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Investigation of Intervention Solutions to Enhance Adherence to Oral Anticancer Medicines in Adults: Overview of Reviews

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Abstract

Background: Adherence to anticancer medicines is critical for the success of cancer treatments; however, nonadherence remains challenging, and there is limited evidence of interventions to improve adherence to medicines in patients with cancer.

Objective: This overview of reviews aimed to identify and summarize available reviews of interventions to improve adherence to oral anticancer medicines in adult cancer survivors.

Methods: A comprehensive search of 7 electronic databases was conducted by 2 reviewers who independently conducted the study selection, quality assessment using the A Measurement Tool to Assess Systematic Reviews 2, and data extraction. The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) 2020 checklist was adapted to report the results.

Results: A total of 29 reviews were included in the narrative synthesis. The overall quality of the systematic reviews was low. The 4 main strategies to promote adherence were focused on education, reminders, behavior and monitoring, and multicomponent approaches. Digital technology–based interventions were reported in most reviews (27/29, 93%). A few interventions applied theories (10/29, 34%), design frameworks (2/29, 7%), or engaged stakeholders (1/29, 3%) in the development processes. The effectiveness of interventions was inconsistent between and within reviews. However, interventions using multiple strategies to promote adherence were more likely to be effective than single-strategy interventions (12/29, 41% reviews). Unidirectional communication (7/29, 24% reviews) and technology alone (11/29, 38% reviews) were not sufficient to demonstrate improvement in adherence outcomes. Nurses and pharmacists played a critical role in promoting patient adherence to oral cancer therapies, especially with the support of digital technologies (7/29, 24% reviews).

Conclusions: Multicomponent interventions are potentially effective in promoting patient adherence to oral anticancer medicines. The seamless integration of digital solutions with direct clinical contacts is likely to be effective in promoting adherence. Future
research for developing comprehensive digital adherence interventions should be evidence-based, theory-based, and rigorously evaluated.

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**KEYWORDS**
digital; intervention; medication adherence; oncology; oral anticancer; systematic review

**Introduction**

With the advent of oral anticancer medicines (OACMs) more than 2 decades ago [1], there has been a gradual shift for cancer treatments to be increasingly administered at home [2]. Oncology care teams and their patients face new challenges in ensuring optimal adherence to therapy. Studies have revealed that the rate of adherence to OACMs varies widely across cancers, but it can be as low as 16% [3] and often worsens over time [4]. Medication adherence (MA) is defined as “the extent to which patients take their medication as recommended by their health care provider” [5]. Adherence is an important predictive factor for the success of OACMs [1,6], particularly when these therapies require patients to take medications correctly over a long period.

Given the high priority of adherence to OACMs in cancer care, there have been an increasing number of interventions to address MA issues, particularly in oral endocrine therapy for breast cancer [7] and oral medications for hematologic malignancies [8]. However, published reviews have disclosed that the evidence for these interventions is limited in both quantity [9] and quality [2].

In recent years, in an effort to provide more evidence in this area, there have been quite a few published reviews of adherence interventions in oncology, especially digital solutions [10-13]. However, these reviews varied in scope, methodology, and outcome of interest, which could overwhelm decision makers. This overview of reviews aimed to identify and summarize the available reviews of interventions to improve adherence to OACMs in adults with cancer. Overviews are new methodological approaches that have been used where multiple reviews already exist on the topic of interest to filter the plethora of information and provide a framework for clinical decision makers [14,15].

**Methods**

**Overview**

The study protocol was registered in the PROSPERO (International Prospective Register of Systematic Reviews) database (CRD42021240578) [16]. The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) 2020 statement was adapted to report this systematic review of reviews [17] and is presented in Multimedia Appendix 1 [17].

**Search Strategy**

A systematic literature search was performed on 7 databases for all publications up to March 2021: Ovid MEDLINE, Ovid Embase, CINAHL, PsycINFO, Web of Science, the Cochrane Database of Systematic Reviews, and the Database of Abstracts of Reviews of Effects. The Peer Review of Electronic Search Strategies checklist [18] was used to guide the development of the search strategy. The electronic search strategy was initially developed in MEDLINE by a reviewer (THD) and was then peer-reviewed by a group of experts in relevant fields (KB, MA, NW, PPJ, and PS) and a librarian to ensure its comprehensiveness. The search strategy combined controlled vocabulary and keywords, including synonyms, antonyms, and acronyms related to adherence, intervention, and cancer, and was adapted for each database. We did not limit the publication date but limited the search to the English language, human studies, and reviews only (refer to Multimedia Appendix 2 for full search strategies).

In addition to the database search, bibliographies of selected studies were also hand-searched to identify relevant studies not detected by the electronic search.

**Criteria for Considering Studies for This Review**

The studies had to meet all the following criteria to be eligible for inclusion:

- Population: adults (≥18 years) diagnosed with any type of cancer undergoing OACMs. Studies on children were excluded because of the specificity of treatment issues in this group. Studies in a group of the population that separately reported results for adults with cancer were also included;
- Intervention: any type of intervention that included a component to enhance patient adherence to oncology treatment;
- Comparator: usual care or active control intervention;
- Outcome: MA compliance or persistence, clinical outcomes, and quality of life of people with cancer;
- Study type: reviews, including literature review or narrative review, scoping review, and systematic review.

**Study Selection**

One reviewer (THD) conducted the searching, deduplication, and initial screening of titles and abstracts of all studies found. A second reviewer (ARMF) conducted a random independent assessment of the identified papers and reviewed the screening results of the first reviewer. Two reviewers independently screened all full texts of potentially eligible papers. When necessary, any differences between the 2 reviewers were discussed until consensus was reached or resolved by a third reviewer. Covidence site, operated by Veritas Health Innovation Ltd [19], was used for data screening, selection, and management.

**Assessment of Methodological Study Quality**

The methodological quality of the included systematic reviews was independently assessed by 2 reviewers (THD and ARMF),
adapting the A Measurement Tool to Assess Systematic Reviews (AMSTAR) 2, which has demonstrated satisfactory reliability and construct validity [20]. AMSTAR 2 is a tool used to evaluate the methodological quality of systematic reviews, which includes randomized and nonrandomized studies of interventions, including 10 domains and 16 items or questions. The answering options were yes, partial yes, or no/no information (corresponding to low or high risk of bias). We used the findings from the AMSTAR 2 critical appraisal to understand the certainty of the evidence base of the systematic reviews. Disagreements were resolved by discussion.

As AMSTAR 2 does not combine individual item ratings to create an overall score, the scheme for interpreting weaknesses detected in critical (7) and noncritical (9) items, proposed by Shea et al [20], was applied. The overall confidence in the results of the review was classified as high, moderate, low, or critically low, according to the number of critical and noncritical weaknesses identified in the systematic review under appraisal.

Data Extraction and Synthesis

Data were independently extracted by 2 reviewers (THD and ARMF) in a standardized table (Multimedia Appendix 3), which was pilot-tested, for 7 random eligible studies, and then, results were compared and agreed upon. THD extracted data for the remaining eligible studies, which were then reviewed by ARMF, with discrepancies resolved through consensus. The corresponding authors of the included studies were contacted for further information or clarification, if necessary. The extracted data included the type of review, research questions, type of interventions, search strategies, search period limits, characteristics of included studies, quality assessments, methods of analyses, and findings. The included reviews were expected to have high heterogeneity in terms of interventions, comparators, outcome measures, study populations, and methodologies. Therefore, statistical pooling through meta-analysis was not appropriate.

Results

Overview

The results of this review are presented in the following order: search results, characteristics of included reviews, quality of systematic reviews, description of interventions, and outcomes of included reviews by group—scoping, systematic, and literature reviews. Owing to the heterogeneity of the included reviews, the findings are presented in a narrative format and refer to meta-analyses performed by the authors of the included reviews whenever available.

Search Results

The search strategy identified 2098 unique results from 7 databases, 1 from the reference lists of the included studies, and 1 from the automatic alerts of the databases. Title and abstract screening identified 51 studies for full-text screening, of which 29 (57%) met the inclusion criteria. Details of the excluded studies and reasons for exclusion are provided in Multimedia Appendix 4 [2,7-9,12,21-46]. A high level of concordance was achieved between the 2 reviewers in the screening process, with disagreement in only 10% (5/51) of cases. These 5 papers were discussed by the 2 reviewers, and consensus was achieved. The selection process is illustrated in the flowchart (Figure 1).

Figure 1. Flow diagram of study selection. CDSR: Cochrane Database of Systematic Reviews; DARE: Database of Abstracts and Reviews of Effects.
Characteristics of the Included Reviews

Study Design and Publication Time

Among the 29 included reviews, 12 (41%) were systematic reviews [2,7-9,12,21-27], 5 (17%) were scoping reviews [11,13,47-49], and the remaining 12 (41%) were literature reviews [10,28,29,50-58]. All 29 reviews were descriptive, with only 1 (3%) including meta-analyses [25]. All the studies were published in English. Of these 29 reviews, 25 (86%) were published between 2014 and 2021 and the remaining 4 (14%) were published before 2014 [28,50-52]. Although literature reviews were published throughout the period from 2009 to 2021, the publication of 5 scoping reviews began in 2018.

Participants

Most reviews included studies on all types of cancer (22/29, 76%) [2,9-11,13,21,22,24,26-29,47-55,58], followed by breast cancer (6/29, 21%) [7,12,23,25,56,57], and hematological cancer (1/29, 3%) [8]. A total of 90% (26/29) reviews [2,7-13,21,23-29,48-57] examined adherence interventions for disease-modifying therapies, and 10% (3/29) reviews [22,47,58] reported adherence interventions for all types of cancer treatments. In total, 17% (5/29) reviews specifically focused on women [7,12,23,25,56], 7% (2/29) on adolescents and young adults [22,58], and 3% (1/29) on socially disadvantaged people with cancer [26]. The characteristics of the 29 studies included in this overview are presented in Multimedia Appendix 5.

Aims of the Reviews

Although all 29 reviews aimed to synthesize evidence of interventions used to promote MA among people with cancer, 6 (21%) narrative reviews also included available literature on adherence to oral anticancer regimens [2,28,50,52,53,58]. Of the 5 scoping reviews, 4 (80%) targeted digital adherence solutions, such as mobile apps [47,49], mobile phone–delivered interventions [48], and digital interventions in general [11]. Of the 12 systematic reviews, 6 (50%) focused on examining either the efficacy [22] or the effectiveness of adherence interventions [9,12,21,24,25]. Some of the reviews specifically focused on the type of interventions (eg, nurse-led [51], pharmacist-led [24], educational [21], and technology-mediated [10,11,47-49,54,55,57]), specific settings (eg, ambulatory care setting [21]), and socially disadvantaged groups in the Organization for Economic Co-operation and Development countries [26].

Quality of Systematic Reviews

Among the 29 reviews, 12 (41%) were systematic reviews, of which only 1 (3%) conducted meta-analyses (Multimedia Appendix 5). Methodological quality was low or critically low overall, with at least 2 out of 16 AMSTAR 2 appraisal items [20] not met in all systematic reviews. The quality assessment of the 7 critical AMSTAR 2 domains is presented in Multimedia Appendix 6. Only 8% (1/12) systematic reviews from the study by Arthurs et al [21] received moderate overall confidence ratings in the reported results, which meant that this systematic review may provide an accurate summary of the results of the included studies to address the questions of interest. Moreover, 33% (4/12) and 59% (7/12) of systematic reviews received low and critically low overall confidence ratings, respectively, meaning that the summarized results of these studies may be inaccurate and that the conclusions need to be interpreted carefully. The best adherence was found for using the components of the PICO (population, intervention, comparison, and outcome) framework when describing the search question and inclusion criteria (item 1) and describing the included studies in adequate detail (item 8). The item that most reviews (9/12, 75%) failed to meet was providing a justification for excluding individual studies (item 7). For the critical domains, 42% (5/12) reviews referred to a review protocol (item 2), and 25% (3/12) reviews provided a list of excluded studies and justified their exclusion (item 7). Nearly all reviews (11/12, 92%) accounted for risk of bias when interpreting the results (item 13). Most of the reviews (10/12, 83%) used a satisfactory technique for assessing the risk of bias in individual studies (item 9), and 75% (9/12) of reviews conducted a comprehensive literature search (item 4). The only review with meta-analyses adhered to the item of using appropriate methods for statistical combination of the results (item 11) and investigated publication bias (item 15). More details on the bias assessments of all 16 AMSTAR 2 items are provided in Multimedia Appendix 7 [2,7-9,12,21-27].

Description of Interventions

Overview

Given the wide range of aims mentioned above, interventions were categorized differently across and within reviews. Most reviews (21/29, 72%) reported diverse and multimodal interventions [2,7-9,12,13,21-29,50-54,56,58]; however, 28% (8/29) of reviews provided detailed technology-mediated interventions [10,11,22,47-49,55,57].

Modes of Delivery

Owing to the heterogeneity and lack of a common approach to categorizing the interventions in the reviews, we describe the modes of delivery for each one in Multimedia Appendix 8. Although interventions could be broadly classified as face-to-face or remote, these categories should only be considered as a guide because they were not always exclusive, owing to the complexity of interventions. For example, the same educational elements could be delivered via direct contact and web-based channels.

Face-to-face Interventions Only

The only 2 reviews in this group of interventions [50,51] were published the earliest among the reviews included in this study. One review [51] focused particularly on nurse-delivered interventions.

Remote Interventions Only

A total of 28% (8/29) of reviews reported only on nonface-to-face interventions with the assistance of technologies [10,11,22,47-49,55,57]. All these reviews were published in the last 6 years. Most were directed at individuals through various delivery modes, including phone, SMS text messages, and mobile apps.
Combined Face-to-face and Remote Interventions
A total of 66% (19/29) of reviews were concerned with either face-to-face or remote modes of delivery or complex multimodal interventions [2,7,9,12,13,21,23-29,52-54,56,58]. Interventions in these reviews were either single or multicomponent, often including education; reminders; and affective components, such as patient navigators, emotional and self-management support, and problem solving.

More details about interventions in each review are presented in Multimedia Appendix 9 [2,7-13,21-29,47-58].

Theoretical Frameworks
Only 34% (10/29) of reviews reported on theoretical frameworks. The most common theories were the Health Belief Model [59] and its subsequent versions, Social Learning Theory, and Social Cognitive Theory [60], which were mentioned in 21% (6/29) of reviews [12,13,22,23,28,48]. The Self-Regulation Model [61] was the second most common framework, featured in 10% (3/29) of reviews [13,22,49]. One review [48] mentioned self-determination theory [62]. None of the face-to-face intervention reviews discussed theoretical frameworks.

Intervention Providers
As interventions are diverse, their providers include a range of professionals in the health care field: clinicians, nurses, pharmacists, and health providers. The interventions in most reviews were delivered by a multidisciplinary team. However, one review specifically focused on nurse-led interventions [28] and another on pharmacist-led interventions [24]. A total of 10% (3/29) of reviews reported on interventions delivered by nurses or pharmacists [21,27,51].

Intervention Development
Most reviews did not discuss the development of interventions. Using design frameworks and engaging stakeholders were rarely mentioned. One review [48] reported that stakeholders were engaged in the design of all included interventions, for example, patients and oncology clinicians were engaged in the early design phases to explore end users’ perceptions of the acceptability and usefulness of the interventions. Stakeholders were patients, caregivers, clinicians, administrators, care providers, the community, and society, depending on the type of intervention. Two design frameworks [63,64] were applied in the development of interventions in 2 reviews [48,49].

Dose and Duration
Although the doses and durations were mentioned in 31% (9/29) of reviews [7,10,13,21,24,29,48,53,57], they were brief and varied for different types of interventions and modes of delivery. For example, the frequency of SMS text messages was daily, bidaily, or weekly [7,10,29,48,57]. Automated voice responses could be set up on a daily, weekly, or monthly basis [10,29]. The duration of multicomponent interventions varied from 9 to 18 months [29]. The follow-up period of interventions could be as short as 2 months or as long as 45 months [24].

Outcomes of Included Reviews by Group

Overview
All reviews, except 3 [47,49,51], reported MA improvement as a primary outcome. Some also reported medication persistence [23]; clinical outcomes, such as symptoms and adverse events [24]; hospital admission rates [9]; subclinical responses; survival time [8]; cancer-related knowledge and self-management skills [22,26]; and some quality-of-life indicators [26]. A total of 10% (3/29) studies [24,26,49] mentioned patient satisfaction and economic impact outcomes [24]. For this review, we focused on MA outcomes and discussed some of the secondary outcomes. The results from the 5 scoping reviews are described first, followed by 12 systematic reviews, and finally, the findings from the 12 narrative reviews.

MA (Primary Outcome)

Overview
Not all reviews specified how MA was measured. In reviews that specified how MA was measured, the methods were diverse: subjective, objective, or biomedical. Subjective measurements, such as patient self-reports and clinician reports, were the easiest reporting methods. However, perhaps because of its potential inaccuracy, it was only used to measure adherence in 12 reviews [2,7,8,10,12,13,21,23,25,52,53,56]. Half (14/29, 48%) of the reviews reported objective measurements, such as pill diaries, pill counts, and medication event monitoring systems [2,7-10,12,13,21,23,25,28,51-53], whereas some (7/29, 24%) mentioned biomedical measurements, such as drug metabolites in urine [2,7-10,52,56].

Scoping Reviews
MA was reported as a primary outcome in 60% (3/5) of scoping reviews [11,13,48] (Multimedia Appendix 10). Skrabal Ross et al [48] explored the evidence of mobile-delivered interventions, mainly SMS text messages and mobile apps (5 studies). Gamblangula et al [11] focused on mobile apps (7 studies). Both reviews concluded that despite the use of digital means in facilitating the adherence of patients with cancer to oral treatments being strongly recognized in the literature, its effectiveness was either underexamined [48] or poorly supported [11]. The engagement of stakeholders and the use of design frameworks in developing digital interventions were very important [48]. In a scoping review of 56 studies evaluating adherence to oral antineoplastic agents [13], less than half (n=25, 45%) reported statistically significant improvements in adherence or persistence. Of these 56 studies, 8 (14%) used a mobile health tool and SMS text messages as the mode of delivery. The results revealed that drug-reminder SMS text messaging, either alone or in combination with a mobile app targeting intentional nonadherence, appeared to be effective among people with a single diagnosis but not among those with different diagnoses. The review also emphasized that theory-based and evidence-based interventions tailored to the needs of patients were more likely to be effective.

In the other 2 scoping reviews [47,49], mobile apps were reported as useful tools in facilitating the delivery of behavioral guidance, real-time capture of patients’ symptoms, monitoring...
of adherence, and supporting the self-management of side effects [49]. Nevertheless, the efficacy of mobile apps in improving symptom management and MA requires further exploration [48].

Systematic Reviews

MA was the primary outcome of all 12 systematic reviews. Findings from the meta-analytic results are presented first, followed by narrative syntheses.

Only 1 systematic review by Finitsis and Vose [25] contained meta-analyses to quantify the aggregate effect of interventions to improve adjuvantendocrine therapy adherence among women with breast cancer and meta-analyzed these effects across studies. A total of 7 studies that reported 8 interventions were included in this review [30-35,65]. Nearly half (3/7, 43%) of the included studies used one-way communication to deliver information and education to patients. Two studies used bidirectional communication between oncology nurses and patients. One study used a multicomponent intervention, including a mobile app and phone call follow-up from the care team. The results showed that interventions using bidirectional communication (ie, eliciting information from patients and sending information to patients) had statistically significant effects compared with the control groups within each study (k=4; Cohen d=0.59; 95% CI 0.23-0.95), whereas those using only one-way communication (ie, purely providing information to patients) did not (k=4; Cohen d=-0.03; 95% CI -0.27 to 0.20). The authors concluded that the interventions failed when only one-way flow communication was used. Interventions to improve adjuvantendocrine therapy adherence should enhance patient engagement via bidirectional platforms. The additional details are presented in Multimedia Appendix 11 [13-19].

MA was reported as a primary outcome in all 11 narrative systematic reviews [2,7,9,12,21-24,26,27]. Four main strategies to promote adherence emerged from these reviews: education, reminders, behavior and monitoring, and multicomponent interventions. The reported results varied between and within reviews, even for the same types of intervention (Multimedia Appendix 12).

The educational strategy was reported in all reviews, either as a stand-alone intervention or as an element of multicomponent interventions. Educational materials often included information about diseases and medications (eg, dosage, side effects, storage, disposal, and ways to remember to take the medication). Studies revealed that education alone, regardless of delivery (eg, face-to-face, leaflets, or mailouts), was insufficient to promote adherence to anticancer regimens [2,7,8,12,23,27].

There are many mechanisms that can be used to remind patients to take their medication. These could be as simple as calendars, diaries, dosing sheets, pillboxes, and charts or more advanced, with the help of technology, such as SMS text messages and mobile apps. Although reminders could be effective in reinforcing the behavior of taking the medication in some chronic conditions, such as HIV or AIDS [52,53], their effectiveness in oncology has not been demonstrated [7,9,26].

The behavioral and monitoring strategies have been broadly used in MA interventions in various forms and modes of delivery: delivered either in a single form or mode (monitoring pill-taking, autopharmacy refills, electronic prescribing, and individual coaching) [2,7,23,24] or an intervention package (monitoring and feedback, side effect management, and positive self-care behavior) [2,7,22,23]. Similar to the diversity of interventions within this group of strategies, their effectiveness in enhancing adherence to oral antineoplastic medicines varied widely within and between reviews [2,7,9,22,26,27].

Multicomponent interventions were reported in 82% (9/11) of systematic reviews [2,7,9,12,21,23,24,26], often including a combination of education; reminders; and behavioral, cognitive, or affective components. Tailored education in combination with drug reminders and counseling delivered by nurses or pharmacists to promote symptom management and adherence behavior was likely to be effective in improving adherence [2,8,9,12,24]. Nevertheless, in a few (4/29, 14%) reviews, nurse-led tailored patient education [21], pharmacist-led intensive care programs [21], and education combined with reminder interventions were not effective [7,23]. The effect of education, pill shaping, and home restructuring was uncertain in the systematic review by Mathes and Antoine [9]. This uncertainty was also observed in multicomponent interventions including education, reminders, and motivational interviewing [23]; or interventions including education and monitoring [27].

