manuscript. JSR, JD, JWC, KS, and FRM processed and pulled the structured analytical data sets. JSR, JD, CS, and NI assessed the validity and quality of data. NI performed numerical analyses. CS, NI, CTJ, and JSR interpreted the results of the analyses. All authors reviewed, provided constructive comments, and agreed to its publication.

Conflicts of Interest

CS is an employee of and holds equity in OncoVerity, and is a consultant to RefinedScience. All other authors declare no conflicts of interest.

Multimedia Appendix 1
Additional pertinent results.
[DOCX File , 7134 KB - cancer_v10i1e54740_app1.docx]

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Abbreviations

AFT: accelerated failure time
aHR: adjusted hazard ratio
alloSCT: allogeneic stem cell transplantation
AML: acute myeloid leukemia
AUC: area under the curve
BMB: bone marrow biopsy
C: concordance
cAUC: cumulative case dynamic control of receiver operative characteristics
CDS: clinical decision support
CIF: cumulative incidence function
CKD: chronic kidney disease
CR: complete remission
CRi: complete remission with incomplete hematologic recovery
CTCAE: Common Terminology Criteria for Adverse Events
CV: cross-validation
DL: deep learning
ELN: European Leukemia Net
eNet: elastic-net
iAUC: incident case dynamic control of receiver operative characteristics
ICU: intensive care unit
LOOCV: leave-one-out-cross-validation
M: median
MCP: minimax concave penalty
ML: machine learning
MLFS: morphologic leukemia-free state
MRD: minimal residual disease
NCCN: National Comprehensive Cancer Network
OS: overall survival
PD: progressive disease
PH: proportional hazard
RBC: red blood cell
ROC: receiver operative characteristic
RSF: random survival forest
RUNX: runt-related transcription factor
SCAD: smoothly clipped absolute deviation
ven/aza: venetoclax plus azacitidine
WBC: white blood cell

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Original Paper

A Machine Learning Approach for Predicting Biochemical Outcome After PSMA-PET–Guided Salvage Radiotherapy in Recurrent Prostate Cancer After Radical Prostatectomy: Retrospective Study

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Abstract

Background: Salvage radiation therapy (sRT) is often the sole curative option in patients with biochemical recurrence after radical prostatectomy. After sRT, we developed and validated a nomogram to predict freedom from biochemical failure.

Objective: This study aims to evaluate prostate-specific membrane antigen–positron emission tomography (PSMA-PET)–based sRT efficacy for postprostatectomy prostate-specific antigen (PSA) persistence or recurrence. Objectives include developing a random survival forest (RSF) model for predicting biochemical failure, comparing it with a Cox model, and assessing predictive accuracy over time. Multinational cohort data will validate the model's performance, aiming to improve clinical management of recurrent prostate cancer.

Methods: This multicenter retrospective study collected data from 13 medical facilities across 5 countries: Germany, Cyprus, Australia, Italy, and Switzerland. A total of 1029 patients who underwent sRT following PSMA-PET–based assessment for PSA persistence or recurrence were included. Patients were treated between July 2013 and June 2020, with clinical decisions guided by PSMA-PET results and contemporary standards. The primary end point was freedom from biochemical failure, defined as 2 consecutive PSA rises >0.2 ng/mL after treatment. Data were divided into training (708 patients), testing (271 patients), and external validation (50 patients) sets for machine learning algorithm development and validation. RSF models were used, with 1000 trees per model, optimizing predictive performance using the Harrell concordance index and Brier score. Statistical analysis used R Statistical Software (R Foundation for Statistical Computing), and ethical approval was obtained from participating institutions.

Results: Baseline characteristics of 1029 patients undergoing sRT PSMA-PET–based assessment were analyzed. The median age at sRT was 70 (IQR 64-74) years. PSMA-PET scans revealed local recurrences in 43.9% (430/979) and nodal recurrences in 27.2% (266/979) of patients. Treatment included dose-escalated sRT to pelvic lymphatics in 35.6% (349/979) of cases. The external outlier validation set showed distinct features, including higher rates of positive lymph nodes (47/50, 94% vs 266/979, 27.2% in the learning cohort) and lower delivered sRT doses (<66 Gy in 57/979, 5.8% vs 46/50, 92% of patients; *P*<.001). The RSF model, validated internally and externally, demonstrated robust predictive performance (Harrell C-index range: 0.54-0.91) across training and validation datasets, outperforming a previously published nomogram.

Conclusions: The developed RSF model demonstrates enhanced predictive accuracy, potentially improving patient outcomes and assisting clinicians in making treatment decisions.

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KEYWORDS

cancer; oncologist; oncologist; metastases; prostate; prostate cancer; prostatectomy; salvage radiotherapy; PSMA-PET; prostate-specific membrane antigen–positron emission tomography; prostate-specific membrane antigen; PET; positron emission tomography; radiotherapy; radiology; radiography; machine learning; ML; artificial intelligence; AI; algorithm; algorithms; predictive model; predictive models; predictive analytics; predictive system; practical model; practical models; deep learning

Introduction

Prostate-specific antigen (PSA) is a protein produced by the prostate gland, and its levels in the blood are commonly used as a marker in the assessment of prostate health. PSA levels are measured using an immunoassay, and elevated levels can be indicative of prostate conditions including benign prostatic hyperplasia or prostate cancer. Biochemical recurrence (BR) refers to the increase in PSA levels after treatment; this occurs in approximately 15% to 25% of patients following radical prostatectomy (RP) for prostate cancer [1]. While BR does not invariably lead to metastatic progression and death, the risk significantly increases [2]. Salvage radiation therapy (sRT) offers these patients with localized disease a second chance at a cure [2-4]. Historically, prognostic nomograms by Stephenson et al [5] and Tendulkar et al [6] provided valuable insights into predicting outcomes after sRT. The Stephenson nomogram was developed on a cohort of patients with a median PSA value of 1.1 (IQR 0.6-2.2) ng/mL. In contrast, the Tendulkar nomogram included patients managed with ultrasensitive PSA assays, with a median pre-sRT PSA of 0.5 (IQR 0.3-1.1) ng/mL.

However, recent advances in imaging have rendered traditional recurrence prediction models obsolete. Prostate-specific membrane antigen–positron emission tomography (PSMA-PET) is a diagnostic tool that uses PSMA ligands to identify prostate cancer. PSMA, a surface protein highly expressed in prostate cancer cells, enables PSMA-PET to achieve exceptional sensitivity and specificity in detecting cancer recurrence [7,8]. This high precision allows for more tailored and effective radiotherapy planning. Both retrospective and prospective studies have demonstrated that integrating PSMA-PET data before sRT modifies the treatment strategy in approximately 30% to 50% of cases. [9,10]. This effect is evident even in patients undergoing early sRT with PSA levels below 0.5 ng/mL, as this group's detection rate is approximately 50% [10,11].

Machine learning (ML) algorithms are increasingly used to create prediction tools because they can swiftly process vast datasets. They have been demonstrated to outperform clinical experts in estimating patient survival in a cohort of patients with lung cancer [12]. Comparisons of outcome prediction models in other entities provided evidence that the reliability of ML-based tools may be superior to those generated by traditional nomograms [13,14]. Given these advancements, new risk models are needed to predict sRT outcomes in the PSMA-PET era.

In previous work from our group, we developed a nomogram to predict outcomes in patients with prostate cancer undergoing sRT after RP [15]. In this study, we present a ML-based random survival forest (RSF) model for risk prediction, using a substantial international dataset of patients who underwent PSMA-PET staging before sRT. We compared the prediction accuracy with our previously published nomogram. This study represents the first prediction tool for PSMA-PET–staged patients using a ML-based method derived from a large international patient cohort.

Methods

Source of Data

Data for this study were contributed by 13 medical facilities across 5 different countries: Germany (n=6), Cyprus (n=1), Australia (n=3), Italy (n=1), and Switzerland (n=2). Each facility contributed between 20 and 175 patients to the cohort (for more details, see Multimedia Appendix 1). The participation of these institutions in this multicenter study was approved by the respective ethics committees. Reporting adhered to the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) reporting guidelines (Multimedia Appendix 1). All ethics committees of the included institutions approved this study.

Participants

Patients who underwent open or laparoscopic RP and received PSMA-PET–based sRT for PSA persistence or recurrence (PSA levels ≥0.1 ng/ml postprostatectomy) were included in this study. Written informed consent was not required due to the retrospective nature of the investigation and by review board guidelines. Exclusion criteria involved distant metastases on PSMA-PET or computed tomography scan and initiation of androgen deprivation therapy (ADT) before PSMA-PET or computed tomography scan. A total of 1221 patients met the inclusion criteria and underwent sRT between July 1, 2013, and June 30, 2020. Out of these, 192 individuals were excluded: 141 individuals had insufficient clinical data, 47 individuals had no prostatic fossa in the sRT field, and 4 individuals had PSMA-PET–positive lesions outside the sRT field.

Consequently, 1029 patients with complete data participated in developing and validating the ML algorithm. A total of 50 patients' data were used for external validation, 708 patients' data were used for training, and 271 patients' data were used for testing.

No formal sample size was elaborated. All patients with inclusion criteria were supposed to be eligible for the analysis, and the number of participants was deemed relevant to developing ML algorithms.

Treatment and Follow-Up

Treating clinicians made clinical choices based on PSMA-PET results and current standards of care. The institutional clinical practice involved intensity-modulated, image-guided sRT to the prostatic fossa, occasionally with a concurrent integrated boost to local recurrence. Additional treatments, such as elective pelvic lymphatic radiation and ADT, were administered based on patient risk characteristics. Follow-up evaluations adhered to institutional clinical practices including periodic serum PSA testing and restaging for BR. BR was defined as 2 consecutive rising PSA values >0.2 ng/mL after treatment.

Predictors

Predictors were strictly the same as in the previous work from our group [15]. They included the International Society of Urological Pathology grade of the surgical specimen, pathological T stage (pT stage), resection status, PSA serum values before sRT, ADT use, dose in the prostate, persistence of PSA levels after surgery, and presence of pelvic lymph nodes or local recurrence before sRT. Based on clinical expertise, some variables with limited predictive value in previous studies were excluded from the analysis [6,16].

Statistical Analysis—Model Development and Validation

We used the RSF classifier for survival analysis, an extension of the random forests ML algorithms in a context of right-censored survival data, based on prior research demonstrating its efficacy in predicting freedom from biochemical failure (FFBF), defined as 2 consecutive PSA rises >0.2 ng/mL after treatment, after sRT [17]. We first separated the dataset into 2 parts: an external outlier validation dataset and a learning dataset.

The outlier validation dataset consisted of 50 patients from the most dissimilar center, which was selected based on a principal component analysis that excluded the center variable (see our previous published work [15]). This ensured that the validation dataset represented a more diverse range of patients than the learning dataset.

The remaining patients (979 patients in total) were used to develop 900 models. Indeed, we selected 30 seeds at random between 1 and 10,000 with uniform distribution. The seeds ensure different random splits of the data, while the uniform distribution avoids bias by giving each seed an equal chance of being chosen. For each seed, to provide an accurate assessment of RSF internal validity, we divided 30 times the learning dataset into training and internal validation datasets (ratio 75:25) with stratified random sampling for stratification factors (see eTable 4 in Supplement 1 in Zamboglou et al [15]), allowing the use of common attributes in the data to form strata before sampling, resulting in a more representative and general sample.

Each model resulted from an RSF that was grown using 1000 trees. Simultaneous optimizations of the number of trees in the forest and the number of predictors available to be selected from at each split were obtained by a grid search (100, 500, and 1000 for the number of trees; 1 to 8 for the number of predictors) with 10-fold cross-validation on the training dataset. The splitting rule was based on the logrank test. A random selection of split points is considered for each predictor.

Several metrics served to evaluate the predictive performances of each model. First, we used the Harrell concordance index (C-index) [18]. The higher the C-index, the better the discriminatory power of the model. The Harrell C-index was further classified according to the Altman Strength of Agreement [19]. Separate boxplots graphically represented the distribution of the predictive performances, in each dataset. We defined the model having the highest Harrell C-index on the internal validation dataset as our best RSF model. The corresponding seed for randomness is given.

Second, we added the Brier score, which served as a measure of both discrimination and calibration [20]. The lower the Brier score, the higher the predictive quality of the model. Minimal and maximal values (ie, range values) of the Harrell C-index and Brier score in the training, internal validation, and external outlier datasets were given separately.

The importance and relative importance values of the predictors were calculated. The relative importance provides a normalized measure, allowing for a comparison between predictors. The higher the value, the greater the importance of variables in the outcome prediction.

The Harrell C-index and Brier score of our best RSF model were measured at each time point between 12 and 85 months, with an interval of 1 month, in the training, internal validation, and external outlier validation datasets. To compare the prediction accuracy with our Cox proportional hazard model, previously published as a nomogram, we applied the latter at each time point, too. Results were displayed graphically, presenting the Harrell C-index and Brier score from our best RSF model and previous Cox proportional hazard model as a function of time. Minimal and maximal values (ie, range values) of the Harrell C-index and Brier score in the training, internal validation, and external outlier datasets were given separately.

All statistical analysis was conducted using R Statistical Software (version 4.2.1; R Foundation for Statistical Computing). Descriptive statistics are given by either range, median (IQR), or number (percentage in %), according to variable nature. Stratified random sampling was performed using the *Splitstackshape* package (version 1.4.8). The Fisher exact or chi-square test was used to compare clinical and treatment characteristics between different subdatasets. We used the *randomForestSRC* package (version 3.2.1) for RFS model training and *SurvMetrics* (version 0.5.0) for the Harrell C-index and Brier score. The importance and relative importance values of the predictors in the RSF were calculated using the *VIMP* function [21]. A 2-sided *P* value of <.05 was considered as the significance level.

Ethics Considerations

This study adhered to ethical standards across all recruiting centers, with ethical approval obtained from each institution involved. Given the retrospective nature of the study, informed consent was waived, as is permitted for studies involving secondary analysis of existing data. The primary data collection was conducted under the appropriate ethical guidelines, with the original informed consent covering the use of data for secondary analysis without requiring additional consent. To ensure privacy and confidentiality, all study data were deidentified, maintaining the anonymity of participants. No compensation was provided to participants in this study, reflecting the nature of the research and ensuring transparency in the process. The file number for ethical approval from Bern University Hospital is BE 2021-02294.

Results

Baseline Patient and Treatment Characteristics

In this study, we adopted the same formulation as previously published [15]. We analyzed the baseline patients and treatment characteristics of the entire cohort, which consisted of 1029 patients with a median age at sRT of 70 (IQR 64-74) years. For that publication, the cohort was already divided into a training set (n=708), an internal validation set (n=271), and an external outlier validation dataset (n=50), and these groups are summarized in Table 1.

Within the learning cohort (comprising the training and internal validation sets; n=979), most patients (n=610, 62.3%) had PSA serum values of 0.5 ng/mL or less before sRT. Locally recurrent disease detected by PET scan was present in 43.9% (n=430) of patients, while 27.2% (n=266) of patients had at least 1 positive pelvic lymph node on PET scan. Among the patients, 32.2% (n=315) of patients received ADT without any escalation of systemic therapy beyond ADT. The most commonly administered equivalent dose of 2 Gy per fraction (EQD2, α/β=1.6 Gy) to the prostatic fossa or locally recurrent disease was 66 to 70 Gy (n=547, 55.9% of patients).

PSMA-PET scans conducted before sRT revealed local recurrences in 43.9% (n=430) of patients and nodal recurrences in 27.2% (n=266) of patients. sRT to elective pelvic lymphatics was administered to 35.6% (n=349) of patients. All pelvic lymph node PETs received dose-escalated sRT; the most frequent dose (149/317, 56%) was 50 to 60 Gy (EQD2, α/β=1.6 Gy).

No significant difference in clinical and treatment characteristics was observed between the patients in the training and the internal validation cohorts (all *P*>.05; Table 2). However, the external outlier cohort exhibited distinct features, with no patients having negative PSMA-PET scans, significantly higher rates of complete resection (44/50, 88% vs 629/979, 64.2% of patients; *P*=.001), and a significantly greater proportion of patients with positive pelvic lymph nodes (47/50, 94% vs 266/979, 27.2% of patients; *P*<.001) as compared to the learning cohort (Table 3). Furthermore, the delivered dose to the prostatic fossa was significantly lower for the patients in the external outlier cohort than in the learning cohort (57/979, 5.8% vs 46/50, 92% of patients with a dose less than 66 Gy; *P*<.001).

Table 1. Baseline treatment characteristics among training set, internal validation set, and external outlier validation set.

Characteristic	Total cohort (n=1029)	Training dataset (n=708)	Internal validation dataset (n=271)	External outlier validation dataset (n=50)
Age at sRT[a] (years), median (IQR)	70 (64-74)	70 (64-74)	69 (63-74)	72.5 (68-76)
pT stage[b], n (%)				
2	460 (44.7)	310 (43.8)	122 (45)	28 (56)
3a	327 (31.8)	230 (32.5)	86 (31.7)	11 (22)
3b	235 (22.8)	163 (23)	61 (22.5)	11 (22)
4	7 (0.7)	5 (0.7)	2 (0.7)	0 (0)
R status[c] in surgery, n (%)				
RO	673 (65.4)	448 (63.3)	181 (66.8)	44 (88)
R1	327 (31.8)	244 (34.5)	77 (28.4)	6 (12)
R2	3 (0.3)	1 (0.1)	2 (0.7)	0 (0)
Rx	26 (2.5)	15 (2.1)	11 (4.1)	0 (0)
ISUP[d] grade in surgery, n (%)				
1+2	371 (36.1)	254 (35.9)	101 (37.3)	16 (32)
3	324 (31.5)	226 (31.9)	84 (31)	14 (28)
4	156 (15.2)	102 (14.4)	44 (16.2)	10 (20)
5	178 (17.3)	126 (17.8)	42 (15.5)	10 (20)
PSA[e] persistence after surgery, n (%)				
No	750 (72.9)	511 (72.2)	197 (72.7)	42 (84)
Yes	279 (27.1)	197 (27.8)	74 (27.3)	8 (16)
PSA (ng/mL) before sRT, n (%)				
0.01-0.2	246 (23.9)	178 (25.1)	63 (23.3)	5 (10)
>0.2-0.5	385 (37.4)	258 (36.4)	111 (41)	16 (32)
>0.5-1	172 (16.7)	122 (17.2)	41 (15.1)	9 (18)
>1	226 (22)	150 (21.2)	56 (20.7)	20 (40)
Local recurrence after PSMA-PET[f], n (%)				
No	592 (57.5)	396 (55.9)	153 (56.5)	43 (86)
Yes	437 (42.5)	312 (44.1)	118 (43.5)	7 (14)
Pelvic lymph nodes after PSMA-PET, n (%)				
No	716 (69.6)	507 (71.6)	206 (76)	3 (6)
Yes	313 (30.4)	201 (28.4)	65 (24)	47 (94)
Dose to the prostatic fossa (Gy[g]), n (%)				
<66	103 (10)	47 (6.6)	10 (3.7)	46 (92)
66-70	551 (53.6)	390 (55.1)	157 (57.9)	4 (8)
>70	375 (36.4)	271 (38.3)	104 (38.4)	0 (0)
sRT to elective pelvic lymphatics, n (%)				
No	633 (61.6)	455 (64.4)	174 (64.2)	4 (8)
Yes	395 (38.4)	252 (35.6)	97 (35.8)	46 (92)
Dose to elective pelvic lymphatics (Gy), n (%)				
<50	312 (30.3)	197 (27.8)	71 (26.2)	44 (100)
>50	47 (4.6)	34 (4.80)	13 (4.79)	0 (0)

Characteristic	Total cohort (n=1029)	Training dataset (n=708)	Internal validation dataset (n=271)	External outlier validation dataset (n=50)
Unknown	36 (3.5)	21 (3)	13 (4.8)	2 (4)
Irradiation to positive pelvic LN[h], n (%)				
No	712 (69.2)	505 (71.3)	204 (75.3)	3 (6)
Yes	317 (30.8)	203 (28.7)	67 (24.7)	47 (94)
Dose to positive pelvic LNs (Gy), n (%)				
<50	15 (1.5)	11 (1.6)	4 (1.5)	0 (0)
50-60	149 (13.5)	113 (16)	36 (13.3)	0 (0)
>60	128 (12.4)	63 (8.9)	20 (7.4)	45 (90)
Unknown	25 (2.4)	16 (2.3)	7 (2.6)	2 (4)
ADT[i], n (%)				
No	704 (68.4)	475 (67.1)	189 (69.7)	40 (80)
Yes	325 (31.6)	233 (32.9)	82 (30.3)	10 (20)
Duration of ADT admission (months), n (%)				
<6	65 (23.1)	50 (24.4)	15 (22.7)	0 (0)
6-12	110 (39.2)	79 (38.5)	24 (36.4)	7 (70)
>12-24	57 (20.3)	39 (19.0)	18 (27.3)	0 (0)
>24	49 (17.4)	37 (18.1)	9 (13.6)	3 (30)
Unknown	44 (4.3)	28 (4.0)	16 (5.9)	0 (0)

[a] sRT: salvage radiation therapy.

[b] pT stage: pathological T stage.

[c] R status: residual disease status.

[d] ISUP: International Society of Urological Pathology.

[e] PSA: prostate-specific antigen.

[f] PSMA-PET: prostate-specific membrane antigen–positron emission tomography.

[g] Gy: gray (a unit of radiation dose).

[h] LN: lymph node.

[i] ADT: androgen deprivation therapy.

Table 2. Comparison between training cohort and internal outlier validation datasets (*P* value based on Fisher exact or chi-square test).

Covariate, n (%)	Training dataset (n=708), n (%)	Internal validation dataset (n=271), n (%)	*P* value
pT stage[a]			.94
pT2	310 (43.8)	122 (45)	
pT3a	230 (32.5)	86 (31.7)	
pT3b+pT4	168 (23.7)	63 (23.3)	
R status[b]			.31
R0	448 (63.3)	181 (66.8)	
R1/2+Rx	260 (36.7)	90 (33.2)	
ISUP[c] **grade**			.69
1+2	254 (35.9)	101 (37.3)	
3+4	328 (46.3)	128 (47.2)	
5	126 (17.8)	42 (15.5)	
Pelvic lymph nodes on PET[d]			.17
No	507 (71.6)	206 (76)	
Yes	201 (28.4)	65 (24)	
PSA[e] **prior to sRT**[f]			.45
<0.5 ng/mL	436 (61.6)	174 (64.2)	
>0.5 ng/mL	272 (38.4)	97 (35.8)	
sRT dose to the prostatic fossa[f]			.20
<66 Gy[g]	47 (6.6)	10 (3.69%)	
66-70 Gy vs <66 Gy	390 (55.1)	157 (57.9)	
>70 Gy	271 (38.3)	104 (38.4)	
ADT[i]			.43
No	475 (67.1)	189 (69.7)	
Yes	233 (32.9)	82 (30.3)	

[a] pT stage: pathological T stage.

[b] R status: residual disease status.

[c] ISUP: International Society of Urological Pathology.

[d] PET: positron emission tomography.

[e] PSA: prostate-specific antigen.

[f] sRT: salvage radiation therapy.

[g] Gy: gray (a unit of radiation dose).

[i] ADT: androgen deprivation therapy.

Table 3. Comparison between learning cohort (training+internal validation cohort) and external outlier cohort (*P* value based on Fisher exact or chi-square test).

Covariate, n (%)	Learning (n=979), n (%)	External (n=50), n (%)	*P* value
pT stage[a]			.21
pT2	432 (44.1)	28 (56)	
pT3a	316 (32.3)	11 (22)	
pT3b+pT4	231 (23.6)	11 (22)	
R status[b]			.001
R0	629 (64.2)	44 (88)	
R1/2+Rx	350 (35.8)	6 (12)	
ISUP[c] **grade**			.79
1+2	355 (36.3)	16 (32)	
3+4	456 (46.6)	24 (48)	
5	168 (17.2)	10 (20)	
Pelvic lymph nodes on PET[d]			<.001
No	713 (72.9)	3 (6)	
Yes	266 (27.2)	47 (94)	
PSA[e] **before sRT**[f]			.004
<0.5 ng/ml	610 (62.3)	21 (42)	
>0.5 ng/ml	369 (37.7)	29 (58)	
sRT dose to the prostatic fossa			<.001
<66 Gy[g]	57 (5.8)	46 (92)	
66-70 Gy vs <66 Gy	547 (55.9)	4 (8)	
>70 Gy	375 (38.3)	0 (0)	
ADT[g]			.07
No	664 (67.8)	40 (80)	
Yes	315 (32.2)	10 (20)	

[a] pT stage: pathological T stage.

[b] R status: residual disease status.

[c] ISUP: International Society of Urological Pathology.