There were some overlaps across systematic reviews at the individual-study level. The results of 18 primary studies, including 7 randomized controlled trials [30,34-37,66,67], were reported in more than 1 systematic review [30,33,44,65-69]. For example, 2 randomized controlled trials on the compliance of patients to anastrozole in a therapy program, published by Hadji et al [66], and the influence of a patient information program on adherence and persistence to an aromatase inhibitor in breast cancer treatment, published by Ziller et al [35], were reported in the same 5 systematic reviews [2,7,12,23,25]. More details on the overlap of primary studies across systematic reviews are presented in Multimedia Appendix 13 [13,15-27,47-50].

Literature Reviews

Among the 12 included literature reviews, 4 (33%) focused on technology-based interventions; 1 (8%) examined nursing interventions [51]; and 2 (17%) expanded the scope of research to areas such as adherence or persistence rates [50] and its impacts [53], challenges to adherence in oncology [28,52,53], and adherence measurements [52]. MA was reported as a primary outcome in all literature reviews except 2 [51,57] (Multimedia Appendix 14).

The results from these literature reviews were consistent with findings from included scoping and systematic reviews: education alone was insufficient to promote adherence to oral medication regimens [29,53,54,58], and multicomponent interventions were more likely to be effective in improving adherence [10,28,29,50,52,55,58]. Behavioral and monitoring strategies did not consistently improve adherence rates when used alone [29,50,53], although some studies have reported positive results [28,29,56].
However, the effectiveness of reminders was controversial. Reminder tools, such as calendars, diaries, and dosing sheets, likely improved patient adherence [28,53], whereas daily pillboxes were unlikely to do so [28,50]. Electronic reminders, such as SMS text messages and mobile apps, were reported to be effective in the review of Accordino and Hershman [52] but ineffective in another review conducted by Cazeau [10]. Narrative reviews also revealed that oncology nurses and pharmacists, as part of a multidisciplinary team, can have a significant influence on patient adherence via education, increased access to medicines, early identification of symptoms, and side effect self-management skills [28,29,51,53].

Secondary Outcomes
In addition to MA rates, clinical outcomes, such as decreased symptoms [24], cytogenetic response, and survival time [8], were evaluated. The effects of education on clinical outcomes were uncertain [8]. However, some multicomponent interventions, including education, tailored counseling, and affective components (eg, home visit support), showed possible positive effects [8,24]. In 2 reviews [22,26], interventions combining side effect management, positive self-care behavioral promotion, education, counseling, or organizational change elements improved cancer-related knowledge and self-efficacy among people with cancer. Two reviews [9,24] listed hospital admission rate as a secondary outcome, but it was not statistically significant in all included interventions.

Discussion

Principal Findings
This overview of reviews aimed to synthesize evidence from available reviews on interventions to improve MA to OACMs in adults with cancer. To the best of our knowledge, this is the first study to achieve this goal. Among the 29 included reviews, only 1 (3%) conducted meta-analyses and 17 (59%) did not follow systematic methodologies in identifying, analyzing, and reporting literature. Consequently, it was impossible to perform quantitative analyses. Nevertheless, including literature reviews in the narrative synthesis is useful for understanding the breadth of the study field. The only systematic reviews of moderate quality focused on therapeutic patient education interventions in ambulatory care settings [21]. The other 11 systematic reviews on the topic of interest had low or critically low confidence rating. Therefore, the results of the included reviews should be interpreted with caution.

The comparability of the study results is limited because of the high heterogeneity of the included reviews (Multimedia Appendix 5) and studies within each review [9,13]. The content of adherence-enhancing interventions is varied [29]. In addition, there are differences in the characteristics of patients whose adherence has been influenced [9]. Furthermore, comparability is constrained owing to different adherence measurements [2,7,8,52]. Accordingly, this review summarizes the main themes of the included reviews rather than comparing them. This review suggests that single strategies to promote adherence (eg, education, reminders, or monitoring) are not sufficient to improve adherence. Multidimensional interventions that used collective strategies to promote adherence (education, reminder, cognitive, behavioral, and affective) were potentially more effective. Our findings are in line with earlier reviews of interventions to improve adherence in various chronic conditions [45,46] and those focusing on cancer [9,50,54,58]. These findings also resonate with the report of the World Health Organization that MA is a multidimensional phenomenon determined by 5 dimensions (social and economic, health system, condition-related, therapy-related, and patient-related) [70]. Thus, multicomponent interventions applying different strategies are needed to address the multifaceted adherence phenomenon [70].

The described theoretical frameworks were neither clear nor validated. One-third of reviews reported on the scattered use of cognitive and behavioral theories in only a few studies [12]. Although the authors [12,48] emphasized the importance of using theoretical grounding in planning, designing, and evaluating outcomes of multilevel interventions, a few [13,23] argued that the effect of this was quite modest. This uncertainty is in line with a meta-analysis of 683 studies that quantified the impact of theory-driven interventions on adherence [71]. The limited use of theory to design interventions means that no conclusions can be drawn regarding the importance and effectiveness of theoretically derived interventions. Furthermore, the complex and multifaceted factors contributing to nonadherence represent another challenge in the selection of an appropriate conceptual model to design interventions. Perhaps, a combination of theories may better explain the diverse barriers and facilitators of MA and provide a stronger direction to formulate interventions. Future research should pay more attention to this aspect of adherence interventions.

The use of digital solutions to enhance adherence to cancer treatment has been increasing in the past decade [47,55]. The literature has emphasized the potential of digital platforms to facilitate oral antineoplastic adherence among people with cancer [11]. Medication nonadherence can be intentional or unintentional. Intentional nonadherence is a patient’s conscious decision not to take a drug, for example, because of unpleasant side effects [72]. Unintentional nonadherence is unplanned by a patient, for example, because of forgetfulness [73]. Therefore, the interventions require different modes of action. A variety of measures, such as patient education and good patient-provider communication, can enable patients to better report and manage therapeutic side effects [55]. Technologies can enhance these measures by providing patients with rapid, continuous, and easy access to both educational resources and symptom self-management strategies, also facilitating communication between patients and their care teams [11,55]. Personal lifestyle and electronic triggers (eg, SMS text messages) remind and motivate patients to take their medication, so that it becomes an integral part of their daily activities [11,52]. In both cases, digital platforms (eg, mobile apps) can enable real-time monitoring of patient self-management [11]. However, this is an emerging field, and most studies have focused only on evaluating the acceptability, usability, and feasibility of interventions. The effectiveness of digital MA interventions in clinical oncology practice is poorly supported [47,48]. Future research should not only focus on determining the effect of...
digital interventions on adherence but also on identifying barriers to delivering high-quality personalized care to end users [11].

Using frameworks and engaging stakeholders in the design and development of digital interventions is crucial. Design frameworks help in planning the resources needed for each stage of the design and to mobilize them effectively and efficiently [48]. The involvement of stakeholders is central in ensuring that the intervention meets the needs of the target audience and in increasing its sustainability [49]. Nevertheless, strategies involving stakeholders (eg, patients, caregivers, oncology clinicians, nurses, pharmacists, and the community) have rarely been reported [48]. The involvement of professionals in the intervention development processes was very limited [49,55]; only 2 studies [74,75] mentioned patients’ and clinicians’ participation. Most interventions did not use or, at least, did not report the use of design frameworks in the development processes [48]. Given the rapid increase of technology applications in MA and the importance of this aspect in intervention development, it is worthy of future research into the involvement of stakeholders and the design framework used in the development of adherence interventions.

The findings from this review show that the use of digital solutions alone may be insufficient and may require cultural adaptive change [57]. Health care professionals’ interaction with patients is pivotal to augmenting the effect of these interventions [51]. Nurses and pharmacists are uniquely positioned to promote adherence to oral cancer therapies [10,51,53]. Findings suggest that clinical support (eg, tailoring education to meet patients’ needs) and symptom assessment and management provided by nurses empowered patients’ ability to adhere to treatments [8,28,55]. Future interventions in cancer should maximize the advantage that health professionals can contribute to patients’ MA with the support of digital technology.

Finally, this review suggests that to consolidate evidence on the effects of MA interventions in cancer, further work is needed using rigorous methods, such as prospective randomized designs in large samples of patients. Study outcomes should not only be limited to adherence rates but also the long-term effects of interventions and meaningful clinical outcomes, such as decreased symptoms and adverse effects of therapy, inhibited disease progression, and increased patient survival and quality of life. These suggestions are consistent with the results of some other systematic reviews of interventions to promote adherence to OACMs that have been published to date [2,9].

Limitations
This review has inevitable limitations owing to the limited existing high-quality quantitative analytic evidence, which also demonstrates a high risk of bias. Similarly, the significant heterogeneity across and within reviews and studies did not allow statistical analyses beyond reporting of results from the only meta-analysis and narrative analyses performed by the authors of the included reviews. Throughout the process, we relied on published evidence rather than aggregated data from individual studies. Therefore, a definitive assessment of the overall strength of evidence and the effectiveness of current interventions to enhance adherence to anticancer medicines among adults with cancer is not possible. Finally, only the reviews published in English were included. Thus, there is a risk of missing the relevant literature published in other languages. However, comprehensive searches were conducted using different databases to minimize this limitation as much as possible.

Conclusions
Despite these challenges, this review suggests the potential effectiveness of multicomponent interventions to promote adherence to OACMs in adults. This review highlights the role of digital health in enabling and enhancing multicomponent adherence interventions. Nurses and pharmacists are in unique positions and play an important role in facilitating and motivating patient adherence behavior in oncology treatments. These processes can be facilitated without creating a burden if they are integrated into the current routine practices with the support of technology. The findings from this review support the need for future research in developing evidence-based digital multicomponent interventions to assist people with cancer in adhering to their oral therapies. This review also underscores the importance of stakeholders’ involvement and the use of a design framework in the development of interventions to increase translatability and sustainability in real oncology practices. Given the rapidly increasing use of oral antineoplastic medicines and the dramatic availability of digital tools worldwide, research in this field is expected to increase rapidly.

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Authors’ Contributions
All authors made substantial contributions and approved the conception, drafting, and final version of the manuscript. THD analyzed and interpreted the data. THD drafted the paper with contributions from ARMF, NW, PPJ, MA, KB, and PS.
Conflicts of Interest
None declared.

Multimedia Appendix 1
PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) 2020 checklist.
[DOCX File, 32 KB - cancer_v8i2e34833_app1.docx ]

Multimedia Appendix 2
Search strategy.
[DOCX File, 17 KB - cancer_v8i2e34833_app2.docx ]

Multimedia Appendix 3
Data extraction table.
[XLSX File (Microsoft Excel File), 11 KB - cancer_v8i2e34833_app3.xlsx ]

Multimedia Appendix 4
Table of excluded studies.
[DOCX File, 57 KB - cancer_v8i2e34833_app4.docx ]

Multimedia Appendix 5
Characteristics of included reviews.
[XLSX File (Microsoft Excel File), 15 KB - cancer_v8i2e34833_app5.xlsx ]

Multimedia Appendix 6
Methodological quality of included systematic reviews (A Measurement Tool to Assess Systematic Reviews 2 critical domains, adapted from Shea et al [20]).
[DOCX File, 41 KB - cancer_v8i2e34833_app6.docx ]

Multimedia Appendix 7
Methodological quality of included systematic reviews.
[DOCX File, 20 KB - cancer_v8i2e34833_app7.docx ]

Multimedia Appendix 8
Interventions grouped according to modes of delivery.
[XLSX File (Microsoft Excel File), 11 KB - cancer_v8i2e34833_app8.xlsx ]

Multimedia Appendix 9
Intervention details of included reviews.
[XLSX File (Microsoft Excel File), 13 KB - cancer_v8i2e34833_app9.xlsx ]

Multimedia Appendix 10
Outcome of included scoping reviews.
[XLSX File (Microsoft Excel File), 12 KB - cancer_v8i2e34833_app10.xlsx ]

Multimedia Appendix 11
Outcomes of included systematic reviews with meta-analyses.
[XLSX File (Microsoft Excel File), 11 KB - cancer_v8i2e34833_app11.xlsx ]

Multimedia Appendix 12
Outcomes of included systematic reviews—narrative reviews.
[XLSX File (Microsoft Excel File), 14 KB - cancer_v8i2e34833_app12.xlsx ]

Multimedia Appendix 13
Primary studies overlap across systematic reviews.
[XLSX File (Microsoft Excel File), 11 KB - cancer_v8i2e34833_app13.xlsx ]
Multimedia Appendix 14
Outcome of included literature reviews.

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**Abbreviations**

**AMSTAR:** A Measurement Tool to Assess Systematic Reviews  
**MA:** medication adherence  
**OACM:** oral anticancer medicine  
**PICO:** population, intervention, comparison, and outcome  
**PRISMA:** Preferred Reporting Items for Systematic Reviews and Meta-Analyses  
**PROSPERO:** International Prospective Register of Systematic Reviews

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Physicians’ Perceptions of and Satisfaction With Artificial Intelligence in Cancer Treatment: A Clinical Decision Support System Experience and Implications for Low-Middle–Income Countries

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Abstract

As technology continues to improve, health care systems have the opportunity to use a variety of innovative tools for decision-making, including artificial intelligence (AI) applications. However, there has been little research on the feasibility and efficacy of integrating AI systems into real-world clinical practice, especially from the perspectives of clinicians who use such tools. In this paper, we review physicians’ perceptions of and satisfaction with an AI tool, Watson for Oncology, which is used for the treatment of cancer. Watson for Oncology has been implemented in several different settings, including Brazil, China, India, South Korea, and Mexico. By focusing on the implementation of an AI-based clinical decision support system for oncology, we aim to demonstrate how AI can be both beneficial and challenging for cancer management globally and particularly for low-middle–income countries. By doing so, we hope to highlight the need for additional research on user experience and the unique social, cultural, and political barriers to the successful implementation of AI in low-middle–income countries for cancer care.

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KEYWORDS

artificial intelligence; cancer; low-middle–income countries; physicians; perceptions; Watson for Oncology; implementation; local context
Introduction

The last several decades have witnessed the rapid growth of artificial intelligence (AI) applications in health care. AI is considered to comprise areas like machine learning, natural language processing, expert systems, and image and signal processing [1]. One group, who cited a study from Global Market Insights, noted that the use of AI in health care was expected to grow annually from 2016 to 2024, with expenditures increasing from US $760 million in 2016 to over US $10 billion in 2024 [2]. In a 2020 study, Global Market Insights noted that the AI in the health care market exceeded US $4 billion in 2020 and would grow at a compound annual growth rate of 33.7% between 2021 and 2027, with an expenditure of US $34.5 billion in 2027 [3]. This market growth has been accompanied by both national initiatives for AI and the rapid growth of academic literature on the use of AI in health care. For example, in India, an “AI for All” policy was established along with NITI (National Institution for Transforming India) Aayog—a Government of India think tank for formulating a national strategy for AI [4]. A bibliometric analysis of the literature reported in the Journal of Medical Internet Research found a growth rate of 45.15% in publications from 2014 to 2019, with 70.67% of all publications occurring in the same period [5]. This analysis also found the following top five health problems in the publications (in order of frequency): cancer, depression, Alzheimer disease, heart failure, and diabetes. Another review of AI applications in health care found the following areas of focus in the applications: sepsis, breast cancer, diabetic retinopathy, and polyps and adenomas [6]. Additionally, this review noted that the implementation of AI applications in real-world clinical settings is not widespread. Another recent review with a focus on patient safety outcomes also noted the lack of AI applications in real-world settings [7]. These articles, and others in the Journal of Medical Internet Research and elsewhere, have started to capture the use and role of AI in health care [8-11].

In this viewpoint, we contribute to this growing literature by detailing physicians’ experiences with an AI application—Watson for Oncology (WoF)—in the treatment of cancer. Physicians’ experiences with WoF are especially relevant, as the application has been implemented in diverse, real-world social and cultural settings. Our summary of physicians’ experiences with WoF relies on the extensive, published literature on this topic. After we describe physicians’ experiences with WoF, we comment about the opportunities and challenges associated with using AI for cancer care in low-middle–income countries (LMICs).

The WoF Clinical Decision Support System Tool

WoF is a therapeutic oncology clinical decision support system (CDSS) that was trained by experts from the Memorial Sloan Kettering Cancer Center [12]. WoF uses both natural language processing and machine learning to process structured and unstructured data about patients with cancer and generate therapeutic options based on available evidence [13]. WoF provides 3 categories of therapeutic options: “recommended” treatments are those that adhere to the preferred training approach of the Memorial Sloan Kettering Cancer Center, treatments “for consideration” refer to alternative treatments based on evidence, and “not recommended” treatments refer to those that are not appropriate for certain patients [14]. Many early adopters of WoF measured the degree to which WoF therapeutic options were concordant with either clinical practice or the decisions of a multidisciplinary tumor board. WoF concordance rates varied widely across countries for many reasons, including differences in standard treatment guidelines, resource availability, and physician or patient preferences [15]. It is well recognized that concordance studies do not measure system accuracy but instead assess agreement with decisions made in practice, which may or may not reflect evidence-based decisions [16].

In this viewpoint, we focus on physicians’ perceptions of and satisfaction with WoF. We believe that an evaluation of physicians’ perceptions of this AI tool will provide valuable insights for the successful implementation of AI-based CDSSs for cancer treatment, especially in LMICs. Additionally, little is known about how physicians perceive the use of AI tools for cancer treatment. We present physicians’ perceptions of the advantages of, as well as the disadvantages and concerns with, AI in a real-world setting. Our summary relies on published literature on physicians’ perceptions of WoF implementation in a number of countries, including China, India, Mexico, South Korea, and Thailand. Multimedia Appendix 1 provides a comprehensive list of the studies on WoF [13-74].

Advantages

The positive perceptions of WoF relate to the system’s ability to aid clinicians during the therapeutic decision-making process by quickly providing relevant scientific evidence. In China, a satisfaction survey, which was completed by 51 oncologists who used WoF, found that 86.3% of oncologists approved the quality of WoF and 88.2% approved the comprehensibility of WoF’s treatment options, justifications, and external literature [17]. The clinicians rated WoF highly in terms of its ability to provide evidence-based medicine medical education (score: 8.1/10) and literature assistance (score: 7.7/10), assist in medical care quality control (score: 7.3/10), act as a second-opinion consultation resource (score: 7.0/10), assist in medical care quality control (score: 6.9/10), and provide decision support (score: 6.4/10). Overall, the oncologists recommended using WoF as a CDSS to other clinicians (score: 7.3/10). At Shanghai Tenth People’s Hospital, the multiple disciplinary team (MDT) also used WoF and found that their treatment plans became “more standardized, reasonable, and personalized” [18].

WoF’s ability to compare treatment options was tested in Mexico, where it was used for a total of 100 patient cases involving lung, breast, gastric, colon, and rectal cancers diagnosed within the last 5 years [19]. In terms of perceived utility, oncologists found WoF to be “very useful” in comparing treatment options. They reported that WoF might be especially valuable for individuals, such as medical students and residents who lack oncology experience, as well as clinics that do not have enough subspecialists. Several implementations of WoF
in China indicate the role of WfO in enhancing the learning experience and efficiency of physicians, particularly junior physicians, and the facilitation of better diagnoses and treatment recommendations [20,21]. This perspective was also substantiated by students from Taipei Medical University Hospital in Taiwan who had limited clinical experience; by using WfO, they performed better on their colon cancer learning assessment than their peers who used traditional search methods and were more clinically experienced [22]. The study also found that students with less clinical experience felt that WfO was “clearer and more understandable” than information found through traditional methods.

WfO’s links to recent and relevant scientific information may provide treatment information that clinicians may not know. In India, an MDT changed their treatment recommendations for 136 of 1000 cases of breast, lung, colon, and rectal cancers because of the data provided by WfO [23]. For 55% of those cases, WfO provided recent evidence of newer treatments. For 30% of the cases, WfO provided new information about genotypic and phenotypic data. For 15% of the cases, WfO provided information on evolving clinical experiences, which influenced the MDT to change their treatment decisions. These results demonstrate the potential of WfO to positively impact cancer outcomes by providing scientific evidence and up-to-date information on clinical guidelines. In a separate study that focused on adjuvant systemic therapy for breast carcinoma, treatment decisions were changed for 4 of 11 patients after the MDT reviewed WfO’s recommendations and EndoPredict (Myriad Genetics Inc) test reports [24]. WfO was able to aid clinicians in providing personalized cancer care while addressing the difficulties of staying informed on evolving cancer guidelines and studies.

Another aspect that must be considered is whether WfO can be useful as a CDSS. At the Instituto Câncer do Ceará in Brazil, a majority of oncologists chose the “agree” or “strongly agree” option for statements that were used to confirm if WfO meets the “CDS Five Rights” criteria [25]. The “CDS Five Rights” contain clinical quality criteria for determining if a CDSS offers benefits that are optimal for a given setting [75]. In the study, 6 of the 7 oncologists at the Instituto Câncer do Ceará believed that WfO provided relevant information that resulted in action being taken and presented the information in a manner that positively aligned with their individual workflows. Further, 5 oncologists agreed that the additional details for each treatment option were easily comprehensible, and 4 oncologists agreed that WfO exceeded their expectations as a CDSS tool for patient management.

### Disadvantages and Concerns

Although WfO appears to be useful for displaying information in a succinct and timely manner, there are concerns regarding the system’s usability and integration into clinician workflows. First, at sites without integrated patient record systems, some users found manual data entry to be a burdensome process [13,26]. At Manipal Hospital in India, it was observed that acclimation to the system reduced the time needed for each patient case [27]. The mean time needed to collect and enter data for nonmetastatic diseases was 20 minutes. This was reduced to 12 minutes after an increased acquaintance of 10 cases with WfO. In comparison, the time needed to collect and enter data for metastatic diseases was 5 to 7 minutes longer than that for localized diseases. On average, WfO took a median of 40 seconds to capture, analyze, and provide treatment recommendations. For physicians with a high patient load, the time needed to enter information into the system may be an issue. Users also want WfO to provide an explanation of its process for scoring and ranking treatment options [26]. In doing so, users would feel more comfortable with trusting the information and recommendations provided by WfO.