[d] PET: positron emission tomography.

[e] PSA: prostate-specific antigen.

[f] sRT: salvage radiation therapy.

[g] Gy: gray (a unit of radiation dose).

[h] ADT: androgen deprivation therapy.

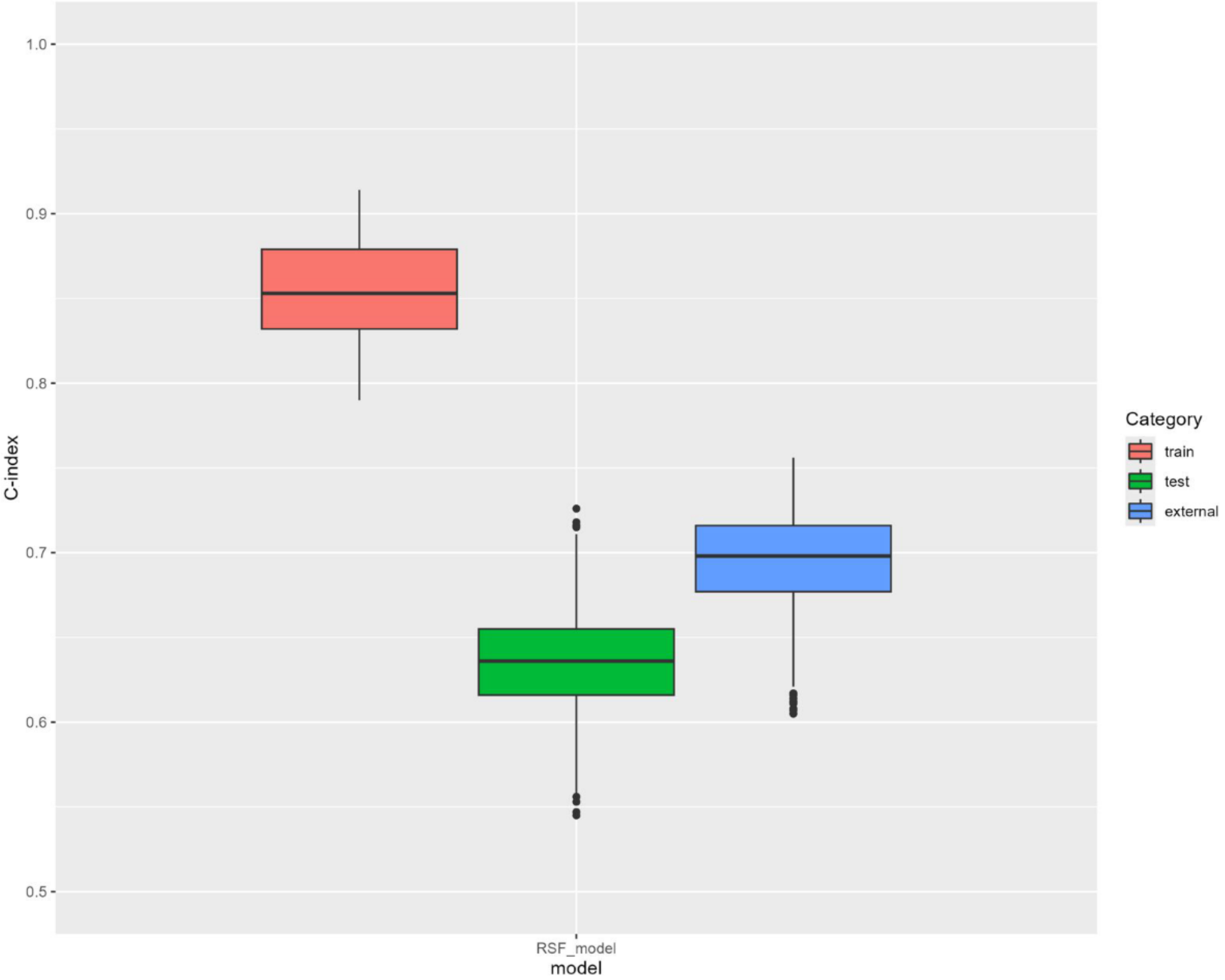
Among the patients with positive lymph nodes detected on PET scans (n=349), 52.4% (n=183) of patients received ADT, whereas 47.6% (n=166) of patients did not. No significant difference was observed in the distribution of the International Society of Urological Pathology (ISUP) grade and pT stage (all *P*>.05; Table 3).

Model Development and Validation

All training subsets comprised 708 patients while corresponding internal validation sets contained the 271 remaining patients.

Figure 1 summarizes the performance obtained from the 900 developed RSF models after training and further application to the internal and external outlier validation datasets. The Harrell C-index values of the training datasets showed good concordances ranging from 0.79 to 0.91. The internal validation dataset showed moderate to good concordances ranging from 0.54 to 0.73, while the external outlier validation dataset, showed good concordances ranging from 0.60 to 0.76.

Figure 1. Harrell C-indexes of the 900 RSF models in the training, internal validation, and external validation datasets. C-index: concordance index. RSF: random survival forest.



Our best model (the highest Harrell C-index on the internal validation dataset) was the one at the 15th iteration with the seed being 7332. Its Harrell C-index values were 0.79, 0.72, and 0.69 in the training, internal validation, and external outlier validation datasets, respectively. The corresponding training and internal validation recorded 200 (28.2%) out of 708 and 77 (28.4%) out of 271 patients with cancer relapse, respectively.

Correspondingly, Brier score results ranged from 0.12 to 0.15, from 0.10 to 0.20, and from 0.12 to 0.16 in the training, internal validation, and external outlier validation datasets, respectively. Brier scores related to our best model equaled 0.13, 0.14, and 0.14, respectively.

Table 4 presents the importance and relative importance values of the predictors in our best RSF model. The predictors with the highest importance values were PSA before sRT and pelvic nodal recurrence. Conversely, the predictor with the lowest importance value was PSA persistence.

In training, internal validation, and external outlier validation datasets, our best RSF model exhibited higher Harrell C-indexes (0.79, 0.72, and 0.69) than our nomogram previously published (0.68, 0.72, and 0.67, respectively). Our best RSF model showed higher Brier scores but more stable results across the datasets than the model for our nomogram (best RSF=0.13, 0,14, 0,14 vs Cox=0.12, 0,13, 0,15 for training, internal validation, and external outlier validation datasets, respectively).

The Harrell C-indexes of our best RSF model compared to our nomogram previously published, when measured at time points of 12-85 months with an interval of 1 month in training, internal, and external outlier validation datasets, are shown in Figure 2A, while Figure 2B shows the Brier scores of our best RSF model and our nomogram previously published when measured at time points of 12-85 months with an interval of 1 month, according to the subdatasets.

Table 4. Predictor importance and relative importance in the RSF[a] model.

Predictor	Importance	Relative importance
PSA[b] prior sRT[c] (ng/mL)	0.071	1
Pelvic nodal recurrence on PET[d]	0.065	0.920
pT status[e]	0.055	0.777
ISUP[f] grade	0.050	0.705
Dose to prostatic fossa (Gy[g])	0.029	0.415
ADT[h]	0.021	0.299
R status[i]	0.014	0.190
Pelvic local recurrence on PET	0.012	0.175
PSA persistence	–0.008	–0.116

[a] RSF: random survival forest.

[b] PSA: prostate-specific antigen.

[c] sRT: salvage radiation therapy.

[d] PET: positron emission tomography.

[e] pT status: pathological T status.

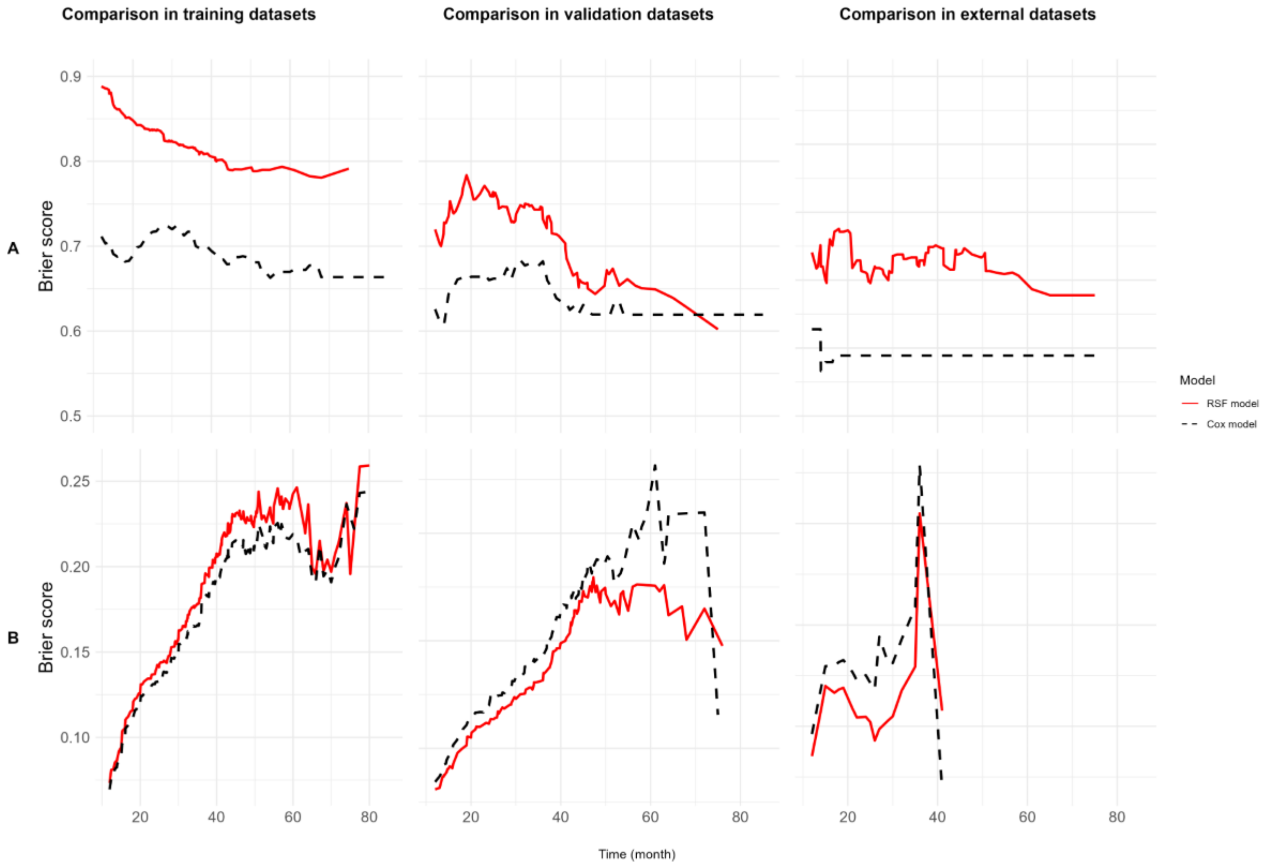
[f] ISUP: International Society of Urological Pathology.

[g] Gy: gray (a unit of radiation dose).

[h] ADT: androgen deprivation therapy.

[i] R status: residual disease status.

Figure 2. (A) Harrell C-indexes and (B) Brier scores of our best RSF model versus our Cox proportional hazard model previously published, in the training, internal validation, and external validation datasets over time (12-85 months interval, with a 1-month increment). RSF: random survival forest.



Discussion

Principal Findings

This study is the first study reporting an RSF model on prostate cancer patients across 5 countries undergoing PSMA-PET–based sRT. It presents a robust predictive performance (Harrel C-index 0.54-0.91) and outperforms the previously published nomogram.

Comparison to Prior Work

The medical community is constantly striving to develop and refine predictive tools that can accurately identify the most effective care management options for patients. By doing so, health care providers can offer personalized care that maximizes patient outcomes while minimizing adverse reactions and being cost-effective. Nomograms were and are constantly used, and the great potential of an ML approach for dynamic prediction in medicine is now emerging [22]. In this context, using a large international dataset of patients who underwent PSMA-PET staging before sRT, this study aimed at developing a ML-based RSF model to predict FFBF and comparing the prediction performances with our previously published nomogram based on a Cox proportional hazards model [15].

Our best RSF model performed well after training (Harrell C-index=0.79). Furthermore, it showed good robustness and generalizability, maintaining good performances on the internal validation set (C-index=0.72) and the external outlier validation dataset (C-index=0.69). In all cases, our best RSF model outperformed the previously built nomogram on the same datasets (0.67, 0.71, and 0.66). Our previously published nomogram included 7 variables found to be statistically significant in our multivariable Cox proportional hazards regression analysis (pre-sRT PSA level, ISUP grade in surgery specimen, pT stage, surgical margins, ADT use, sRT dose to the fossa, and nodal recurrence detected on PSMA-PET scans) [15]. In addition to these 7 variables, our best RSF evaluated PSA persistence, based on the known literature of poor prognosis when this characteristic is present, and pelvic local recurrence on PSMA-PET scan, based on a recent paper showing that the presence of local recurrence was associated with favorable BR-free survival [23-25].

Out of the 9 variables, the one with the highest importance was the value of PSA before sRT, which was consequently associated with a relative importance of the model of 1. This result confirms what is known in the literature, and specifically, in a very recent paper studying a retrospective cohort of 25,551 patients over a period time of 30 years, it was found that performing sRT when PSA values fall above 0.25 ng/mL was associated with an increased all-cause mortality risk [24,26]. The second variable with the highest relative importance (0.92) for the model was the nodal recurrence detected on PSMA-PET scans. These data confirm the importance of performing a PSMA-PET in patients with BR, as well as the data found in the previous preliminary analysis [16,25].

On the other hand, the presence of pelvic local recurrence on the PSMA-PET scan had a relative importance of 0.175. Surprisingly, PSA persistence had a negative relative importance (–0.11). This statistical result suggests that randomly shuffling this variable helped the model perform slightly better, meaning that the variable might be adding confusion rather than helping with predictions. This needs to be further analyzed, as this would imply that PSA persistence after RP may have a negligible impact on the prediction of the outcome of sRT.

Yet, our findings align with the guidelines of the American Urological Association, American Society for Radiation Oncology, and Society of Urologic Oncology, which recommend treatment intensification for patients undergoing sRT when risk factors, such as elevated PSA levels, higher ISUP, advanced T-stage, and pelvic lymph node metastases, are present. These factors have also been significant predictors of FFBS in our analysis. Additionally, our findings may help identify patients most likely to encounter biochemical failure by weighing risk factors against each other. Thus, our RSF model may allow more differentiated decision-making in terms of potential treatment intensification such as the administration of ADT.

As expected, our best RSF model performed better on the training dataset than on the validation datasets. One could suspect some indication of overfitting to the data from the training set since there was a difference of –0.10 in prediction performances between the training and the external outlier validation datasets. However, our best RSF model still outperformed our previously published nomogram, as the former almost reached a threshold of 0.70 regarding its performance in the external validation dataset. Due to the extensive recruitment in the study, and even if unbalanced classification setting, we deemed training and internal validation datasets to have appropriate numbers of events and numbers of patients (200/708, 28.2% and 77/271, 28%, respectively) to feel confident in the performance estimates. In the external validation dataset, the 50 patients experienced 24 events and performances, which may need further confirmation, as discussed later.

Strengths

This study relied on solid methodological foundations. First, being multicenter, this study captured clinically relevant information across the differences in care management and clinical practices from 13 centers in 5 countries. Second, our recruitment period can be considered relatively short. Even in a retrospective setting, it helped reduce the impact of follow-up and care support that were not standardized from one center to another, from one country to another. Third, our training and internal validation datasets contained large numbers of patients and were highly comparable. This helped us choose the best model on similar and naïve data owing to unseen data when training the ML model (internal validation dataset). Fourth, all variables exhibited a reasonable unbalance across their categories during the training, without class counting less than 20% of patients except for the ISUP grade 5 and the sRT dose to the prostatic fossa <66 Gy, with 17.8% and only 6.6% of concerned patients, respectively. Fifth, we designed a prediction model study of type 3 according to the Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis (TRIPOD) statement, with the most dissimilar center being available as a separate dataset for validation [27]. Sixth, to compare the prediction accuracies of our best ML-based RSF with our previously published nomogram, we used the same design, including seeds, splits, and datasets, as those exploited for the nomogram. This allowed us to compare the exact and meaningful metrics (Harrell C-index and Brier score) on the internal validation dataset, and more importantly, the external outlier validation dataset. Seventh, we used the same variables to develop our previously published nomogram and our best ML-based RSF. No new variable was added for the training of our ML-based as compared to the development of our previously published nomogram.

Limitations

Nevertheless, this study is subject to many limitations previously reported with our nomogram [15]. First, this study had a large patient cohort, but its multicenter nature meant different treatment regimens. Therefore, to make the model transferable, we did not include the variable "center" in the analysis. Second, our analysis is subject to bias inherent in retrospective studies, highlighting the need for prospective trials. Continuous variables were recorded, and this may have limited our ability to make better prognostic assessments. Third, the external outlier validation cohort, the same one used for our previous nomogram, only had 50 patients, which could affect the generalizability of the RSF model [15]. So, further evaluation within another external center, or even in another country, may help obtain more patients, thus providing more accurate estimates for predictive performances and better delineating the ability to generalize. We would then present a type 4 analysis, which is the highest degree of development and validation of a prediction model according to the TRIPOD classification of prediction model studies until TRIPOD-AI is published [27,28]. In addition, no other models than RSFs were trained. This could be done in the following work. In particular, it could be interesting to develop models, such as gradient boosting, support vector, or Bayesian theories, based on other theoretical grounds than those from decision trees.

Fourth, missing data were handled by exclusion only. This led to 141 potential patients being useless for developing and validating our previously published nomogram and our best RSF presented here. Creating missing data could be explored to detect those missing at random, and a replacement strategy could then be put in place, at least for some patients, in sensitivity analyses for the training. Sabbagh et al [29] expressed the criticism that our previously published nomogram was based on a Cox proportional hazards model without accounting for competing risks. One can address the same remark to our best RSF here. However, adapting ML algorithms in the presence of competing risks is still under development and is not yet fully ready for use. One application could be misleading in its interpretation and give a false conclusion.

Future Directions

Despite these limitations, the findings of this study provide valuable insights into the possibility of integrating the RSF model when evaluating variables for predictive models, and the reliable performance of the RSF model in both validation sets enhances its applicability in real-world clinical settings. This includes the assessment of the personalized risk of FFBF, which could, in turn, lead to customized follow-up management or the assessment of risk stratification [27].

By going one step further, we are already aware that PSMA dosage and FFBF risk stratification are expected to expand in the next few months and years. This should influence patients' management, follow-up, and prognosis by changing the probability of persistence or relapse. This means that our best RSF should be updated by retraining and transfer learning in some days, even if we cannot give a precise horizon yet. We also have developed a user-friendly app to facilitate easy access to our risk prediction model for clinicians and researchers [30].

Conclusions

This study is the first prediction tool for PET-staged patients in the sRT field, highlighting the potential of an RSF model compared to a nomogram in predicting treatment outcomes. The RSF model demonstrated improved predictive accuracy compared to the model for identifying patients who may benefit from PSMA-PET-based sRT, maintaining robustness and generalizability across validation sets. Including additional variables in the RSF model, such as PSA persistence and pelvic local recurrence on PSMA-PET scans, provided valuable insights. Despite limitations, this study enhances the applicability of the RSF model in real-world clinical settings. It can improve patient outcomes and assist clinicians in making treatment decisions.

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Data Availability

The datasets generated or analyzed during this study are not publicly available due to ethical and legal issues regarding the General Data Protection Regulation but are available from the corresponding author upon reasonable request.

Authors' Contributions

AJ was responsible for the formal analysis, conducted the investigation, and wrote the original draft of the manuscript. AF contributed to the conceptualization and methodology. AGA also contributed to the conceptualization and methodology and provided resources for the research. LR provided additional resources for statistical analysis and contributed to the writing and editing. SS, SF, FS, JCP, SK, IS, KF, SAK, MEV, SEC, AV, AGM, SKBS, ALG, FC, CH, SGCK, MG, CB, PB, GH, LE, AAO,

NSS-H, LM, and DMA provided resources. CZ managed the project, provided resources, and contributed to the writing and editing of the manuscript. TW contributed resources, was involved in the writing and editing, and provided supervision. MS was responsible for conceptualization and methodology, conducted the investigation, and provided supervision throughout the research process. All authors reviewed and approved the final version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Participating centers and STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) checklist.
[DOCX File , 26 KB - cancer_v10i1e60323_app1.docx]

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Abbreviations

ADT: androgen deprivation therapy
BR: biochemical recurrence
C-index: concordance index
FFBF: freedom from biochemical failure
ISUP: International Society of Urological Pathology
ML: machine learning
PSA: prostate-specific antigen
PSMA-PET: prostate-specific membrane antigen-positron emission tomography
pT stage: pathological T stage
RP: radical prostatectomy
RSF: random survival forest
sRT: salvage radiation therapy

STROBE: Strengthening the Reporting of Observational Studies in Epidemiology
TRIPOD: Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis

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Examining Racial Disparities in Colorectal Cancer Screening and the Role of Online Medical Record Use: Findings From a Cross-Sectional Study of a National Survey

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Abstract

Background: Colorectal cancer (CRC) is the second leading cause of cancer-related deaths in the United States. Early detection via routine CRC screening can significantly lower risks for CRC-specific morbidity and mortality. Public health initiatives between 2000 and 2015 nearly doubled CRC screening rates for some US adults. However, screening rates remain lowest for adults aged 45 - 49 years (20%), patients of safety net health care facilities (42%), adults without insurance (44%), and other subgroups compared with national averages (72%). Given the evolving landscape of digital health care and trends in web-based health information–seeking behaviors, leveraging online medical record (OMR) systems may be an underutilized resource to promote CRC screening utilization. Recognizing trends in OMR usage and patient demographics may enhance digital inclusion—a key social determinant of health—and support equitable web-based interventions aimed at boosting CRC screening across diverse populations.

Objective: This study examined the association of accessing an OMR with CRC screening utilization and corresponding sociodemographic characteristics of US adults.

Methods: In 2023, we conducted a secondary data analysis using a pooled, weighted sample from Health Information National Trends Survey (HINTS) 5 cycles, 2, 3, and 4 (2018 - 2020), a nationally representative survey assessing how US adults access and use health-related information. We analyzed the association between sociodemographic characteristics, medical conditions, OMR access, and CRC screening behaviors via logistic regression.

Results: The sample included adults aged 45 - 75 years (N=5143). The mean age was 59 (SD 8) years for those who reported CRC screening and 52 (SD 6) years for those never screened. Nearly 70% (4029/5143) of participants reported CRC screening and 52% (2707/5143) reported OMR access in the past year. Adjusted odds of CRC screening were higher among non-Hispanic African American or Black adults than among non-Hispanic White adults (odds ratio [OR] 1.76, 95% CI 1.22 - 2.53), adults who accessed an OMR (OR 1.89, 95% CI 1.45 - 2.46), older individuals (OR 1.18, 95% CI 1.16 - 1.21), the insured (OR 3.69, 95% CI 2.34 - 5.82), and those with a professional or graduate degree versus those with a high school diploma or less (OR 2.65, 95% CI 1.28 - 5.47). Individuals aged 65 - 75 years were significantly more likely (P<.001) to be screened (1687/1831, 91%) than those aged 45 - 49 years (190/610, 29%).

Conclusions: Promoting OMR access, especially among the most disadvantaged Americans, may assist in reaching national screening goals. Emphasis should be placed on the mutability of OMR use compared with most other statistically significant associations with CRC screening behaviors. OMR access provides an intervenable means of promoting CRC education and screening, especially among those facing structural barriers to cancer diagnoses and care. Future research should focus on tailored and accessible interventions that expand OMR access, particularly for younger populations.

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KEYWORDS

colorectal cancer; cancer screening; early detection; Health Information National Trends Survey; cancer disparities; online medical records; secondary data analysis

Introduction

Colorectal Cancer Screening Disparities

Due to initiatives in public health aimed at encouraging colorectal cancer (CRC) screening among demographics with historically low rates, the screening rates for CRC have more than doubled from 2000 to 2015 for non-Hispanic Black, Hispanic, and non-Hispanic Asian adults aged 50-75 years in the United States [1]. According to reports, CRC screening rates are now comparable for non-Hispanic Black adults (75%) and non-Hispanic White adults (74%), but lower for Hispanic adults (64%) and non-Hispanic Asian adults (61%) in the United States [2]. Furthermore, lower than national average rates of CRC screening (72%) are still reported among adults younger than 65 years (ie, pre-Medicare eligibility) and those who report less educational attainment than a college degree, are uninsured, and have recently immigrated to the United States [3-6]. CRC screening promotion remains critical, as adherence to recommendations by the United States Preventive Services Task Force (USPSTF)—recently updated in 2021—could prevent deaths or effectively treat at least 35,000 CRC diagnoses over the lifetime of age-eligible adults [7].