A second important concern that has been identified in studies is localizing WfO’s treatment recommendations to the country of implementation. In the previously mentioned satisfaction study conducted in China, 66.7% of physicians recommended that WfO should integrate data on locally available treatments to improve the system [17]. For example, WfO did not take into consideration whether the immunotherapy drugs it recommended had been approved by the China Food and Drug Administration. Physicians also chose chemotherapy instead of WfO’s recommended medication because the medication was too expensive for patients. Similar challenges were found for WfO users in Mexico and Thailand [19,28]. In Mexico, clinicians deviated from WfO’s recommendations due to the high costs associated with them and the fact that they did not adhere to Mexican cancer treatment guidelines [19]. In Thailand, oncologists preferred basing their treatment recommendations on other countries’ guidelines instead of US guidelines [28].

### Implications for LMICs

In 2012, 65% of all cancer deaths worldwide occurred in LMICs, and the projection for 2030 is that this will increase to 75% [76]. LMICs may also be experiencing an even higher burden from cancer than that experienced by high-income countries (HICs) for several reasons. LMICs have restrained funding and often lack optimal cancer registries and surveillance data; thus, they are unable to implement evidence-based cancer control programs [76]. Treatment modalities are also more limited in LMICs than in HICs; radiotherapy and chemotherapy are available in 43% to 51% of LMICs but are available in 94% of HICs [77]. However, there is a high demand for such therapies, as 5 million new people annually are estimated to need radiation therapy in LMICs [78]. LMICs also lack specialized medical personnel, such as oncologists and oncology nurses, who are needed to address those affected by cancer in LMICs [79]. According to a World Health Organization report, LMICs have the lowest density of health care workers in comparison to HICs, where the density of health care workers is significantly higher [80]. A lack of health care workers for serving the population makes offering high-quality, personalized care a difficult task.

Oncologists also often require the expertise of their colleagues and additional literary resources to determine a course of treatment for unique cancer cases. Gaining access to high-quality medical information is key for creating an appropriate treatment plan, but oncologists may need additional help with sorting information that is both relevant to their patients and viable in...
terms of what resources are available. AI-based platforms such as WfO may be able to address the growing challenges of providing cancer treatment plans in LMICs. AI can address issues of access to knowledge bases in a comprehensive and easy-to-access manner. The ability of AI tools to quickly provide evidence-based cancer treatment options would be especially helpful in low-resource settings where the lack of time, expertise, and other needed resources can become a barrier to providing care. Using AI in this manner may also promote international partnerships on cancer therapy research and standardize guidelines for certain cancer types. The studies reviewed in this viewpoint demonstrate the potential of AI to reduce the cognitive burdens of less experienced physicians who would benefit from additional medical education resources.

The experiences with WfO in different settings also reveal a positive perception of AI with regard to its ability to reassure clinicians and confirm their interpretations of data and the potential of such a tool to do so in an LMIC. The ability of AI to act as a second opinion resource and standardize treatments may prove especially useful for cancer care in LMICs where the likelihood of receiving comprehensive care and achieving positive outcomes is lower than that in HICs. A lack of available specialized medical personnel in LMICs, especially in rural regions, is one of the factors contributing to poor cancer outcomes in LMICs [81]. The ability of AI tools, such as WfO, to provide subspecialty treatment information makes such tools a much-needed resource that existing physicians can use to meet population demands, especially in rural areas, as envisioned for the use of AI in an LMIC like India [4,82]. Approximately 60 oncologists serve over 300 million people in West Africa, and only 2000 oncologists are available for 10 million patients in India [83-85]. WfO’s open-access information, which can be used to supplement self-paced learning, would be an ideal resource for cancer physicians in LMICs where medical education resources are lacking [86,87].

The use of an AI tool such as WfO in LMICs also poses certain challenges. The technological challenges that are unique to LMICs and should be mentioned include access to the internet, technology training, and whether local technology teams would be able to address technical issues [87]. Providing a decision support tool, such as WfO, that is user-friendly and aligns with daily workflows is essential for implementation in LMICs, where physicians’ experiences with technology can vary [87]. Additionally, there is concern about whether AI tools would exacerbate the divide in health care access and use, especially with respect to socioeconomic status. There is a fear that AI would recommend treatment options that patients cannot afford or that only high-income and educated patients who are aware of AI tools may benefit from the use of AI in LMICs [4,19,28].

Another important concern—one that applies to a tool such as WfO—is that the data and training of AI tools may not incorporate patient characteristics into treatment recommendations. For example, in China, local patient characteristics such as gene mutations and the weaker physiques of Chinese patients, which can influence treatment recommendations, were not accounted for in WfO recommendations [20]. Similarly, the need to consider the presence of multiple ethnic groups in countries like India during the implementation of AI tools developed by Western countries will be an important factor to address in LMICs [88].

Conclusion

It is undeniable that oncology physicians in LMICs need much additional support as possible. The implementation of AI tools, such as WfO, in different settings has revealed that access to a second opinion CDSS resource, concise scientific evidence, and international clinical guidelines can help physicians feel more confident in their final treatment decisions. To improve the clinical utility of AI tools such as WfO, it is necessary that the experiences and satisfaction of physicians who use such tools are explored more in-depth, especially those of physicians in LMICs. These perspectives are especially key to tailoring AI systems for use in real-world clinical settings [6,7]. Such perspectives are of course embedded in the local social, cultural, and political LMIC contexts within which AI is implemented and the ways in which local contexts can shape the use of AI. We are gaining experience with respect to the implementation of AI tools, such as WfO, in real-world settings for the treatment of cancer. However, we still need to address some of the challenges in the “last mile” stage of implementation, specifically those related to local contexts [89].

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Conflicts of Interest

SE, AR, and DWB received salary support from a grant funded by IBM Watson Health. DWB has received research support from and consults for EarlySense, which makes patient safety monitoring systems. He receives cash compensation from the Center for Digital Innovation (Negev), which is a not-for-profit incubator for health information technology start-ups. He receives equity from ValeraHealth, which makes software to help patients with chronic diseases; Clew, which makes software to support clinical decision-making in intensive care; and MDClone, which takes clinical data and produces deidentified versions of them. He consults for and receives equity from AESOP, which makes software to reduce medication error rates, and FeelBetter. He has received research support from MedAware. RFR is employed by IBM Watson Health. GPJ was employed by IBM Watson Health at the time of manuscript submission and GPJ’s compensation included salary and equity. All other authors declare no conflicts of interests.
### References


**Abbreviations**

- **AI**: artificial intelligence
- **CDSS**: clinical decision support system
- **HIC**: high-income country
- **LMIC**: low-middle–income country
- **MDT**: multiple disciplinary team
- **NITI**: National Institution for Transforming India
- **WfO**: Watson for Oncology

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Exploring Resource-Sharing Behaviors for Finding Relevant Health Resources: Analysis of an Online Ovarian Cancer Community

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Abstract

Background: Online health communities (OHCs) provide patients and survivors of ovarian cancer (OvCa) and their caregivers with help beyond traditional support channels, such as health care providers and clinicians. OvCa OHCs promote connections and exchanges of information among users with similar experiences. Users often exchange information, which leads to the sharing of resources in the form of web links. Although OHCs are important platforms for health management, concerns exist regarding the quality and relevance of shared resources. Previous studies have examined different aspects of resource-sharing behaviors, such as the purpose of sharing, the type of shared resources, and peer user reactions to shared resources in OHCs to evaluate resource exchange scenarios. However, there is a paucity of research examining whether resource-sharing behaviors can ultimately determine the relevance of shared resources.

Objective: This study aimed to examine the association between OHC resource-sharing behaviors and the relevance of shared resources. We analyzed three aspects of resource-sharing behaviors: types of shared resources, purposes of sharing resources, and OHC users’ reactions to shared resources.

Methods: Using a retrospective design, data were extracted from the National Ovarian Cancer Coalition discussion forum. The relevance of a resource was classified into three levels: relevant, partially relevant, and not relevant. Resource-sharing behaviors were identified through manual content analysis. A significance test was performed to determine the association between resource relevance and resource-sharing behaviors.

Results: Approximately 48.3% (85/176) of the shared resources were identified as relevant, 29.5% (52/176) as partially relevant, and 22.2% (39/176) as irrelevant. The study established a significant association between the types of shared resources ($\chi^2_{18}=33.2$, $P<.001$) and resource relevance (through chi-square tests of independence). Among the types of shared resources, health consumer materials such as health news ($P<.001$) and health organizations ($P=.02$) exhibited significantly more relevant resources. Patient educational materials ($P<.001$) and patient-generated resources ($P=.01$) were more significantly associated with partially relevant and irrelevant resources, respectively. Expert health materials, including academic literature, were only shared a few times but had significantly ($P<.001$) more relevant resources. A significant association ($\chi^2_{10}=22.9$, $P<.001$) was also established between the purpose of resource sharing and overall resource relevance. Resources shared with the purpose of providing additional readings ($P=.01$) and pointing to resources ($P=.03$) had significantly more relevant resources, whereas subjects for discussion and staying connected did not include any relevant shared resources.
Conclusions: The associations found between resource-sharing behaviors and the relevance of these resources can help in collecting relevant resources, along with the corresponding information needs from OvCa OHCs, on a large scale through automation. The results from this study can be leveraged to prioritize the resources required by survivors of OvCa and their caregivers, as well as to automate the search for relevant shared resources in OvCa OHCs.

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KEYWORDS
online health community; resource sharing; link sharing; topical relevance; information seeking; ovarian cancer; user behavior modeling

Introduction

Background and Motivation

Ovarian cancer (OvCa) affects approximately 22,000 women per year in the United States [1-3] with a 70% recurrence rate [4]. Survivors of OvCa are individuals diagnosed with cancer irrespective of their state of disease [5]. They typically receive intensive oncological treatment, which has adverse effects on their quality of life [6-10]. Both survivors of OvCa and their caregivers require support and have various information needs throughout the course of OvCa [11,12]. Health care providers try to address their common information needs through standardized patient and caregiver educational materials; however, these materials may lack information to address both survivors’ and their caregivers’ unique and dynamic information needs [13,14].

To meet their unique information needs, a growing number of survivors of OvCa and their caregivers generally seek support from online health communities (OHCs) on a regular basis. OHCs enable these individuals to connect and exchange information with other individuals with similar experiences [15-18]. OHCs specific to gynecological cancer also provide a platform where women with OvCa can freely share their experiences and feel a strong sense of belonging [19]. Owing to their powerful communal nature, OHCs could offer survivors of OvCa and their caregivers an opportunity to exchange information individualized to their needs. This exchange of information often leads to resource sharing among users in the form of web links [17,18]. The resources shared among OHC users can serve as educational materials that address their unique information needs. These shared resources can potentially benefit survivors and caregivers by helping them acquire knowledge about different aspects of the disease, including but not limited to treatment, diagnosis, and disease management.

Despite the benefits of shared resources, some important questions arise, given that OHC users are health consumers and might not be health experts: which resources shared by the OHC peers are relevant to the information needs of survivors of OvCa and their caregivers, and what aspects of resource sharing can help us determine resource relevance? Previous research examined health literacy in OHCs and revealed that most of the content is generated by users with underdeveloped skills in validating information sources and navigating the internet [20]. Therefore, users need help in finding the relevant resources generated or shared in OHCs [21]. Motivated by this, the objective of this study is to examine the connections between users’ resource-sharing behaviors and the relevance of shared resources. The outcomes can help future research locate relevant resources that are helpful in educating survivors and caregivers on OvCa OHCs. This study is part of an ongoing project, Health e-Librarian with Personalized Recommender (HELPeR), which aims to recommend personalized, relevant information resources to survivors of OvCa and their caregivers (HELPeR study 1R01LM013038-01A1). The ultimate goal of HELPeR is to improve the quality of user-focused recommendations in all aspects of OvCa care.

Most previous studies examined resource sharing in OHCs [22,23], although little attention has been paid to understanding if these resources are relevant to user information needs. Few studies have examined the quality and relevance of user-generated data on OHCs [24-27]; however, these studies are based on the content of the user post and do not address the quality of shared resources. This study fills this gap by exploring the relevance of the shared resources. This study extends previous studies by determining the relevance of shared resources and post content. Examining the relevance of resources will reveal what resources can help fulfill the information needs of survivors of OvCa and caregivers. Resource relevance has multiple dimensions, including topical relevance, readability, trustworthiness, timeliness, and clinical validity [28,29]. This paper considers topical relevance, which defines whether the content addresses the information needed [28]. A resource is relevant if its content addresses the information needed by the user; otherwise, the resource is irrelevant. In the rest of the paper, the words relevance and topical relevance are used interchangeably.

User behavior has been substantially explored in the context of search engines and recommender systems [30-33]. For example, users’ seeking behaviors are examined to improve search quality by determining the relevance of a search result against users’ information needs [30,31,34]. User behavior can help provide 2 types of user feedback. Explicit feedback is where users themselves provide feedback about the relevance of an item (eg, liking a search result). On the other hand, implicit feedback is obtained without user intervention (eg, by tracking the dwell time on a search result page). Recently, user behavior has also been used in web-based community research [24,35]. Wan et al [24] used web-based community–specific user behaviors, including the presence of quotations in a post (implicit) and the number of replies to a post (implicit), along with other features to train a post quality scoring algorithm. Explicit feedback, including post likes [35], and implicit feedback, including participant reputation [36], were also used to determine the relevant posts in a thread in a social media forum. Differing
from previous studies, this study explores resource-sharing behaviors pertaining to OHC users to determine shared resource relevance. In OHCs, resource-sharing behaviors are examined to determine how OHC members engage with shared resources [22,23]. Zhang and Sun [22] examined the purpose of resource sharing in a web-based diabetes forum to reveal the support that shared resources provide. Nathan et al [23] studied the types of resources shared in an OHC and OHC users’ like reaction on WebMD threads [37] to reveal the types of resources trusted by OHC users. Although resource-sharing behaviors have been studied in OHCs, there is no study on whether these resource-sharing behaviors can determine the relevance of shared resources. Given the dearth of research in this area, the purpose of this study is to examine (1) the relevance of resource sharing on an OvCa OHC and (2) users’ resource-sharing behaviors associated with shared resource relevance in an OvCa OHC. Examining both resource relevance and resource-sharing behaviors provides insights into which user behaviors are associated with relevant and irrelevant resources.

**Objectives**

Figure 1 provides the overall description of our study design. This study was a descriptive analysis of the OvCa OHC threads.

![Figure 1. Workflow of the study. NOCC: National Ovarian Cancer Coalition.](image)

**Methods**

The study was performed on the National Ovarian Cancer Coalition (NOCC) forum. To address the RQs, we first determined the relevance of the shared resources and later used different resource-sharing behaviors to calculate their association with relevance using a chi-square test.

**Data Source and Collection**

For OvCa OHC data, we relied on NOCC [38]. NOCC is a subcommunity of the Cancer Connect Community [39], which brings together survivors of OvCa and caregivers. NOCC users start threads in seeking information, receiving a second opinion, sharing experience, and receiving emotional support, whereas other participants provide support by replying to these threads in the form of comments. Forum users also express gratitude toward posts and comments using the like button. The NOCC is a patient-oriented community in which moderators are also survivors of OvCa or caregivers. We selected the NOCC because of its two unique properties:

1. It is an OvCa-specific community, which is a rare cancer with less exposure or awareness among general survivors of cancer and caregivers.
2. OvCa is a women-only cancer; therefore, the platform allows for the free exchange of information and resources with other individuals with similar experiences, where OHC users' reactions on the shared link and the relevance of these resources in an OvCa OHC?
users have developed a sense of community and connection [19].

NOCC is not a public community; therefore, we obtained permission from the institutional review board to collect and analyze the forum content. We collected data available from June 2010 to December 2020. Each thread comprises an initial post and replies to comments. For each thread, the following information was recorded: the title of the thread, initial post content, poster’s name, all comments on the post, comment users’ names, number of likes on comments, number of likes on posts, users who liked, time of posts, and time of comments. Figure 2 shows an example of a NOCC thread and its different components. The actual content of the post was removed to better show the basic structure of the thread and ensure patient privacy. Each thread is initiated by a NOCC user, which includes the title of the thread and an initial post. The initial post is followed by comments and replies from the forum users. Comments or reply posts are where the resources are shared in response to the information needed in the initial post.

Figure 2. A typical National Ovarian Cancer Coalition thread component, which includes the thread poster, title of thread, initial post, reply posts, and like button. The actual content of the thread was removed for privacy of National Ovarian Cancer Coalition users. The purpose of this figure is to provide readers with a basic understanding of communication patterns on this forum.

The data for analysis were deidentified to remove participant information from the initial posts and all comments. From the 909 threads, we selected 105 (11.6%) threads for this study, as explained below:

1. First, we filtered posts containing advertisements from health organizations. These threads included advertisements such as survey enrollment, product advertisements, and monthly updates from the NOCC moderator.
2. Then, of the 909 threads, 495 (54.5%) threads were selected in which the initial post contained a question. For simplicity, in the following sections, we would refer to this data set of 105 threads as NOCC question threads.
3. From the 495 selected threads, we further examined 105 (21.2%) threads where users shared resources (URLs) in their reply comments.
4. Links were extracted from 105 threads using regular expressions [23]. We found 176 links shared among these 105 threads.
5. For our final data set, we assembled 176 post–comment pairs, where each post had a question, and each comment contained a shared link. Thereafter, we will call this data set with 176 post–comment pairs the NOCC shared resource (NOCC-RS) data set.

Manual content analysis was performed on NOCC-RS to annotate relevance, types of resources, and purpose of sharing resources (Figure 1). Each annotation procedure was performed separately to ensure that one annotation did not influence the other. To report the quality of each annotation, we calculated the intrater reliability score using Cohen $\kappa$ [40]. Cohen $\kappa$ (equation 1) is a widely accepted measure for ensuring the quality of annotator agreement and is more robust than calculating percentage agreement [40]. A percentage agreement of $\geq 0.85$ [41] and a Cohen $\kappa$ coefficient of $\geq 0.5$ [42] are acceptable quality for annotations. As a result, an acceptable $\kappa$ measure was obtained:
Here, \( \alpha_o \) is the probability of an item receiving the same code from both annotators, and \( \alpha_c \) is the probability of agreement occurring by chance. \( N \) is the total number of items for annotation, and \( n_{li} \) is the number of times an annotator \( i \) predicted label \( l \).

All annotators met every week to decide the coding schema for each annotation, discuss disagreements on overlapping samples, and calculate the \( \kappa \) score. In the following sections, each annotation process is discussed in detail, along with the coding schema.

Resource Relevance Annotation

To assess the relevance of each resource shared for the corresponding information needed (ie, the question in the initial post), we developed a coding scheme that classified the resources into three categories: relevant, partially relevant, and irrelevant. For each resource, annotators, VH and YC, first checked the initial post that contained the question and then read the comment post that contained the link. Relevance was judged based on the topical relevance between the link and the question asked in the corresponding thread. The study engaged two domain experts to accomplish this task: VH was a nurse, and YC was a researcher focused on the needs of survivors of OvCa and caregivers. Initially, the annotators started with a binary coding scheme: relevant and irrelevant. Later, after discussion among annotators, they found that there were many resources that did not provide the original information needed by the user but were still helpful to the user. Thus, although partially relevant resources did not answer the question, they were either usable for users, given their information needs, or helpful to the user to reach the relevant resource. This resulted in the 3 categories described in Textbox 1. Textbox 2 provides examples of all 3 categories from the NOCC forum post. The interrater agreement between the 2 annotators is Cohen \( \kappa = 0.65 \), calculated on 39.8% (70/176) data overlap, with a substantial agreement of 81%.

Textbox 1. The classification scheme for resource relevancy with description and corresponding example.

<table>
<thead>
<tr>
<th>Code and description (all relevance annotations were based on topical relevance)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Irrelevant</td>
</tr>
<tr>
<td>• The information provided through the resource does not address the corresponding question asked.</td>
</tr>
<tr>
<td>• Partially relevant</td>
</tr>
<tr>
<td>• The information provided through the resource does not provide a direct answer to the corresponding question but can either provide some related information to find relevant information or is useful to the user.</td>
</tr>
<tr>
<td>• Relevant</td>
</tr>
<tr>
<td>• The information provided through the resource directly addresses the corresponding question and provides an answer to the corresponding question.</td>
</tr>
</tbody>
</table>

Textbox 2. Example posts (some information is removed for anonymization).

**Initial post with a question**

• “I was diagnosed with ovarian stage 3c—background information—My doctor wants to add Avastin to my next 3 rounds of chemo. I am worried about adding it because of all the side effects I already had a reaction to the carbo once and that was very bad. Do you know anything about the side effects of Avastin?”

**Relevance and comments with a shared resource**

• Relevant resource: “Avastin definitely plays a major role in both treatment and maintenance therapy for a number of cancers. About Avastin: news.cancerconnect.com/treatment-care/answers-to-faq-s-about-avastin/”

• Partially relevant resource: “Hi XXX, treatment decision-making can be so difficult. Good for you for looking at all your options. Have you had a second opinion at another large cancer center? Asking your doctors about the risks and benefits of each treatment option is important. The NCCN patient guidelines for ovarian cancer might also be a helpful resource for you (www.nccn.org/patients/guidelines/ovarian/index.html). Hope this helps and keep us posted!”

• Irrelevant: “If you want to discuss this more and want to connect, please connect to my blog: http://xxx.blogspot.com”

Resource Type Annotation

To answer RQ1, the shared resources were categorized. Each resource was categorized based on the domain and content of the links. For domain name–based categorization, we relied on the top-level domain (TLD) of the URL, as in the study by Nathan et al [23]. Domain names are designed to represent websites distributed among various hosts and network systems,
with a string of characters usually separated by dots as their structure. The TLD is the last part of the domain name of US websites. If a domain name is outside the United States, its TLD is the second to last part of the URL. From the TLD, one can determine the entity, administrator, and intended use of a website [43]. For example, the TLD of ncbi.nlm.nih.gov is .gov, indicating that the website belongs to a governmental entity, and that of ovarian.org is .org, indicating that it is an organization website. This study adopted 6 TLDs, including .com, .edu, .org, .net, .io, and .gov.