CRC Screening Modalities

The USPSTF recommends various CRC screening methods for individuals at average risk and beginning at age 45 years [7]. These include stool-based tests and direct visualization techniques at respective intervals. Stool-based tests, which are done at home without the need for bowel preparation or anesthesia, include the annual guaiac-based fecal occult blood test, the annual fecal immunochemical test (FIT), and the FIT-sDNA test, administered every 1-3 years. A positive result from any of these tests requires a follow-up colonoscopy.

Direct visualization tests, such as colonoscopy every 10 years, computed tomographic colonography every 5 years, flexible sigmoidoscopy every 5 years, and flexible sigmoidoscopy (every 10 years) with an annual FIT, involve more invasive procedures such as bowel preparation and anesthesia. Any positive result from these tests, other than a colonoscopy, also necessitates a follow-up colonoscopy.

Evidence-Based Initiatives for CRC Screening Promotion

Primary reasons for underutilization of CRC screening are low patient awareness of the importance and need for screening, poor access to regular medical care and screening tests, lack of insurance, and lack of health care provider recommendation for the test [8-13]. While physician recommendation is one of the strongest predictors of screening uptake, health care providers encounter time and resource constraints that limit their ability to effectively educate patients and discuss screening recommendations during visits [9-12]. As such, there has been a proliferation of interventions to increase CRC screening. These interventions have been directed at several levels including the client (eg, patient education, tailored or nontailored print media or videos, etc), the provider (eg, provider incentives, provider assessment and feedback, etc) and health system or organization (eg, client reminders, patient navigation, etc), or any combination of levels [14]. However, there still exists disparities in utilization of repeat CRC screening, CRC screening among “newly” screen age-eligible adults between 45 and 49 years of age, and CRC screening completion among adults who have received an abnormal stool-based test result [15-17]. Online medical records (OMRs), either as an educational tool for patients or as a clinical tool that enhances patient-provider communication, may be an existing and underutilized resource for promoting CRC screening interventions and addressing remaining disparities in CRC screening utilization across the continuum.

OMRs for CRC Screening Promotion

Patient education and awareness concerning the importance of CRC screening remains a constant need, especially within US community clinics that report CRC screening rates as low as 43% [18-20]. Targeted web-based cancer education interventions may leverage growing trends in web-based health information–seeking behaviors—more than 60% of US adults report seeking web-based health information [21-24]. Leveraging existing platforms, including OMRs with embedded patient portals, could alleviate barriers to health care access and communication shortcomings to improve CRC screening completion rates [25-29]. OMRs have been used to remind patients about screening, refer patients to specialists, schedule appointments, and empower patients to take charge of their own care [30]. Furthermore, the integration of electronic health records with patient access to OMRs has been associated with improved CRC screening and other preventative health screenings [31]. Therefore, this study aims to investigate the association between OMR access and CRC screening behaviors among age-eligible adults in the United States, with particular emphasis on understanding racial and ethnic disparities. The goal is to explore whether OMR access can serve as an effective tool in promoting CRC screening. In addition, the study seeks to identify potential OMR-based interventions that could address existing disparities and improve CRC screening rates across diverse and socially vulnerable populations. Identifying growing OMR usage patterns and patient profiles could promote digital inclusion—a social determinant of health—and equitable web-based cancer education–based interventions to increase CRC screening among diverse groups [32].

Methods

Study Design and Data Source

Data for this secondary data analysis study were obtained from the Health Information National Trends Survey (HINTS) 5 cycles 2, 3, and 4, conducted between 2018 and 2020 [33]. Full details about HINTS methodology can be seen on the HINTS website [34]. HINTS is a nationally representative survey conducted by the National Cancer Institute to assess health communication, health information–seeking behaviors, and health-related attitudes and behaviors in the United States. The survey is designed to provide cross-sectional data that can inform cancer-related communication and health promotion efforts at a population level.

Study Population

This study population consisted of nonincarcerated, US adults aged 45 ‐ 75 years (N=5143) who participated in the HINTS survey during the specified cycles. This age range was chosen to focus on the national population of average-risk adults recommended to undergo screening for CRC by the USPSTF [7].

Ethical Considerations

The HINTS 5 survey, conducted with the general population, underwent expedited review and received approval from the Westat institutional review board (IRB) on March 28, 2016 (project no. 6048.14). In addition, on April 25, 2016, the National Institutes of Health Office of Human Subjects Research determined that the survey did not involve human subjects research, providing an exemption (exempt no. 13204) [35]. This analysis used deidentified, publicly available data from the HINTS, which did not constitute human subjects research as defined by 45 CFR 46.102 and, therefore, did not require IRB review. The original consent and IRB approval cover secondary analysis without the need for additional consent. No compensation was provided for participation.

Measures

Primary Outcome

The primary outcome was assessed using the following survey item: “Have you ever had a test to check for colon cancer?” Responses were dichotomized as yes or “ever screened” and no or “never screened.” Participants were categorized as “ever screened” if they reported undergoing any CRC screening test in the past.

Independent Variables

Sociodemographic characteristics included age, gender, education level, income, and insurance status. Age was treated as a continuous variable, while gender was categorized as male or female. Education level was categorized into groups such as high school or less, some college, and postgraduate degree. Income was categorized into income brackets (eg, <US $20,000, US $20,000-US $35,000, etc), and insurance status was dichotomized as insured or uninsured.

Race and ethnicity were self-reported and categorized as non-Hispanic White, non-Hispanic Black, Hispanic, non-Hispanic Asian, and other.

Medical conditions were self-reported and included diabetes, high blood pressure, heart conditions, lung disease, depression, or family history of cancer. Responses were dichotomized as yes or no.

Accessing an OMR was assessed by asking participants whether they had accessed their OMR at least once in the last 12 months. This variable was dichotomized as yes or no.

Statistical Analysis

Survey Weights

Survey weights were essential in the analysis of the HINTS dataset to account for the complex survey design and adjust for potential biases. The survey weights provided by HINTS were derived using the jackknife replication method and adjusted for selection bias resulting from the complex sampling design, nonresponse bias due to differential participation rates (ie, lower responses from men compared with women), and poststratification to align the sample with the population distribution by key sociodemographic characteristics. A method similar to the quasi-randomization approach was used for (HINTS) 5 cycles 2, 3, and 4 to adjust for household-level nonresponse. Adjustments were made for sample stratum (ie, lower response among those in high concentrations of minority populations), census region, address, metropolitical status, and high Spanish linguistically isolated areas [36-38].

Survey weights were applied to account for the complex survey design and produce generalizable population estimates. Weighted analyses were conducted, considering the appropriate weight variable provided by HINTS, to ensure that the results accurately reflected the target population of adults aged 45 ‐ 75 years in the United States.

Analysis

All statistical analyses were conducted in R Statistical Software (v4.1.2; R Core Team 2021). Descriptive statistics were reported to summarize characteristics of the study population. Frequencies and percentages were calculated for categorical variables, while means and SDs were computed for continuous variables. These descriptive statistics provided an overview of the sample and the distribution of key variables.

Bivariate analyses were conducted to examine the associations between the primary outcome (CRC screening) and various independent variables. Chi-square tests were performed to assess associations between CRC screening and variables of interest, such as race and ethnicity, accessing an OMR, sociodemographic characteristics, and medical conditions.

Multivariable logistic regression analysis was used to assess the independent associations between the primary outcome and key independent variables, while controlling for potential confounders. Missing data were handled using listwise deletion, excluding participants with missing values on any of the variables included in the models. This approach was chosen because the proportion of missing data for the primary outcome of interest was small (<5%), and no patterns of missingness were identified that would suggest systematic bias. Adjustments were made for relevant covariates, such as age, gender, education, income, and insurance status. The adjusted odds ratios and their corresponding 95% CIs were calculated to estimate the strength and direction of the associations between the independent variables and CRC screening. The multivariable logistic regression analysis allowed for the identification of significant predictors of CRC screening, considering the potential influence of confounding factors.

Results

Study Population Characteristics

Among the weighted sample (N=257,211,194), approximately 70% (4029/5143) of the participants reported having undergone CRC screening (Table 1). Most participants were non-Hispanic White (3527/5143, 72%). The mean age for individuals who reported CRC screening was 59 (SD 8) years, while it was 52 (SD 6) years for those who had never been screened (Table 2). A little more than half of the participants (2707/5143, 52%) reported accessing their OMR at least once in the past year. Table 2 presents the results of the bivariate analyses, examining the associations between CRC screening, various sociodemographic characteristics, medical condition variables, and main predictors (race and OMR access).

Table . Characteristics of main outcomes.

Characteristic (N=257,211,194)[a]		n (%)
Colorectal cancer screening		
	Ever screened	4029 (70)
	Never screened	1114 (30)
	Total	5143
Race		
	NH[b] White	3527 (72)
	Hispanic	582 (12)
	NH Black or African American	674 (9.3)
	NH Asian	191 (4.3)
	NH other[c]	169 (2.7)
	Total	5143
Access online medical record		
	None	2436 (48)
	At least 1 time	2707 (52)
	Total	5143

[a] Weighted counts based on pooled sample of 5143 adult participants, derived using weights.

[b] NH: non-Hispanic.

[c] Includes non-Hispanic (NH) American Indian or Alaska Native, NH Native Hawaiian or other Pacific Islander, and NH Multiple Races Mentioned.

Table . Participant characteristics by colorectal cancer screening comparisons.

		Ever screened[a]	Never screened[a]	*P* value
Race, n (%)				<.001
	NH[b] White	2820 (72)	707 (28)	
	Hispanic	412 (71)	170 (29)	
	NH Black or African American	544 (74)	130 (26)	
	NH Asian	130 (60)	61 (40)	
	NH other[c]	123 (60)	46 (40)	
Access online medical record, n (%)				<.001
	None	1748 (63)	688 (37)	
	At least 1 time	2281 (75)	426 (25)	
Age (years), mean (SD)		59 (8)	52 (6)	<.001
Age group (years), n (%)				<.001
	45 - 49	190 (29)	420 (71)	
	50 - 64	2152 (76)	550 (24)	
	65 - 75	1687 (91)	144 (9)	
Sex, n (%)				.79
	Male	1752 (69)	451 (31)	
	Female	2271 (70)	659 (30)	
Education, n (%)				<.001
	High school or less	104 (52)	59 (48)	
	Post–high school/some college	522 (65)	186 (35)	
	College graduate	1306 (70)	345 (30)	
	Postgraduate	2090 (74)	523 (26)	
Insurance, n (%)				<.001
	No	66 (28)	109 (72)	
	Yes	3936 (72)	996 (28)	
	Missing	27 (71)	9 (29)	
Income, n (%)				.11
	<US $20,000	420 (65)	167 (35)	
	US $20,000-US $35,000	411 (65)	122 (35)	
	US $35,000-US $50,000	473 (65)	142 (35)	
	US $50,000-US $75,000	728 (71)	178 (29)	
	≥US $75,000	1723 (72)	443 (28)	
Diabetes, n (%)				.39
	No	3013 (69)	903 (31)	
	Yes	972 (72)	205 (28)	
	Missing	44 (77)	6 (23)	
High BP [d] , n (%)				<.001
	No	1890 (66)	675 (34)	
	Yes	2090 (73)	434 (27)	
	Missing	49 (89)	5 (11)	

		Ever screened[a]	Never screened[a]	*P* value
Heart condition, n (%)				.24
	No	3578 (69)	1041 (31)	
	Yes	413 (75)	68 (25)	
	Missing	38 (80)	5 (20)	
Lung disease, n (%)				.07
	No	3443 (69)	996 (31)	
	Yes	553 (76)	113 (24)	
	Missing	33 (79)	5 (21)	
Depression, n (%)				.19
	No	3043 (69)	862 (31)	
	Yes	942 (72)	247 (28)	
	Missing	44 (87)	5 (13)	
Family history of cancer, n (%)				.33
	No	478 (65)	163 (35)	
	Yes	2037 (69)	529 (31)	
	Missing	121 (62)	43 (38)	

[a] Weighted percentages based on pooled sample of 5143 adult participants, derived using weights. Significant differences in CRC screening were evaluated with Rao-Scott tests for weighted data.

[b] NH: non-Hispanic.

[c] Includes non-Hispanic (NH) American Indian or Alaska Native, NH Native Hawaiian or other Pacific Islander, and NH Multiple Races Mentioned.

[d] BP: blood pressure.

CRC Screening by Participant Characteristics

Overall, higher proportions of non-Hispanic White participants (2820/3527, 72%) and non-Hispanic Black participants (544/674, 74%) reported CRC screening, while only 54% (412/582) of Hispanic participants reported CRC screening (*P*<.001) (Table 2). Age was significantly associated with CRC screening, with older individuals having higher rates of screening (*P*<.001). Fewer participants between the ages of 45 - 49 years reported CRC screening (190/610, 29%) compared with older age groups between the ages of 50 - 64 years (2152/2702, 76%) and 65 - 75 years (1687/1831, 92%) (*P*<.001). Higher educational attainment was significantly associated with CRC screening, with 52% (104/201) of participants with a high school degree or less screened, compared with 74% (2090/2813) of participants with postgraduate degrees (*P*<.001). Being insured was associated with CRC screening, with 72% (3936/4932) of insured participants reporting CRC screening compared with 28% (66/235) of uninsured participants (*P*<.001). Among participants with high blood pressure, 73% (2090/2524) reported CRC screening, while 66% (1890/2565) of participants with no high blood pressure reported CRC screening (*P*<.001).

Accessing an OMR and Participant Characteristics

Table 3 shows results of the bivariate analyses, examining associations between accessing an OMR and race and ethnicity, as well as other sociodemographic characteristics and medical conditions. More than half of Hispanic participants (338/582, 62%) and non-Hispanic Black participants (343/674, 56%) reported no access to their OMR in the last 12 months, compared with 45% (1587/3527) of non-Hispanic White participants (*P*<.001). The proportion of participants who accessed their OMR at least once in the last 12 months increased with higher educational attainment, with 62% (1580/2613) of participants with postgraduate degrees accessing their OMR compared with 25% (35/163) of participants with a high school degree or less (*P*<.001). Gender was significantly associated with accessing an OMR, with 54% (1617/2930) of women accessing their OMR compared with 49% (1084/2203) of men (*P*=.02). Insurance status was strongly associated with accessing an OMR, with 53% (2662/4932) of insured participants accessing their OMR compared with 20% (36/235) of uninsured participants (*P*<.001). Higher proportions of participants with higher income reported accessing an OMR (*P*<.001). Participants reporting diabetes (658/1177, 57%) and high blood pressure (1361/2524, 55%) reported significantly higher OMR access than participants with no specified medical conditions (*P*=.02 and *P*=.03, respectively).

Table . Participant characteristics by online medical record access status.

		At least 1 time[a]	None[a]	*P* value
Race, n (%)				<.001
	NH[b] White	1940 (55)	1587 (45)	
	Hispanic	244 (38)	338 (62)	
	NH Black or African American	331 (44)	343 (56)	
	NH Asian	102 (52)	89 (48)	
	NH other[c]	90 (52)	79 (48)	
Age (years), mean (SD)		57 (8)	57 (8)	.75
Age group (years), n (%)				.87
	45 - 49	306 (51)	304 (49)	
	50 - 64	1416 (51)	1286 (49)	
	65 - 75	985 (53)	846 (47)	
Sex, n (%)				.02
	Male	1084 (49)	1119 (51)	
	Female	1617 (54)	1313 (46)	
Education, n (%)				<.001
	High school or less	35 (25)	128 (75)	
	Post–high school/some college	283 (39)	425 (61)	
	College graduate	804 (52)	847 (48)	
	Postgraduate	1580 (62)	1033 (38)	
Insurance, n (%)				<.001
	No	36 (20)	139 (80)	
	Yes	2662 (53)	2270 (47)	
	Missing	9 (24)	27 (76)	
Income, n (%)				<.001
	<US $20,000	209 (33)	378 (67)	
	US $20,000-US $35,000	230 (45)	303 (55)	
	US $35,000-US $50,000	291 (43)	324 (57)	
	US $50,000-US $75,000	482 (52)	424 (48)	
	≥US $75,000	1318 (59)	848 (41)	
Diabetes, n (%)				.02
	No	2021 (50)	1895 (50)	
	Yes	658 (57)	519 (43)	
	Missing	28 (62)	22 (38)	
High BP[d], n (%)				.03
	No	1316 (49)	1249 (51)	
	Yes	1361 (55)	1163 (45)	
	Missing	30 (45)	24 (55)	
Heart condition, n (%)				.06
	No	2416 (51)	2203 (49)	
	Yes	265 (57)	216 (43)	

		At least 1 time[a]	None[a]	*P* value
	Missing	26 (71)	17 (29)	
Lung disease, n (%)				.32
	No	2312 (51)	2127 (49)	
	Yes	373 (53)	293 (47)	
	Missing	22 (69)	16 (32)	
Depression, n (%)				.18
	No	2009 (51)	1896 (49)	
	Yes	669 (55)	520 (45)	
	Missing	29 (60)	20 (40)	
History of cancer, n (%)				.21
	No	321 (51)	320 (49)	
	Yes	1413 (54)	1153 (46)	
	Missing	67 (42)	97 (58)	

[a] Weighted percentages based on pooled sample of 5143 adult participants, derived using weights. Significant differences in CRC screening were evaluated with Rao-Scott tests for weighted data.

[b] NH: non-Hispanic.

[c] Includes non-Hispanic (NH) American Indian or Alaska Native, NH Native Hawaiian or other Pacific Islander, and NH Multiple Races Mentioned.

[d] BP: blood pressure.

Multivariable Logistic Regression Analysis

Unadjusted and adjusted odds ratios were obtained using different logistic regression analysis models (Table 4). After adjusting for sociodemographic characteristics, access to OMR, and medical conditions (high blood pressure and diabetes), non-Hispanic Black adults reported significantly higher odds of CRC screening compared with non-Hispanic White adults (OR 1.76, 95% CI 1.22 - 2.53).

Table . Unadjusted and adjusted odds ratios of colorectal cancer screening between race/ethnicity groups.

		Odds ratios	Lower limit (95% CI)	Upper limit (95% CI)	*P* value
Model 1: Unadjusted [a]					
	NH White (reference)	—[b]	—	—	—
	Hispanic	0.46	0.33	0.63	<.001
	NH Black or African American	1.08	0.79	1.46	.63
	NH Asian	0.58	0.33	1.02	.06
	NH other	0.57	0.30	1.09	.09
Model 2: Adjusted [c] **for access online medical records**					
	NH White (reference)	—	—	—	—
	Hispanic	0.49	0.37	0.66	<.001
	NH Black or African American	1.14	0.84	1.56	.40
	NH Asian	0.58	0.33	1.02	.06
	NH other	0.58	0.30	1.10	.10
Model 3: Adjusted [d] **for gender and sociodemographic variables (age, education, and insurance)**					
	NH White (reference)	—	—	—	—
	Hispanic	0.83	0.58	1.19	.31
	NH Black or African American	1.65	1.16	2.35	.01
	NH Asian	0.76	0.38	1.51	.43
	NH other	0.99	0.50	1.93	.97
Model 4: Adjusted [e] **for gender, sociodemographic variables, and access online medical records**					
	NH White (reference)	—	—	—	—
	Hispanic	0.90	0.64	1.26	.54
	NH Black or African American	1.74	1.22	2.48	.002
	NH Asian	0.78	0.40	1.52	.46
	NH other	0.99	0.52	1.91	.98
Model 5: Adjusted [f] **for gender, sociodemographic variables, access online medical records, and medical conditions (high blood pressure and diabetes)**					
	NH White (reference)	—	—	—	—
	Hispanic	0.89	0.63	1.25	.49
	NH Black or African American	1.76	1.22	2.53	.003
	NH Asian	0.78	0.40	1.53	.46
	NH other	0.93	0.49	1.77	.82

[a] Unadjusted odds ratio (OR). Model 1 included only the main predictor (race and ethnicity [ie, non-Hispanic (NH) or Hispanic]).

[b] Not applicable.

[c] Adjusted OR. Model 2 adjusted for access online medical records.

[d] Adjusted OR. Model 3 adjusted for age, gender, education, and insurance.

[e] Adjusted OR. Model 4 adjusted for access online medical records, age, gender, education, and insurance.

[f] Adjusted OR. Model 5 adjusted for access online medical records, age, gender, education, insurance, and medical conditions (high blood pressure and diabetes).

Access to OMRs was associated with higher odds of CRC screening, with individuals who accessed their OMR at least once having 1.89 times the odds of CRC screening compared with those who never used an OMR (95% CI 1.45 - 2.46). Increasing age was also associated with higher odds of CRC screening, with 1.18 times the odds for each additional year of age (95% CI 1.16 - 1.21). In addition, individuals with postgraduate degrees had significantly higher odds of CRC screening (OR 2.65, 95% CI 1.28 - 5.47) than those with a high school degree or less. Having insurance was strongly associated with higher odds of CRC screening, with individuals having 3.69 times greater odds of CRC screening if they had insurance compared with those with no insurance (95% CI 2.34 - 5.82).

Discussion

Summary of Findings

Our study was designed to examine, via cross-sectional survey, the association between accessing an OMR and CRC screening behavior among age-eligible adults in the US general population, with specific attention to disparities according to race and ethnicity. Early detection through routine CRC screening has the potential to prevent more than 50% of CRCs, reduce advanced stage diagnoses, and increase the effectiveness of treatment for at least average-risk adults in the United States [39]. Racial and ethnic minorities presently experience elevated rates of CRC incidence and mortality, underscoring the importance of intensified promotion efforts for CRC screening within these communities [40]. Our study results revealed associations between CRC screening behavior and current OMR access, suggesting that OMR utility may potentially contribute to utilization of CRC screening among age-eligible adults. Findings also revealed nearly twice the odds of CRC screening utilization among non-Hispanic Black adults when compared with non-Hispanic White adults after adjusting for several factors. Further research is needed to explore these associations.

Our study corroborates report on mitigation in the gap between CRC screening rates of US adults self-identifying as non-Hispanic Black and others [41]. Non-Hispanic Black individuals in our study reported even higher odds of CRC screening when compared with non-Hispanic White individuals, after adjusting for various sociocontextual and medical factors. While significant, these findings do not convey rates of up-to-date CRC screening according to USPSTF guidelines, nor align with CRC screening rates reported by safety net clinics serving adults from lower-resourced communities. For example, abnormal results of stool-based testing (ie, FITs, etc) require follow-up examination via visual inspection colonoscopy [7]. With remaining disparities in CRC-specific morbidity and mortality among racial and ethnic minorities, efforts to eliminate CRC screening disparities should continue to address issues across the care continuum from screening uptake, quality, and follow-up of abnormal screening results [42]. Findings do suggest that health equity–centered strategies should be continued for non-Hispanic Black adults and replicated for men, adults aged 45 - 49 years, other racial and ethnic minority groups, the uninsured, and other groups experiencing poorer CRC screening–related outcomes and continued disparities in CRC incidence and mortality [43,44].

Lower CRC screening rates based on other sociodemographic characteristics (ie, age, lower educational attainment, and being uninsured) and not having a preexisting medical condition suggest the need for personalized, patient-centered approaches [45]. The use of technology may still be an underutilized tool with potential to increase CRC screening rates (29%) among younger adults (ie, adults pre-Medicare, newly CRC screening age-eligible adults aged 45 - 49 years, millennials who are nearly CRC screening age-eligible, etc) and adults requiring lower literacy and lower-cost CRC screening options (ie, adults with lower educational attainment, adults who are uninsured, etc). Web-based dissemination of CRC educational materials has already proven successful when delivering preparatory instructions (eg, on how to complete at-home stool-based testing or colonoscopy preparation) or reminding patients to complete CRC screening [23,24,46,47]. Exploring other web-based interventions for individuals who are age-eligible for CRC screening could reduce lower screening rates among diverse subgroups and provide helpful insights into the development and design of more effective health communication strategies.

Results from our study support readily available resources, such as OMRs, as potentially effective tools to promote CRC screening. Despite known disparities, OMRs are reportedly used by 90% of US health care systems and constantly increasing patient enrollment [48-50]. With user instruction, the patient portal may be an ideal tool for increasing patient-provider communication regarding CRC screening completion [51]. Notably, while our study does identify stronger predictors of CRC screening behaviors, such as insurance status and educational attainment, patient portal use is much more easily accessible and operationalized among a patient population than, for instance, expanding insurance access or increasing patients' educational attainment. Promoting age-eligible CRC screening information and locale of free or reduced cost screening programs or events via the patient portal may potentially circumvent disparities based on insurance status, particularly within federally qualified health care centers that provide services despite a patient's ability to pay or on a sliding-fee scale. Disseminating information on the various CRC screening modalities (ie, at-home stool-based tests, colonoscopy, etc) may also be helpful to address patient fear or concerns for procedural discomfort. Furthermore, review of the literature provides evidence that tailored or targeted interventions including patient education and access to screening are most effective for increasing CRC screening [52,53]. More research exploring OMR utility with socially vulnerable populations is needed.