To move beyond simple domain name–based analysis, we manually examined each link and classified the shared resources into content-focused categories. Initially, two coders (KT and YC) separately coded the links using the coding scheme mentioned in [44], which is specifically used for the classification of health domain webpages during the consumer search process. During the subsequent debriefing, the discussion among coders about disagreements led to the refinement of the original categories. Two new categories were introduced—nonhealth articles and patient educational resources—which were missing from the previous study. Table 1 provides the final 10 types used to classify resources. It is assumed that the links belonging to each category have similar types of content and are for similar consumers. The interannotator agreement between 2 annotators was Cohen κ=0.8, calculated on 19.3% (34/176) data overlap.

Table 1. Coding scheme for resource types with description and corresponding example.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Example domains</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health articles</td>
<td>A link containing focused information about one specific health topic with content written for health consumers in mind; this could include health articles, health expert blogs, and health topic information websites</td>
<td>Cancer.net [45], Med-Health.com [46]</td>
</tr>
<tr>
<td>Health news</td>
<td>A webpage presenting health news; this could include news about findings in research, treatment results, and updates on medications and clinical trials</td>
<td>CancerConnectNews [39], Medicaexpress [47]</td>
</tr>
<tr>
<td>Patient educational resource</td>
<td>Resources provided by government and cancer organizations, including patient guidelines, factsheets, and patient booklets</td>
<td>Cancer.gov [48], NCCN.org [49]</td>
</tr>
<tr>
<td>Academic literature</td>
<td>Research articles and clinical trial articles</td>
<td>NCBI.gov [50], Eurekalert.org [51]</td>
</tr>
<tr>
<td>Web-based social groups</td>
<td>A link containing user discussions and posts on web-based communities, question answering forums, and social networking sites</td>
<td>NOCC.ovarian.org [52], CSN.Cancer.org [53], Facebook [54]</td>
</tr>
<tr>
<td>Health organizations</td>
<td>A link referring to the home page of a health organization, medical school, nonprofit institute, or government website</td>
<td>Ovarian.org [38], Dana-Farber.org [55]</td>
</tr>
<tr>
<td>Patient blogs</td>
<td>Patient- or caregiver-generated personal websites and blogs</td>
<td>xxx.blogspot.com</td>
</tr>
<tr>
<td>e-Commerce</td>
<td>Online shopping sites and product promotion/advertisement web pages</td>
<td>Omiana [56], 100percentpure [57]</td>
</tr>
<tr>
<td>Videos</td>
<td>Links to video content</td>
<td>YouTube [58]</td>
</tr>
<tr>
<td>Nonhealth articles</td>
<td>Shared content outside of the health domain</td>
<td>Lawfirm [59], Wikipedia [60]</td>
</tr>
</tbody>
</table>

Resource Purpose Annotation

The purpose of a link refers to the role the link serves in a post [22]. Zhang et al [22] unveiled the relationship between the type of forum user (frequent vs occasional contributors) and the purpose of their link-sharing behavior. The coders started with the coding schema of Zhang et al [22], which defined six roles of links shared in the initial posts: providing additional reading, supporting arguments, subjects for discussion, recommendations for peers, the source of a post, and asking for help. As coding proceeded, we removed two categories that we considered inapplicable to the link-sharing purpose in the comments (recommendation for peers and asking for help), and we added two new categories: pointing to resources and staying connected. The coding scheme includes providing additional readings, supporting arguments, subjects for discussion, pointing to resources, and staying connected. Table 2 presents the final definition of each purpose and an example comment with a URL link.

Resource purpose annotation was performed independently of resource relevance annotation and only by reading the comment and ignoring the initial post. Two coders independently annotated the role of the shared link with a 34.1% (60/176) overlap of comments between them. The final agreement after the second round of annotation was 93%, with Cohen κ=0.88, which indicates a substantial agreement. After addressing all the disagreements between the 2 coders, KT proceeded to code all the remaining comments.
User Reaction to Shared Resources

OHC websites usually provide ways for users to provide feedback (liking, disliking, and helpfulness) on posts and comments. NOCC offers its users a like button that can be used to display gratitude and other positive feelings about a post or comment. In modern recommender systems, signs of user appreciation such as thumbs-up and likes are signs of item relevance for the user and form the main source of knowledge for recommendations [32]. The motivation for RQ3 was to reassess this assumption in the context of an OHC and determine whether like reactions of OHC users on comments that contained shared resources could be used as a sign of relevance to cross-recommend liked resources and to serve as a gold standard for resource relevance studies. The like reactions were explored in two ways: first, like reaction from the user who asked the question in the initial post and second, like reactions from all peers on NOCC. Our hypothesis is that as the resource is shared for the information needed from the thread initiator, the like from this user might be a good indicator of the relevance of a resource.

Ethical Approval

NOCC is not a public community; therefore, we obtained permission from the institutional review board to collect and analyze the forum content. Ethical approval for the study was granted in June 2021 by the Institutional Review Board of University of Pittsburgh (STUDY21050190). The institutional review board determined that the proposed activity is not research involving human subjects as defined by Department of Health and Human Services and Food and Drug Administration regulations.

Results

Overview

We obtained all threads from a period of 10 years from the NOCC, which is a well-known site for patients with OvCa. OvCa is a rare cancer; therefore, the NOCC had 909 threads from a period of 10 years of data collection. Furthermore, from the 909 threads, we obtained 105 (11.6%) threads with an information need (NOCC question threads), where 176 links were shared in the comments. These 176 shared links, along with the initial posts and comments with links, formed our NOCC-RS data set.

In the following sections, first, the statistics on resource relevance are presented, followed by a discussion of the association between resource relevance and resource-sharing behaviors.

Resource Relevance

There were 85 relevant, 52 partially relevant, and 39 irrelevant resources. The relevance distribution indicates that 48.3% (85/176) of all shared links lead to resources that are relevant to the needs expressed in the original post. Furthermore, we observed that out of 105 threads, only 53 (50.5%) were answered by sharing at least one relevant resource. Of the remaining 52 posts, 48 (92%) obtained no relevant resources but ≥1 partially relevant resource. Finally, 3.8% (4/105) of posts did not receive any relevant or partially relevant resources in response.
Resource Type

Resource Type Based on TLD

The most frequent TLD was .com, which covers 56.3% (51/176) of all shared resources (eg, cancerconnect.com, youtube.com, and xxx.blogspot.com), followed by .org (eg, nccn.org, ovarian.org, and dana-farber.org), .gov (eg, cancer.gov, ncbi.nlm.nih.gov, and nccih.nih.gov), .edu (eg, harvard.edu, mit.edu, and vcu.edu), .io (eg, mavendoctors.io), and .net (eg, med-health.net and cancer.net). We merged the remaining 2 TLDs together, which were .me and .nz, and were shared only once. Table 3 provides details on the number of links shared in each TLD and percentage of relevant resources.

To answer RQ1, we examined the association between TLDs and the relevance of a resource. The chi-square test of independence was performed on two categorical variables: TLDs (.com, .gov, .org, .edu, .io, and .net) and relevance (relevant, partially relevant, and irrelevant). The results indicated no association between TLD and relevance ($\chi^2_{15}=19.2; P=.10$).

Table 3. Top-level domain (TLD)-based distribution of shared resources and percentage of relevant resources (N=176 links).

<table>
<thead>
<tr>
<th>TLD</th>
<th>Links, n (%)</th>
<th>Relevant resources (n=85), n (%)</th>
<th>Partially relevant resources (n=52), n (%)</th>
<th>Irrelevant resources (n=39), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>.com</td>
<td>99 (56.3)</td>
<td>50 (58.8)</td>
<td>27 (51.9)</td>
<td>22 (56.4)</td>
</tr>
<tr>
<td>.org</td>
<td>45 (25.6)</td>
<td>20 (23.5)</td>
<td>16 (30.8)</td>
<td>9 (23.1)</td>
</tr>
<tr>
<td>.gov</td>
<td>16 (9.1)</td>
<td>9 (10.6)</td>
<td>5 (9.6)</td>
<td>2 (5.1)</td>
</tr>
<tr>
<td>.edu</td>
<td>8 (4.5)</td>
<td>2 (2.4)</td>
<td>2 (3.8)</td>
<td>4 (10.3)</td>
</tr>
<tr>
<td>.io</td>
<td>3 (1.7)</td>
<td>2 (2.4)</td>
<td>1 (1.9)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>.net</td>
<td>3 (1.7)</td>
<td>2 (2.4)</td>
<td>0 (0)</td>
<td>1 (2.6)</td>
</tr>
<tr>
<td>Other</td>
<td>2 (1.1)</td>
<td>0 (0)</td>
<td>1 (1.9)</td>
<td>1 (2.6)</td>
</tr>
</tbody>
</table>

Resource Type Based on Content

Table 4 provides the distribution of resources based on content type, whereas Table 1 shows an example of each resource type. Health news and health articles were the topmost shared types of resources and together accounted for 42% (74/176) of the links shared. These types were closely followed by health organizations and patient educational resources. The videos were shared in approximately 4.5% (8/176) of cases and included discussions by health experts (OncLive TV [61]), patient experiences, and other emotional support videos (relaxing music). NOCC peers also shared health organizations’ websites to fulfill information needs related to physician listings, funding institutes, and nearby nonprofit organizations. Web-based social groups were shared most of the time to point to similar previous discussions in the same OHC or another OHC. NOCC users shared their own blogs and their life journeys with their peers. Patient blogs were shared so that other OHC users could contact them, whereas commerce websites were used to share organic cosmetic products or clothing for patients with cancer.

Table 4. Resource type-based distribution of shared resources and percentage of relevant resources (N=176 links).

<table>
<thead>
<tr>
<th>Resource type</th>
<th>Links, n (%)</th>
<th>Relevant resources (n=85), n (%)</th>
<th>Partially relevant resources (n=52), n (%)</th>
<th>Irrelevant resources (n=39), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health news</td>
<td>38 (21.6)</td>
<td>23 (27.1)</td>
<td>12 (23.1)</td>
<td>3 (7.7)</td>
</tr>
<tr>
<td>Health articles</td>
<td>36 (20.5)</td>
<td>20 (23.5)</td>
<td>11 (21.2)</td>
<td>5 (12.8)</td>
</tr>
<tr>
<td>Health organizations</td>
<td>21 (11.9)</td>
<td>12 (14.1)</td>
<td>6 (11.5)</td>
<td>3 (7.7)</td>
</tr>
<tr>
<td>Web-based social groups</td>
<td>20 (11.4)</td>
<td>8 (9.4)</td>
<td>6 (11.5)</td>
<td>6 (15.4)</td>
</tr>
<tr>
<td>Patient resources</td>
<td>18 (10.2)</td>
<td>5 (5.9)</td>
<td>11 (21.2)</td>
<td>2 (5.1)</td>
</tr>
<tr>
<td>E-commerce</td>
<td>12 (6.8)</td>
<td>6 (7.1)</td>
<td>1 (1.9)</td>
<td>5 (12.8)</td>
</tr>
<tr>
<td>Academic literature</td>
<td>11 (6.3)</td>
<td>8 (9.4)</td>
<td>2 (3.8)</td>
<td>1 (2.6)</td>
</tr>
<tr>
<td>Patient blogs</td>
<td>9 (5.1)</td>
<td>2 (2.4)</td>
<td>3 (5.8)</td>
<td>4 (10.3)</td>
</tr>
<tr>
<td>Video</td>
<td>8 (4.5)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>8 (20.5)</td>
</tr>
<tr>
<td>Nonhealth articles</td>
<td>3 (1.7)</td>
<td>1 (1.2)</td>
<td>0 (0)</td>
<td>2 (5.1)</td>
</tr>
</tbody>
</table>

To answer RQ1, the distribution of resource relevance was checked for each resource type. Table 4 provides details of the distribution of these resources. Table 4 shows that most of the relevant resources came from health news and articles, followed by health organizations. It was also interesting that the fraction of relevant resources within the category was the highest for shared academic articles. To answer RQ1, we performed a chi-square test of independence between resource relevance and resource types. We found a significant association between resource relevance and resource type ($\chi^2_{18}=33.2; P<.001$). Furthermore, we applied the chi-square test of goodness of fit for each resource type. The results indicated that health news
\( \chi^2 = 22.4; P < .001 \), health organizations \( \chi^2 = 6.0; P = .02 \), patient educational materials \( \chi^2 = 7.0; P < .001 \), and academic articles \( \chi^2 = 7.8; P = .01 \) were not equally distributed among relevant, nonrelevant, and partially relevant resources.

**Resource Purpose**

Table 5 shows the distribution of the purposes of resource sharing. Most of the resources were shared to provide additional readings and point to resources. A much smaller proportion of the resources was shared to provide supporting arguments and subjects for discussion and to stay connected. Figure 3 shows the distribution of resource types in each of the purposes of sharing resources. It can be observed that providing additional readings can be achieved by sharing every resource type except videos. NOCC users found most of the additional readings from health articles and health news. Pointing to resources came mostly from health organizations. Academic literature was mostly shared to provide additional reading and supporting arguments.

**Table 5.** Purpose-based distribution of shared resources and percentage of relevant resources (N=176 links).

<table>
<thead>
<tr>
<th>Purpose of shared resource</th>
<th>Relevant resources (n=85), n (%)</th>
<th>Partially relevant resources (n=52), n (%)</th>
<th>Irrelevant resources (n=39), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Providing additional readings</td>
<td>84 (47.7)</td>
<td>43 (50.6)</td>
<td>26 (50)</td>
</tr>
<tr>
<td>Pointing to resources</td>
<td>67 (37.6)</td>
<td>32 (36.8)</td>
<td>21 (40.4)</td>
</tr>
<tr>
<td>Supporting argument</td>
<td>13 (7.3)</td>
<td>10 (11.5)</td>
<td>2 (3.8)</td>
</tr>
<tr>
<td>Subject for discussion</td>
<td>6 (3.4)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Staying connected</td>
<td>6 (3.4)</td>
<td>0 (0)</td>
<td>3 (5.8)</td>
</tr>
</tbody>
</table>

**User Reaction to Shared Resources**

**Overview**

In this section, we examine the *like* reactions of the forum users to a post in the thread and its connection to the information value of the post. This analysis is important to assess whether the number of *likes* from the community could be considered as a sign of a post’s *value* so that posts with many *likes* could be promoted and recommended as valuable. Table 6 arranges the *like* statistics for different groups of posts in order of general increase of their value. We considered comments with links and
comments to a post started by a question as potentially more valuable than average comments, as a link could provide valuable information, and a comment to a question is likely to contain a valuable answer. Comments with both properties (posted in response to a question and has a link) should be more valuable than comments with only one of these properties. To examine these most valuable comments in more detail, we selected 105 threads where a question was asked in initial posts and links were shared in comment posts. In Table 6, these threads are referred to as filtered threads. Arguably, the peak value is reached in comments within the threads that have links that are judged to be relevant to the question by the annotators. It should be noted that just the fact that a post has a link and is posted in response to a question does not assure that the link is relevant: only approximately 48.3% (85/176) of these links are relevant.

Table 6. Details of OHC\textsuperscript{a} user reactions on comments with shared resources\textsuperscript{b}.

<table>
<thead>
<tr>
<th>Comments</th>
<th>Relevance</th>
<th>Number of threads</th>
<th>Number of comments</th>
<th>Likes on comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>All comments (909 threads)</td>
<td></td>
<td>909</td>
<td>14,814</td>
<td>11,853 (80.01)</td>
</tr>
<tr>
<td>Comments with links</td>
<td></td>
<td>187</td>
<td>487</td>
<td>374 (76.83)</td>
</tr>
<tr>
<td>Comments in NOCC-QT\textsuperscript{c}</td>
<td></td>
<td>435</td>
<td>6063</td>
<td>4382 (72.27)</td>
</tr>
<tr>
<td>Comments in NOCC-RS\textsuperscript{d}</td>
<td></td>
<td>105</td>
<td>176</td>
<td>110 (63.21)</td>
</tr>
<tr>
<td>Comments in NOCC-RS</td>
<td>Irrelevant</td>
<td>21</td>
<td>39</td>
<td>23 (58.82)</td>
</tr>
<tr>
<td>Comments in NOCC-RS</td>
<td>Partially relevant</td>
<td>37</td>
<td>52</td>
<td>27 (52.83)</td>
</tr>
<tr>
<td>Comments in NOCC-RS</td>
<td>Relevant</td>
<td>57</td>
<td>85</td>
<td>60 (70.93)</td>
</tr>
</tbody>
</table>

\textsuperscript{a}OHC: online health community.
\textsuperscript{b}Filtered threads are 105 threads considered in this study where a question is asked in initial posts and links are shared in comments posts.
\textsuperscript{c}NOCC: National Ovarian Cancer Coalition.
\textsuperscript{d}Not available.
\textsuperscript{e}NOCC-QT: National Ovarian Cancer Coalition question threads.
\textsuperscript{f}NOCC-RS: National Ovarian Cancer Coalition shared resource.

**Reaction From Thread Initiator**

We started by examining the like reactions from the user who started the thread with a question, as shown in the last column of Table 6. As the data show, the assumption that the likes of the target user (who wants an answer) reflect the value of the post is correct: the fraction of liked posts increases as we go down the table. The assumption that the target user will have a stronger like reaction to relevant documents shared in response to the original post is generally correct. The proportion of target user likes for any response to a question (119/6063, 2.04%) is higher than the number of their likes of an arbitrary post (283/14,814, 1.91%). The proportion of likes for a response to a question with links is even higher (7/176, 2.8%), and the proportion of likes on responses with relevant links (3/85, 4%) is the highest overall, approximately twice as high as an average post with a resource link (8/487, 1.6%). Unfortunately, even for relevant links, the proportion of cases in which the post initiator likes a comment to their post is very low. Although these likes follow the expected trend, their low proportion makes it impractical to use the like behavior of the target user as a source of data to distinguish and recommend relevant documents. To examine whether the like behavior is associated with the relevance of a shared resource, we performed a nonparametric Kruskal-Wallis test ($H$ test). The $H$ test was performed as the data were not normally distributed, and the $H$ test was performed to compare likes by thread initiators on filtered threads. Although the percentage of likes was higher for comments with relevant resources, there was no significant difference ($H=0.073; P=0.70$) between likes on comments with shared links and comments with shared relevant links.

**Reaction From the Community**

If we consider the whole community (ie, the like reaction of all forum users), the coverage of comments with likes remarkably increases. Although only 1.91% (283/14,814) of all comments were liked by the originating user, 80.01% (909/119481) of comments received at least one like from the whole community, with 2.95 likes per comment on average. However, the connection between the likes and the information value of the post surprisingly goes in the opposite direction. Although the proportion of likes from the target user increases as we go down the table to more valuable posts, the proportion of community likes decreases. Instead of increasing the likeability of a post, adding a link decreases the community likeability of a post to 76.8% (187/487; mean 2.34, SD 2.01 likes). This trend is even more pronounced in filtered threads that start with a question, where likeability falls from 72.27% (435/6063; mean 2.55, SD 2.47) to 63.2% (105/176; mean 1.47, SD 1.69) for replies with a link. This trend breaks only at the very end of the table: answers with relevant links (57/85, 71%; mean 1.94 likes) were still slightly more likable than average answers with links but
were still less likable than an average reply to a post with a question (436/6063, 72.27%; mean 2.55). This interesting data indicate that the liking behavior of the originating user is different from the liking behavior of the whole community. We hypothesized that the likes of the target user were driven mostly by appreciation of the information and its relevance, whereas the likes of the community are driven more by compassion and acknowledgment of the effort to answer. In this situation, posts with links, which require more cognitive effort to consume before acknowledging, receive a lower share of likes, even if these posts look relevant. Unfortunately, this observation also means that community liking behavior cannot be considered a reliable indicator of a post’s value. An $H$ test on likes from the community on comments with filtered threads further revealed that there was no significant difference ($H=2.1; P=.10$) between likes on comments with shared links and likes on comments with relevant shared links.

## Discussion

### Principal Findings

Survivors of OvCa and caregivers increasingly rely on OHCs for informational support [15,16]. Survivors of OvCa and caregivers can exchange information individualized to their needs on OvCa OHCs [15-18]. As a result of this information exchange, users often share resources through web links [17,18]. Survivors of OvCa and caregivers might not be health experts [62]; thus, it is vital to know if the resources shared on OvCa OHCs are relevant to their information needs. Research has examined resource sharing in OHCs in the past; however, there is a paucity of studies that look at the relevance of such resources. This study fills this gap by examining the relevance of shared resources on an OvCa OHC forum and extends prior research [22,23] by examining the association of resource relevance with different aspects of resource-sharing behavior. An in-depth understanding of resource-sharing behaviors associated with resource relevance can help find informative resources shared in OHCs. As expected, this study found that only half of the shared resources were relevant to information needs. An analysis of different aspects of resource-sharing behavior suggests that resource behavior, including the purpose of sharing a resource and the type of resource, can be a reliable indicator of relevant shared resources, whereas explicit feedback of OHC users on a shared resource was not a reliable indicator of resource relevance.

### Resource Relevance

The results show that OvCa OHC peers can provide relevant resources related to the information needs of OvCa OHC users only half the time. This result does not indicate that users’ information needs from the initial post were not met. Rather, the results indicate that OvCa OHC users, who are survivors of OvCa and their caregivers (health care consumers who most of the time are not health care experts), might not be as efficient as we expected in finding relevant resources. For example, the user asks about the side effects of specific chemotherapy (altretamine), but the resource shared is pointing to the National Comprehensive Cancer Network guidelines [63], which contain general side effects from any chemotherapy but not specific to altretamine. In addition, from the shared resources, approximately 29.5% (52/176) of time the resources shared were partially relevant, which indicates that OvCa OHC users’ information needs are sometimes individualized and not addressed by generalized OvCa resources, such as patient education materials. This insight provides motivation for building a health resource recommender system that would individualize resources based on patients’ information needs and current disease trajectories.

This study found two important indicators for the topical relevance of shared resources: the types of shared resources and the purpose of shared resources. The findings related to the relationship between topical relevance and different resource-sharing behaviors complement and extend the study conducted by Zhang and Sun [22]. They studied the shared resources in the initial posts of a thread, whereas we investigated the shared resources in the comment posts to address the information needed in the initial post from the same thread. The fact that we studied the topical relevance of these resources and unveiled the association between resource-sharing behaviors and topical relevance may have the following benefits: (1) recognize the sources from which OvCa OHC users find relevant resources, (2) use resource-sharing behaviors to aggregate reliable shared resources in an OHC, and (3) recommend resources to OHC users with similar information needs so that they do not have to always rely on peer users.