Given its substantiation in previous literature, plus its clear potential to bridge sociodemographic divides that exist among the adult population for CRC, the OMR is an ideal tool for dissemination of tailored, language-concordant material promoting awareness of CRC and CRC screening completion. However, researchers have yet to identify suitable, OMR-based interventions for age-appropriate CRC screening promotion across health care settings [54-58]. By leveraging technology and facilitating access to OMRs, health care providers can potentially improve communication with patients and encourage CRC screening completion.

Limitations

It is essential to acknowledge that our study findings are based on the analysis of the HINTS dataset and subject to limitations inherent in cross-sectional, survey-based research, including the nature of the data to restrict the ability to establish causality. Notably, we were unable to accurately determine risk for CRC based on limited survey items assessing genetic predisposition or family history of CRC. Self-report of access to OMRs and CRC screening may also have limited our results, as well as the inability to infer education on CRC alongside reported OMR use. In addition, dichotomization of CRC screening into ever or never categories might imply that patients who are not up-to-date with screenings per USPSTF recommendations have similar screening behaviors as those who are in concordance with guidelines. Also important to note, lower rates of CRC screening among younger individuals in this sample may be partially explained by the years of HINTS survey data analyzed (2018 - 2020) not coinciding with the 2021 update by the USPSTF to expand the recommended age of CRC screening to include average-risk adults aged 45 - 49 years [59]. Further research is needed to explore underlying mechanisms and to develop targeted interventions to reduce disparities in CRC screening based on risk status and promote the use of OMRs to enhance preventive care and early detection of CRC.

Strengths

Access to the web and use of technology have now been identified as social determinants of health [32,60,61]. Our study is among the first to present findings on the utility of OMRs for CRC screening among the general population. Our study provides behavioral and sociocontextual information related to addressing this social determinant of health and hopefully reducing the second leading cause of cancer-related deaths through early detection of CRC. The generalizability of our study results is strengthened by the use of a nationally representative sample from HINTS, which includes diverse sociodemographic groups across the United States. However, the findings may be particularly relevant to populations already engaged with digital health tools, such as OMRs. Future research should explore interventions that expand OMR access to underrepresented and younger populations to ensure broader applicability of these results.

Suggestions for Further Research

Utilization of web-based technology to promote CRC screening presents an ideal opportunity for health care centers to expand on existing behaviors, including web use for cancer health information seeking and cell phone use [62]. Future studies should explore and design language-concordant, patient-centered CRC prevention interventions through web-based patient portals for priming and promoting CRC screening completion among age-eligible adults [63-65]. These studies should also examine barriers at the systemic level (eg, readiness to implement cancer prevention interventions for screening age-eligible patients, patient navigation, etc), provider level (eg, communication strategies for motivating screening adherence, staff capacity, etc), and patient level (addressing facilitators and barriers to adhere to current recommendations as well as preference for web-based information delivery) [54-56,66,67]. Finally, given the recent USPSTF recommendations to expand CRC screenings to the 45 - 49 years age group, targeted approaches to how this age group might benefit and interact with web-based patient portals will be especially relevant to future research in CRC screening promotion.

Conclusions

OMRs are underutilized resources that may potentially accelerate cancer education, awareness, and screening utilization. More than ever, there exists an ideal opportunity to expand culturally inclusive client communication to promote age-appropriate CRC screenings beyond conventional, print-based materials typically offered from health care centers [22,54-58]. This study provides findings of client-centered, behavioral (access to OMR), and sociocontextual information (age, gender, socioeconomic status, and preexisting medical conditions) directly related to addressing social determinants of health and potentially reducing the second leading cause of cancer-related deaths in the United States through early detection. These findings are critical for designing and implementing future interventions that can reduce existing CRC screening–related disparities and more effectively leverage existing health care resources.

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Disclaimer

At no point in the conceptualization, writing, analysis, or review of this manuscript was generative artificial intelligence software used.

Data Availability

All data analyzed in this manuscript were taken from the Health Information National Trends Survey (HINTS) 5 cycles, 2, 3, and 4 (2018-2020) publicly available datasets. Data can be found at the hints.cancer.gov website [34].

Authors' Contributions

APE contributed to conceptualization, methodology, formal analysis, investigation, resources, data curation, writing—original draft, writing—review and editing, supervision, and funding acquisition. DM did the formal analysis, writing—original draft, and writing—review and editing. FT contributed to methodology, formal analysis, writing—original draft, and writing—review and editing. AVH did the formal analysis, writing—original draft, and writing—review and editing. MA-R contributed to methodology, formal analysis, and writing—review and editing. SMcE contributed to writing—review and editing. JC contributed to writing—review and editing. JH contributed to conceptualization and writing—review and editing. PZ contributed to writing—review and editing. TSN contributed to writing—review and editing. CAD contributed to conceptualization and writing—review and editing.

Conflicts of Interest

JLH is an associate editor of JMIR Medical Informatics. There are no other conflicts of interest to disclose.

Checklist 1
STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) checklist.
[PDF File, 168 KB - cancer_v10i1e53229_app1.pdf]

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Abbreviations

CRC: colorectal cancer
FIT: fecal immunochemical test
gFOBT: guaiac-based fecal occult blood test
HINTS: Health Information National Trends Survey
IRB: institutional review board
OMR: online medical record
OR: odds ratio
US: United States
USPSTF: United States Preventive Services Task Force

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Original Paper

Patterns of Prescription Medication Use Before Diagnosis of Early Age-Onset Colorectal Cancer: Population-Based Descriptive Study

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Abstract

Background: Colorectal cancer (CRC) is estimated to be the fourth most common cancer diagnosis in Canada (except for nonmelanoma skin cancers) and the second and third leading cause of cancer-related death in male and female individuals, respectively.

Objective: The rising incidence of early age-onset colorectal cancer (EAO-CRC; diagnosis at less than 50 years) calls for a better understanding of patients’ pathway to diagnosis. Therefore, we evaluated patterns of prescription medication use before EAO-CRC diagnosis.

Methods: We used linked administrative health databases in British Columbia (BC), Canada, to identify individuals diagnosed with EAO-CRC between January 1, 2010, and December 31, 2016 (hereinafter referred to as “cases”), along with cancer-free controls (1:10), matched by age and sex. We identified all prescriptions dispensed from community pharmacies during the year prior to diagnosis and used the Anatomical Therapeutic Chemical Classification system Level 3 to group prescriptions according to the drug class. A parallel assessment was conducted for individuals diagnosed with average age-onset CRC (diagnosis at age 50 years and older).

Results: We included 1001 EAO-CRC cases (n=450, 45% female participants; mean 41.0, SD 6.1 years), and 12,989 prescriptions were filled in the year before diagnosis by 797 (79.7%) individuals. Top-filled drugs were antidepressants (first; n=1698, 13.1%). Drugs for peptic ulcer disease and gastroesophageal reflux disease (third; n=795, 6.1%) were more likely filled by EAO-CRC cases than controls (odds ratio [OR] 1.4, 95% CI 1.2-1.7) and with more frequent fills (OR 1.8, 95% CI 1.7-1.9). We noted similar patterns for topical agents for hemorrhoids and anal fissures, which were more likely filled by EAO-CRC cases than controls (OR 7.4, 95% CI 5.8-9.4) and with more frequent fills (OR 15.6, 95% CI 13.1-18.6).

Conclusions: We observed frequent prescription medication use in the year before diagnosis of EAO-CRC, including for drugs to treat commonly reported symptoms of EAO-CRC.

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KEYWORDS

colorectal cancer; medications; medication patterns; cancer diagnosis; prediagnosis; prescriptions; patterns; early-onset; population-based; incidence; male individuals; female individuals; health databases; pharmacology; diagnostic; descriptive study; gastroenterology; cancers

Introduction

Colorectal cancer (CRC) is estimated to be the fourth most common cancer diagnosis in Canada (except for nonmelanoma skin cancers) and the second and third leading cause of cancer-related death in male and female individuals, respectively [1]. Given the marked onset of CRC among individuals aged 50 years, it was historically considered a disease for older adults. However, recent evidence particularly over the past decade has revealed a rise in the incidence of early age-onset CRC (EAO-CRC), defined as diagnosis among those younger than 50 years [2]. For example, a 2020 Canadian study [3] showed that between 2008 and 2017, the 30- to 39-year age group accounted for the most significant increase with age-specific average annual percent changes of 4.33 (95% CI 2.79-5.91) for female individuals and 4.53 (95% CI 2.89-6.19) for male individuals.

The increasing incidence of EAO-CRC has called for research to better understand various aspects of the disease [2-4], including the path to diagnosis, particularly patterns of health care use. Using administrative health databases in British Columbia (BC), Canada, a 2022 case-control study found that in comparison to age- and sex-matched cancer-free controls, individuals diagnosed with EAO-CRC experienced a marked increase in outpatient physician visits during the year prior to diagnosis, with the reason for visit most commonly documented as nausea, vomiting, and abdominal pain [5]. Therefore, delineating patterns of prescription medication use before diagnosis of EAO-CRC may provide further insight, particularly as certain pharmacologic treatments may suggest potential diagnostic opportunities for EAO-CRC. In 2017, Pottegård and Hallas [6] used the Danish Cancer Registry to evaluate prescription drug use in the 24 months preceding a diagnosis of lung, breast, colon, and prostate cancers and found a stable pattern that markedly increased at 6 months before diagnosis. Among a prespecified list of drug classes that may likely be prescribed for early symptoms of one of the cancers studied (eg, drugs against overactive bladder may be associated with future prostate cancer diagnosis and drugs against constipation or diarrhea may be associated with future colon cancer diagnosis), such as opioids, oral antidiabetics, and statins, authors found that for those with colon cancer, the increased prescription rates before diagnosis were for proton pump inhibitors and antibiotics [6]. It is important to assess whether a similar pattern is presenting in another jurisdiction with a specific focus on CRC and considering age at diagnosis, particularly given the increasing incidence of EAO-CRC [2-4]. Thus, our primary aim was to assess patterns of prescription medication use among individuals with EAO-CRC during the year preceding diagnosis. To contextualize our findings, we also assessed patterns of prescription medication use among age- and sex-matched cancer-free controls and individuals diagnosed with average-age onset CRC (AAO-CRC; 50 years and older). We aim to better understand the pathway to diagnosis through evaluating patterns of prescription medication use in the year preceding EAO-CRC diagnosis.

Methods

Data Sources

As with prior population-based research on the epidemiology of EAO-CRC [7], we linked administrative health databases capturing longitudinal and deidentified individual-level health services data for the province of BC, Canada [8-14]. Population Data BC facilitated data access to the Medical Services Plan database on outpatient visits [13], the Discharge Abstract Database on inpatient visits [14], the Consolidation File for demographics [11], the Vital Statistics File for deaths [12], and the PharmaNet database on all prescriptions dispensed in community pharmacies regardless of payer [15]. These databases were linked to the BC Cancer Registry, which includes data on cancer diagnosis (eg, date and site) [9].

Study Design

A population-based descriptive observational study was conducted. First, we identified CRC cases as individuals diagnosed with CRC between January 1, 2010, and December 31, 2016, using *International Classification of Diseases for Oncology, Third Edition* (ICD-O-3) codes, specifically: C18.2-C18.9 (colon), C19.9 (rectosigmoid), and C20 and C21.8 (rectum). Our study period coincided with the beginning (in 2010) of population-based reporting of staging data, based on American Joint Committee on Cancer staging guidelines, with >85% capture in the BC Cancer Registry [16,17]. We assigned the *index date* as the date of definitive diagnosis from the BC Cancer Registry based on tissue diagnosis of CRC (endoscopist, surgeon, or oncologist). Next, we further classified cases as those with EAO-CRC (diagnosed at less than 50 years of age) and AAO-CRC (diagnosed at 50 years of age or later). We matched individuals with CRC to cancer-free controls (1:up to 10) on age and sex. Controls were also required to have a health care use (ie, outpatient visit, hospitalization, or prescription fill) within the same year their matched case was diagnosed. Controls were assigned an index date, which corresponded to their match date (Multimedia Appendix 1 illustrates data sources and study sample).

Prescription Medication Use

We assessed the use of prescription medications over the 1-year period preceding the index date using the PharmaNet database. We drew rationale for evaluating the 1-year period before diagnosis from the study by Pottegård and Hallas [6] showing marked prescription drug use 6 months before cancer diagnosis and from our own prior work with patterns of outpatient physician visits the year before cancer diagnosis [5]. By law, prescriptions dispensed from community pharmacies in BC must be entered in PharmaNet, a province-wide network [15].

Thus, we were able to assess all prescriptions, regardless of payer, and extracted relevant information including prescription date, drug identification number, and Anatomical Therapeutic Chemical (ATC) classification [18]. In particular, we used the third-level ATC code, allowing us to categorize drugs according to first level—main anatomical or pharmacological group (eg, A alimentary tract and metabolism); second level—pharmacological or therapeutic subgroup (eg, A10 drugs used in diabetes); third and fourth levels—chemical, pharmacological, or therapeutic subgroup (eg, A10B blood glucose–lowering drugs and A10BA biguanides; Multimedia Appendix 2).

Statistical Analysis

We used descriptive statistics (eg, mean and proportions) to characterize all individuals included in our study sample according to age, sex (female or male), socioeconomic status (determined using neighborhood income per person equivalent adjusted for household size), type of residence (rural vs urban, determined using Census Metropolitan Area or Census Agglomeration from geographical census data). For individuals with CRC, the cancer site using ICD-O-3 codes (eg, rectum, left colon, right colon, and transverse colon) and stage at diagnosis were also determined.

We assessed patterns of prescriptions among EAO-CRC cases overall and according to sex and stage age at diagnosis, reporting counts and proportions using both prescriptions and persons as units of analyses. Using logistic regression, we evaluated determinants of our outcome of having ≥1 prescription filled in the year before diagnosis among EAO-CRC cases. Potential determinants included age, sex, neighborhood income quintile, residence, cancer diagnosis site, and stage. We used a backward stepwise approach and retained the model variables based on statistical or clinical significance. We then compared patterns of prescription medications among EAO-CRC cases and controls, reporting counts, proportions, and odds ratios (ORs) and corresponding 95% CI, where relevant. We also compared patterns of prescription medications among EAO-CRC and AAO-CRC cases, reporting counts, proportions, ORs and corresponding 95% CIs, where relevant. We completed all these analyses using SAS statistical software (version 9.4; SAS Institute).

Study Conduct

All inferences, opinions, and conclusions drawn in this paper are those of the authors and do not reflect the opinions or policies of the Data Stewards.

Ethical Considerations

This study was approved by the University of British Columbia’s Behavioural Research Ethics Board (H17-03530) and was performed in accordance with relevant guidelines and regulations. Consent to participate was waived by the University of British Columbia’s Behavioural Research Ethics Board, as this research involves secondary use of data. Individual-level health services data from the linked administrative health databases were deidentified or scrambled.

Results

Our study included 1001 cases with EAO-CRC (n=450, 45% female participants; mean age 41.0, SD 6.1 years) and 10,010 matched cancer-free controls (n=4500, 45% female participants; mean age 41.0, SD 6.1 years). As shown in Table 1, EAO-CRC cases were most frequently diagnosed with cancer in the rectum (n=418, 41.8%) and with stage III (n=351, 35%) and stage IV (n=270, 27%) disease. In our parallel analyses, we identified 12,331 cases with AAO-CRC (n=5536, 44.9% female participants, mean age 66.6, SD 9.2 years), who were most frequently diagnosed with cancer in the left colon (n=5210, 42.3%) and stage III (n=3644, 29.6%) or stage II (n=2996, 24.3%) disease.

There were 12,989 prescription events among 797 (79.7%) EAO-CRC cases and 174,806 prescription events among 7796 (77.9%) matched cancer-free controls. With respect to individuals, there is no significant difference in the proportions of EAO-CRC cases and controls filling prescriptions (OR 1.11, 95% CI 0.94-1.3). However, with respect to the number of prescriptions filled, among 797 EAO-CRC cases, there was a mean of 16.3 (SD 73.7) prescriptions (median 5.0) per case; whereas for 7796 controls, there was a mean of 22.4 (SD 99.3) prescriptions (median 6.0) per control. Multimedia Appendix 3 summarizes medication classes that represent ≥1% (n≥130 prescriptions for EAO-CRC cases and n≥1748 prescriptions for controls) of all prescriptions in the year before diagnosis for EAO-CRC cases and controls. Assessing specific medications including ranking and frequency revealed patterns of use. For example, antidepressants (ATC3 N06A) were the top medications filled by both EAO-CRC cases (n=1698, 13.1% of prescriptions) and controls (n=17,262, 9.9% of prescriptions) with EAO-CRC having more frequent fills (OR 1.4, 95% CI 1.3-1.4) than cases. Gastrointestinal drugs (ATC3 N02A; for peptic ulcer disease and gastroesophageal reflux disease) were the third most filled prescriptions by EAO-CRC cases (n=795, 6.1% of prescriptions) and fifth most filled by controls (n=6126, 3.5% of prescriptions) with EAO-CRC cases having higher odds of filling (OR 1.4, 95% CI 1.2-1.7) and having more frequent fills (OR 1.8, 95% CI 1.7-1.9). Relatedly, agents for the treatment of hemorrhoids and anal fissures for topical use (ATC3 C05A) and drugs for constipation (ATC3 A06A) represent the ninth (n=275, 2.1% of prescriptions) and tenth (n=250, 1.9% of prescriptions) most filled prescriptions by EAO-CRC cases, respectively, but were not among ≥1% (n≥1748 prescriptions) of prescriptions for controls. EAO-CRC cases had higher odds of filling (OR 7.4, 95% CI 5.8-9.4) and had more frequent fills (OR 15.6, 95% CI 13.1-18.6) for topical agents for hemorrhoids and anal fissures. Among EAO-CRC cases, factors associated with filling 1 or more prescriptions in the year before diagnosis included having inflammatory bowel disease (adjusted odds ratio [aOR] 3.43; 95% CI 1.20-9.78) and depression (aOR 4.20, 95% CI 1.49-11.85). As well, number of outpatient visits was also a determinant with an aOR of 1.14 (95% CI 1.09-1.18).

Table 1. Characteristics of individuals with EAO-CRC[a] (less than 50 years), AAO-CRC[b] (50 years and older), and their respective controls.

Characteristic	EAO-CRC		AAO-CRC	
	Cases (n=1001)	Controls (n=10,010)	Cases (n=12,331)	Controls[c] (n=123,310)
Age (years), mean (SD)	41 (6.1)	41 (6.1)	66.6 (9.2)	66.6 (9.2)
Female participants, n (%)	450 (45)	4500 (45)	5536 (44.9)	55,360 (44.9)
Neighborhood income quintile, n (%)				
Quintile 1	191 (19.5)	2178 (21.8)	2585 (21)	24,750 (20.1)
Quintile 2	202 (19.6)	2071 (20.7)	2409 (19.7)	24,748 (20.1)
Quintile 3	205 (20.3)	2024 (20.2)	2455 (19.9)	24,561 (19.9)
Quintile 4	230 (22.9)	1993 (19.9)	2487 (20.1)	24,093 (19.5)
Quintile 5	173 (17.8)	1744 (17.4)	2395 (19.4)	25,158 (20.4)
Residence, n (%)				
Urban	887 (88.6)	9070 (90.6)	10,530 (85.4)	106,516 (86.4)
Rural	114 (11.4)	940 (9.4)	1801 (14.6)	16,794 (13.6)
Cancer diagnosis site, n (%)				
Rectum	418 (41.8)	N/A[d]	3848 (31.2)	N/A
Left colon	410 (41)	N/A	5210 (42.3)	N/A
Right colon	102 (10.2)	N/A	2232 (18.1)	N/A
Transverse colon	55 (5.5)	N/A	753 (6.1)	N/A
Cancer diagnostic stage, n (%)				
IV	270 (27)	N/A	2340 (19)	N/A
III	351 (35)	N/A	3644 (29.6)	N/A
II	205 (20.5)	N/A	2996 (24.3)	N/A
I	143 (14.3)	N/A	2680 (21.7)	N/A
0	32 (3.2)	N/A	671 (5.4)	N/A

[a] EAO-CRC: early age-onset colorectal cancer.

[b] AAO-CRC: average age-onset colorectal cancer.

[c] Cancer-free controls for individuals with AAO-CRC were not analyzed for study purposes but reported demographic characteristics for completeness.

[d] N/A: not applicable.

We further assessed patterns of prescription medication use among EAO-CRC cases stratified by sex and stage. Multimedia Appendix 4 shows medication classes that represent ≥1% (n≥130 prescriptions) of all prescription events in the year before EAO-CRC diagnosis according to sex. We observed a higher number of prescriptions (n=7295) representing 56.2% of all events among 420/551 (76.2%) male EAO-CRC cases. In contrast, 377/450 (83.8%) female EAO-CRC cases had a lower number of prescriptions (n=5694) representing 43.8% of events. In terms of frequency of prescriptions by sex, we found higher fills for antidepressants (n=1075, 14.7% male patients and n=623, 10.9% female patients), antiepileptics (n=711, 9.8% male patients and n=421, 7.4% female patients), gastrointestinal drugs (n=582, 8% male patients and n=213, 3.7% female patients), as well as pain-related medications such as opioids (n=426, 5.8% male patients and n=219, 3.9% female patients) and other analgesics and antipyretics (n=79, 1.1% male patients and n=33, <1% female patients) for male patients with EAO-CRC than female patients with EAO-CRC. When EAO-CRC cases were stratified by stage, we observed the following prescription events among individuals: stage I (1620 prescription events in 112, 78.3% cases), stage II (3523 prescription events in 167, 81.5% cases), stage III (3226 prescription events in 283, 80.6% cases), and stage IV (4620 prescription events in 209, 77.4% cases). As seen visually by the blue bars in Multimedia Appendix 5, drugs belonging to the nervous system class were the most represented across all 4 stages. Of note, when considering number of prescriptions, those among stage IV EAO-CRC cases represented 35.6% (n=4620) of all prescription events in contrast to those among stage I EAO-CRC cases, which represented 12.5% (n=1620) of all prescription events. Antidepressants were the most filled medications among individuals diagnosed at stage II (n=502, 14.2%) and IV (n=880, 19%; Multimedia Appendix 5). Of interest, gastrointestinal drugs were the most used in stage IV EAO-CRC cases (n=510, 11%). Topical agents for the treatment of hemorrhoids and anal fissures were mostly filled by stage III EAO-CRC cases (n=128, 4%). Drugs for constipation were the highest used in stage II EAO-CRC cases (n=92, 2.6%) and lowest in stage I EAO-CRC cases (n=22, 1.4%).

For further context, when we analyzed 12,331 AAO-CRC cases, we observed a total of 317,271 prescription events among 10,979 (89%) individuals (Multimedia Appendix 6), mean of 28.9 (SD 83.9) prescriptions (median 13.0) per AAO-CRC case. While antidepressants (n=1698, 13.1%) and antiepileptics (n=1132, 8.7%) were the top 2 most frequently filled medications among EAO-CRC cases, these drug classes were observed to be the third and seventh most used medications among AAO-CCRC cases (n=15,097, 4.8% and n=10,689, 3.4%, respectively). Instead, the AAO-CRC group showed lipid modifying agents (n=21,898, 6.9%) and angiotensin-converting enzyme inhibitors (n=16,292, 5.1%) as the top 2 most used medication classes. Drugs that may be used to treat symptoms associated with potential CRC diagnosis were more frequently filled among EAO-CRC cases than AAO-CRC cases including gastrointestinal drugs (EAO-CRC: n=795, 6.1% and AAO-CRC: n=14,964, 4.7%), nonsteroidal anti-inflammatory and antirheumatic products (EAO-CRC: n=449, 3.5% and AAO-CRC: n=3430, 1.1%), topical agents for treatment of hemorrhoids and anal fissures (EAO-CRC: n=275, 2.1% and AAO-CRC: n=1672, <1%), and drugs for constipation (EAO-CRC: n=250, 1.9% and n=2897, <1%). EAO-CRC cases also revealed a higher use of opioids (EAO-CRC: n=645, 5% and AAO-CRC: n=9602, 3%).