### Resource Type and Resource Relevance

Exploration of resource type sharing revealed that NOCC users rely more on health consumer materials, including health news, health articles, and patient education resources, and less on health professional materials, such as academic literature (only 11/176, 6.3%). This could be as survivors of OvCa and caregivers often do not have adequate health literacy to understand health professional articles. On the other hand, patient materials targeted toward health consumers are probably more suitable [64]. However, when shared, academic literature was relevant to the information needed 73% (8/11) of the time. We assume that the high relevance of academic literature is because it can fulfill the complex information needs of OvCa OHC users.

NOCC peers also shared patient-generated materials, including patient blogs. Most of the time, patient blogs were meant to share their life journey and survival experiences with fellow users going through the OvCa journey. “...Is there anyone who has something similar?...” and “...Anyone out there survived against all odds for longer than 3 years before recurrence?” are some examples of information needed for which patient blogs were shared. A few times, patient blogs were also shared with the purpose of staying connected to the user who asked the question, as shown in the two following comments: “If XXX or you would like to connect with me more, I am at www.xxxblog.com” and “I recommend you go to my blog www.xxx.blogspot.com if you would like to stay in touch.” Thus, patient blogs are important resources that contain real patient experiences and provide a platform for connecting with fellow OHC users. Previous studies have found that forum users prefer narrative articles and user blogs over nonnarrative articles

https://cancer.jmir.org/2022/2/e33110

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(page number not for citation purposes)
[65,66]. However, our study observed that patient blogs were shared only 4.5% (8/176) of the time. In addition, patient blogs shared with the purpose of staying connected were mostly partially relevant or irrelevant, as they were not targeted to answer OHC users’ specific information needs. We assume that the reason could be the complex and unique information needs of OvCa forum users. Hence, finding similar experiences is not always feasible. Therefore, only a few patient-generated articles were shared.

Prior research [22] observed that news articles were shared only 13% of the time, whereas we observed that news articles were shared many times (38/176, 21.6%). One of the reasons for this could be the rarity of OvCa. Survivors of OvCa and caregivers are looking for new treatments and information on clinical trials, and symptom management and health news are good resources for identifying these new findings. There were many shared resources pertaining to the news that included news on new clinical trials, the studied effect of OvCa medication, and recent studies about new treatments, which further clarified that survivors of OvCa and caregivers are eager to learn about new findings and treatments available for a cure.

Resource Purpose and Resource Relevance

Zhang and Sun [22] studied the different purposes of resource sharing in a diabetes OHC. They studied resource sharing in initial posts, which were posted to share experiences, start discussions, and ask questions. However, we studied resource sharing in reply comments, which were intended to answer questions asked in the initial post of the thread. This is important as this study aimed to understand the relevance of shared resources, and questions asked in the initial post act as information needed against which the resource is shared.

Similar to Zhang et al [22], OvCa OHC users’ purposes for sharing resources include staying connected, providing further reading, subjects for discussion, and supporting arguments. However, a new category of pointing to resources was introduced in this study after the first round of annotator discussion. The pointing to resources category was added to handle cases where the purpose of the link was to provide available health resources (health institutions, search engines, or physicians) rather than providing direct reading material. We believe the reason for this category in our post is that Zhang et al [22] studied link sharing in initial posts, whereas this study focused on comment posts, where resources were shared to answer questions in the initial post. The pointing to resources purpose was used to answer questions regarding funding resources, clinical trials, and physicians’ listings. This category had the second-highest purpose of sharing resources. This finding also provides an important insight that patients on OvCa OHC require much advice on searching for treatment and funding resources. A chi-square test revealed that pointing of resources is associated with relevant articles and is an important indicator of relevant resources.

User Reaction to Shared Resource and Resource Relevance

Previous studies have shown that the perceived credibility of a post increases if more people like the post or show gratitude toward it [67]. NOCC followed a similar pattern, with more likes on relevant links and fewer likes on nonrelevant and partially relevant links. However, these likes are different from average like behavior on links; thus, they are difficult to rely on as they are not significantly associated with shared resource relevance (Table 6). This can be inferred from users’ average like behavior, which changed from 1.41 to 1.74; therefore, is hardly noticeable and is not significant, as shown in Table 6. Sarma et al [36] observed that user like reactions were not useful in ranking informative comments on the Twitter platform [68].

In line with previous studies, despite higher coverage, the like reaction of the whole community might not be a reliable indicator of the overall usefulness of a resource in NOCC [69-71]. Furthermore, a like reaction from the original user with the question could serve as an indicator of resource relevance; however, the low coverage of these likes (at maximum 3/85, 4% for relevant resources) makes it difficult to use this source of feedback in practice for finding relevant resources.

Future Work and Practical Implications

Health Care Educators

Our study observed that patient education materials were shared only 10.2% (18/176) of the time and were partially relevant or irrelevant 72% (13/18) of the time. This result informs health educators that patients often seek other materials to fulfill their information needs. One of the well-known education materials for patients with OvCa is the OvCa guidelines from the National Comprehensive Cancer Network. The guidelines were identified as partially relevant to the needs 86% (6/7) of the times shared. A possible reason could be that patient education materials have to be more personalized to satisfy an individual patient’s needs. This finding highlights a research gap for further improvement of patient education materials. For example, educational materials could include relevant patient case studies to be more personalized.

Another insight on patient educational materials is that patients with OvCa found more relevant documents from the news. This suggests that patient education materials can be updated with new facts and findings so that patients do not have to rely on external resources, which can potentially be misleading or untrustworthy.

OHC Administrators and Users

This study found that it is not informative on the relevance of shared resources to examine OHC users’ behaviors on the like button as feedback. This informs OHC forum administrators that a better and more informative feedback mechanism should be considered for OHCs. Our finding is also consistent with that of a recent study by Sarma et al [36], who found that forum user feedback in the form of likes is not enough to obtain informative feedback. A few examples of more informative feedback are the helpful button for shared resources, best answer button for initial post user feedback, and best answer button for forum moderator feedback. A more comprehensive study is required to understand better ways of obtaining user feedback on OHCs.

The study also reveals that there is an association between relevance and different aspects of resource-sharing behaviors.
An important implication of this study could be the accumulation of a library of patients with OvCa and their caregivers. OHC administrators can collect the resources shared by users and provide a library of resources to users so that they can bookmark and use these resources for future use. Survivors of OvCa have different information needs at different stages of the disease and treatment trajectory [72]. A health article library with predefined information needs and topics could work as a frequently asked questions list, which patients can browse through to meet their specific needs.

### Recommender Engine

It is a challenge to make informative content discoverable for patients with cancer. In addition, OvCa is a rare disease for which the internet has relatively fewer resources and experiences low quality [73]. Search engines help patients find information; however, their precision on the internet is low [16]. This study was conducted as part of our HELPeR project [74]. The goal of the HELPeR is to provide survivors of OvCa and caregivers with personalized health resources and reading materials. The study finding that relevant resources are shared only half of the time for a corresponding information need provides a motivation for the requirement of a recommender engine. It also provides insights that inform the types of resources to include and what roles these sources can fulfill; for instance, recommending more health news, health articles, and resources from health organizations that are frequently shared on NOCC. The finding of an association between relevance and resource-sharing behaviors reveals which user behaviors are reliable in determining the relevance of a resource. This can be used to automate data collection for training a machine learning–based recommender engine.

### Limitations

First, the relevance of a resource is based on topical relevance, which measures whether the provided resource addresses the corresponding question asked by the user. While checking for relevance, users’ knowledge level is not considered, which could play a major role in the relevance of a resource to an individual’s information need. For example, if a person with no medical background is provided with academic literature to fulfill their information needs, it may be difficult for them to understand the literature [20,75,76]. Similarly, other aspects of relevance, including the trustworthiness and clinical validity of the document, were not considered in this study [23,77]. Future work should combine the three aspects together to understand the relevance of a document, including topical relevance, users’ knowledge level, and resource trustworthiness.

Second, the study assumed OHC users’ information needs based on the questions asked by the user and the background information provided by the user within this post. The relevance of the shared resources is based on the user’s expressed information needs. This might not affect relevance if the actual information needed is different. For example, the user may not know how to express their information needs, or the user may not provide a proper context to fully understand their information needs.

Third, the study only analyzed 1 OvCa OHC; therefore, the results cannot be generalized to all OvCa OHCs. NOCC is a private and closely connected community; therefore, these results cannot be generalized to open OHCs such as WebMD [37] and question answering forums such as Yahoo Answers [78]. The study included data generated by the NOCC from 2010 to 2020 (10 years). However, NOCC contained only 909 threads during this period. This could be as OvCa is a rare cancer and is diagnosed in later stages. Hence, the study was performed on a very small data set. Future studies can include data from other OvCa OHCs to further improve the generalization and study scale.

Fourth, the study did not differentiate forum users based on their cancer stage and disease trajectory. We acknowledge that users in the later stages of the disease trajectory might have more expertise in handling the disease and treatment [76] and would thus have different views of relevant resources. However, as presented before, this is an inherent limitation of using a web-based forum, as users’ information about the disease trajectory, medications, and ongoing treatment might not be available.

In future work, we would also like to study how different types of information needs influence the relevance of resources. The type of information needed can range from early diagnosis to treatment decisions, disease management, and palliative care. This investigation can reveal specific cases or topics for which peers are unable to find relevant information. This will help in determining the simple and complex needs of OvCa OHC users and help us investigate which needs are still not fulfilled by OvCa OHC peers.

### Conclusions

Health professionals and clinicians are unable to support each need of survivors of OvCa and their caregivers. Health professionals provide survivors of OvCa with generic patient educational materials that are not sufficiently individualized to meet the needs specific to each patient. OHCs provide clinicians and researchers with a platform to observe the needs of survivors of OvCa and the resources that they rely on. In this study, we leveraged OHCs to investigate the resources that survivors of OvCa and their caregivers entrust to accomplish their and their peers’ information needs. Our study revealed that OHC users found more relevant resources from health news and health articles. Further investigation of OHC resource-sharing behavior revealed that direct evidence such as user reactions and TLDs were not enough to reveal the relevance of a resource, whereas implicit behavior, including types of resources shared and the purpose of resource sharing, had a direct association with resource relevance. The findings present implications and motivations for designing web-based recommender systems to support health information–seeking survivors of OvCa and caregivers. Subsequently, this resource collection will become part of our recommender system. Subsequent studies should further investigate how a resource’s relevance is influenced by the different types of information needs.
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Conflicts of Interest
None declared.

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Abbreviations

HELPeR: Health e-Librarian with Personalized Recommender
NOCC: National Ovarian Cancer Coalition
NOCC-RS: National Ovarian Cancer Coalition shared resource
OHC: online health community
OvCa: ovarian cancer
RQ: research question
TLD: top-level domain
Implementing a Health Care Professional–Supported Digital Intervention for Survivors of Cancer in Primary Care: Qualitative Process Evaluation of the Renewed Intervention

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Abstract

Background: Primary care plays an important role in supporting survivors of cancer; however, support is limited because of practitioners’ perceived lack of expertise and time. A digital intervention for survivors of cancer could provide an efficient way for primary care staff to support survivors of cancer without the need to accumulate expertise and skills to help patients make behavior changes; providing very brief support alongside this could maximize adherence to digital interventions. Renewed is a digital intervention that combines web-based behavior change advice with brief health care practitioner support from a nurse or health care assistant. Knowledge about the views and experiences of primary care staff providing support alongside a digital intervention for survivors of cancer is sparse, limiting the understanding of the acceptability and feasibility of this type of intervention.

Objective: This study aims to explore supporters’ experiences of providing support to survivors of cancer using Renewed, understand potential barriers to and facilitators of the implementation of Renewed in practice, and investigate the strengths and weaknesses of the intervention from the perspective of health care professionals.

Methods: This was a qualitative process evaluation nested within a large trial evaluating Renewed. A total of 28 semistructured telephone interviews were conducted with nurses and health care assistants. Data were analyzed using inductive thematic analysis.

Results: Four themes were developed during the analysis, which reflected the factors that supporters identified as hindering or enabling them to provide support alongside Renewed Online: Renewed Online as an acceptable digital tool with some improvements, confidence in enacting the supporter role, practicalities of delivering support alongside a digital intervention, and managing a patient-led approach. The analysis suggests that supporters perceived that a digital intervention such as Renewed would be beneficial in supporting survivors of cancer in primary care and fit within current practices. However, barriers to providing support alongside the intervention were also identified, including concerns about how to facilitate rapport building and, in a minority, concerns about using a nondirective approach, in which most advice and support is provided through digital interventions, with brief additional support provided by primary care staff.
Conclusions: These findings add to the literature on how best to provide support alongside digital interventions, suggesting that although most practitioners cope well with a nondirective approach, a minority requires more training to feel confident in implementing this. This study suggests that the barriers to providing formal support to survivors of cancer in primary care could be successfully overcome with an approach such as Renewed, where a digital intervention provides most of the support and expertise, and health care practitioners provide additional brief human support to maximize engagement. Strategies to maximize the chances of successful implementation for this type of intervention are also discussed.

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KEYWORDS
process evaluation; digital intervention; primary care; health care professional; web-based; quality of life; posttreatment; oncology

Introduction

Background

In 2018, the total number of people alive within 5 years of a cancer diagnosis was estimated to be 43.8 million worldwide [1]. Currently, there are 2.5 million survivors in the United Kingdom, which is estimated to increase to 4 million by 2030 [2]. However, up to 86% of people who complete cancer treatment in the United Kingdom, Australia, and the United States experience enduring side effects [3-5], including fear of cancer recurrence, anxiety, depression, fatigue, and weight gain, contributing to a reduced quality of life (QoL) [4].

The rising cancer burden places a strain on health systems worldwide [6]. Health care professionals (HCPs) based in primary care are central to providing support for people who have had cancer after completion of their primary treatment (eg, chemotherapy). However, these services are becoming overstretched and are increasingly unable to meet the needs of survivors of cancer [7]. For instance, survivors of cancer have expressed a need for more support with the emotional effects of cancer and issues such as fatigue that can occur months or years after treatment [8]. Primary care staff describe a lack of clear guidance on how survivors of cancer should be supported [9]. Patients and oncologists have expressed concerns that primary care staff are not experts, and their busy workloads lead to deficiencies in the continuity of care [8,9], meaning that survivors of cancer may not receive access to appropriate support with their ongoing symptoms after cancer treatment. Therefore, there is a need for clearer, more effective, and cost-efficient means of providing support. Digital interventions, such as websites or mobile apps, offer the potential to help survivors of cancer improve their QoL [10]. The addition of brief human support can boost engagement with digital interventions [11,12]. Digital interventions combined with brief support from primary care staff may facilitate improved QoL after cancer treatment. It may provide efficient and low-cost models for delivering support without the need to accumulate expertise in the skills and knowledge needed to help patients make the behavioral changes needed to increase their QoL. However, the acceptability and feasibility of implementing digital interventions among survivors of cancer in primary care is still to be determined. An important aspect of this involves understanding the capability of HCPs to deliver brief support along with digital interventions.

Renewed [13-16] is a complex intervention designed to improve the QoL of survivors of cancer. It combines a digital intervention focused on changing key behaviors that can improve the QoL of survivors of cancer with brief support from a nurse or health care assistant to maximize engagement. Renewed was designed for implementation in primary care within the United Kingdom’s National Health Service (NHS). Renewed is currently being tested in a randomized controlled trial (RCT) to determine its effectiveness and cost-effectiveness. In addition to determining the effectiveness and cost-effectiveness of an RCT, it is critical to examine whether an intervention might be implemented well in practice. Understanding barriers to and facilitators of implementation could help optimize the implementation of Renewed Online and also provide helpful insights for others developing digital interventions that include human support.

Objectives

National guidance recommends conducting process evaluations to identify how new interventions are implemented in practice, the likely mechanisms through which they might produce an effect, or factors in the health care environment that might stop an intervention from producing an effect [17]. This paper reports a process study exploring HCPs’ perceptions of Renewed. Although the RCT of Renewed [13] is ongoing, as recommended by the Medical Research Council guidelines, qualitative process data are reported here before obtaining knowledge of the RCT outcomes to avoid biased interpretation [17]. This process study has been used to explore potential barriers to and facilitators of implementing Renewed in primary care and evaluate the acceptability of providing this type of support, which might contribute to the success (or not) of the intervention. Specifically, this study aims to explore (1) supporters’ experiences of providing support to patients using the Renewed Online digital intervention (from hereon referred to as Renewed Online) and (2) barriers to and enablers of the successful implementation of Renewed Online in practice.

Methods

Study Design

The study design entailed a qualitative process evaluation of the Renewed intervention, which explored HCPs’ perceptions of delivering support alongside Renewed Online. The COREQ (Consolidated criteria for Reporting Qualitative studies) checklist [18] guided the reporting (Multimedia Appendix 1 [18]). Participants in the RCT were randomized to (1) Renewed Online, (2) Renewed Online with brief human (HCP) support, or (3) usual care. For full details of the Renewed RCT, see the study by Krusche et al [13]. Briefly, survivors of cancer in the
Renewed RCT (n=2712) had completed treatment for colon cancer (432/2712, 15.93%), breast cancer (1216/2712, 44.84%), or prostate cancer (864/2712, 31.86%). Mean years since the completion of treatment was 4 (SD 3.1) years; mean age was 64.5 (SD 10.9) years; and mean baseline QoL score was 72.4 (SD 11.9; as defined by scores <85 on the European Organization for Research and Treatment of Cancer measure [19]).

Ethics Approval

Ethical approval was granted by the University of Southampton (ERGO reference 31000.A8) and National Health Service (reference 18/NW/0013) ethics committees.

The Renewed Intervention

Overview

Renewed comprises a component website, Renewed Online, and brief HCP support. Renewed Online comprises an introductory session that provides an overview of what to expect from Renewed, brief advice on how to treat symptoms, and tailored recommendations about which components of the program would be most helpful based on the users’ responses to the European Organization for Research and Treatment of Cancer measure [19]. Users can then choose to use Getting Active (support for increasing physical activity), Eat for Health (support with healthy eating), POWeR (an evidence-based weight loss program [11,20-23]), or Healthy Paths (support with reducing stress or difficult feelings [24]). A full description of Renewed Online is provided in Figure 1 [13], incorporating the TiDIER (Template for Intervention Description and Replication) guidelines (Multimedia Appendix 2) [25].

HCP Support

HCP support was designed to boost adherence to both using the website and engaging with offline behavior changes (eg, physical activity) by promoting autonomous motivation. Survivors of cancer allocated to the Renewed Online with brief human support group were able to access support sessions provided by an HCP, delivered using the congratulate, ask,
**reassure, and encourage (CARE)** approach [26]. CARE is based on the self-determination theory and aims to facilitate an autonomy-supportive relationship that promotes feelings of autonomy, competence, and relatedness [21], thus building internal motivation for change [27]. CARE was designed to be easy to deliver and fit within HCPs’ busy schedules, without practitioners needing to become experts in a particular condition or way of treating that condition as this more detailed behavioral support was instead provided by the website.

Supporters were practice nurses, practice-based health care assistants, or clinical research nurses who were part of a comprehensive research network outside of general practitioner (GP) practices, a model representing delivery of care similar to that provided by private companies supporting digital interventions in the NHS, who tend to provide phone rather than in-person support and do not have access to patient records [28]. At the start of the study, supporters completed brief 15- to 20-minute web-based training outlining the study procedures and how to provide support to patients using the CARE approach. Before the sessions, the supporters were asked to send emails to patients 2 and 4 weeks after the patients began the study. Friendly email templates were provided, which were framed around the CARE approach, asking how patients were getting on and encouraging them to get in touch for a support session if they wished. Support sessions of 10 minutes were offered 2, 4, and 8 weeks after the patients had begun the study via telephone, email, or face to face. Textbox 1 shows a brief summary of the key messages from supporter training on how to provide support.

### Textbox 1. Supporter training key messages.

**Brief summary of the guidance given to supporters on how to provide support**

**Use the congratulate, ask, reassure, encourage approach with patients during support sessions**

- Congratulate the patient; for example, “That’s great that you want to get more active”
- Ask the patient; for example, “Have you decided to make any of the changes that Renewed suggested might be helpful?”
- Reassure the patient; for example, “Yes, doing more physical activity is safe and should help you to feel better.”
- Encourage the patient; for example, “Keep going with that as it should start to help you to feel better soon.”

**Tips for providing support**

- Be warm and friendly
- Praise any achievements
- Listen and show understanding

**When sessions should take place**

- 2, 4, and 8 weeks after the patient signs up for **Renewed**
- Send an encouraging email at 2 and 4 weeks using the supporter website; editable prewritten email templates are available
- Log all emails and appointments on the support log

**If a patient does not contact for support**

- Send an encouraging email

**If you find it hard to talk to the patient for only 10 minutes**

- Start the session by saying, “Nice to speak to you today. This is just a short appointment, we have around 10 minutes to talk. It would be great to hear how you’re getting on with Renewed.”
- In the last few minutes, say, “We are coming to towards the end of our time, is there anything else that you wanted to discuss quickly today?”
- Let the patient know that the session is about to end; say, “Thank you for your time, it’s been nice to chat with you”

**If the patient asks for advice**

- Ask them what they think would work best for them or what they think would be best to do.
- It is okay to ask, “what does the website say to do in that situation?”
- If the patient is concerned about whether making a change is safe, you can reassure them that everything recommended on **Renewed** is safe.

### Sampling and Recruitment

Supporters were identified for interviews through the **Renewed** supporter database and the study team’s records of HCPs providing support as part of the RCT. Emails or phone calls were used to invite supporters to participate in a telephone interview about their experience of supporting patients using **Renewed Online**. In the early stages of recruitment, supporters were sampled purposively based on their job roles (practice nurse, practice-based health care assistant, or clinical research...
interventions and factors that hindered or enabled them to support patients as intended. The themes were (1) Renewed Online as an acceptable digital tool with some improvements, (2) confidence in enacting the supporter role, (3) practicalities of delivering support alongside a digital intervention, and (4) managing a patient-led approach. Each theme is outlined in the following sections, including representative quotes to illustrate key points. Participants are referred to by their identification number, role, and the number of patients they supported.

**Renewed Online as an Acceptable Digital Tool With Some Improvements**

Overall, supporters perceived Renewed as consistent with current practice, with the increasing use of web-based interventions. They could see how a digital tool such as Renewed Online would be useful for patients, especially as it allowed patients to work through rehabilitation at their own pace:

> They're [GPs] signposting patients to online resources all the time more and more at the moment...So this [Renewed Online] is a similar thing. So I could see that it would be beneficial and would fit in. [Participant 10, practice nurse, 2 patients]

Email support was also generally acceptable to supporters. However, a few worried that patients were not receiving emails from the supporter website; hence, they preferred to use their own email to contact patients.

A minority of supporters reported that their patients described the content of the information on the Renewed Online website as generic, not personal, and failing to provide anything new. These patients chose not to be part of the program:

> He felt that the website was very generic and wasn’t personal to him. He was like, “I already know all of that.” he felt that it couldn’t offer him any support at all...I couldn’t then offer him any support with anything because he didn’t want it. He said, “If you could give me advice on specific areas,” which obviously we couldn’t do. [Participant 23, practice nurse, 1 patient]

Approximately 7% (2/28) of supporters raised concerns over the timing of providing Renewed Online. They suggested that it was important for Renewed to be introduced to patients when they first finish treatment and support from the hospital ends. At that point, they felt that Renewed Online could better support them and be more of a teachable moment before patients form their own habits for managing side effects or returning to old ones:

> What would be brilliant, would be to get it in...very soon after they’ve finished their final treatment...because that’s when they’re perhaps the most vulnerable...giving them a tool where they can work out what’s gonna benefit them in their life at that point. I think two, three years down the line, however they’ve got there, they’ve got there on their own without that [Renewed] kind of support. [Participant 15, practice nurse, 4 patients]
Confidence in Enacting the Supporter Role

Supporters received web-based training at the start of the study on how to provide support alongside digital interventions (Textbox 1). This explained how to use the CARE approach to support patients’ engagement with Renewed Online and emphasized that the supporter did not need to be an expert in cancer. Most supporters reported that the length of training was adequate and provided clarity on what was needed for the role:

*It was thorough, it explained everything really well I wasn’t left with any questions. It was clear and easy to follow.* [Participant 13, clinical research nurse, 1 patient]

Some supporters possessed prior experience in cancer care and expressed confidence in their role supporting Renewed Online. Although not previously experienced in this area, others still expressed confidence but reported that this had grown as they gained experience in delivering the intervention. Although there appeared to be little substantive differences in the experiences of HCPs who supported multiple patients compared with 1 patient, the associated greater frequency of delivering support appeared to allow HCPs more opportunities to build confidence:

*The more you do the calls, or the email correspondence...the much easier I feel it’s become.* [Participant 1, clinical research nurse, 3 patients]

On the other hand, deviant case analysis highlighted that 33% (2/6) of health care assistants were the only supporters to report an initial lack of confidence based on preheld perceptions that they were unqualified for the supporter role. The first (participant 5, 2 patients) reported that the training did not prepare her for the role, expressing a lack of understanding of how to provide support and wanting to receive practical demonstrations of someone providing support. The second doubted her suitability for the role, initially being concerned that she was not an expert in cancer. However, these perceptions changed, and their confidence appeared to grow when actually delivering sessions, demonstrating that their initial concerns were perhaps unwarranted:

*I felt like a bit of a fraud at the beginning, thinking am I really qualified to do this, I feel like the patient’s phoning me up thinking I’m some sort of expert, but it wasn’t like that at all.* [Participant 17, health care assistant, 2 patients]

Differences in where the supporters were based (either practice based or remote in the case of clinical research nurses) appeared important to their experiences in supporting patients. In particular, a few clinical research nurses felt disadvantaged based on the assumption that practice staff were probably more familiar with patients. They felt that this would facilitate rapport with patients and improve the quality of the support sessions:

*It [Supporter role] would need to be somebody from the practice actually doing it who has access to their medical notes...just so that you’re aware when you’re listening to them, so you know what they’re going through rather than being completely blind.* [Participant 8, clinical research nurse, 3 patients]

Practicalities of Delivering Support Alongside a Digital Intervention

Reflected in this theme is an exploration of the logistical problems supporters faced while delivering support to patients using Renewed Online.

Most of the current sample expressed difficulty in conducting sessions in the recommended 10 minutes, often reporting sessions of approximately 15 minutes. Sessions lasted >10 minutes for various reported reasons, including allowing time for introductions, the perception that patients felt lonely and were longing for someone to talk to, and not wanting the patient to feel rushed. In particular, the primary care staff expressed guilt about potentially rushing patients, considering that they had made an effort to come in for sessions. A clinical research nurse expressed difficulty in managing the 10-minute sessions as she was not used to working within this time limit:

*I’d given myself longer than what was suggested because I knew from experience that if somebody is opening up to you about how they’re feeling the worst possible thing that you can do is run out of time and have to end it.* [Participant 24, practice nurse, 2 patients]

A few supporters expressed a preference for lengthening sessions, particularly the first, to allow more time to get to know the patients and address any initial concerns. Relatedly, some clinical research nurses reported finding it challenging to build rapport with patients during the brief support sessions:

*The appointment seemed very short. Especially on your initial one. I think your initial appointment should be twenty. So you can get to know the patient a bit before you bang straight into the CARE approach. Otherwise there’s no real time to even introduce myself, introduce themselves.* [Participant 23, practice nurse, 1 patient]

HCPs viewed both face-to-face and telephone support as acceptable but with different benefits. Face-to-face sessions allowed them to read the patients’ body language, whereas phone support was better for patients who may have difficulty in coming into a GP surgery because of travel disruptions, weather conditions, and location. In addition, phone sessions provided greater flexibility to supporters as it was easier to slot into their schedules:

*That [phone sessions] works really well for me because it means that I can support patients when I’m not in the office...that’s given me a greater flexibility with the patients.* [Participant 2, clinical research nurse, 5 patients]

Furthermore, phone sessions reportedly helped some supporters manage the length of sessions by preventing them from performing health care checks unrelated to Renewed. Supporters also expressed less guilt of having patients make the journey into practice.

Managing a Patient-Led Approach

Reflected in this theme were supporters’ perceptions and experiences of using a patient-led approach and what they saw...
As helpful and found difficult. In this context, a patient-led approach refers to one in which an autonomy-supportive relationship was facilitated using CARE to support the digital intervention rather than giving advice, which was instead provided through the digital intervention. Most supporters reported that they liked the CARE approach and believed that it provided a useful prompt and session guide:

I liked that idea [CARE approach]. I thought that was really well planned and it’s easy to remember...a good thing to just prompt you. [Participant 26, practice nurse, 1 patient]

During sessions, patients would often discuss their behavior change goals and progress. Supporters expressed that it was initially a challenge not to give direct advice to patients during sessions. However, this reportedly became easier as they delivered more appointments. One of the supporters expressed that it was nice to see patients who were actively interested in improving their health:

It was refreshing to see them wanting to make life changes themselves rather than making lifestyle changes because they’d been advised to by a clinician. [Participant 24, practice nurse, 2 patients]

In addition, some supporters expressed that not giving direct advice was a positive change and welcomed patients being more involved in their care:

It’s all about them giving us the answers as opposed to the other way round, which I’m all for. I think that’s better. [Participant 23, practice nurse, 1 patient]

A few supporters’ experiences portrayed a lack of understanding of the CARE approach and how to implement it, which caused some difficulty in delivering support alongside the digital intervention. For example, one of the supporters found it challenging to implement this approach when the patients went off on a tangent. She believed that this was because she viewed the CARE approach as a script to be followed strictly in a specific order, which made the conversation rigid:

I think that’s why sometimes I didn’t manage to get the CARE aspects in the way I’d like because sometimes you would start at one element of it, and you think, “Okay, I must make sure I go back to the C element or the A element...” And then I’d be like, “Well, do I sort of interject that in now? Now we’re kind of talking about something slightly different.” I wanted it to be more fluid. [Participant 12, clinical research nurse, 1 patient]

This supporter viewing CARE as a script may reflect a more traditional understanding of HCP-patient relationships in which HCPs provide systematic education and instruction. However, CARE encourages an approach that prompts supporters to help patients decide what works best for them, perhaps indicating the supporter’s misunderstanding or lack of familiarity with the CARE approach.

Relatedly, a practice nurse doubted the CARE approach as she perceived that patients wanted direct advice from her rather than just the website. Consequently, she felt quite limited in her supporter role.

Approximately 7% (2/28) of supporters highlighted that they would have liked to be able to review patients’ Renewed Online activity so that they could be aware of what patients were referring to during appointments:

They would talk to me and I’m not completely sure I knew everything that they were covering [Renewed Online activity]...So that’s something that I found difficult because they would talk away as if I knew what they were talking about. [Participant 8, clinical research nurse, 3 patients]

Other supporters printed off pages from the Renewed Online demo and brought them into support sessions to overcome this.

Discussion

Principal Findings

This process evaluation used qualitative interviews to understand supporters’ experiences of providing support to survivors of cancer alongside a digital intervention in primary care. Exploring supporters’ experiences enabled the identification of possible factors that hindered or enabled support being delivered as intended alongside a digital intervention, highlighting lessons for future intervention development and implementation. Overall, supporters felt that they were able to follow the protocol and deliver support as needed; however, several issues were identified that might hamper implementation, and some minor alterations to Renewed Online would likely be required to ensure that the intervention is optimized for successful implementation in practice. Considering implementation theory in process evaluations can provide a framework for evaluating and explaining the success of implementation [35]. Therefore, the findings will be discussed in relation to the normalization process theory (NPT) [36], an implementation theory that explains the processes through which new practices of thinking, enacting, and organizing work are operationalized in health care [37]. An outline of the NPT, as described by McEvoy et al [38], is provided in Textbox 2.

The aspects of the intervention that supported implementation included the ease of training and the perceived similarity of Renewed Online to digital tools used in current practice. In relation to NPT, this demonstrates a high degree of coherence regarding the value of Renewed Online, which is needed for an intervention to be successfully implemented well in practice. Positive perceptions of the utility of an intervention have been shown to be key facilitators of implementation [39], and implementation failure occurred when HCPs did not perceive intervention use as a legitimate activity for patients or providers [40]. Previous literature has suggested that HCPs in primary care may not be well placed to provide support to survivors of cancer as they lack the expertise and time necessary to make these changes and desire clearer guidance on how to do so [8,9]. However, this study found that primary care staff felt that supporting survivors of cancer by using a digital intervention would be appropriate and beneficial. It is possible that this finding differs from previous literature as this is the first study to explore the views of primary care staff providing support alongside a digital intervention. In most cases, this format seemed to overcome concerns about the lack of expertise and
time, as the digital intervention provided specific advice, avoiding the need to develop expertise, and vastly reduced the amount of input needed to support survivors of cancer to make behavioral changes. A minority of supporters initially believed that their perceived lack of expertise would affect their ability to support patients. However, their confidence in this approach improved once they began to support the patients, suggesting that this was not a significant barrier to implementation.

Previous research on digital interventions for other conditions has shown that primary care staff have reservations about providing phone support, viewing it as less effective than face-to-face support [21]. The acceptability of phone support seen in this study may reflect the fact that primary care is changing and is increasingly using phone appointments to manage increasing workloads [41]. This may normalize more rapidly in the current climate, as telemedicine is increasingly advocated for use in those with cancer during the COVID-19 pandemic to minimize the number of visits to health care settings and risk of exposure [42]. This increase in acceptability has implications for the implementation of future digital interventions using primary care staff to support digital intervention users, as phone support may provide similar effects and be more cost-effective [20].

**Textbox 2. Normalization process theory outline.**

<table>
<thead>
<tr>
<th>Construct and definition</th>
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<tbody>
<tr>
<td>Coherence</td>
<td></td>
</tr>
<tr>
<td>The work individuals and organizations have to go through to understand a new practice to promote or inhibit it; these processes are energized by investments of meaning made by participants</td>
<td></td>
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<tr>
<td>Cognitive participation</td>
<td></td>
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<tr>
<td>The work individuals and organizations have to go through to enroll users and engage with a new practice; these processes are energized by investments of commitment made by participants</td>
<td></td>
</tr>
<tr>
<td>Collective action</td>
<td></td>
</tr>
<tr>
<td>The work individuals and organizations have to go through to enact a new practice; these processes are energized by investments of effort made by participants</td>
<td></td>
</tr>
<tr>
<td>Reflexive monitoring</td>
<td></td>
</tr>
<tr>
<td>The work of formal or informal appraising an intervention to develop participants’ comprehension of the effects of the intervention; these processes are energized by investments in the appraisal made by participants</td>
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Most supporters successfully engaged with the CARE approach, with some noting that not giving direct advice was a positive change and welcomed patients being more involved in their care. This provided evidence of both **cognitive participation** and **collective action** and suggested that for most supporters, the CARE approach would likely normalize well in practice. However, a minority experienced difficulty adjusting to providing nondirective support and instead allowing the digital intervention to provide the advice. In terms of NPT, there was an apparent lack of **cognitive participation**, which suggests a potential challenge for successful implementation. In the wider literature, HCPs’ difficulty in adjusting to not giving direct advice is a prevalent pattern. Encouraging health care workers to switch from a more traditional paternalistic approach, in which they hold all the knowledge and power and give it to the patient, to an equal relationship using nondirective support often requires intensive training, including reflective practices [43,44]. This is an issue that is pertinent to providing human support alongside many digital interventions, where health care workers are often employed to boost engagement but are not expected to be experts or to give advice [20,26]. It is possible that more intensive training might help the minority who struggle with the CARE approach. Alternatively, it may be that employing staff specifically to provide this support is more feasible than implementing more intensive training to change the behavior of health care workers whose daily work usually involves working in a directive way (eg, giving advice). Such an approach has been adopted successfully in a digital diabetes prevention program in which a commercial company (Changing Health) provides telephone support to NHS patients using digital services [28].

Some clinical research nurses perceived that not being based within GP practices was a barrier to delivering support as intended, as they did not have a pre-existing relationship with patients or access to their medical records and consequently reported finding it challenging to build rapport during 10-minute sessions. NPT would see this as a challenge to **collective action**, which examines the work HCPs have to do to enact a process [36]. This is an important issue, as the model of using research nurses adopted in this study is similar to that adopted within health care elsewhere, such as when private companies provide telephone support alongside digital interventions to patients in the United Kingdom’s NHS (eg, the NHS digital diabetes prevention program); these workers do not have prior relationships with patients or access to their medical records. It may be that within such a context, a longer (perhaps double) appointment is needed to provide time to build rapport, as rapport building is considered crucial to quality health care support [41].

Some supporters suggested that Renewed Online should be offered to patients sooner after finishing treatment as this may be when patients are most vulnerable and motivated for behavior change. This demonstrates the NPT construct of **reflective monitoring**, whereby supporters’ appraisal of Renewed Online considered the potential disadvantages and suggested how implementation may be improved in the future. In line with supporters’ suggestions, previous research found that survivors...
of cancer described feeling the drive to adopt a healthier lifestyle to feel better and more empowered immediately after finishing treatment, and hence, it may be that this is the optimal teachable moment [15].

Table 1. Plans for addressing challenges faced by supporters.

<table>
<thead>
<tr>
<th>Challenges faced by supporters</th>
<th>Plans for addressing those challenges</th>
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<tbody>
<tr>
<td>Many supporters were concerned that the 10-minute support sessions were too short.</td>
<td>Giving the option for the first session to be a double appointment should allow the time for initial introductions and addressing concerns.</td>
</tr>
<tr>
<td>Some clinical research nurses perceived that not knowing the patient before the first session was a disadvantage, as they had no existing rapport to build on.</td>
<td>Having the first session be an optional double appointment should allow time to build more rapport before beginning support.</td>
</tr>
<tr>
<td>Some HCPs expressed a desire to see patients’ activity on Renewed to enable easier and most salient conversations during sessions.</td>
<td>It may be useful to provide supporters with access to patients’ Renewed activity.</td>
</tr>
<tr>
<td>Supporters suggested Renewed should be introduced at the point when patients are leaving cancer treatment as this is potentially when they are most in need of support.</td>
<td>Future implementation of Renewed may need to concentrate on patients who have finished treatment more recently instead of up to 10 years after treatment.</td>
</tr>
<tr>
<td>A few supporters were reluctant to use the CARE approach as it was different from a traditional health care worker–patient relationship where the HCP is seen as having control and provides advice.</td>
<td>Training could be intensified for the minority who have concerns about not giving advice. This could include reflective practices, which have been shown to help people switch from a directive to nondirective approach [43,44].</td>
</tr>
<tr>
<td>A few supporters expressed a misunderstanding of how to use the CARE approach.</td>
<td>Update supporter training to include video demonstrations of how CARE can be delivered.</td>
</tr>
<tr>
<td>Some supporters expressed that delivering more support enabled them to build confidence.</td>
<td>Have fewer supporters so that they are able to support a greater number of patients, which could give them the opportunity to build confidence in delivering support.</td>
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</table>

*aHCP: health care professional.

bCARE: congratulate, ask, reassure, and encourage.

**Strengths and Limitations**

The variation in HCP roles included in the study allowed the nuanced experience of those in different job roles to be explored. This study has several limitations. First, the data could not be analyzed iteratively during the interview period. This meant that the themes developed in early interviews could not be explored further in later ones, which can develop meaning and understanding [45]. Second, most (401/557, 71.9%) logged support sessions in the Renewed RCT were reported as sticking to 10 minutes within support sessions; however, those who consented to the interview gave patients 15 minutes on average within support sessions. It is difficult to know why this study’s sample differs from the overall trial sample in this way and whether it might limit the transferability of results. This difference may be because of the use of paper self-report measures to collect the duration of support sessions within the trial, possibly resulting in a social desirability bias [46]. However, given the opportunity in an interview to discuss this in more detail, HCPs may have been more inclined to mention if they went over 10 minutes and why. Third, we were unable to record consultations with supporters within this study; hence, we could not corroborate supporters’ reports on how they implemented the CARE approach. Further research exploring the recorded consultations of supporters using CARE would be useful. Finally, there was a low response rate to the interview invitations. There may be various reasons for such a low response, one of which may be the capacity for HCPs to conduct interviews because of busy schedules. The perceptions and experiences of implementing support alongside Renewed may have differed for those who did not accept an invitation to interview.

**Conclusions**

Our results suggest that HCPs generally found providing support alongside a digital intervention acceptable and were amenable to contributing to the delivery of support to survivors of cancer in primary care. Key factors that may support the successful implementation of this type of digital intervention in practice include the increasing acceptability of phone support and the utility and acceptability of nondirective support among most HCPs, such as the CARE approach. Challenges to implementing support alongside a digital intervention were also identified, including concerns about not having enough time during support sessions to build rapport and, in a minority, concerns about using a nondirective approach. This study shows that even when support for a digital intervention is designed to be brief, sufficient time needs to be allowed in the initial support sessions to allow practitioners to feel confident that rapport can be built. Further research is needed to explore whether additional training might be enough to support a minority of health care practitioners who were concerned about giving nondirective support to adopt this approach. If not, then primary care could consider employing other staff, such as social prescribers of health coaches, who work in a less directive way than nurses and health care assistants and who are now becoming increasingly common in the United Kingdom’s NHS [47].
There is a clear need for primary care to provide support to survivors of cancer [7]; however, previous research has suggested that lack of time and training on how to support this patient group are key barriers to providing this support [8,9]. This study showed that providing support alongside a digital intervention might be an acceptable way of overcoming these barriers, as only a small amount of support is required, and there is no need to develop cancer-specific expertise or behavior change skills. This approach of mixing digital and human support will likely be useful to others in developing and implementing interventions to support other aspects of care for survivors of cancer, which are not targeted within Renewed Online, such as support for sexual dysfunction, smoking cessation, alcohol consumption, returning to work, and lack of social connection and support.

Acknowledgments

The authors would like to thank the health care professionals who were interviewed for this study. The National Institute for Health Research (NIHR) recognizes and values the role of patient data, securely accessed and stored, both in underpinning and leading to improvements in research and care. The authors would also like to thank all the Patient and Public Involvement members who helped provide critical review and editing of the manuscript drafts: Tamsin Burford, Geoff Sharman, Lesley Turner, and Roger Bacon.

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Authors' Contributions

JS, JSB, KB, AR, and LY contributed to the early conception of the qualitative process evaluation. JS and KB developed the interview schedule. JS and JSB collected the data. KB, LY, PL, JSB, and AWAG were involved in the development of Renewed. JS, RE, AR, and KB contributed to the analysis. JS wrote the initial draft of the manuscript. RE, KB, AR, and LY critically reviewed and edited the initial and subsequent drafts of the manuscript. CF, EW, CG, AWAG, and PL critically reviewed subsequent drafts of the manuscript. All authors read, critically revised, and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
COREQ (Consolidated Criteria for Reporting Qualitative studies): a 32-item checklist.
[DOCX File, 18 KB - cancer_v8i2e36364_app1.docx ]

Multimedia Appendix 2
The TiDIER (Template for Intervention Description and Replication) checklist.
[DOCX File, 20 KB - cancer_v8i2e36364_app2.docx ]

References


34. Kulnik ST, P


Abbreviations

CARE: congratulate, ask, reassure, and encourage
COREQ: Consolidated Criteria for Reporting Qualitative studies
GP: general practitioner
HCP: health care professional
Implementing a Health Care Professional–Supported Digital Intervention for Survivors of Cancer in Primary Care: Qualitative Process Evaluation of the Renewed Intervention

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The Acceptability of an Electronically Delivered Acceptance- and Mindfulness-Based Physical Activity Intervention for Survivors of Breast Cancer: One-Group Pretest-Posttest Design

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Abstract

Background: Survivors of breast cancer can face internal barriers to physical activity, such as uncertainty and frustration stemming from physical limitations, decreased physical functioning, fatigue, and pain. Interventions that draw from the principles of Acceptance and Commitment Therapy (ACT) may help survivors of breast cancer overcome some of the internal barriers associated with physical activity.

Objective: The primary aim of this study was to investigate the acceptability of an electronically delivered physical activity intervention for survivors of breast cancer, centered on ACT processes.