Discussion

Overview

Using population-based administrative data, we assessed patterns of prescription medications in the year before diagnosis among individuals with EAO-CRC to understand the role of medications in the pathway to diagnosis in a condition that has seen a considerable increase in incidence [2-4]. Among 1001 EAO-CRC cases, 12,989 prescriptions were filled in the year before diagnosis by 797 (79.7%) individuals. With respect to medications, antidepressants were most commonly filled (n=1698, 13.1%), followed by antiepileptics (n=1132, 8.7%) and gastrointestinal drugs (ie, drugs for peptic ulcer disease and gastroesophageal reflux disease; n=795, 6.1%). Sex-based analyses revealed that male EAO-CRC cases had a higher number of prescriptions (n=7295, 56.2% of prescription events) but at a lower proportion (420/551, 76.2%), whereas female EAO-CRC cases had a lower number of prescriptions (n=5694, 43.8% of prescription events) but at a higher proportion (377/450, 83.8%).

Principal Findings and Comparison to Prior Work

Given the increasing risk of EAO-CRC [4] and reported diagnostic delays in prior studies [19,20], we were particularly interested in studying the patterns of prescription medication use leading to diagnosis in individuals with EAO-CRC and understanding potential diagnostic opportunities. To our knowledge, this study is the first to assess patterns of prescription use before diagnosis of EAO-CRC. In 2017, using Danish nationwide health registries on cancer and prescription drugs, Pottegård and Hallas [6] assessed the new use of prescription drugs among patients with lung, breast, colon, and prostate cancers 24 months preceding their cancer diagnosis. Authors found similar patterns of drug use between cancer cases and population controls in the 24- to 12-month period before cancer diagnosis. Among colon cancer cases, authors showed an increase in the use of prespecified drug classes that were likely prescribed for symptoms relating to their cancer, namely, proton pump inhibitors, laxatives or drugs against diarrhea, and opioid analgesics. However, this study did not characterize participants, and as such, it is not feasible to draw findings according to age as well as sex and stage, as with our study. With respect to prescription medication use specifically among individuals with CRC, a 2021 cohort study by Engeland et al [21] using data from the Cancer Registry of Norway primarily assessed prescription medications after diagnosis but also reported on use in the year before diagnosis. Authors evaluated a prespecified list of drugs according to 5 major categories and reported the top 3 most commonly used drug groups in the year before diagnosis such as those for cardiovascular diseases (use prevalence 24.8%); endocrine, nutritional, and metabolic diseases (use prevalence 17.8%); and mental and behavioral disorders (use prevalence 6.7%). Although the study included patients with CRC aged 20-84 years, there was no reporting of drug use according to age groups. Furthermore, with 530 individuals in the 20- to 39-year age category comprising 2% of the study population, reported findings largely reflect drug use among older patients with CRC.

Indeed, this study provides a better understanding of patterns of prescription medication use specifically in EAO-CRC. In contrast to the aforementioned studies [6,21], which assessed prespecified lists of drugs based on reimbursement, we were able to assess all prescriptions, regardless of payer, given comprehensive capture in the PharmaNet database. At the outset, we initially assumed that the most common prescriptions filled during the year of diagnosis were for gastrointestinal and pain, based on previously reported symptoms of EAO-CRC [22]. Indeed, among the top 10 classes of most frequently filled prescriptions by EAO-CRC cases were gastrointestinal drugs for peptic ulcer disease and gastroesophageal reflux disease (third), opioids (fourth), anti-inflammatory and antirheumatic drugs and nonsteroids (sixth), topical agents for hemorrhoids and anal fissures (ninth), and drugs for constipation (10th). We believe the increased use of these drugs for EAO-CRC symptoms in the year prior to diagnosis may be the early manifestations of red flag signs and symptoms of CRC. A 2023 population-based case-control study by Fritz et al [23] identified 4 red-flag signs and symptoms (rectal bleeding, abdominal pain, diarrhea, and iron-deficiency anemia) that were associated with a heightened risk of EAO-CRC between 3 months to 2 years preceding diagnosis (ORs range between 1.34 and 5.13). These red flag symptoms align with the clinical indications of our results, where gastrointestinal drugs, pain medications, and rectal medications were among the top 10 classes of most frequently filled prescriptions by EAO-CRC cases in the year prior to diagnosis. These results highlight the importance of ensuring individuals younger than 50 years consistently presenting with these early warning signs, and symptoms or medication use patterns are being given ample opportunities for further work-up and early detection of CRC at their health care interactions. Stratified analyses by sex and stage further reveal patterns such as higher use of pain-related medications and gastrointestinal drugs by male EAO-CRC cases. Our findings also suggest sex differences in health care use in terms of more frequent prescriptions among a smaller number of male EAO-CRC cases compared to less frequent prescriptions among a greater number of female EAO-CRC cases. With respect to stage, gastrointestinal drugs were most used in stage IV EAO-CRC cases, topical agents for treatment of hemorrhoids and anal fissures were by stage III EAO-CRC cases, and drugs for constipation were the highest used in stage II EAO-CRC cases and lowest in stage IV EAO-CRC cases. In contextualizing findings with those of controls, while opioids (fourth), gastrointestinal drugs (fifth), and nonsteroidal anti-inflammatory and antirheumatic drugs (seventh) were among the top 10 classes of filled prescriptions by matched cancer-free controls, they were at a lower frequency than EAO-CRC cases. Interestingly, topical agents for hemorrhoids and anal fissures and drugs for constipation were not among ≥1% (n≥1748 prescriptions) of prescription events among controls.

Our findings on patterns of prescription medication use before diagnosis support a study rationale of exploring targets for raised awareness and education on the increasing risk of EAO-CRC to allied health care providers, particularly pharmacists. With patients reportedly seeing pharmacists 1.5 to 10 times more frequently than primary care physicians [24], these may represent windows of opportunity for education or identification of risks for diseases, including cancer. A survey of community pharmacists suggests that patients have long sought advice from pharmacists about possible cancer signs and symptoms [25]. With respect to CRC, pharmacists are gaining recognition for their roles in the initiation of average age screening in various jurisdictions [26-28]. In the United States, a 2-phased study showed high satisfaction among individuals from limited-income populations with pharmacists speaking to them regarding CRC screening [27]. In Spain, evaluation of a population-based CRC screening program showed high adherence by participating pharmacies (82.4%) with respect to distributing fecal immunochemical test kits and a high return rate by invitees (93.5%), demonstrating the important role that pharmacists play in the program [29]. There is indeed potential to expand on pharmacists' roles when it comes to educating individuals regarding CRC, including younger adults about EAO-CRC. To date, calls to action have largely focused on increasing awareness among primary care physicians on the increasing risk of EAO-CRC [30,31]; however, it is also important to consider other health care providers, particularly pharmacists, given their accessibility and as prescriptions represent a frequent health care encounter prior to CRC diagnosis.

Aside from patterns of prescription medication use, a noteworthy finding from this study is that antidepressants represent the top prescribed drug class for EAO-CRC cases in the year before diagnosis, representing 13.1% (n=1698) of all prescription events. For context, antidepressants were also the top prescribed drug class for matched cancer-free controls but at a lower frequency, 9.9% (n=17,262). For further context, among AAO-CRC cases, antidepressants were the third most prescribed drug class (n=15,097, 4.8%) after angiotensin-converting enzyme inhibitors (n=16,292, 5.1%) and lipid modifying agents (n=21,898, 6.9%). A potential reason for this finding is a diagnostic delay of CRC that commonly occurs in the young patient population [20], which may lead to anxiety and depressive symptoms [32]. A systematic review that compared the delays and outcomes between younger and older patients with CRC found that younger patients are at a higher risk of experiencing delays from symptom onset to presentation, as they are not eligible for screening [20]. Consequently, a delay in cancer diagnosis in the younger population is associated with an increased risk of anxiety and depression [32]. A cross-sectional study in 2022 found that patient intervals (symptom onset to first seeing a general practitioner) of ≥1 month were associated with greater depression (aOR 1.7, 95% CI 1.1-2.5) compared to <1 month and having ≥3 prereferral general practitioner consultations were associated with greater anxiety (aOR 1.6, 95% CI 1.1-2.3) compared to 1-2 consultations [32]. The main reasons that could contribute to the increased risk of emotional distress in the adolescents and young adult population prior to a diagnosis include patients' persistent symptoms being dismissed due to young age, unresolved symptoms, and the fear of a potential cancerous diagnosis [32,33]. Furthermore, a 2022 cohort study that used the same administrative databases as this study found that compared to individuals without cancer, those with EAO-CRC did not have a higher onset of depression after diagnosis (adjusted hazard ratio [aHR] 1.00, 95% CI 0.92-1.10) [34]. However, individuals with EAO-CRC had a 41% higher risk of onset of depression after diagnosis compared to individuals with AAO-CRC (aHR 1.41, 95% CI 1.25-1.60) [34]. Since we were not able to link indications to prescription events, we do not know whether antidepressants were prescribed for depression or for other reasons, such as pain. Nonetheless, findings in this study suggest a substantial burden of depression even before EAO-CRC diagnosis, which further indicates the need for person-centered mental health services for individuals with EAO-CRC across the entire spectrum of care.

Strengths and Limitations

The strengths and limitations of this study warrant discussion. We drew EAO-CRC cases and controls from population-based administrative health databases, namely Population Data BC and the BC Cancer Registry, which capture data on approximately 95% of all cancer cases in the province [9]. The BC Cancer Registry is reviewed annually for quality, completeness, and accuracy by the North American Association of Central Cancer Registries [9]. Nevertheless, this study is vulnerable to inherent limitations with administrative health data, which are not collected for research purposes. Although we have data on cancer stage, it is important to note this information in the BC Cancer Registry is not acquired using a systematic approach with sources including death certificates, pathology reports, and death certificates. Finally, administrative databases in BC do not yet capture information on the social construct of gender, and as such, we are not able to incorporate this into our analysis.

Conclusions and Future Directions

Altogether, using generalizable, population-based data, including a complete capture of all prescriptions, we delineated patterns of medication use before diagnosis of EAO-CRC. Our findings suggest a high frequency of prescription fills in the year before diagnosis of EAO-CRC, including for drugs to treat commonly reported symptoms of EAO-CRC. As efforts continue to raise awareness on the increasing risk of EAO-CRC, our findings provide support for also considering the role of other health care providers, particularly pharmacists. Altogether, prescription medications represent a common and potentially, frequent, point-of-contact with the health care system and thus may lend to a better understanding of trajectories for individuals with EAO-CRC.

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Data Availability

The data that support the findings of this study are available from Population Data BC but restrictions apply to the availability of these data, which were used under license for this study, and so are not publicly available. Data are available from Population Data BC through a data access request. Therefore, the data sets generated and analyzed during this study are not publicly available due to strict data sharing agreements with the BC Ministry of Health but are available from the corresponding author on reasonable request.

Authors' Contributions

Vienna C contributed to conceptualization, formal analysis, investigation, methodology, project administration, visualization, data interpretation, and writing original draft. ECS contributed to data curation, formal analysis, investigation, methodology, software, validation, and visualization. Vicki C and RG contributed to conceptualization, investigation, visualization, data interpretation, and writing original draft. MADV contributed to funding acquisition, conceptualization, data curation, formal analysis, investigation, methodology, project administration, resources, supervision, visualization, data interpretation, and writing original draft. All authors reviewed and edited the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Overview of data sources and study sample (dashed arrow indicates linkages between databases using personal health numbers, which are then deidentified or scrambled).
[PDF File (Adobe PDF File), 90 KB - cancer_v10i1e50402_app1.pdf]

Multimedia Appendix 2
Anatomical Therapeutic Chemical Level 1 groups.
[DOCX File , 14 KB - cancer_v10i1e50402_app2.docx]

Multimedia Appendix 3
Frequency of prescriptions in the year before diagnosis for early age-onset colorectal cancer cases and cancer-free controls according to Anatomical Therapeutic Chemical Level 3 Classification.
[DOCX File , 21 KB - cancer_v10i1e50402_app3.docx]

Multimedia Appendix 4
Frequency of prescriptions in the year before diagnosis among male and female early age-onset colorectal cancer cases, according to Anatomical Therapeutic Chemical Level 3 Classification.
[DOCX File , 21 KB - cancer_v10i1e50402_app4.docx]

Multimedia Appendix 5
Bar charts showing percentage of prescriptions for the top 10 drug classes by Anatomical Therapeutic Chemical Classification Level 3 code, according to stage for early age-onset colorectal cancer cases.
[PDF File (Adobe PDF File), 423 KB - cancer_v10i1e50402_app5.pdf]

Multimedia Appendix 6
Frequency of prescriptions in the year before diagnosis for early age-onset colorectal cancer and average age-onset colorectal cancer cases according to Anatomical Therapeutic Chemical Level 3 Classification.
[DOCX File , 21 KB - cancer_v10i1e50402_app6.docx]

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Abbreviations

AAO-CRC: average age-onset colorectal cancer
aHR: adjusted hazard ratio
aOR: adjusted odds ratio
ATC: Anatomical Therapeutic Chemical
BC: British Columbia
CRC: colorectal cancer
EAO-CRC: early age-onset colorectal cancer
ICD-O-3: International Classification of Diseases for Oncology, Third Edition
OR: odds ratio

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Viewpoint

“Notification! You May Have Cancer.” Could Smartphones and Wearables Help Detect Cancer Early?

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Abstract

This viewpoint paper considers the authors’ perspectives on the potential role of smartphones, wearables, and other technologies in the diagnosis of cancer. We believe that these technologies could be valuable additions in the pursuit of early cancer diagnosis, as they offer solutions to the timely detection of signals or symptoms and monitoring of subtle changes in behavior that may otherwise be missed. In addition to signal detection, technologies could assist symptom interpretation and guide and facilitate access to health care. This paper aims to provide an overview of the scientific rationale as to why these technologies could be valuable for early cancer detection, as well as outline the next steps for research and development to drive investigation into the potential for smartphones and wearables in this context and optimize implementation. We draw attention to potential barriers to successful implementation, including the difficulty of the development of signals and sensors with sufficient utility and accuracy through robust research with the target group. There are regulatory challenges; the potential for innovations to exacerbate inequalities; and questions surrounding acceptability, uptake, and correct use by the intended target group and health care practitioners. Finally, there is potential for unintended consequences on individuals and health care services including unnecessary anxiety, increased symptom burden, overinvestigation, and inappropriate use of health care resources.

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KEYWORDS

wearables; early diagnosis; cancer; challenges; diagnosis; wearable; detect; detection; smartphone; cancer diagnosis; symptoms; monitoring; monitor; implementation; anxiety; health care service; mobile phone

Introduction

There is growing use of smartphones, wearables, and other technologies in health and wellness, either as consumer products or medical devices. The *National Health Service (NHS) Long Term Plan* [1] anticipates that in 10 years, people will have “the option for their physiology to be effortlessly monitored by wearable devices. People will be helped to stay well, to recognize important symptoms early, and to manage their own health, guided by digital tools.” Similarly, in 2020, the US Food and Drug Administration (FDA) launched a *Digital Health Innovation Action Plan* to encourage digital health innovation as “digital health technologies can empower consumers to make better-informed decisions about their own health and provide new options for facilitating prevention, early diagnosis of life-threatening diseases, and management of chronic conditions outside of traditional care settings” [2]. Wearables are devices that can be worn to detect and monitor biometric data such as heart rate, blood oxygen saturation, sleep pattern, or temperature while the wearer continues their normal routines. A further category of wearables involves skin patches used to measure biochemical signals (ie, glucose) on a continuous basis that are increasingly being considered as a standard of care for individuals with certain conditions (eg, diabetes) [3]. While most wearables have been wrist-worn devices, similar physiologic signals are now being generated from other devices such as rings or earbuds. Smartphones are also increasingly being used for health and wellness; they have the advantage of far higher use (compared with wearables), and a growing array of different sensors are routinely embedded. Could smartphones and wearables help detect cancer and, importantly, detect cancer earlier in its disease course when it is more likely to be localized and with a better prognosis? This paper provides an overview of the scientific rationale as to why these technologies could be valuable for early detection of cancer, the potential barriers to successful implementation, and the next steps for research and development.

Potential of Smartphones and Wearables for Early Detection of Cancer

While national cancer screening programs offer the opportunity to detect cancer or precancerous lesions in asymptomatic individuals, routine screening currently only accounts for the minority (<10%) of cancer diagnoses [4,5]. The predominant route to a cancer diagnosis is symptomatic presentation to ambulatory care. Thus, the diagnosis of cancer heavily relies on patients' ability to notice and attend to relevant bodily changes and their decision to consult a health care professional [6,7]. However, noticing relevant bodily changes is challenging given the multiple subtle changes that may signal cancer among the plethora of daily bodily changes; fluctuations of normal bodily processes; self-limiting, transient symptoms; and the presence of chronic conditions. The signal-to-noise ratio is weak. This issue is exacerbated by individuals' limited ability to accurately interpret vague bodily changes, many of which can be associated with cancer (eg, fatigue, weight loss, and stomach upset). This is because our awareness, attention, and interpretation are affected by expectations; emotions; beliefs; and biological, environmental, sociodemographic, and contextual factors [8-11]. Furthermore, symptoms may evolve very slowly over time, making it difficult to notice subtle changes. It is reported that the predominant risk factor for delay in seeking help following the detection of cancer symptoms is the "lack of interpretation by patients of the serious nature of their symptoms" [12].

Smartphones and wearable technologies have the potential to facilitate the detection and tracking of bodily changes that might otherwise be dismissed or interpreted as only needing self-medication rather than the attention of a health care professional. There is emerging data about early, subtle signs of cancer, and some of these may be amenable to detection by electronic sensors and monitoring of behavior (see Table 1).

Table 1. Potential signals of cancer that can be measured using sensors in smartphones or wearables.

Sensors currently available on some smartphones or wearables	Examples of signals for health features that could be related to cancer
Audio signals from microphones [13]	• Changes in cough and breathing difficulty (associated with lung cancer) [14] • Changes in voice such as hoarseness (associated with head and neck cancer and lung cancer) [14]
GPS location tracking and activity tracking [15]	• Reduced activity resulting from fatigue (associated with multiple cancers) [14]
Image capture and analysis [16-18]	• Anemia detected from images of the skin or eyes (associated with multiple cancers) [19] • Jaundice detected from images of the skin or eyes (associated with pancreatic cancer) [20] • Changes in skin lesions (associated with skin cancer) [14]
Temperature measurement [21]	• Rise in temperature (associated with pancreatic cancer) [22]
Body composition using image analysis and electro dermal activity [23]	• Weight loss (associated with multiple cancers) [14]
Photoplethysmogram [24]	• Anemia (associated with multiple cancers) [19]

Sensors could allow the detection of changes prior to them being noticed or interpreted as symptoms, for example, a reduction in activity prior to fatigue or changes in food consumption prior to weight loss. There is recent evidence that monitoring day-to-day purchases could detect an increase in over-the-counter pain and indigestion medication 8 months prior to ovarian cancer diagnosis [25]. This demonstrates how tracking and monitoring change over time could allow insight into emerging disease. This is particularly useful for clinicians working in health care settings with limited time and resources and where cancer is a relatively rare occurrence among the burden of other diseases. In addition to the detection of signals, smartphones and wearables could alert the user to the need for health care consultation and provide an endorsement to seek care. This could overcome the commonly reported barrier to presentation ("concern about bothering the doctor") that arises when there is uncertainty about the need for care [26-28].

Potential Barriers to Successful Implementation

Overview

Despite the promise of smartphones and wearables for early detection of cancer, there are several hurdles to implementation that require attention. Key barriers to success are outlined here, alongside suggestions for how these may be addressed with future research.

Signals and Sensors With Accuracy and Utility

The use and adoption of smartphones and wearables in this context require robust research into the selection of a signal, the development of sensors, and the generating evidence of accuracy and utility of those sensors in the real world. This includes identifying physiologic (or emerging pathophysiologic) signals that are most predictive of cancer, determining how often these need to be collected, and elucidating what other data would add precision to results (eg, age, risk factors, and presence of symptoms). For technology developers, sensors are usually designed and prioritized for a number of potential applications, mainly targeting overall health and wellness rather than diagnostic capabilities per se. Prioritizing these research and development efforts for cancer detection specifically over and above other priorities could be challenging to justify for business development reasons. Relatedly, the original intended commercial purpose of existing sensors may not have been connected to cancer detection. To make headway in this field of research, technology developers and device users will need to be willing to provide access to data for research. General Data Protection Regulation allows device users to share their data with third-party organizations under the right to portability. Developing systems to facilitate data sharing, in formats compatible with health data, could allow the generation of new data sets to signal cancer risk. This will prevent duplication of effort and maximize the use of existing data for public benefit.

While initial evidence on the accuracy of a sensor to detect a given health signal could involve case-control studies (eg, individuals recently diagnosed with cancer and matched controls), subsequent research would likely require large prospective cohorts. Further, given the weak signal-to-noise ratio, it is likely that signals from wearables or smartphones alone might lack sensitivity or specificity. Therefore, research that combines signals from wearables or smartphones with other digital sources of data (eg, symptoms recorded in health records and initial laboratory tests in primary care) will almost certainly be needed to demonstrate sufficient accuracy and utility in target populations. This was recently highlighted in a systematic review [29] of artificial intelligence technologies for skin cancer detection. Despite an abundance of digital products, the review highlighted that there has been very little testing in low-prevalence populations and limited data on the use of lower-quality images (eg, taken by patients or family physicians or using lower-quality phones), and as such, widespread adoption into practice has been limited [30].

Innovators also need to consider (and test) whether these new digital tools should and could detect more than 1 type of cancer (or detect other potentially important nonmalignant diseases; eg, cirrhosis in individuals with jaundice or depression in individuals with weight loss). Other considerations include who the target group is (eg, all adults or only those at higher risk of developing cancer), at what point in time (eg, certain age), and at what periodicity that group should begin using this technology for the detection of cancer. Further, it is well documented that symptom monitoring increases selective attention to the body, resulting in increased symptom reporting [31]; thus, the monitoring of symptoms could result in increased symptom burden. Development and testing need to determine the extent to which the monitoring of activity, symptoms, and other signals changes the outputs of those measurements [32,33].

Regulatory Challenges

Given the burden involved in fulfilling regulatory approvals for diagnostic devices, many smartphone technologies and wearables that could potentially have value for cancer detection will instead be introduced as products for overall health and wellness management. As the field expands, more guidance and standards for digital health tools are being introduced to ensure that they are not only safe and effective but also adoptable by the health care system [34]. For example, the recent UK National Institute of Health and Care Excellence (NICE) evidence standards framework [35] is intended to ensure new digital health technologies are clinically effective and offer value to the health care system. The framework includes standards concerning safety, quality, acceptability, bias mitigation, data practices, professional oversight, credibility with health professionals, safeguarding assurances, scalability, as well as evidence of real-world performance and use. In some countries, consumer protection regulations also determine standards that certain wellness features (eg, step counting and heart rate measurement) need to fulfill, even though these are not regulated medical devices. As specified in the CanTest framework for early cancer detection [36], research and development will benefit from this early specification of the criteria (eg, target product profiles) needed for successful digital products for cancer detection [37-39].

Ensuring Equity

A key issue of wearables and smartphone technologies is the potential for new innovations to exacerbate inequalities in cancer outcomes. Sociodemographic factors such as household income, age, level of education, and gender have been found to influence the use of mobile health (mHealth) technology [40-44] and there is "a real risk that the increased use of digital technologies will make care experiences and outcomes worse for some people (or communities)" [45]. Development of wearables and smartphone technologies for cancer detection should be conducted with an equity lens to focus on the views and needs of those living or working in more deprived areas and those at risk of lower health literacy (eg, those with lower educational level, older age, lower income, and ethnic minority groups) [46,47], so that cultural attitudes toward the use of technology, affordability, and access can be a focus in their development. Inclusion and diversity within the development and testing of sensors are vital so that products are not biased and work equally regardless of skin color or other physiological differences [29]. Affordability is also a crucial point. Even though smartphone use is extensive [48] in both higher- and lower-income countries, the availability and quality of sensors differ across brands and models of smartphones. Wearable devices have far lower penetration in most high-income countries and lower still in those individuals with lower socioeconomic status. If accurate and reliable sensors are only available on high-end devices, then the net result will be inequitable outcomes. The consideration of a reverse innovation approach may be useful here if it is possible, to focus testing on inexpensive, easy-to-use products that can be rolled out at scale.

Acceptability and Adherence

Crucial to the successful implementation of any innovation is early insight into the user perspective, including acceptability, uptake, and correct use by the intended target group [49-51]. Yet, this consultation is often omitted or occurs too late in mHealth implementation, resulting in user burden; technical issues; poor designs; and ultimately the lack of uptake, adherence, and impact of the technology [49,52-54]. Indeed, there is currently an absence of research on user perspectives on wearables and smartphone technologies for the detection of cancer. While key issues such as cost, motivation, comfort, ease of use, trust in data use, visibility, and interpretability of data are applicable across the spectrum of wearables and smartphone technologies in health [40,55], there may be additional, specific challenges for using these innovations for the detection of cancer.