Methods: This study used a 1-group pretest-posttest design. We recruited 80 insufficiently active female survivors of breast cancer using a web-based recruitment strategy. The 8-week intervention consisted of weekly modules that featured didactic lessons and experiential exercises targeting key ACT processes in the context of physical activity promotion (namely, values, committed action, acceptance, defusion, and contacting the present moment). We determined intervention acceptability according to study retention (≥70%), adherence rates (≥75% of the participants completing ≥50% of the modules), and posttest survey scores reflecting the perceived ease of use, perceived usefulness, and interest and enjoyment of the intervention (≥5 on a 7-point Likert-type scale). We also evaluated changes in self-reported aerobic and muscle strengthening–physical activity, physical activity acceptance (cognitive acceptance: Cohen d=0.35; behavioral commitment: Cohen d=0.51), physical activity regulation (identified regulation: Cohen d=0.37; integrated regulation: Cohen d=0.66), increased their ability to participate in social roles and activities (Cohen d=0.18), and reported less fatigue (Cohen d=0.33) and sleep disturbance (Cohen d=0.53).

Conclusions: Electronically delivered acceptance- and mindfulness-based interventions may be useful for promoting physical activity in survivors of breast cancer. Further research is needed to refine these approaches and evaluate their effectiveness.
Introduction

Background

Despite the well-documented benefits of physical activity, most survivors of breast cancer do not meet the nationally recommended physical activity guidelines [1,2]. This population may encounter challenges in meeting the recommended levels of physical activity common to the general US population, along with barriers attributable to cancer and its treatment. These can include uncertainty and frustration stemming from physical limitations, decreased physical functioning, fatigue, and pain associated with physical activity [3-6]. Behavioral interventions based on the principles of Acceptance and Commitment Therapy (ACT) may be useful in helping survivors of breast cancer increase physical activity. This is partly because many of the barriers to physical activity attributable to cancer and its treatment are internal in nature and are not necessarily amenable to immediate problem solving. ACT is an approach to behavioral therapy that supplements behavioral skill building with techniques centered on developing psychological flexibility: the ability to be aware of, accept, and proceed with gentle persistence despite uncomfortable sensations, thoughts, and feelings that may accompany behaviors consistent with personal values [7]. It encourages individuals to set goals and take committed action in the service of clearly defined values. Rather than identifying and seeking to change problematic thoughts, emotions, and physical sensations that can stand in the way of valued living, ACT focuses on changing how individuals relate to these thoughts and feelings. Compelling evidence demonstrates that ACT is effective in bringing about a broad range of psychological and behavioral outcomes [8,9] and has shown promise for helping cancer survivors cope with negative internal experiences that can accompany cancer diagnosis and treatment [10,11].

Although ACT is typically delivered face-to-face by trained mental health professionals in clinical settings, ACT principles and skills are increasingly being applied remotely to promote behavior change for public health priorities, such as smoking cessation, weight management, diabetes management, and physical activity [12-16]. A recent systematic review and meta-analysis concluded that interventions based on ACT principles hold promise for increasing physical activity, but their application to this end is nascent [17]. The degree to which this approach to physical activity promotion, delivered electronically, may be appropriate and useful for survivors of breast cancer is unknown.

Objectives

The primary aim of this study was to investigate the acceptability of the ACTive program, an electronically delivered acceptance- and mindfulness-based physical activity intervention designed for survivors of breast cancer. This research corresponds to phase IIa: Proof-of-Concept of the Obesity-Related Behavioral Intervention Trials model for developing behavioral treatments [18]. It follows formative qualitative research [19] and systematic intervention development and refinement [20]. Our primary hypothesis was that female survivors of breast cancer exposed to the ACTive program would rate it as acceptable, as defined by study retention, program adherence, and ratings of perceived ease of use (PEOU), usefulness, and intrinsic motivation. Exploratory aims were to evaluate changes in participants’ physical activity, related cognition, and health-related outcomes associated with receiving the behavioral intervention.

Methods

Recruitment

Eligibility criteria included that the participants be female adults with a history of breast cancer diagnosis who were not undergoing chemotherapy or irradiation treatment and were not planning on or preparing for surgery. Furthermore, participants were not eligible for inclusion if upon eligibility screening their modified Physical Activity Readiness Questionnaire [21] score indicated that unsupervised physical activity may not be safe, or the modified Godin Leisure-Time Exercise Questionnaire [21] indicated that they tended to engage in ≥150 minutes of moderate intensity aerobic exercise per week (or ≥75 minutes of vigorous intensity aerobic exercise per week or an equivalent combination of physical activity volume).

We recruited participants using the services of the Love Research Army of the Dr Susan Love Research Foundation. The recruitment material was emailed to a large listserv consisting of approximately 79,000 individuals who had signed up to receive information about breast cancer–related research studies. Interested participants provided their contact information. The study staff contacted interested individuals via telephone to assess eligibility and engage in the informed consent process.

Study Design

This study used a 1-group pretest-posttest design. Participants were recruited in September 2020 and completed a baseline survey about demographic information, physical activity levels, physical activity acceptance, physical activity regulation, and quality of life. The intervention content was delivered over the course of 8 weeks, starting in the last week of September 2020. All participants started the intervention simultaneously. A week after completing the intervention, participants completed a follow-up survey gathering information about the acceptability of the intervention, physical activity levels, physical activity acceptance, physical activity regulation, and quality of life. Surveys were delivered via REDCap (Research Electronic Data Capture; Vanderbilt University).
Ethics Approval

All study procedures were approved by the University of Texas School of Public Health Committee for the Protection of Human Subjects (HSC-SPH-18-1025). All participants provided informed consent for participation before taking part in the study.

Intervention Development

Before this study, we developed the ACTive program using an iterative design process. We used an existing manual to guide the application of ACT principles to help insufficiently active individuals increase physical activity [22]. To frame the intervention development process, we used the Information Systems Research framework [23]. This approach frames intervention development in three cycles (ie, design, rigor, and relevance cycles), which are iteratively repeated (Figure 1). Throughout this process, we included insights from individuals from the target population (30/80, 37% of the participants met the aforementioned eligibility criteria and were recruited using the same methods). The lead author (MCR) conducted individual interviews with participants after they experienced the development of intervention content and revised the intervention based on the findings from these interviews. The results of qualitative analyses are presented in the qualitative study by Robertson et al [20]. Throughout this process, we identified and iteratively tested the practical aspects of the ACTive program design. For example, we found REDCap to be an intervention delivery modality that could securely deliver intervention content (including potentially sensitive information) in a way that was perceived as simple and easy to navigate. Furthermore, we included mixed types of media (eg, short videos and audio files, images, text, and documents) and added components that participants requested, such as resources with instructions on how to safely engage in muscle strengthening–physical activity and gentle yoga classes.

Figure 1. Information Systems Research iterative design framework for the intervention.

Intervention

The ACTive program (Textbox 1) [24] was designed to help insufficiently active survivors of breast cancer meet the 2018 aerobic- and muscle strengthening–physical activity guidelines for Americans according to their own physical activity–related preferences and abilities. Target guidelines included engaging in 150 minutes of moderate intensity aerobic physical activity per week (or 75 minutes of vigorous intensity aerobic physical activity per week or an equivalent combination of both exercise intensities), engaging in at least two bouts of muscle strengthening–physical activity that targeted all major muscle groups per week [25].

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The ACTive program briefs and description

• Why?
  • Despite the well-documented benefits, most survivors of breast cancer do not meet nationally recommended physical activity guidelines. Behavioral interventions based on the Acceptance and Commitment Therapy principles may be useful for helping survivors of breast cancer to increase physical activity. Digital behavior change interventions minimize barriers to access that can undermine traditional behavioral interventions.

• What (materials)?
  • The ACTive program consisted of 9 modules that featured didactic lessons and experiential exercises targeting key Acceptance and Commitment Therapy processes (Table 1). In addition, the ACTive program featured cancer survivor–specific resources for engaging in aerobic- and muscle strengthening–physical activity and delivered behavior change techniques for safely increasing physical activity. See the Methods section for more details and references to external content.

• What (procedures)?
  • The ACTive program was designed to help insufficiently active survivors of breast cancer gradually strive toward meeting the 2018 physical activity guidelines for Americans in accordance with their own physical activity–related preferences and abilities. The participants were sent intervention content weekly. They were encouraged to view all intervention content and provide responses to all queries before the next weekly module was sent.

• Who provided?
  • All intervention content was created or curated by the principal investigator of the study (MCR), a doctoral student with an Master’s in Public Health studying behavioral science. See the Methods section for more details and references to external content.

• How?
  • The intervention was delivered via REDCap (Research Electronic Data Capture). REDCap was also used to periodically send participants emails from the principal investigator’s (MCR) email address acknowledging the participants’ effort and responses (eg, providing participants with their statements of values, goals, and committed action).

• Where?
  • The intervention content was delivered via the internet to participants throughout the United States.

• When and how much?
  • The ACTive program was delivered over the course of 8 weeks, starting from the last week of September 2020. Per week, 1 module was sent (the first week additionally contained a brief Getting Started module).

• Tailoring:
  • The participants were regularly reminded of their previous responses and were prompted to build upon them (eg, in week 3, participants were presented with the personal values they identified in week 2 and asked to set corresponding goals and engage in action planning). The intervention also provided optional resources, and individuals were encouraged to use those that they found to be personally relevant (eg, information pertaining to physical activity and lymphedema).

• How well?
  • All intervention content was successfully sent to participants’ preferred email addresses. Study retention and intervention adherence are the end points detailed in the Results section of this paper.
The intervention consisted of 9 modules that featured didactic lessons and experiential exercises targeting key ACT processes (namely, values, committed action, acceptance, defusion, and contacting the present moment) in the context of physical activity promotion for cancer survivors (Table 1). Sessions began with a mindfulness exercise designed to focus participants’ attention in preparation for lesson content and foster the initiation of a mindfulness practice. Didactic lessons typically consisted of multiple 3- to 5-minute video and audio files narrated by the principal investigator of the study (MCR); these were supplemented by outside sources from ACT experts (eg, videos created by Dr Russ Harris [27,28]). Sessions also featured workbook-type activities and exercises designed to apply didactic content to their lives (eg, having participants identify their personally held values).

In addition to acceptance- and mindfulness-based content, the ACTive program featured resources for engaging in physical activity and applying commonly used behavior change techniques for physical activity promotion (Table 1) [26]. These resources included cancer survivor–specific how-to videos for engaging in muscle strengthening–physical activity (eg, embedded links to the Oncology, Nutrition and Exercise Group exercise videos by PennState [29], a video on proper walking posture by an exercise physiologist, and recorded yoga sessions for cancer survivors) as well as other audiovisual components (eg, images with supportive messages or inspirational quotes) and supporting documents (eg, a habit tracker and a printable calendar). The participants were prompted to report their weekly physical activity levels to facilitate self-monitoring. If participants (1) reported meeting the recommended guidelines for aerobic physical activity or muscle strengthening exercise, they would be more resistant to short term changes.

## Table 1. ACTive program module topics and featured behavior change techniques (BCTs).

<table>
<thead>
<tr>
<th>Module</th>
<th>Main topic (with the Acceptance and Commitment Therapy processes)</th>
<th>BCTs for physical activity promotion&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Introductory session: introduces study staff; establishes expectations</td>
<td>Motivational interviewing (confidence ruler to elicit positive change talk); time management</td>
</tr>
<tr>
<td>2</td>
<td>The benefits of physical activity: relevant scientific literature on physical activity; ways to gauge intensity</td>
<td>Provide information on consequences of behavior in general; environmental restructuring; provide instructions on how to perform the behavior; demonstrate the behavior</td>
</tr>
<tr>
<td>3</td>
<td>Values: identifying and clarifying personal values; how adherence to physical activity may support these values; increasing motivation</td>
<td>Stress management and emotional control training; prompt self-monitoring of behavior; provide instructions on how to perform the behavior; demonstrate the behavior</td>
</tr>
<tr>
<td>4</td>
<td>Goals and committed action: identifying goals consistent with values, including at least one physical activity–related goal; taking committed action to accomplish goals; distinguishing internal and external barriers to physical activity</td>
<td>Stress management and emotional control training; prompt self-monitoring of behavior; goal setting (behavior); action planning; provide instructions on how to perform the behavior; demonstrate the behavior</td>
</tr>
<tr>
<td>5</td>
<td>Acceptance: increasing acceptance as it applies to distress tolerance and physical activity; discriminating between acknowledgment and avoidance of internal discomfort; also included a creative hopelessness exercise</td>
<td>Stress management and emotional control training; prompt self-monitoring of behavior; goal setting (behavior); set graded tasks; provide rewards contingent on successful behavior; barrier identification and problem solving&lt;sup&gt;b&lt;/sup&gt;; provide instructions on how to perform the behavior; demonstrate the behavior</td>
</tr>
<tr>
<td>6</td>
<td>Cognitive defusion: breaking the link between thoughts and behavior; becoming more aware of thoughts that may interfere with exercise plans</td>
<td>Stress management and emotional control training; prompt self-monitoring of behavior; goal setting (behavior); set graded tasks; provide rewards contingent on successful behavior; barrier identification and problem solving&lt;sup&gt;b&lt;/sup&gt;; provide instructions on how to perform the behavior; demonstrate the behavior</td>
</tr>
<tr>
<td>7</td>
<td>Mindfulness: contacting the present moment; being present; allowing negative internal events to pass without disrupting committed action; engaging in nonjudgmental contact with psychological and physical events that occur; increasing awareness during physical activity</td>
<td>Stress management and emotional control training; prompt self-monitoring of behavior; goal setting (behavior); set graded tasks; provide rewards contingent on successful behavior; provide instructions on how to perform the behavior; demonstrate the behavior</td>
</tr>
<tr>
<td>8</td>
<td>Review: review and integrate key concepts</td>
<td>Stress management and emotional control training; prompt self-monitoring of behavior; goal setting (behavior); set graded tasks; provide rewards contingent on successful behavior; provide instructions on how to perform the behavior; demonstrate the behavior</td>
</tr>
<tr>
<td>9</td>
<td>Maintenance: how to maintain adherence to physical activity; navigating lapses; preventing relapse</td>
<td>Plan social support or social change; relapse prevention and coping planning; stress management and emotional control training; prompt self-monitoring of behavior; provide rewards contingent on successful behavior; provide instructions on how to perform the behavior; demonstrate the behavior</td>
</tr>
</tbody>
</table>

<sup>a</sup>On the basis of the Michie taxonomy [26].

<sup>b</sup>Problem solving was applied to external problems that may be readily amenable to change, but acceptance was applied to internal problems that may be more resistant to short term changes.

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(2) met their own personally set physical activity–related goals, or (3) improved their aerobic physical activity from the week before, they were immediately rewarded with celebratory images and statements acknowledging the achievement (no additional content was added if participants did not meet any of these criteria).

The intervention was delivered in an automated fashion via REDCap, which sent surveys containing all intervention content through a dedicated study email address. To facilitate a sense of supportive accountability [30], REDCap was used to automatically send participants emails from the principal investigator’s (MCR) email address upon completion of various aspects of the intervention. These emails acknowledged participation and provided participants with their own responses for their records (eg, providing participants with their values, goals, and statements of committed action). Further, the REDCap surveys were programmed to automatically provide reminders of previous input responses so that participants could build upon them (eg, participants were presented with what they put as their values upon being prompted to engage in goal setting and action planning).

Measures

Acceptability

Our conceptualization of the ACTive program’s acceptability was based on study retention and adherence rates and the Integrated Model of Technology Acceptance (IMTA). [31,32]. We calculated the ACTive program’s retention rate as the percentage of participants who completed the follow-up survey. We calculated the adherence rate from the percentage of modules completed by each participant as indicated by the REDCap system use data. IMTA is a measurement model for eHealth technology acceptance. It unifies previous lines of research of information systems acceptance and posits that technology adoption is best predicted by PEOU, perceived usefulness (PU), and intrinsic motivation [31,32]. To measure these constructs, we used the PEOU scale [31,32], the PU scale [31,32], and the interest/enjoyment subscale of the Intrinsic Motivation Inventory (IMIe) [33] (Table 2). The PEOU and PU scales consist of six 7-point Likert-type items (eg, “Learning to operate this intervention would be easy for me” and “I would find this intervention to be useful for being more physically active,” respectively), with responses ranging from Extremely unlikely to Extremely likely. A psychometric analysis of these scales found evidence of reliability (Cronbach α of .98 for PU and .94 for PEOU) and convergent, discriminant, and factorial validity [34]. The IMIe scale consists of seven 7-point Likert-type items (eg, “I enjoyed doing this activity very much”), with responses ranging from 1 (Not at all true) to 7 (very true). This subscale has demonstrated good internal consistency and test-retest reliability in diverse populations [33,35,36].
<table>
<thead>
<tr>
<th>Construct and component</th>
<th>Operationalization</th>
<th>Internal reliability</th>
<th>Example item</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acceptability</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Retention</td>
<td>Percentage of participants who completed the follow-up survey</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Adherence</td>
<td>Percentage of modules completed</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Ease of use</td>
<td>Perceived ease of use scale [31,32]</td>
<td>.95</td>
<td>“Learning to operate this intervention would be easy for me.”</td>
</tr>
<tr>
<td>Usefulness</td>
<td>Perceived usefulness scale [31,32]</td>
<td>.97</td>
<td>“I would find this intervention to be useful for being more physically active.”</td>
</tr>
<tr>
<td>Enjoyability</td>
<td>Interest and enjoyment subscale of the Intrinsic Motivation Inventory [33]</td>
<td>.92</td>
<td>“I enjoyed doing this activity very much.”</td>
</tr>
<tr>
<td><strong>Physical activity</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leisure-time aerobic physical activity</td>
<td>Godin Leisure-Time Exercise Questionnaire [37]</td>
<td>N/A</td>
<td>“During a typical 7-d period (a week), how many times on average do you do the following kinds of exercise for more than 15 minutes during your free time? Moderate Exercise (not exhausting; eg, fast walking, baseball, tennis, easy bicycling, volleyball, badminton, easy swimming, alpine skiing, popular and folk dancing).”</td>
</tr>
<tr>
<td>Muscle strengthening–physical activity</td>
<td>Modified Godin Leisure-Time Exercise Questionnaire [38,39]</td>
<td>N/A</td>
<td>“In a typical week, outside of your job or work around the house, how many days do you do leisure-time physical activities specifically designed to strengthen your muscles such as lifting weights, circuit training, or resistance bands? (Do not include cardio/aerobic types of exercise).”</td>
</tr>
<tr>
<td><strong>Physical activity acceptance</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cognitive acceptance</td>
<td>Cognitive acceptance subscale of PAAQ</td>
<td>.75</td>
<td>“I need to concentrate on getting rid of my urges to stop exercising or put off exercise.”</td>
</tr>
<tr>
<td>Behavioral commitment</td>
<td>Behavioral commitment subscale of PAAQ</td>
<td>.81</td>
<td>“I am committing to being physically active no matter what feels uncomfortable or challenging about that.”</td>
</tr>
<tr>
<td><strong>Physical activity motivation</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amotivation</td>
<td>Amotivation subscale of BREQ-3</td>
<td>.84</td>
<td>“I don’t see why I should have to exercise.”</td>
</tr>
<tr>
<td>External regulation</td>
<td>External regulation subscale of BREQ-3</td>
<td>.86</td>
<td>“I exercise because other people say I should.”</td>
</tr>
<tr>
<td>Introjected regulation</td>
<td>Introjected regulation subscale of BREQ-3</td>
<td>.84</td>
<td>“I feel guilty when I don’t exercise.”</td>
</tr>
<tr>
<td>Identified regulation</td>
<td>Identified regulation subscale of BREQ-3</td>
<td>.79</td>
<td>“It’s important to me to exercise regularly.”</td>
</tr>
<tr>
<td>Integrated regulation</td>
<td>Integrated regulation subscale of BREQ-3</td>
<td>.88</td>
<td>“I exercise because it is consistent with my life goals.”</td>
</tr>
<tr>
<td>Intrinsic regulation</td>
<td>Intrinsic regulation subscale of BREQ-3</td>
<td>.93</td>
<td>“I exercise because it’s fun.”</td>
</tr>
<tr>
<td><strong>Health-related outcomes</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical function</td>
<td>Physical function subscale of PROMIS-29</td>
<td>.78</td>
<td>“Are you able to do chores such as vacuuming or yard work?”</td>
</tr>
<tr>
<td>Anxiety</td>
<td>Anxiety subscale of PROMIS-29</td>
<td>.89</td>
<td>“In the past 7 days...I felt fearful.”</td>
</tr>
<tr>
<td>Depressive symptoms</td>
<td>Depressive symptoms subscale of PROMIS-29</td>
<td>.87</td>
<td>“In the past 7 days...I felt worthless.”</td>
</tr>
<tr>
<td>Fatigue</td>
<td>Fatigue subscale of PROMIS-29</td>
<td>.94</td>
<td>“In the past 7 days...how run-down did you feel on average?”</td>
</tr>
<tr>
<td>Sleep disturbance</td>
<td>Sleep disturbance subscale of PROMIS-29</td>
<td>.88</td>
<td>“In the past 7 days...I had difficulty falling asleep...”</td>
</tr>
<tr>
<td>Ability to participate in social roles and activities</td>
<td>Ability to participate in social roles and activities subscale of PROMIS-29</td>
<td>.90</td>
<td>“I have trouble doing all of the activities with friends that I want to.”</td>
</tr>
<tr>
<td>Pain interference</td>
<td>Pain interference subscale of PROMIS-29</td>
<td>.94</td>
<td>“In the past 7 days...how much did pain interfere with your day to day activities?”</td>
</tr>
</tbody>
</table>
Physical Activity

To assess physical activity levels, the Godin Leisure-Time Exercise Questionnaire was administered. This questionnaire has shown to have good retest reliability (reliability coefficient=0.81) and convergent validity with measures of fitness such as maximum rate of oxygen consumption during intense exercise [37] and has been identified as a useful measure for understanding physical activity patterns in survivors of breast cancer [43]. We modified the Godin Leisure-Time Exercise Questionnaire to add an item measuring muscle strengthening–physical activity as has been done elsewhere in populations of cancer survivors [38,39]. This item reads, “In a typical week, outside of your job or work around the house, how many days do you do leisure-time physical activities specifically designed to strengthen your muscles such as lifting weights, circuit training, or resistance bands? (Do not include cardio/aerobic types of exercise)” and response options ranged from 0 to 7.