In this context, acceptability also pertains to individuals' willingness to share their data from smartphones and wearables with researchers, medical professionals, or private companies. Willingness to share data from wearables was reported to be lower than that for other commercial data [56]. Less than 15% (n=65) of survey respondents aged 60 years and older were willing to share wearable device data with academic research institutions and only 40% (n=423) of those aged 18-59 years were willing to do so. Trust in organizations and worry about data misuse have been shown to be a key factor in people's willingness to share commercial data for health research [56]. Ensuring clear and transparent data use and data-sharing policies is vital for success. There are real concerns about the misuse of data, commercialization, and access to data by unauthorized people [57]. While data sharing is an essential component in the use of smartphones and wearables for cancer detection, data protection is equally as vital.

In research studies of wearables, dropout rates can be up to 44% [40], and nonadherence to wearing devices for the study duration can be up to 50% [58,59]. Nonadherence is likely to be even higher in people with preexisting comorbidities and for technologies requiring long-term engagement, as may be needed for cancer detection to track signals over time. Balancing the advantages and disadvantages of continuous versus intermittent measurements at certain intervals should be a key consideration.

It is, therefore, essential to investigate user perspectives in parallel with the development and potential future deployment of wearables and smartphone technologies for cancer detection. This also includes encompassing the views of clinicians who are involved in the ongoing surveillance and care of those with a history of cancer and would inevitably be involved in shared decision-making on the potential implementation of such technologies and, crucially, the ongoing clinical management of individuals whose sensors indicate signals of possible cancer. In general, primary care clinicians have not typically been deeply engaged in the implementation of other consumer-grade or regulated medical devices; understanding from these clinicians' viewpoint on how they could use information from smartphones and wearables within their clinical care pathways is critical to any adoption [60].

Unintended Consequences on Individuals and Health Care Services

The exciting potential of wearable technologies for cancer detection must be considered alongside the possible negative consequences. As seen with other new developments in cancer detection, given the overall very low prevalence of cancer, even tests with very high specificity will lead to a large number of individuals with false positives. The subsequent need for investigation and resources needed to differentiate those with false versus true positives (ie, do have cancer) could be considerable. For the majority of individuals, this could lead to huge risks of overinvestigation and inappropriate use of health care resources [61]. For cancer detection specifically, we can anticipate a far higher potential for wearables and smartphone technologies to generate anxiety than for other conditions (eg, detection of sleep apnea, or detection of irregular heartbeat), especially among those already fearful of cancer recurrence. This is particularly relevant to the question of how "results" should be delivered to users, what support would be needed at that time, and whose responsibility this would be. On the other hand, wearable use may lead to a false sense of reassurance, leading to a lower perceived need to attend cancer screening or respond to symptoms (eg, "my wearable says I am healthy...there is no need to see my doctor"). This is similar to when a negative cancer screening test result can overly reassure patients and affect subsequent decisions to seek care [62]. These issues about the psychological and behavioral impact of smartphone technologies and wearables to detect cancer remain unexplored and need focused behavioral science research.

Conclusions

For most cancers, the time from detecting a bodily change to interpreting that change as requiring the advice of a health care professional constitutes a substantial proportion of the time prior to diagnosis. The detection of cancer remains one of the most prominent priorities of many health systems, governments, and private and public research funders [63,64], and "leaving no stone unturned" in technologies that could potentially improve early detection is a priority. The rapid advances in the hardware (ie, sensors) and software embedded in smartphones and wearables offer exciting and potentially untapped opportunities to detect early warning signs of cancer that may otherwise be missed. The research and development needed to advance this field include the selection of appropriate signals and development of effective sensors followed by robust clinical research into accuracy in real-world settings. This relies on the up-front specification of the target groups and their needs. Target product profiles should be developed specifically for cancer detection technologies, and innovators should consult these and consider regulatory challenges early in the process of development, to design products in line with the requirements of individuals, clinicians, and health care systems. The potential negative consequences of this type of technology should be acknowledged and investigated up-front, and mitigations should be incorporated into the design and implementation strategies. To avoid exacerbation of inequalities in cancer outcomes, research into the use of wearables and smartphone technologies in cancer detection should be done with an equity lens to ensure that products are developed for those who have poorer health outcomes, for whom new innovations could have the most impact. There is a need for research to explore the patient, public, and health care perspectives about the use of smartphones and wearables for the early detection of cancer while this field is in its infancy, so that these can be incorporated into product design to optimize acceptability and adherence, avoid unintended consequences, and maximize the chance of their success.

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Authors' Contributions

SES and MJT conceived the work that led to the submission. SES drafted the manuscript. SES and MJT revised the manuscript and approved the final version.

Conflicts of Interest

SES declares no conflicts of interest. MJT is an employee of Google and owns Alphabet stock. None of the opinions or views stated in this paper reflect the opinions or views of Google Inc.

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Abbreviations

FDA: Food and Drug Administration
NICE: National Institute of Health and Care Excellence
NHS: National Health Service
mHealth: mobile health

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Viewpoint

Artificial Intelligence as a Potential Catalyst to a More Equitable Cancer Care

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Abstract

As we enter the era of digital interdependence, artificial intelligence (AI) emerges as a key instrument to transform health care and address disparities and barriers in access to services. This viewpoint explores AI's potential to reduce inequalities in cancer care by improving diagnostic accuracy, optimizing resource allocation, and expanding access to medical care, especially in underserved communities. Despite persistent barriers, such as socioeconomic and geographical disparities, AI can significantly improve health care delivery. Key applications include AI-driven health equity monitoring, predictive analytics, mental health support, and personalized medicine. This viewpoint highlights the need for inclusive development practices and ethical considerations to ensure diverse data representation and equitable access. Emphasizing the role of AI in cancer care, especially in low- and middle-income countries, we underscore the importance of collaborative and multidisciplinary efforts to integrate AI effectively and ethically into health systems. This call to action highlights the need for further research on user experiences and the unique social, cultural, and political barriers to AI implementation in cancer care.

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KEYWORDS

digital health; public health; cancer; artificial intelligence; AI; catalyst; cancer care; cost; costs; demographic; epidemiological; change; changes; healthcare; equality; health system; mHealth; mobile health

Introduction

In an era called the Age of Digital Interdependence by the United Nations Secretary-General [1], where technological advancements continually reshape the world, the health sector is facing a significant transformation.

Artificial Intelligence (AI) emerges not just as a technological innovation but as a critical instrument with the potential to help overcome critical health challenges, including health care costs, unmet health needs related to the double burden of infectious and noncommunicable diseases, a considerable shortage of trained health professionals, and more importantly, the profound and long-standing inequities in the distribution of the opportunities to health care and well-being [2].

This viewpoint explores the potential of AI as a catalyst in bridging the gap in cancer health care, from a broader and scientifically grounded perspective on its integration into health systems. Fulfilling health equity, however, goes beyond achieving digital equity: leaving no one behind in the digital age requires not only reaching those who are not digitally literate but also populations in situations of greatest social, economic, geographic, and cultural vulnerability or disadvantage—the proverbial determinants of, and barriers to, timely and quality access to health care. Information and communications technologies have the potential to reduce health inequalities by enabling people to access information and digital tools for prevention and care at the right time and in the right format. Digital inclusion involves ensuring appropriate access, digital skills, usability, and navigability in the development of technological solutions. This approach should promote inclusion while respecting the autonomy of individuals and groups who decide not to use digital services [3,4].

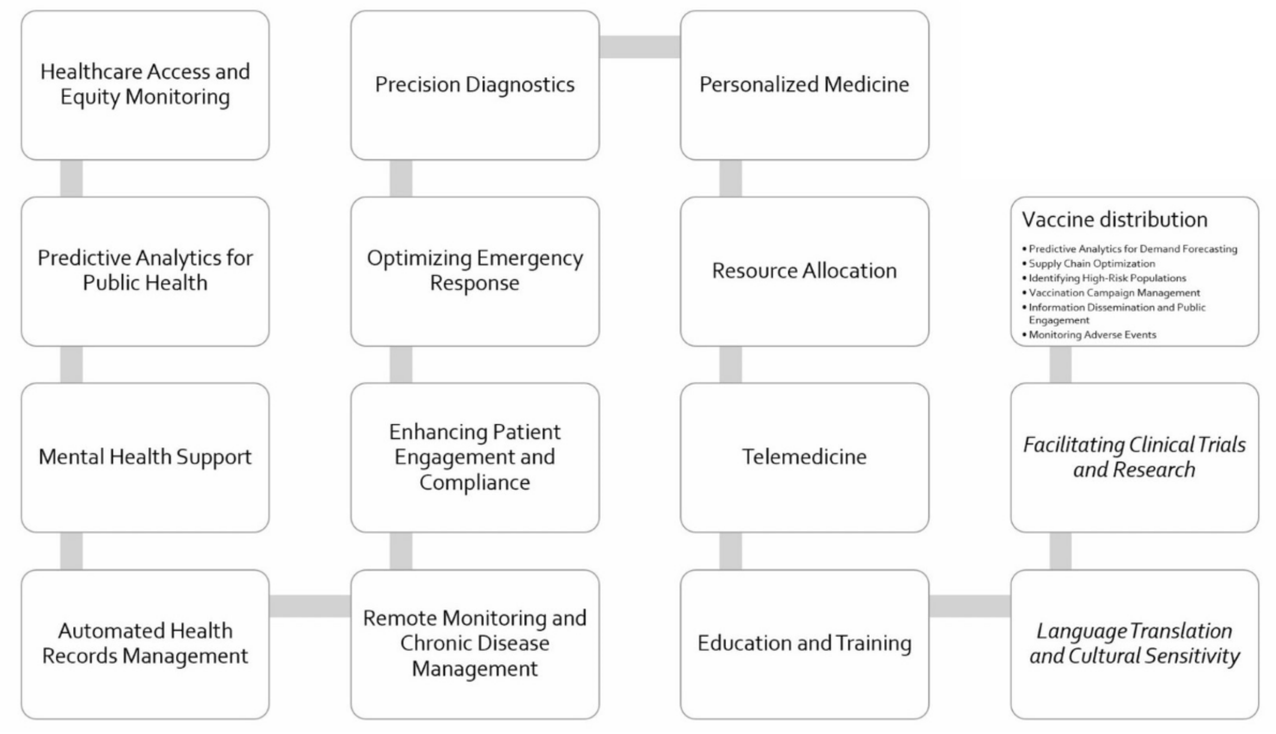
The Current Landscape

Cancer continues to pose a great and ever-growing burden of disease, being the second leading cause of death worldwide. Recently released estimates from the World Health Organization account for nearly 20 million incident cases and 10 million deaths in 2022, projecting almost double these figures by the year 2050 [5]. Although the cumulative risk of developing cancer before the age of 75 years is unequivocally greater in countries with a higher Human Development Index and larger income per capita, most of the cancer burden is concentrated in countries with lower Human Development Index and smaller income per capita. More dramatically, inequalities in cancer care—as is usually the case with noncancer burden as well—bear a disproportionate impact in underserved populations [6]. These inequalities, shaped by highly context-specific socioeconomic, geographical, and cultural barriers, manifest in varied health care dimensions—from access to screening to palliative care, diagnostic accuracy, treatment options, pain management, premature mortality, survival, quality of life, and other health outcomes. This web of challenges underscores the need for a comprehensive and customized approach to equitable access to health, one that is robustly supported by the digital transformation of the health sector [7]. In this context, AI presents a unique opportunity to facilitate and improve access to health services, making it more equitable, accessible, and personalized, especially for underserved communities.

AI as a Transformative Agent in Reducing Health Care Inequalities

AI's capacity to process and analyze vast amounts of data swiftly and accurately positions it as an invaluable tool in health care. Its applications range from enhancing diagnostic precision to optimizing resource allocation and extending health care reach to remote areas [8]. The implications of these advancements are profound, especially in regions where health care resources are scarce, and the burden of disease is high. AI can play a significant role in making health care more inclusive, accessible, and effective for all segments of the population, particularly in the following areas (Figure 1):

Figure 1. Artificial intelligence (AI) as a transformative agent in reducing health care inequalities.



Health Care Access and Equity Monitoring

AI can analyze health service utilization patterns to identify inequalities in access to care. This information can inform policies and strategies to make health care more equitable. AI algorithms evaluate data on health care use, patient demographics, and service availability. This analysis identifies regions or groups with reduced access, guiding targeted policy interventions to address these gaps [9].

Predictive Analytics for Public Health

AI can analyze data from various sources to predict outbreaks and public health emergencies. This foresight can help in deploying resources more effectively to underserved areas, potentially preventing or mitigating health crises. By aggregating and analyzing health care data, social media, environmental conditions, and other relevant sources, AI models can forecast potential health threats, allowing for proactive resource allocation and emergency planning in vulnerable areas [10,11].

Mental Health Support

AI-driven chatbots and virtual assistants can provide preliminary mental health support, especially in regions lacking mental health professionals. These tools can offer coping strategies, guidance, and early intervention. Utilizing natural language processing and sentiment analysis, AI tools interact with users, offering support, and identifying those who may require urgent care, thereby bridging the gap in mental health services [12,13].

Automated Health Records Management

AI can streamline health records management, ensuring that patient data are accurately recorded and easily accessible. This efficiency can improve health care delivery, particularly in underresourced settings. AI systems automate the sorting, storage, and retrieval of electronic health records, reducing errors and saving time. This enhancement in overall health care efficiency is especially critical in underresourced areas [14,15].

Remote Monitoring and Chronic Disease Management

AI can be used in remote patient monitoring systems to track the health status of patients with chronic diseases, alerting health care providers to changes that may require intervention. AI algorithms analyze data from wearable devices and home monitoring equipment, detecting deviations in health metrics, enabling timely interventions and better management of chronic conditions [8,16].

Enhancing Patient Engagement and Compliance

AI-powered applications can remind patients about medication schedules, appointments, and health check-ups, especially helping those with limited access to regular health care. These AI tools personalize reminders and health tips based on patient data and interaction patterns, increasing adherence to treatment and preventive care routines [17-19].

Optimizing Emergency Response

AI algorithms can help in planning and optimizing emergency medical responses, ensuring quicker and more efficient care delivery during critical situations. By simulating various emergency scenarios and analyzing historical response data, AI can optimize resource allocation, route planning for ambulances, and emergency room preparedness, enhancing the responsiveness of emergency services [20].

Precision Diagnostics

AI algorithms can rapidly analyze complex medical data, leading to more accurate diagnoses and early intervention, especially in areas lacking specialist health care providers. AI models, particularly those trained in image recognition and pattern detection, can assist in diagnosing diseases from medical imagery and lab results with high accuracy, supplementing the expertise in underserved areas [21].

Personalized Medicine

By considering individual genetic, environmental, and lifestyle factors, AI can tailor treatment plans, ensuring each patient receives the most effective care. AI systems analyze patient-specific data, including genetic profiles and health histories, to predict individual responses to different medical treatments, enabling more effective, customized care [22,23].

Resource Allocation

In resource-limited settings, AI can optimize the use of medical supplies and personnel, ensuring the most efficient use of available resources. AI tools forecast health care demands and optimize the distribution and allocation of medical resources, helping to ensure that scarce resources are used where they are most needed.

Telemedicine

AI-enhanced telemedicine can bridge distances, bringing expert medical advice to the most remote corners of the globe. AI supports telemedicine through diagnostic assistance, patient management systems, and enhanced communication tools, making health care accessible in remote and underserved areas.

Education and Training

AI's role in educating health care professionals is invaluable, providing access to the latest medical knowledge and training, irrespective of geographical barriers. AI-driven educational platforms and simulations adapt to individual learning styles and needs, offering health care professionals personalized and up-to-date medical training.

Language Translation and Cultural Sensitivity

AI-powered tools can provide real-time translation services, making health care more accessible to nonnative speakers and reducing cultural barriers. These tools can also be trained to recognize and adapt to cultural nuances in patient care. AI-based translation and cultural sensitivity tools analyze and adapt health care information and interactions to various languages and cultural contexts, thereby enhancing the accessibility and effectiveness of health care services for diverse patient groups.

Facilitating Clinical Trials and Research

AI can assist in identifying suitable candidates for clinical trials, particularly from underrepresented groups, ensuring broader inclusivity in research. AI algorithms analyze vast amounts of health care data to identify potential clinical trial participants, considering various factors like genetic profiles, health conditions, and demographic characteristics. This process helps in creating more diverse and representative participant groups for clinical trials, which is essential for the generalizability and effectiveness of medical research [24,25].

Vaccine Distribution

AI is also revolutionizing the approach to vaccine distribution and management, a crucial aspect of health equity, particularly in the context of pandemics. AI tools and algorithms can optimize vaccine distribution strategies, ensuring that vaccines are delivered efficiently and equitably. AI offers a range of solutions, from predictive analytics for demand forecasting to supply chain optimization, each addressing a key facet of the vaccine distribution challenge. These AI-driven approaches are not only enhancing the effectiveness of vaccination campaigns but also ensuring that high-risk populations are prioritized and that public health messages are communicated effectively.

Discussion

AI's Role in Ensuring Equitable Cancer Care

The rapid advancement of AI in health care, particularly in the fight against cancer, has sparked new expectations about its capabilities. However, it is crucial to critically examine AI's role in ensuring equitable cancer care. This discussion emphasizes the necessity for AI models to incorporate globally diverse data, highlighting the need for inclusive development practices and an ethical commitment to making these potentially life-saving technologies accessible to all, not just a select few. It underscores the importance of considering a wide range of genetic and environmental factors, as well as the need for data that universally represents diverse populations. These considerations form a compelling case for a holistic and fair approach. As we progress in applying AI to cancer research, we must also strive to realize a future where advanced cancer treatments are both effective and equitable for every individual, irrespective of their geographic location or socioeconomic status. Some particular reflections are highlighted below.

Equity in AI Development: Serving All Communities in the Technological Era

It is essential that emerging technologies are not shaped only by technology companies and those in wealthy countries. If models are not trained on data from people in underresourced places, those populations might be poorly served by the algorithms. AI development must prioritize inclusivity, ensuring that datasets reflect the global population's diversity. This inclusivity extends beyond data collection to involve collaboration with local health care providers and communities to understand and address unique health care challenges. The integration of diverse data sources can improve the robustness and accuracy of AI models, leading to more effective and equitable health care solutions [26,27].

Global Perspectives in AI: Bridging the Gap in Cancer Care

It is imperative that AI technologies are developed with a global perspective. Ensuring that AI models incorporate diverse datasets, including those from less affluent regions, is not just an ethical imperative but necessary for providing equitable health care outcomes for all. Global collaboration in AI research and development can bridge the gap in cancer care by sharing knowledge, resources, and best practices across borders. Such efforts can lead to AI tools that are adaptable to various health care settings and capable of addressing the unique needs of different populations [28,29].

Data Diversity: The Key to Personalized AI in Oncology

For AI to truly be a force for good in cancer treatment, we must broaden the scope of data collection to encompass the varied genetic and environmental factors present in all communities, offering precise and personalized care to every patient regardless of their geographic or socioeconomic factor. Diverse data sources, including genomic data, clinical records, and environmental exposure information, can enhance AI's ability to identify risk factors, predict disease progression, and tailor treatments to individual patients. This approach ensures that AI-driven cancer care is not only precise but also personalized, improving outcomes for patients worldwide [30].

Mitigating Bias in AI Algorithms

Bias in AI algorithms can significantly affect health care outcomes, particularly for underserved and marginalized communities. Addressing this issue requires comprehensive strategies to ensure AI systems are equitable and devoid of discriminatory biases. One critical approach is to use diverse and representative datasets, actively collecting data from underrepresented groups to create inclusive AI models. Additionally, implementing robust bias detection and correction methods, such as fairness-aware machine learning, helps identify and rectify biases in data and algorithms. Enhancing transparency and explainability allows stakeholders to understand AI decision-making processes, ensuring greater accountability. Inclusive development practices, involving ethicists, sociologists, and representatives from marginalized communities, provide valuable insights to address potential biases. Establishing comprehensive ethical guidelines and frameworks is essential to address issues like data privacy, informed consent, algorithmic transparency, and accountability [31,32].

Diversifying AI Learning to Combat Health Care Inequalities in Cancer

The effectiveness of AI in cancer care hinges on the diversity of its learning. Without incorporating data from underrepresented groups, we risk perpetuating existing health care disparities. Therefore, it is our collective responsibility to ensure that AI systems are as diverse as the populations they aim to serve [33].

Cultural Convergence and the Use of AI in Cancer Treatments

It is essential to consider cultural differences, which could, in some cases, be subtle but significant, as they influence the manifestation of the disease, responses to treatment, and patient care preferences. AI models must not only be trained on diverse data sets but must also be sensitive to the cultural contexts that shape health behaviors and outcomes. This approach reinforces the need for multifaceted equity that goes beyond data diversity to encompass the entire human experience in cancer treatment. Culturally sensitive AI models can improve patient engagement, adherence to treatment protocols, and overall satisfaction with care, leading to better health outcomes [34,35].

Telemedicine and Remote Monitoring

AI-enhanced telemedicine can bridge distances, bringing expert medical advice to the most remote corners of the globe. AI supports telemedicine through diagnostic assistance, patient management systems, and enhanced communication tools, making health care accessible in remote and underserved areas. Remote monitoring systems powered by AI can track the health status of patients with chronic diseases, alerting health care providers to changes that may require intervention. This continuous monitoring can prevent complications and reduce the need for hospital visits, thus alleviating the burden on health care systems and improving patients' quality of life [8,16].

Education and Training

AI’s role in educating health care professionals is invaluable for all areas, providing open and real-time access to the latest medical knowledge, training materials, and learning objects, irrespective of geographical barriers. AI-driven educational and simulation platforms adapt to individual learning styles and needs, offering health care professionals personalized and up-to-date medical training. This approach ensures that all health care workers, regardless of their location, have access to the best practices and emerging knowledge in cancer care, enhancing the overall quality of care provided to patients [36].

Resource Allocation and Optimization

AI can play a critical role in optimizing resource allocation in health care settings, particularly in underresourced regions. Through the examination of patterns in health care utilization, AI can identify areas where resources are most needed and predict future demands. This capability is crucial for efficient health care delivery, ensuring that medical supplies, personnel, and infrastructure are utilized optimally. For example, AI algorithms can help in planning and optimizing emergency medical responses, ensuring quicker and more efficient care delivery during critical situations. This optimization can significantly enhance the responsiveness of health care systems, especially in emergencies, ultimately improving patient outcomes [20].

By analogy with precision medicine, precision public health has been conceptualized as the practice that aims at multidimensionally characterizing social position and accurately pinpointing mechanisms to reduce health inequities [37]. AI can play a crucial role in providing ever greater precision in public health, inasmuch as it directs its prodigious capabilities toward ensuring their equitable distribution across populations and territories. In the context of exceedingly unequal societies with highly segmented and fragmented health care systems, under the rule of the inverse health equity law [38], it is worth recalling the four equity considerations for the use of AI in public health, proposed by Smith et al [39] as the starting point for the promotion of equitable AI in public health—the digital divide, algorithmic bias and values, plurality of values across systems, and fair decision-making procedures. It should be quite clear that strengthening equity monitoring is paramount when introducing AI technologies to make sure they do not inadvertently increase or create inequities [40].

Case Studies of AI Implementation in Health Care

Real-world examples of AI implementation in health care provide concrete evidence of its impact on reducing disparities and offer valuable insights into best practices, challenges encountered, and strategies for overcoming these challenges. One notable example is the use of AI in breast cancer screening in the United States. Researchers developed an AI model that outperformed radiologists in detecting breast cancer from mammograms, demonstrating the potential for AI to enhance diagnostic accuracy and reduce diagnostic disparities [41]. Another significant case is Artemisia, a deep-learning model developed at the Hospital Italiano de Buenos Aires for automatic breast density categorization. Artemisia was validated using 10,229 digital screening mammogram images to classify breast density according to the American College of Radiology’s patterns. This AI system showed significant accuracy, achieving professional-level performance when compared to the majority reports and a commercial software application [42].

A Call for Collaborative Action

To harness the power of AI in creating a more equitable public health landscape, a concerted, collaborative, and multidisciplinary approach is essential. This initiative calls for a synergy of efforts from various stakeholders in the health care ecosystem. Policy makers, health care providers, AI technology experts, patient advocacy groups, and community leaders all play pivotal roles in shaping how AI is integrated into health care systems. Engaging with policy makers is crucial for establishing regulations and guidelines that ensure the ethical use of AI and addressing critical concerns, such as data privacy, patient consent, and algorithmic transparency. Health care providers, on the front lines of patient care, offer invaluable insights into practical needs and challenges, ensuring that AI solutions are tailored to real-world applications and are patient centric. Collaboration with AI technology experts, including data scientists and engineers, is fundamental for developing robust, accurate, and reliable AI systems. Their expertise is vital in translating health care needs into technological solutions that are both innovative and practical. In addition, it is essential to involve patient advocacy groups and community leaders, particularly from underserved and marginalized populations. Their perspectives and experiences are crucial in identifying and addressing specific health disparities, ensuring that AI solutions are inclusive and equitable. Ethical considerations, such as addressing biases in AI algorithms and ensuring equitable access to AI-enhanced health care, are paramount. Data privacy remains a top concern, especially in handling sensitive health data. Mitigating potential risks, such as unintended consequences of AI decisions or misuse of AI technologies, requires comprehensive strategies and constant vigilance [17].

The Path Forward

The digital transformation in the health sector is not only about how to use information and communication technologies as supporting tools or about technological modernization alone. Digital transformation is a cultural change that must consider new health care models, process reengineering, systems reorganization, and a deeper understanding of people’s behavior and digital skills. Likewise, such transformation requires a new multisectoral and interdisciplinary approach in the development and implementation of public policies, regulatory frameworks and national digital literacy programs [36].

In this evolving landscape of health care and looking at more resilient health systems, it is crucial to position AI as a critical agent in reducing health disparities. AI’s role should be seen not as replacing human expertise but as augmenting the capabilities of health care professionals, enabling them to deliver more effective and inclusive care. The integration of AI into health care systems is a promising stride toward democratizing health care access and removing barriers related to geography, socioeconomic status, and cultural differences. AI's potential in identifying and addressing health disparities is profound. Through advanced data analysis and predictive capabilities, AI can illuminate hidden patterns of inequality, guiding targeted interventions where they are most needed. For instance, AI can help tailor public health strategies to address the specific needs of underserved communities, ensuring that preventive care and medical treatments are not only available but also resonate with diverse cultural and socioeconomic contexts. Moreover, AI's role in enhancing diagnostic accuracy, personalizing treatment plans, and improving patient engagement offers a direct pathway to narrowing the health equity gap. AI, through the timely provision of quality medical care to all persons irrespective of background, works as a key driver toward an equalized health care platform. The adoption of AI in health care is not just a technological shift; it represents a fundamental step toward a health system in which equity and inclusivity are considered key factors for success. AI in cancer treatment offers new opportunities to create a future of health where access to services is possible for every individual who needs it, wherever they need it [43].

Conclusions

The exploration of AI in cancer care underscores its potential to bridge health care disparities through enhanced diagnostic accuracy, optimized resource allocation, and improved access to care, particularly in underserved communities. Key applications, such as AI-driven health equity monitoring, predictive analytics, mental health support, and personalized medicine, highlight AI's transformative role. Case studies like the AI model for breast cancer screening in the United States and Artemisia at the Hospital Italiano de Buenos Aires illustrate successful implementations. However, achieving equitable AI integration requires addressing biases, ensuring data diversity, and fostering inclusive development practices. It is crucial to consider local social, cultural, and political contexts to tailor AI solutions effectively. Additionally, more high-quality and disaggregated data at the local level is needed to enhance AI's accuracy and relevance. Continued research, multidisciplinary collaboration, and ethical considerations are essential for overcoming implementation challenges and maximizing AI's benefits in cancer care.

Conflicts of Interest

None declared.

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Abbreviations

AI: artificial intelligence

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Viewpoint

Lessons Learned From Shared Decision-Making With Oral Anticoagulants: Viewpoint on Suggestions for the Development of Oral Chemotherapy Decision Aids

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Abstract

Oral chemotherapy is commonly prescribed, and by using decision aids (DAs), clinicians can facilitate shared decision-making (SDM) to align treatment choices with patient goals and values. Although products exist commercially, little evidence informs the development of DAs targeting the unique challenges of oral chemotherapy. To address this gap in the literature, our objective was to review DAs developed for oral anticoagulation, DA use in oncology, and patient preference surveys to guide the development of DAs for oral chemotherapy. We focused on reviewing SDM, patient preferences, and specifically the development, efficacy, and patient experience of DAs in oral anticoagulation and oncologic conditions, ultimately including conclusions and data from 30 peer-reviewed publications in our viewpoint paper. We found that effective DAs in oral anticoagulation improved knowledge, lowered decisional conflict, increased adherence, and covered a broad range of SDM elements; however, limited information on patient experience was a common shortcoming. In oncology, DAs increased knowledge and aligned decisions with the values of the patients. Ineffective oncology DAs provided general, unclear, or overly optimistic information, while providing "too much" information was not shown to do harm. Patients preferred DAs that included pros and cons, side effects, questions to ask, and expected quality of life changes. In developing DAs for oral chemotherapy, patients should be included in the development process, and DA content should be specifically tailored to patient preferences. Providing DAs ahead of appointments proved more effective than during, and additional considerations included addressing barriers to efficacy. There is a need for evidence-based DAs to facilitate SDM for patients considering oral chemotherapy. Developers should use data from studies in oral anticoagulation, oncology, and preference surveys to optimize SDM.

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KEYWORDS

shared decision-making; SDM; decision aids; decision aids design; oral chemotherapy; oral anticoagulants; drug delivery; chemotherapy; chemo; anticoagulants; drug deliveries; cancer; oncology; oncologist; metastases; literature review; literature reviews

Introduction

Oral systemic treatment is becoming an increasingly common modality of anticancer therapy [1]. It may be preferred to traditional intravenous administration due to patient convenience, its noninvasive nature, the safety of prodrugs relative to intravenous "full drugs," and reducing the costs that accompany additional outpatient appointments and inpatient resource usage [2]. However, it is not without its drawbacks. Adherence can be difficult, absorption can be variable, and administration may be impossible in patients with dysphagia. In addition, administration may be confusing for patients, for example, some drugs (sorafenib) present challenges when taken with food while others (imatinib) must be taken with food [2].

Shared decision-making (SDM), a process through which providers and patients weigh evidence and make decisions together [3] that is becoming increasingly important in clinical practice, can help patients balance these strengths and shortcomings. Studies have shown that patients like playing an active role in care-related decision-making [4,5], clinician education is becoming geared toward facilitating SDM [6], and a lack of SDM has been associated with lower medication adherence, even when concrete decisions are made [7]. To help facilitate SDM, interventions such as mobile apps, videos, or informative visuals, known as decision aids (DAs), can provide patients with information regarding treatment options, their associated risks and benefits, and how drug administration aligns with a patient's goals and values [8].

In oncology, DAs have been used since at least the advent of the "Decision Board" in 1992 for adjuvant chemotherapy in node-negative breast cancer [9,10], and although considerable research exists on their use and efficacy in oncology as a whole, and products do exist commercially [11], there is little in the current literature examining the development and efficacy of DAs targeting the unique challenges of oral chemotherapy. This article addresses this gap by reviewing what is known about the use of DAs in oncology and using the example of oral anticoagulation DAs to examine how they may be best leveraged to facilitate SDM in oral chemotherapy.

Decision Aids in Oncology: Patient Preferences, Successes, and Shortcomings

In considering how to approach the development of a DA for oral chemotherapy, we should first consider the preferences of the target population and how DAs have been successfully implemented in the field of oncology. A study involving patients with all tumor types revealed that patients want their DAs to be specific, which may include the pros and cons of each treatment choice and a list of questions to ask their provider [4]. Another study, although only specific to men with prostate cancer, indicated that patients like when DAs include information regarding potential side effects and a clear discussion of the expected quality of life resulting from treatment [12]. These findings could be especially important for patients considering oral chemotherapy, as focusing only on deciding between systemic therapy as a general category versus surgery or observation may miss the unique factors that make a rigid, daily oral medication schedule challenging when compared with hospital-based intravenous treatment. Expected quality of life may be of particular importance to this patient population, as prostate cancer has a more favorable prognosis than many other malignancies. However, it stands to reason that it could be important to patients with less favorable prognoses as well, especially when considering whether they would like such therapy to be a part of the time that they do have left. In addition, patients report that they prefer DAs that are targeted to their specific needs [4], which may extend beyond only their disease process, as there have been calls for DAs in oncology to account for the diversity of patient populations [13].

Regarding how much information to disseminate to patients, a study of men with advanced cancer found that full discussions regarding prognosis decreased depressive symptoms; however, patient anxiety was found to be higher if the clinician felt that such a discussion had taken place [14]. However, it should be noted that this study did not address baseline anxiety or depression before their diagnosis. While this study was specific to men, another study that included men and women found that clinician-driven encouragement to participate in treatment decisions was associated with increased patient anxiety persisting after a 2-week period, suggesting that this change may be independent of baseline anxiety [15]. This raises some concern that providing too much information and involving patients more in decisions regarding their care could be overwhelming or distressing and could ultimately do more harm than good. However, Cripe et al [14] suggest that such results may be due to the content of the provider's encouragement and discussion: it may not align with patient preferences and therefore contribute to anxiety development. This is supported by the findings of Gattellari et al [15] that information disclosure itself was not associated with increased anxiety. Ultimately, Cripe et al [14] propose that patient anxiety is a signal that further discussions regarding patient goals and preferences should occur. DAs may help facilitate such discussions by including surveys that specifically elicit individual patient values [16], and multigender studies in patients with advanced cancer, including a systematic review, have shown that providing more information through DAs does not do harm [17,18]. Likewise, although it has been observed that patients with advanced gastrointestinal cancer reported lower quality of life scores and higher anxiety if they acknowledged that their illness was terminal [19], DAs can help mitigate this as well, as it has been shown through a meta-analysis of 16 studies of adult patients of varying tumor types that DAs may help reduce anxiety and fear, especially in newly diagnosed patients [16]. Finally, for many patients, additional information may be seen as a positive: 1 study, which interviewed 27 patients with cancer, found that patients nearly always wanted to know as much as possible about cancer as a whole, their prognosis, treatment benefits, and side effects [20].

DAs in oncology have been reported acceptable by both patients and providers [21], have been shown to increase patient knowledge [9,16], and lower decisional conflict, aligning patients' ultimate decisions with their personal values [16,22]. In addition, DAs in cancer care have been shown to increase patient satisfaction with both the information presented and their treatment decision [4,9,16]. However, it is worth acknowledging that the mere presence of a DA is insufficient. A study of a DA for oral complementary and alternative medications for patients on chemotherapy, which provided predominantly general information, did not help decrease decisional conflict or patient regret [23]. DAs presenting unclear or overly optimistic information, especially regarding side effects, have been shown to provide patients with a worse experience, as this can lead to a misperception of the risks and benefits of treatment and may ultimately affect decision-making [17].

Oral Anticoagulation Decision Aids as a Model

With similar treatment schedules, required monitoring, and experience of self-administering medication, oral anticoagulation presents similar advantages and challenges to oral chemotherapy. As significant data exists regarding the efficacy and implementation of DAs in oral anticoagulation, these findings can be used to help inform the development of evidence-based DAs in oral chemotherapy. Using DAs in oral anticoagulation has been shown to help with improving patient knowledge [21,24,25], lowering decisional conflict [21,24-27], increasing medication adherence [24], and increasing the likelihood of making a choice [25].

Oral anticoagulation DAs considered effective, defined as improving health outcomes or at least increasing or enhancing SDM, have focused on covering a broad range of 6 SDM elements, that are situation diagnosis, choice awareness, option clarification, discussion of harms and benefits, deliberation of patient preferences, and decision-making [24]. In a study of 10 DAs in which 7 were deemed successful, 6 included discussions of harms and benefits and at least one of choice awareness and deliberation of patient preferences. This suggests that, although all merit inclusion, these 3 may be the most critical to consider when developing DAs for patients contemplating oral therapy [24].

Oral anticoagulation DA studies can also demonstrate what has not been successful in DA development. Logically, including a narrower range of the 6 elements of SDM does not support efficacy [24]. In addition, a review of 14 SDM tools focused on choosing between Warfarin and direct oral anticoagulants from Torres Roldan et al [28] showed that the current DA developmental process rarely includes patients. The studies observed were overall unsuccessful, as only 2 of the 14 DAs reviewed improved adherence, and 3 of the 14 did not support SDM. The authors note that a common shortcoming of these DAs was that they lack information on the day-to-day patient experience, including “what it means to take a pill every day” and “what it takes to attend periodic clinic appointments” [28]. This demonstrates that, despite the fact that they usually did include good information regarding treatment options, outcomes, prognosis, costs, dosing, and side effects, these DAs may have fallen short of their potential maximum effect [28]. Involving the patient in the developmental process could help fine-tune DA content to include information that will most benefit patients.

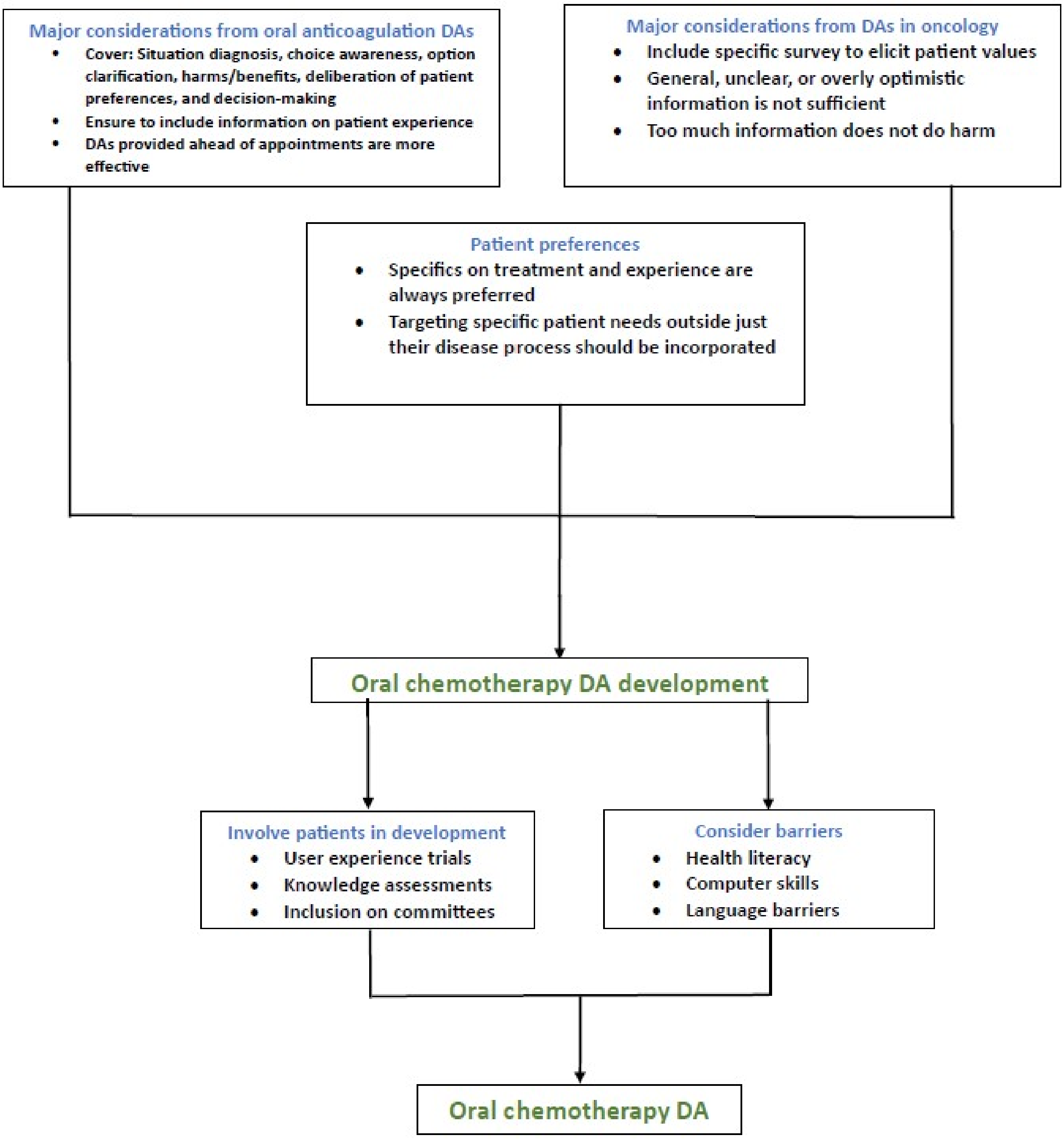
Although it should be noted that the disease processes themselves (hypercoagulable state vs malignancy) carry significantly different clinical implications, which could influence patient priorities when using DAs, the advantages and challenges of the administration of oral anticoagulation and oral chemotherapy are similar. Therefore, this information should be used in conjunction with what is known about DA use in oncology to develop DAs ideally suited for patients with cancer contemplating oral therapy.

The Ideal Design of an Oral Chemotherapy Decision Aid

Patient Involvement in Decision Aid Development

Data regarding patient preferences, current DA use in oncology, and DAs in oral anticoagulation serve as a framework for informing what the development, implementation, and DA product itself should look like for oral chemotherapy (Figure 1). Most importantly, patients should be involved in the developmental process from its early stages. Doing so would help direct focus toward user experience, and it also allows for early identification of issues and provides time for modifications. For example, a common shortcoming of DAs in both oncology and oral anticoagulation is that they can lead patients to have an inadequate perception of risk [17,26]. It has been shown that involving patients early can help minimize this; for example, 1 DA for oral anticoagulation, which did have patients involved during development, identified this issue early in the process, and developers were able to adjust by incorporating a user-friendly, color-coded visual depiction of risk level in the next version of the application [26]. In addition, although DAs often improve patient knowledge [9,16,21,24,25], 1 study on DAs for second-line palliative chemotherapy demonstrated improved subjective knowledge, which is the patient’s perception of their own understanding, but not objective knowledge [17]. We propose that the difference between the 2 could be teased apart by running pilot tests, including knowledge assessments, with patients during the developmental process. These assessments should be geared toward answering the question “Does this convey the information necessary for a patient to make an informed decision?” If not, modifications can be made.

Figure 1. Schematic of major considerations in the development of decision aids for oral chemotherapy, demonstrating the use of knowledge gained from decision aids in oral anticoagulation, oncology, and patient preference surveys in the predevelopment process and the involvement of patients and consideration of barriers in the development process. DAs: decision aids.



Tailoring Decision Aids to Patient Needs

Regarding the dissemination of information, DAs should be targeted to specific patient needs and include specific information, including regarding side effects, which has been shown to be important for patients with cancer [4,12]. Surveys incorporated into a DA's interface that elicit user values can help, especially in selecting a treatment that best aligns with their values. However, the challenge of integrating a simple, user-friendly interface with sufficient detail to provide patients with the information necessary to make complex medical decisions remains. A small pilot study of just 27 patients of varying genders, educational backgrounds, and tumor types did find that nearly all of their patients preferred to know as much as possible [20], but health literacy may vary, and different patients may require or prefer different levels of nuanced discussion. An example of a successful DA for oral anticoagulation included a multi-tiered system in which the main points were presented on one page, and additional links were included that provided options for patients to receive more granular, detailed information if they chose [26]. This should serve as a framework for the development of any DA for similar treatment modalities, including oral chemotherapy, as it can help disseminate an appropriate level of information to a large range of patients. For example, it would be essential for all patients to understand "what it means to take a pill every day," as described by Torres Roldan et al [28], and this, along with basic side effect information, could be included on the main page. Meanwhile, the "linked" pages could have detailed example schedules for both dosing and follow-up appointments, explanations of drug mechanisms, and detailed side-effect profiles.

Inclusion of Rarer Diseases

Tailoring DAs to the specific needs of patients [4] should include developing aids for less common indications and treatment options. A systematic review on DAs for SDM in urologic malignancies found 22 DAs available for prostate cancer and just 2 for renal cancer and 1 for bladder cancer [29], demonstrating a need for DAs in rarer diseases. Another systematic review that examined DA use in decisions that include "active surveillance" as a management option found that, despite active surveillance being used in colorectal, thyroid, and head and neck cancer management, 21 of the 23 included studies were focused specifically on prostate cancer [30], which also suggests a need for further investigation of DA use in a wider spectrum of malignancies. In developing DAs for oral chemotherapy, consideration should be given to rarer indications and diseases. Incorporating additional links within the interface of an app directed at a specific therapy could be one method of including information that may be critically relevant to a subset of patients with a particular disease or comorbidity. It bears mentioning that such considerations, while mentioned in this context specifically for oral chemotherapy, may also benefit patients in oncology as a whole, as options for patients with rarer diseases often extend beyond only the nuances of oral treatment and may require further education that has thus far been marginalized in DA development.

Addressing Barriers to Success in the Clinical Setting

Developing successful DAs for oral chemotherapy also requires considering potential barriers to efficacy. If not considered during development, language and computer literacy can present challenges, so alternative methods of delivering information [16] within the same interface may be necessary because the information is useless if it is not accessible. Incorporation of an audio option within an app could be an example, and although additional studies would be needed to examine the relative efficacy of audio versus textual dissemination of information, this is yet another reason to involve patients in the development and testing processes. In addition, although it has been shown that DAs can be effective in populations of lower socioeconomic status [21,26], this also requires targeted delivery, as patients may have limited funds for an application or downloadable content. One proposition to address this includes preloading health-related content on mobile devices analogous to how many cell phones are preloaded with games; alternatively, DAs could be presented as open-access downloadable content [31]. Similar to using DAs for rarer diseases, it should be noted that addressing barriers to access and optimal information delivery is not specific to oral chemotherapy and can have wide-reaching implications in DA development in oncology and beyond.

Timing of Decision Aid Delivery

Essential consideration should also be given to the timing of DA presentation to patients. Current literature shows that doing so before a treatment consultation or discussion provides an evidence-based method of maximizing efficacy. Again, using oral anticoagulation as a model, the study by Song et al [24] of 10 DAs that found 7 to be considered "effective" demonstrated that all 3 ineffective DAs were given to patients during a consult, while 5 of the 7 effective ones were provided in advance. In other words, all 5 DAs provided ahead of a consult were effective, while only 2 of the 5 provided during the consult were. The authors postulate that this is because patients have time to digest information ahead of their appointment [24], and another potential factor may be that doing so allows for time to formulate clarifying questions [16], especially since patients have indicated that they like when DAs include a list of questions worth asking their provider [4]. Literature also shows that, for patients with cancer, the use of DAs can also help increase caregiver involvement [16]. Providing DAs ahead of a consult would increase opportunities for patients to discuss their thoughts, preferences, and concerns with caregivers and family members if they choose. Importantly, consideration should be given to the possibility of increased anxiety that may occur if patients are encouraged to participate in their care before the eliciting of patient preferences [14]. It would likely be important to include an accompanying note that briefly describes the type of information included in the DA and an explanation that its contents could be reviewed at the appointment if the patient would prefer to go over it with a clinician first. This would provide patients with the opportunity to review in advance and maximize potential efficacy, but it would also provide a safeguard of an initial review with their provider if they would prefer.

Further Investigation

Once the initial developmental process is complete, trialing the DA could commence. User experience trials evaluating DA design, experience with the interface, and perceptions of ease of use would likely occur first and would be best optimized with user response surveys. To optimize feedback and maximize the impact of patient perspectives, qualitative and quantitative data should be collected. Panels that include user experience specialists, product designers, physicians, and volunteer patients could then meet on developmental committees to fine-tune the pilot DA based on this feedback. Although practical considerations would likely limit patient selection at this stage to a convenience sample, it would provide valuable insight into the patient experience of using the DA before optimizing its clinical use.

This would be followed by knowledge assessments conducted through randomized controlled trials in a simulated environment. Knowledge retention would be compared between individuals provided information through standardized clinical encounters with a physician versus those who were also provided with the DA. If this trial demonstrates efficacy (improved SDM), the product then can move to clinical practice in select environments, with ongoing quality improvement studies to optimize their use. These would ideally be set up as prospective cohort studies but could also use a case-control or retrospective cohort design if institution-specific questions regarding their use and implementation arise.

In addition, many questions remain unanswered, warranting further critical discussion and investigation. Providing DAs ahead of appointments may be beneficial relative to during appointments [24], but is there a need for further outreach to maximize the uptake rate and limit potential patient anxiety? Although difficult to concretely define the specific needs of individual patients [4], would involving technological user experience specialists in development help get us closer to doing so? As Bennett et al [13] allude to, how can we leverage DAs to address inherent shortcomings in communication, especially bias, from the clinician side?

Limitations

As this paper is presented as a viewpoint, a review of relevant literature was conducted in a nonsystematic manner. This may subject the paper to reviewer bias and does render it possible that potentially pertinent articles were not included. However, the purpose of this viewpoint and the associated literature review is not to provide a definitive, comprehensive state of multiple fields, as there is no extant literature on the development and implementation of DAs for oral chemotherapy. Rather, its purpose is to take the initial steps to address this gap in the literature by using evidence from related fields (DA use in oncology and oral anticoagulation) to provide suggestions for the development of oral chemotherapy–specific DAs. Ultimately, its aim is to inform future research so that evidence-based guidelines may be developed in the future.

Conclusions

There is a need for evidence-based, effective DAs to facilitate SDM for patients considering oral chemotherapy. Important considerations in the development of these DAs include including a broad range of SDM elements, involving patients in the development process, tailoring content to specific patient needs, and anticipating and addressing potential barriers to efficacy. Further research is needed to investigate the efficacy of DAs developed specifically for oral chemotherapy.

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Authors' Contributions

DEM, FMME, and SMB conceived the project. DEM conducted a literature review. DEM wrote the original draft. DEM, FMME, and SMB critically revised the manuscript. SMB provided oversight for the project. DEM, FMME, and SMB provided approval for the publication of the content.

Conflicts of Interest

SMB has consultancy roles with Chiesi, Inc, Bluebird Bio Inc, Vertex Pharmaceuticals Inc, Forma Therapeutics – Novo Nordisk, Global Blood Therapeutis – Pfizer, Bristol-Myers Squibb, and Editas Medicine. DEM and FMME have declared no conflicts of interest.

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Abbreviations

DA: decision aid
SDM: shared decision-making

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Viewpoint

Impact of Patient Personality on Adherence to Oral Anticancer Medications: An Opportunity?

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Abstract

Adherence to prescribed oral anticancer therapy is an important determinant of patient outcomes, including progression-free and overall survival. While many factors (eg, medication side effects and out-of-pocket costs, problems with insurance authorization, and timely medication refills) can affect adherence, one that is relatively unexplored is the impact of a patient's attitude and personality. Patient personality influences medication adherence and persistence in nonmalignant chronic conditions such as cardiovascular disease and diabetes. In breast cancer and chronic myeloid leukemia, studies suggest that personality also affects adherence to oral chemotherapy which can be targeted to improve adherence. In this viewpoint, we highlight the opportunity of incorporating patient personality as interventions to oral cancer therapy adherence and discuss current barriers to implementation.

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KEYWORDS

cancer; medication adherence; medication persistence; Five-Factor Model; Type D personality; oncology; cancer medications; oral anticancer therapy; chemotherapy

Introduction

With acceleration in development of oral anticancer medications in recent years, a substantial number of patients with cancer are responsible for managing their medication. While oral anticancer medications have many advantages over parenteral chemotherapy, including eliminating the need for venous access devices, many patients struggle with adhering to their prescribed regimens. Whereas medication adherence rates among patients with chronic diseases on oral treatment are estimated at approximately 50%, adherence rates for oral anticancer medications are substantially lower, with studies reporting adherence rates as low as 30% to 46% in patients with cancer [1-3]. Similarly, persistence to oral anticancer medications, defined as continuing treatment for the prescribed duration of therapy, is also suboptimal; for example, at 12 and 24 months, treatment persistence in patients with gastrointestinal stroma tumors and chronic myeloid leukemia was reported to be 41% and 56%, respectively [4]. These are concerning statistics given that poor adherence to prescribed cancer therapy can lead to serious consequences such as disease progression, reduced treatment efficacy, increased symptom burden, an increased risk for recurrent cancer, and decreased overall survival [5-7].

Many patient-related factors can contribute to nonadherence and nonpersistence to prescribed therapies, including health literacy [8], social determinants of health including food insecurity and housing instability [9], out-of-pocket medication costs [10,11], patient age [12,13], number of prescribed medications [14], and medication side effects [15-17]. However, the impact of patient personality and psychosocial characteristics has remained relatively underexplored [18-22]. In this viewpoint, we review literature on the impact of personality on medication adherence and argue that developing patient education that is tailored toward each individual patient's personality may improve anticancer medication adherence.

Assessment of Personality Types

The psychological literature frequently assesses personality using the Five Factor Model (FFM) [23]. Also known as the universal model, the FFM is one of the most empirically supported personality models to date and consists of 5 personality categories (Table 1): openness, conscientiousness, extraversion, agreeableness, and neuroticism. An alternative model recognizes 4 personality types (types A, B, C, and D) [24]. The original categories of type A (competitive, ambitious) and type B (patient, creative) were first defined and studied in patients with cardiovascular disease [25], and were subsequently expanded to include types C (analytical, introverted) and D (anxious, negative). In particular, the type D personality is a trait associated with negative emotions such as worrying, and a lack of social interaction out of fear of disapproval (Textbox 1) [26-28]. The relationship between the FFM and ABCD personality models has not been fully defined, but type D subjects display FFM traits ranging from neurotic introversion with relatively low conscientiousness to stable extraversion with relatively high conscientiousness [29]. The Eysenck personality theory recognizes personality traits across 3 dimensions, extraversion/introversion, neuroticism/stability, and psychoticism/superego [30], and is commonly assessed using the Eysenck Personality Questionnaire-Revised Short Scale [31].

Table 1. The Five Factor personalities and associated adjectives (adapted from [23]).

Personality	Adjectives
Openness	Artistic, curious, imaginative, insightful, original, and wide interests
Conscientiousness	Efficient, organized, planful, reliable, responsible, and thorough
Extraversion	Active, assertive, energetic, enthusiastic, outgoing, and talkative
Agreeableness	Appreciative, forgiving, generous, kind, sympathetic, and trusting
Neuroticism	Anxious, self-pitying, tense, touchy, unstable, and worrying

Textbox 1. Characteristics of type D personality [26].

Type D traits

- Tendency to experience negative emotions.
- Propensity to suppress the expression of emotions and behaviors in social contacts.
- Feeling of unhappiness, worry, irritability, and low self-esteem.
- Distance in social relations, introversion.

Impact of Personality on Medication Adherence in Cardiovascular Disease and Diabetes

Association between patient personality assessed by the Five Factor Model and medication adherence has been studied in patients with cardiovascular disease [32]. In a recent study, patient personality was measured using the Japanese Ten-Item Personality Inventory for evaluation of the Big Five personality traits. A 12-item adherence scale measured medication compliance, health care provider collaboration, willingness to access medication information, and acceptance of needing to take medication. Having higher conscientiousness was significantly associated with greater medication compliance, patient-provider–shared decision-making, and willingness to access information about medications [32]. Conscientiousness has also been associated significantly with health-related quality of life, self-efficacy, and satisfaction with life in patients with cardiovascular disease [33]. The type D personality trait, a measure of low social interaction and negative affectivity, is frequently observed in patients with cardiovascular disease [34,35]. Type D individuals have significantly poorer medication adherence patterns in patients with myocardial infarction [36], heart failure [35,37], and acute coronary syndrome [38]. This is in addition to the type D personality being a significant predictor of mortality in patients suffering from coronary heart disease [34].

Another common disease where medication adherence and personality have been studied is diabetes. Low adherence is a known issue in diabetic patients, leading to increased adverse outcomes such as higher hemoglobin A_{1c} (HbA_{1c}) levels and peripheral neuropathy [39]. More recently, studies have investigated the role the Five Factor personalities have in diabetes [40,41]. In one study, diabetics determined to possess the neuroticism trait based on the Eysenck Personality Questionnaire-Revised Short Scale were significantly less likely to be adherent to medication in bivariate analyses. The authors hypothesized an indirect relationship between adherence and neuroticism mediated through neuroticism's association with a lack of social support and self-efficacy [40]. Another study also showed a significant negative relationship between neuroticism and adherence along with self-care behaviors [41], but found a significant positive relationship between agreeableness and adherence. Finally, conscientiousness has also been demonstrated to be significantly positively correlated to taking medications as prescribed in type 2 diabetics [42]. These trends are not exclusive to type 2 diabetes, as adolescents with type 1 diabetes who possessed the conscientiousness trait were significantly more adherent to insulin administration while those with the neuroticism trait showed a significantly negative correlation [43]. Like cardiovascular disease, type D personality has also been linked to poor medication adherence in type 2 diabetics [44,45] and to be associated with increased HbA_{1c} [45].

Medication Adherence and Personality in Patients With Cancer

As in other chronic nonmalignant diseases, nonadherence and nonpersistence to oral anticancer medication can be associated with multiple patient-related factors, some of which may be specific to the type or stage of cancer diagnosis or the duration of the prescribed therapy. The mental impact that accompanies a diagnosis of cancer may trigger or exacerbate behaviors that tend to be associated with the specific personality type of a patient [46-48]. For example, it is possible that some patients with aspects of the type D personality may express negative social and affective traits when confronted with cancer. Relative to other chronic diseases like hypertension and diabetes, cancer therapy is unique in that patients are dealing with an imminent life-threatening condition with medications where the drug choices may be limited, and the side effects are substantial. Indeed, many studies in cancer patients identify medication side effects to be a major factor contributing to poor adherence and persistence [3,49-51]. It follows that a patient's attitude and personality might have a major effect on coping with such symptoms. However, literature examining personality traits and adherence in patients with cancer is limited. A study that examined the link between the Five Factor Model and adherence to outpatient cancer therapies suggested that the 2 personality types of conscientiousness and agreeableness correlated with increased adherence [52], but the specific types of cancer and treatments were not explored in detail. Other studies have focused on aspects of a patient's emotional state rather than on personality traits per se, as a functional relationship between personality type and the regulation of emotions has been documented [53-55]. For example, a review of psychosocial determinants of adherence to oral anticancer treatment found high levels of distress (anxiety and depression) to be a major factor contributing to nonadherence [56]. Medication beliefs have also been found to impact adherence to cancer medications [50,57-59].

Two cancer types where adherence has been studied in significant detail are early-stage breast cancer and chronic myeloid leukemia [7]. Patients with either of these vastly different malignancies share 2 characteristics: minimal symptoms arising from the cancer itself and a major impact of medication nonadherence on progression-free and overall survival. Patients with early-stage hormone-receptor positive breast cancer are frequently treated with oral medications targeting estrogen and progesterone signaling (adjuvant endocrine therapy [AET]) following surgical management of the primary tumor. Nonadherence and nonpersistence to prescribed AET have been shown in numerous studies to correlate with significantly reduced overall survival [60-62], particularly in Black women [63]. Side effects of AET represent a major factor associated with nonadherence in this population [49,64,65]. Patient personality has not been studied explicitly as a factor in AET adherence, but other studies have identified anticipatory positive emotions [66] and lower depressive symptoms associated with greater social support [67] to be associated with increased adherence.

Therapy of chronic myeloid leukemia (CML) has been revolutionized by Abelson 1 tyrosine kinase inhibitors (TKIs) such as imatinib (Gleevec). Most patients with CML achieve cytogenetic remission with TKI treatment [68,69] and enjoy age-adjusted normal life expectancy [70], but therapy must be lifelong for most patients [71]. Adherence and persistence to TKI therapy is of paramount importance to clinical outcomes of patients with CML, as missing just 1 dose a week is associated with suboptimal response [72] and treatment failure [73,74]. As a consequence, the factors associated with TKI adherence in CML have been studied extensively [75,76] and include out-of-pocket costs [77,78], long-term side effects [79,80], and dosing schedule [81]. In CML as in breast cancer, the impact of patient personality on medication adherence has been largely unexplored, but a recent study found that patients with either type A or type D personality (particularly negative affectivity) were more prone to TKI nonadherence [82].

Can an Understanding of Patient Personality Be Leveraged to Improve Medication Adherence in Patients With Cancer?

A patient's personality can inform differences in the way they think, behave and feel [83]. It can help predict their compliance with follow-up appointments, adherence to medications, and the tendency to accept and implement medical advice [84,85]. Furthermore, the personality of a patient likely influences other patient-related factors including emotional state, regulation, and stability [54,55]. The specific mechanisms through which a patient's personality type might impact their adherence to medication have not been fully defined. It is possible that personality might have a direct effect on adherence, or a given personality trait might moderate the relationship between other factors that influence adherence, for example, between stress and levels of anxiety or depression. Previous studies of the moderating effects of personality on stress responses have yielded mixed results. For example, the neuroticism personality type has been found to moderate the relationship between stress and negative affect or health behaviors [86,87] and between medication beliefs and adherence during the COVID-19 pandemic [88], while another study demonstrated a correlation between personality and health trajectory but no moderating effect of personality type on the effect of stress on health outcomes [89]. Further studies are necessary to clarify the mechanistic relationship between personality and medication adherence and to inform strategies for intervention.

Given the current state of our knowledge, what opportunities exist to leverage a patient's personality to improve their adherence to prescribed medication in general and in cancer specifically? One approach might be to attempt to alter or modify a patient's personality toward one that is more favorable for medication adherence (for example, from type D to type A, or from neuroticism to conscientiousness). While there is general agreement that one's personality can change, most adult personalities are relatively stable over time and the degree of any change is small [90,91]. Furthermore, attempts to change personality may be complicated by the challenges imposed by a cancer diagnosis. Although personality trait change has been recognized as a potentially fruitful area for health policy initiatives [92], there is a dearth of published research on this method to improve medication adherence. A better approach might be to adapt patient educational and motivational materials to an individual's personality to ensure that the information is conveyed in a way that is most effective. Communications tailored to personality have been shown to be more effective than standard one size fits all messaging in advertising [93], education [94], and health care [95,96], but have not yet been applied to medication adherence.

For example, patients who exhibit a neurotic personality type could be more likely to experience negative emotions like irritability and anxiety following a cancer diagnosis, negatively impacting adherence [97]. A behavioral intervention strategy that acknowledges the neurotic patient's emotions and uses positive psychology techniques could prove helpful in this case [98]. For a patient who is extroverted or outgoing, allowing a safe and nonjudgmental space to share their opinions before educating them on their medication usage could ensure improved listening and adherence. Since extroverts thrive on being creative, they could also be empowered to take control of their own health and identify strategies that help them remember to take medications. It is important to note, however, that each of the 5 personality traits in the FFM represent a range between 2 extremes [23]. For instance, the extraversion trait represents a continuum between extreme extraversion and extreme introversion. In general, however, since most people lie at neither end of the spectrum but somewhere in between, multiple strategies for each patient's unique disposition would likely be more effective [23].

A more frequently applied strategy to increase medication adherence is to focus interventions on psychosocial factors, some of which may be associated with personality. Several recent studies in patients with breast cancer have used interventions focused on personal attitudes and values to increase adherence to AET [99,100]. Post hoc analysis of a randomized controlled trial found relaxation training to be more effective than cognitive behavioral therapy in improving adherence to AET [101]. A remotely delivered intervention based on personal values demonstrated feasibility and acceptability and showed promise in improving AET adherence [102]. In CML, an education program tailored to individual patients based on interviews and a designed set of distinct adherence aids improved TKI adherence in a randomized trial [103]. However, most efforts to improve TKI adherence have relied on analysis of large datasets to identify interventions and lack patient-focused approaches [104]. To address this, we (the authors) have launched a clinical trial aimed at better understanding the correlation between patient personality (the dominant trait as assessed by the FFM) and TKI adherence in patients with CML (ClinicalTrials.gov NCT06229860).

Before these strategies can be explored further in the real-world setting, existing FFM personality assessments currently used in cancer care or literature must be evaluated. Although assessments of patient personality often appear in medical records, they are usually 1-sided remarks limited to terms such as "pleasant," "short-tempered," or "difficult" and portray a rather superficial and incomplete perspective, which can in turn lead to biased intuitions [105,106], suboptimal care, and poor adherence. Instead, a structured and validated approach should be adopted to provide a more reliable breakdown of personality. A recent study examined the use of the 20-item Mini International Personality Item Pool (mini-IPIP) scale in adults with cancer and reported potential validity of the tool in oncologic clinical settings [107]. Despite being a shorter version compared with other full versions of FFM personality measures, such as the NEO-Five Factor Inventory [108], the mini-IPIP has also been widely cited in studies including healthy adults and illustrated sufficient internal reliability across diverse population samples [109]. Since the mini-IPIP is a 20-item questionnaire with potential internal and external validity, the tool could be reasonably administered to cancer patients. To facilitate smooth patient-provider interactions, patients could be requested to complete these assessments during a patient intake process or before an appointment through patient portals to allow providers ample time to review their personality profiles and prepare as needed before an encounter.

Conclusion

Behavioral intervention studies that seek to address each personality type should be conducted to reinforce positive health behaviors and promote adherence. Instead of using a cookie-cutter approach to patient counseling, understanding each person's unique personality, and adopting communication strategies that encourage optimal adherence can improve oncologic patient care. However, further research is needed to evaluate the impact of personality-specific medication counseling on adherence to oral anticancer medications. This includes validation studies that confirm the reliability of personality assessments in cancer patients, as well as studies that explore the effectiveness of psychological behavioral techniques on adherence in different personalities. At the same time, there are enough data to encourage research in this direction. We strongly believe that incorporating personality into oncological care will redefine how we approach patient care as a whole, especially in this age where personalized care models like precision medicine are on the rise.

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Conflicts of Interest

None declared.

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Abbreviations

AET: adjuvant endocrine therapy
CML: chronic myeloid leukemia
FFM: Five Factor Model
HbA1c: hemoglobin A1c
IPIP: International Personality Item Pool
TKI: tyrosine kinase inhibitors

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Research Letter

Web-Based Scaffolds: The Feasibility of a Constructivist Approach to Oncology Fellow Learning

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Abstract

In this 2-institution feasibility pilot, oncology fellows used and updated freely available web-based learning tools (scaffolds) in a constructivist fashion.

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KEYWORDS

constructivist learning; scaffolded learning; graduate medical education; fellowship training; oncology; feasibility; medical education; pilot study; study; online learning; online tool; online tools; remote learning; e-learning; training; cancer

Introduction

Succinct and updated oncology fellow learning materials are lacking. Additionally, fellow didactic learning often takes the form of passive lectures, which is undesirable [1,2]. Constructivist learning, wherein learners construct their own knowledge, is rare for fellows.

We piloted “scaffolds”—succinct slide sets shared across oncology trainees—and evaluated feasibility [3,4]. Throughout training, fellows can update the shared scaffolds in a constructivist fashion, thereby providing updated resources for themselves and colleagues.

Methods

Study Design

Two institutions participated—University of California, San Francisco (UCSF), and Stanford University. From 2018 to 2019, SB—a UCSF oncologist—designed 12 scaffolds, using Google Slides covering the solid tumor chapters from the American Society of Clinical Oncology’s Self-Evaluation Program (ASCO-SEP) textbook [5]. Hematology, gynecologic oncology, and neuro-oncology were omitted for this pilot. Scaffolds included text and images synthesized from ASCO-SEP and National Comprehensive Cancer Center guidelines. For brevity, the slides instructed fellows to adhere to length limits when making edits.

We emailed scaffold links to all first- to third-year UCSF (n=21) and Stanford University (n=27) oncology fellows in July 2019 and July 2020. Use was optional, and fellows could access and update the scaffolds anonymously at any time. Updates were audited by SB.

In December 2021, to evaluate feasibility outcomes (*fidelity*: degree to which the innovation was implemented as intended; *appropriateness*: perceived fit of the innovation; *self-efficacy*: belief in the ability to execute the innovation’s goals) [6], we reviewed updates tracked in Google Slides and conducted 2 voluntary feedback focus groups (UCSF: facilitated by SB; Stanford University: facilitated by MS—a Stanford University oncology fellow) with 4 fellows each. Focus group size was determined by responses to recruitment emails. Consent and demographic information were obtained. Participants did not need to use the scaffolds, as we were also exploring barriers to use. Focus groups were recorded and professionally transcribed. SB and MS independently reviewed the transcripts and generated themes through iterative discussion [7].

The scaffolds were updated in 2023 by SB (available on Google Drive) [8].

Ethical Considerations

UCSF and Stanford University institutional review boards granted exemption (#20-31645) and approval (#57766), respectively. Participants received an information sheet and verbally consented before each focus group. Transcripts omitted personal identifiers, and interviewers never revealed participant identities to the rest of the study team. Participants received a US $10 electronic gift card.

Results

Fidelity

From July 2019 to December 2021, fellows made 60 updates (Table 1), ranging from new trials to changes in management; none were erroneous. SB made 9 edits for brevity.

Table 1. Number of updates to solid oncology scaffolds during the pilot period (July 2019 to December 2021).

Scaffolds	Updates by fellows (N=60), n	Updates by auditor (N=9), n
Bladder/kidney/adrenal	1	1
Breast	17	0
Gastrointestinal (lower)	5	0
Gastrointestinal (upper)	9	1
Germ cell	2	2
Head/neck	1	0
Lung (nonsmall cell)	3	1
Lung (small cell/other thoracic)	1	1
Melanoma	1	1
Prostate	6	0
Salivary/thyroid	2	1
Sarcoma	12	1

Appropriateness

Focus group participants (N=8) were women and included Asian (n=3, 37.5%), White (n=3, 37.5%), Black (n=1, 12.5%), mixed-race (n=2, 25%), first-year (n=5, 62.5%), second-year (n=2, 25%), and third-year (n=1, 12.5%) fellows. Most (n=7, 87.5%) used the scaffolds. Qualitative analysis (Table 2) revealed that fellows felt the scaffolds were accessible and succinct learning tools, addressed the dearth of similar resources, served as effective preparation materials for clinical work and examinations, provided structured information for rapid reviews, and made interactions with complex resources easier.

Table 2. Qualitative analysis of transcripts from 2 oncology fellow focus groups (1 at the University of California, San Francisco, and 1 at Stanford University) that evaluated a pilot of solid oncology scaffolds (July 2019 to December 2021).

Theme	Supportive quotation
Advantages	
Accessible, succinct resource	"[The scaffolds were] online and quickly accessible, for example on the shuttle on the way to work."
Addressed the dearth of similar resources	"There are few resources currently available for oncology fellows. [The scaffolds] filled a niche not currently filled by other resources."
Effective preparation materials for clinical work and examinations	"[The scaffolds] were a security blanket…helpful for clinic prep and inpatient consults."
Structured information for rapid reviews	"[The scaffolds] were helpful in that they provided frameworks…and approaches."
Easier subsequent use of more complex resources	"The guidelines felt less 'foreign' after reviewing the scaffolds…[the scaffolds] helped with knowledge retention from more complex resources."
Challenges	
Lack of fellow confidence in updating the scaffolds	"I wasn't sure whether my learning points were important enough to add to the scaffold."
Lack of fellow ownership over the scaffolds	"I think fellows are probably less likely to update the scaffolds if they don't feel responsible for them."
Too simple and broad to help with nuanced patient care	"Clinical care is so nuanced…the scaffolds may be too broad to help with some clinical situations."
Suggestions	
Improve visual appeal	"Maybe make them more visually appealing by including more figures or tables."
Clarify purpose and the fact that scaffolds can be updated	"I would make it clear that the slides are editable and that fellows should update them."
Facilitate opportunities for fellows to update scaffolds	"Asking fellows to update these might be good for their learning."

Self-Efficacy

Qualitative analysis revealed barriers to updating the scaffolds—fellows' lack of ownership over the scaffolds and low confidence regarding appropriate updates.

Discussion

Principal Results

This pilot explored the feasibility of implementing constructivist scaffolds for oncology fellows. We found evidence of fidelity and appropriateness and delineated next steps to optimize self-efficacy. The scaffolds [8] can be downloaded and modified to avoid generating institution-specific scaffolds from scratch. To promote ownership and confidence, we recommend assigning fellows to update the scaffolds under faculty mentorship.

Despite demonstrating superior outcomes when compared to passive lectures, constructivist learning is rarely studied at the fellowship level [9-11]. We recommend evaluating constructivist learning modalities, such as scaffolds, in graduate medical education to enhance learning outcomes.

Limitations

Though the focus groups suggested that multiple fellows used the scaffolds, Google Slides did not track how many fellows accessed or updated them. We did not incorporate multimedia components beyond images and tables (some needed to be removed before publication to respect copyright), nor did we include assessments in this pilot. We recommend that institutions consider incorporating multimedia content and assessments into the scaffolds. The number of focus group participants was small and not gender-diverse. Future studies should quantitatively evaluate usage patterns and user satisfaction to examine what factors drive utilization.

Conclusion

We piloted a novel constructivist approach to fellow learning and found evidence of feasibility. Oncology educators may use and modify the scaffolds [8] to jump-start constructivist education for fellows at their institutions. Educators in other fields may wish to apply this model to their specialties.

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Data Availability

The data sets analyzed during this study are not publicly available due to institutional review board restrictions but are available from the corresponding author on reasonable request.

Authors' Contributions

SB designed the scaffolds, conceived the study, conducted the quantitative analysis, and wrote the manuscript. SB and MS each conducted 1 focus group. SB and MS conducted the qualitative analysis. All authors contributed manuscript edits and approved the final manuscript for submission.

Conflicts of Interest

None declared.

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Abbreviations

ASCO-SEP: American Society of Clinical Oncology's Self-Evaluation Program
UCSF: University of California, San Francisco

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