Physical Activity Acceptance

A central construct targeted by the ACTive program is experiential acceptance, defined as the propensity to acknowledge negative internal experiences rather than avoid them. We operationalized this construct using the Physical Activity Acceptance Questionnaire (PAAQ) [40]. This questionnaire consists of two subscales, cognitive acceptance (eg, “I need to concentrate on getting rid of my urges to stop exercising or put off exercise”) and behavioral commitment (eg, “I am committing to being physically active no matter what feels uncomfortable or challenging about that.”). Responses ranged from 1 (Never true) to 7 (Always true). This questionnaire has demonstrated sound psychometric properties in survivors of breast cancer, with high internal validity (Cronbach α=.89), test-retest reliability, and convergent validity with established measures of mindfulness and physical activity (both self-reported and accelerometer-measured) [40].

Physical Activity Motivation

A recent meta-analysis and systematic review revealed that mindfulness can have marked effects on motivation for health-related behaviors (as conceptualized by Self-Determination Theory) [44]. To investigate this link in the context of this study, we evaluated the participants’ physical activity–related motivation at baseline and after the intervention. To do so, we administered the 24-item Behavioral Regulation for Exercise Questionnaire-3 (BREQ-3) [41]. This questionnaire contains 5 subscales that operationalize Self-Determination Theory constructs of amotivation, external regulation, introjected regulation, identified regulation, integrated regulation, and intrinsic regulation (eg, “It’s important to me to exercise regularly”). Responses ranged from 0 (Not true for me) to 4 (very true for me). This questionnaire was found to have acceptable internal consistency in a sample of 414 survivors of colorectal cancer [45].

Health-Related Outcomes

To measure quality of life and physical functioning, we administered the Patient-Reported Outcomes Measurement Information System-29 profile measure (version 2.1; PROMIS-29) [42]. The PROMIS initiative is a National Institutes of Health initiative that aims to create psychometrically sound self-report measures designed to assess well-being in various domains of human health [46]. PROMIS-29 includes eight subscales, seven of which (physical function, anxiety, depressive symptoms, fatigue, sleep disturbance, ability to participate in social roles and activities, and pain interference) have 4 items with 5 Likert-type responses each (eg, ranging from Not at all to very much). The final subscale (pain intensity) has 1 item with responses ranging from 0 (No Pain) to 10 (Worst pain imaginable). Scores were coded and summed such that higher scores indicate more of the concept being measured (ie, higher scores for physical function are favorable, but higher scores for anxiety are not favorable). Raw scores were then converted to T-scores using standardized PROMIS tables [42], which were rescaled such that the mean was 50 and the SD was 10. This questionnaire has demonstrated strong psychometric properties across a variety of populations, including cancer survivors [42,47-49].

Data Analysis

We computed participants’ average PEOU, PU, and IMIe scores in accordance with their recommended scoring procedures. We calculated the average weekly moderate to vigorous physical activity using the Godin Leisure-Time Exercise Questionnaire [37] and the average subscale scores for the PAAQ and BREQ-3, following the scoring instructions. We followed the recommended PROMIS procedures to calculate the T-score metrics from the participant responses. We used listwise deletion to handle missing data, which assumes that missing data are completely missing at random [50]. We set the nominal α to .05 and used R (version 4.0.3) [51] and the tidyverse package [52] to conduct the data analysis.

Following the CONSORT (Consolidated Standards of Reporting Trials) guidelines [53], we determined the a priori criteria upon which to base our decision regarding the acceptability of the ACTive program. These were based on retention rate, adherence rate, and IMTA-based acceptability questionnaire data. As has been done elsewhere, we set the criteria for an acceptable retention rate of ≥70% [54,55]. Our criterion for the adherence rate was that ≥75% of participants completed at least four of the modules, which is comparable with other digital behavior change interventions (DBCIs) for cancer survivors [55-57]. Finally, our acceptability criteria included that the average scores of PEOU, PU, and IMIe were ≥5 (out of the 7 points of the Likert-type scales) [58]. To pursue exploratory aims, we...
conducted 2-tailed, paired sample $t$ tests (or paired sample Wilcoxon signed-rank test, as appropriate) and computed Cohen effect size values [59] for pre- and postintervention Godin Leisure-Time Exercise Questionnaire, PAAQ, BREQ-3, and PROMIS-29 subscale scores.

**Results**

**Overview**

We attempted to contact 134 participants who expressed interest in the study and met the prescreening eligibility criteria. Of the 134 participants, a total of 91 (67.9%) participants were formally screened. Of the 91 participants, 9 (10%) were found not eligible to participate (in most cases, because they were taking drugs for a heart condition), and 2 (2%) were found to be eligible but did not subsequently take part in the study. We engaged in an informed consent process with 90% (82/91) of participants, all of whom agreed to participate in the study. Of these 82 participants, 2 (2%) did not complete the baseline survey or receive any intervention content. Thus, 80 participants were included in the study’s analytic sample.

**Participant Characteristics**

The mean age of the sample was 57.5 (SD 11.4, range 31-79) years, and the median time since breast cancer diagnosis was 7 (IQR 3-12) years. The study sample was relatively well-educated (64/80, 80% college graduates), mostly non-Hispanic White (58/80, 73%), and mostly either overweight or obese (58/79, 73%; Table 3).
Table 3. Participant characteristics (N=80).

<table>
<thead>
<tr>
<th>Characteristic and category</th>
<th>Values, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Education level</strong></td>
<td></td>
</tr>
<tr>
<td>Some college</td>
<td>16 (20)</td>
</tr>
<tr>
<td>Bachelor’s degree</td>
<td>36 (45)</td>
</tr>
<tr>
<td>Graduate school degree</td>
<td>28 (35)</td>
</tr>
<tr>
<td><strong>Employment status</strong></td>
<td></td>
</tr>
<tr>
<td>Employed full time</td>
<td>41 (51)</td>
</tr>
<tr>
<td>Employed part-time</td>
<td>9 (11)</td>
</tr>
<tr>
<td>Retired</td>
<td>20 (25)</td>
</tr>
<tr>
<td>Other</td>
<td>10 (13)</td>
</tr>
<tr>
<td><strong>Marital status</strong></td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>12 (15)</td>
</tr>
<tr>
<td>Married</td>
<td>58 (73)</td>
</tr>
<tr>
<td>Living with significant other</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Divorced</td>
<td>5 (6)</td>
</tr>
<tr>
<td>Widowed</td>
<td>3 (4)</td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
</tr>
<tr>
<td>American Indian, Alaska Native, or other</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Asian</td>
<td>4 (5)</td>
</tr>
<tr>
<td>Black or African American</td>
<td>7 (9)</td>
</tr>
<tr>
<td>White</td>
<td>65 (83)</td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>7 (9)</td>
</tr>
<tr>
<td>Non-Hispanic</td>
<td>72 (91)</td>
</tr>
<tr>
<td><strong>Stage of breast cancer at diagnosis</strong></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>33 (44)</td>
</tr>
<tr>
<td>2</td>
<td>30 (40)</td>
</tr>
<tr>
<td>3</td>
<td>10 (13)</td>
</tr>
<tr>
<td>4</td>
<td>2 (3)</td>
</tr>
<tr>
<td><strong>BMI status</strong></td>
<td></td>
</tr>
<tr>
<td>Underweight</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Normal</td>
<td>20 (25)</td>
</tr>
<tr>
<td>Overweight</td>
<td>34 (43)</td>
</tr>
<tr>
<td>Obese</td>
<td>24 (30)</td>
</tr>
</tbody>
</table>

**Acceptability**

Of the 80 participants in the analytic sample, 61 (76%) completed the follow-up survey after the 8-week intervention, yielding a retention rate of 76.3%. The participants completed 71.5% of all modules in total, and the adherence rate (percentage of participants who completed at least 4 modules) was 75% (60/80; Figure 2). The participants’ average PEOU, PU, and IMIe scores were 6.17 (SD 1.17), 5.59 (SD 1.40), and 5.43 (SD 1.40), respectively (Figure 3). The retention rate, adherence rate, and IMTA-based acceptability scores met the predetermined acceptability criteria.
Figure 2. Participant completion of intervention modules.
Exploratory Outcomes

Table 4 presents the results of the exploratory analyses. On average, participating in the ACTive program was associated with an increase in nearly 90 minutes of self-reported moderate to vigorous intensity aerobic physical activity per week (Cohen $d=1.04$; Table 4; Figure 4) and 1.3 additional bouts of muscle strengthening–physical activity per week (Cohen $d=1.02$; Table 4; Figure 5). The participants exhibited statistically significant increases in scores for both the cognitive acceptance (Cohen $d=0.35$) and behavioral commitment subscales (Cohen $d=0.51$) of the PAAQ as well as for the identified regulation (Cohen $d=0.37$) and integrated regulation (Cohen $d=0.66$) subscales of the BREQ-3. There was no statistically significant increase in the intrinsic regulation subscale of the BREQ-3. Finally, participants exhibited decreased PROMIS-29 scores for fatigue (Cohen $d=-0.33$) and sleep disturbance (Cohen $d=-0.53$), and increased scores for ability to participate in social roles and activities (Cohen $d=0.18$) over the course of the study. The changes in the other PROMIS-29 subscales were not statistically significant (Table 4).
Table 4. Changes in exploratory outcomes associated with the ACTive program (n=59).

<table>
<thead>
<tr>
<th>Questionnaire and construct or subscale</th>
<th>Baseline score, mean (SD)</th>
<th>Follow-up score, mean (SD)</th>
<th>Change, mean (SD)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Godin Leisure-Time Physical Activity Questionnaire</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average weekly minutes of moderate to vigorous aerobic physical activity</td>
<td>36.2 (69.2)</td>
<td>127.4 (111.1)</td>
<td>91.6 (114.1)</td>
<td>&lt;.001(^a)</td>
</tr>
<tr>
<td>Average weekly bouts of muscle strengthening–physical activity</td>
<td>0.3 (0.8)</td>
<td>1.6 (1.6)</td>
<td>1.3 (1.6)</td>
<td>&lt;.001(^a)</td>
</tr>
<tr>
<td><strong>Physical Activity Acceptance Questionnaire</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cognitive acceptance</td>
<td>18.9 (6.9)</td>
<td>20.4 (6.0)</td>
<td>2.3 (6.9)</td>
<td>.01(^b)</td>
</tr>
<tr>
<td>Behavioral commitment</td>
<td>21.3 (5.5)</td>
<td>23.8 (4.7)</td>
<td>2.5 (5.2)</td>
<td>&lt;.001(^a)</td>
</tr>
<tr>
<td><strong>Behavioral Regulation for Exercise Questionnaire-3</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Identified regulation</td>
<td>2.5 (0.9)</td>
<td>2.8 (0.8)</td>
<td>0.3 (0.6)</td>
<td>&lt;.001(^a)</td>
</tr>
<tr>
<td>Integrated regulation</td>
<td>1.5 (1.1)</td>
<td>2.1 (1.0)</td>
<td>0.6 (0.9)</td>
<td>&lt;.001(^a)</td>
</tr>
<tr>
<td>Intrinsic regulation</td>
<td>1.7 (1.0)</td>
<td>1.9 (1.1)</td>
<td>0.2 (0.9)</td>
<td>.07(^b)</td>
</tr>
<tr>
<td><strong>Patient-Reported Outcomes Measurement Information System-29 profile measure (version 2.1; T-scores)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical function</td>
<td>53.1 (6.4)</td>
<td>53.3 (5.6)</td>
<td>0.2 (7.0)</td>
<td>.95(^a)</td>
</tr>
<tr>
<td>Anxiety</td>
<td>54.5 (9.1)</td>
<td>52.9 (8.6)</td>
<td>−0.6 (7.4)</td>
<td>.51(^b)</td>
</tr>
<tr>
<td>Depressive symptoms</td>
<td>51.1 (7.0)</td>
<td>49.8 (7.1)</td>
<td>−1.2 (5.6)</td>
<td>.11(^a)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>53.3 (8.6)</td>
<td>50.2 (8.9)</td>
<td>−2.9 (9.2)</td>
<td>.02(^b)</td>
</tr>
<tr>
<td>Sleep disturbance</td>
<td>53.0 (7.8)</td>
<td>48.8 (8.0)</td>
<td>−4.2 (7.1)</td>
<td>&lt;.001(^b)</td>
</tr>
<tr>
<td>Ability to participate in social roles and activities</td>
<td>52.1 (7.5)</td>
<td>53.5 (7.3)</td>
<td>1.3 (5.5)</td>
<td>.03(^a)</td>
</tr>
<tr>
<td>Pain interference</td>
<td>49.7 (7.8)</td>
<td>50.2 (8.2)</td>
<td>0.5 (8.1)</td>
<td>.69(^a)</td>
</tr>
<tr>
<td>Pain intensity (raw score)</td>
<td>3.5 (2.0)</td>
<td>3.5 (1.9)</td>
<td>0.08 (2.1)</td>
<td>.60(^a)</td>
</tr>
</tbody>
</table>

\(^a\)Paired-sample Wilcoxon signed-rank test.
\(^b\)2-tailed, paired sample t test.
Figure 4. Pre- to postintervention change in average weekly moderate to vigorous physical activity as measured by the Godin Leisure-Time Physical Activity Questionnaire.

Figure 5. Pre- to postintervention changes in the average number of days participants engaged in muscle strengthening–physical activity as measured by the modified Godin Leisure-Time Physical Activity Questionnaire.
Discussion

Principal Findings

In this study, we evaluated the acceptability of the ACTive program, an acceptance- and mindfulness-based physical activity DBCI for insufficiently active survivors of breast cancer. The 8-week electronically delivered intervention was centered on the application of ACT principles to increase psychological flexibility and acceptance in the context of physical activity. The study retention rate; participant adherence rate; and PEOU, PU, and IMIe scores supported the acceptability of this approach for promoting physical activity in survivors of breast cancer. Exploratory findings suggest that participation in the program was associated with increased aerobic- and muscle strengthening–physical activity, physical activity acceptance, identified and integrated regulation of physical activity, and decreased fatigue and sleep disturbance.

Although it met the threshold we determined to be acceptable for this early phase of research, the retention rate for this study (74%) was relatively low. High attrition is a challenge commonly encountered in physical activity–related DBCIs [60], but our retention rate was modestly lower than some other studies in cancer survivors [61] and the general population [62]. In addition to extraneous factors such as the possibility of reduced participation because of the COVID-19 pandemic [63], this may be in part because of a relatively high participant burden. Full participation in the ACT-derived content featured in this study required a considerable degree of concentration and reflective thought. It may have been that participants who were lost to follow-up were not able to do so because of competing demands for time and energy. Future studies should investigate which subpopulations of survivors of breast cancer are most amenable to this unique approach to promote physical activity. Adaptive interventions may feature acceptance- and mindfulness-based modules for those who may benefit from this content the most.

Study adherence, operationalized in this study as the completion of the weekly modules, was relatively high. This is another known challenge to remotely deliver digital health studies; the participants commonly cease interacting with DBCI-related content in health-related studies in less than a week [64]. In this study, participation was close to 100% for approximately half of the participants (48/80, 60%) and gradually tapered off over time for the other half (32/80, 40%; Figure 2). Evidence suggests that physician referral is associated with markedly increased adherence to digital health studies and may be a way to improve adherence to empirically supported DBCIs. Physical activity–related DBCIs may be a useful tool to supplement health care providers’ physical activity counseling, which has been shown to be effective but is often limited by time constraints [65]. Although the default assumption may be that more interactions with DBCI content is necessarily better, there is increasing recognition of the importance of parsing from intervention interaction that might constitute effective engagement or the level and type of engagement that is linked to key outcomes of interest [66]. The ACTive program was structured such that each module generally targeted specific ACT processes. It may be that some processes should be prioritized in the context of physical activity promotion if they predict a disproportionate amount of variance in physical activity–related outcomes. Future studies designed to evaluate intervention effectiveness should investigate what constitutes effective engagement with physical activity interventions centered on ACT principles. Furthermore, it may be useful to investigate the optimal constitution of ACT-based programs for promoting physical activity.

Findings pertaining to PEOU, PU, and IMIe scores indicated that the ACTive program was well received. These constructs predict the use and appraisal of web-based learning platforms [34,67-69] and the likelihood of cancer survivors sharing health-related information with others [70]. In this study, PEOU scores were particularly high (Figure 3). This finding supports the delivery of ACT-derived content to promote physical activity via digital means. This is a noteworthy finding, because to date, most physical activity interventions derived from ACT concepts have been conducted in person [17]. The findings suggest that this approach to physical activity promotion may be extended using DBCI technologies to increase public health impact. In this study, we used the REDCap survey delivery system. Although audiovisual program delivery is not its primary purpose, it seems to be useful for developing and evaluating beginning stage behavioral interventions. Furthermore, this may be a particularly attractive option when privacy and data security are paramount.

High PU and IMIe scores suggest that participating survivors of breast cancer felt that the application of acceptance- and mindfulness-based techniques to increase physical activity was relevant and enjoyable. This is an important finding given the marked heterogeneity of motivations for physical activity, physical abilities, and the range of desired DBCI features found in survivors of breast cancer [71]. This study is among the first to evaluate the use of acceptance- and mindfulness-based techniques for physical activity promotion in cancer survivors; although, ACT is increasingly being used to inform physical activity promotion interventions in other groups [17] and has been recommended as a useful therapeutic modality for cancer survivors [10,11]. The paradigm shifting emphasis to change your relationship with problematic thoughts and feelings, rather than changing the thoughts and feelings themselves, appears to resonate with insufficiently active survivors of breast cancer. High ratings of the PU of the intervention suggest that participants felt the program was effective at increasing their physical activity levels, and this notion was supported by exploratory findings.

The study participants tended to report substantial increases in aerobic- and muscle strengthening–physical activity levels from before the intervention to after the intervention. The participants averaged approximately 90 minutes per week increases in moderate to vigorous intensity aerobic physical activity and approximately 1.3 bouts per week increase in muscle strengthening–physical activity. Given the dose response, negative association between physical activity and overall and cancer-specific mortality in survivors of breast cancer [72-75] and recommended guidelines for cancer survivors [76-78], these increases are clinically meaningful. The results are in accordance with the current research and practice guidelines.
with a recent systematic review and meta-analysis that concluded that interventions based on ACT principles hold promise for increasing physical activity [17] and are supported by both high PU ratings and corresponding increases in PAAQ scores. Given the importance of long-term adherence to physical activity, future research is needed to evaluate the effectiveness of acceptance- and mindfulness-based interventions for both initiation and long-term maintenance of physical activity in survivors of breast cancer.

We observed small and medium effect sizes for changes in the PAAQ subscales of cognitive acceptance and behavioral commitment, respectively. This suggests that the participants experienced increases in both their experiential acceptance of physical activity–related internal experiences (eg, sensations, cognitions, and emotions) and their behavioral commitment to engaging in physical activity. This has implications for long-term change: increases in cognitive acceptance have been found to be associated with long-term changes in objectively measured physical activity [40]. As ACT is centered on increasing psychological flexibility, and in the context of physical activity promotion, this is perhaps most clearly manifested as physical activity acceptance. It may be that effective physical activity interventions derived from ACT tenets are partly mediated by this construct. Future studies should investigate this possibility in survivors of breast cancer.

Participants tended to report an increase in both identified regulation and integrated regulation of physical activity from before the intervention to after the intervention. These constructs are held by Self-Determination Theory to reflect autonomous forms of extrinsic regulation and have been shown to be consistently predictive of physical activity [79]. The findings of this study are concordant with the literature that has found mindfulness interventions to be associated with increases in autonomous motivation [44]. Practicing mindfulness exercises, such as engaging in mindful walking, might be theorized to increase the interest or enjoyment derived from physical activity and thus, engender increases in intrinsic regulation [44]. As changes in this study were observed for identified regulation and integrated regulation for physical activity but not for intrinsic regulation, it may have been that participants’ reflection on the benefits of physical activity alongside value clarification exercises caused them to value physical activity more deeply and increasingly identify as someone who prioritizes it. Future research should investigate this notion and how Self-Determination Theory and ACT may inform behavior change interventions in tandem.

Finally, sleep disturbance, fatigue, and the ability to participate in social roles and activities are challenges faced by cancer survivors that can begin with primary treatment and persist long into survivorship [80-82]. In this study, participants tended to report clinically meaningful decreases in these issues from before the intervention to after the intervention [83]. This finding is in accordance with the literature that has found effective physical activity interventions to impact these health-related outcomes in cancer survivors [84,85]. Indeed, the American College of Sports Medicine guidelines for cancer survivors provide specific physical activity recommendations for achieving improvements in these domains [77], and such changes may occur relatively quickly with increasing physical activity levels [86,87]. Other mean changes in health-related outcomes were not statistically significant; although, there were trends toward a reduction in depressive symptoms. However, the interpretation of changes in PROMIS-29 health-related needs to be considered in light of the COVID-19 pandemic and its societal ramifications, which may have influenced these variables.

Strengths and Limitations
The findings of this study must be considered in the context of its limitations. The generalizability of this study is limited by convenience sampling methods that yielded a relatively well-educated sample and limited diversity in terms of race and ethnicity. Furthermore, participants who responded to the recruitment material may have been particularly motivated to increase their physical activity. The COVID-19 pandemic precluded more active forms of recruitment that may have yielded a more diverse sample, but our recruitment methods allowed individuals from all over the United States to participate. The study’s high attrition rate has potential implications for the findings regarding the acceptability of the intervention. It may have been that those who were lost to follow-up produced lower ratings. However, the results met the a priori criteria for determining the acceptability. Our study design was centered on investigating the acceptability of the ACTive program and precluded making causal inferences regarding the efficacy of the intervention. We observed that changes in reported physical activity along with high ratings of PU of the intervention and concomitant changes in theorized determinants and outcomes linked to physical activity are somewhat encouraging, but alternate explanations may account for these observations. Salient threats to internal validity include history (particularly given the COVID-19 pandemic), potential reactivity to the experimental situation, regression to the mean, and self-reported assessment of physical activity (which is prone to social desirability and recall bias). There is also an inflated chance of type 1 error given that we conducted multiple statistical tests (eg, evaluating changes in all survey subscales individually). We did not adjust the P values given the exploratory nature of this investigation. The strengths of this study include the use of a theory-based intervention that can be implemented with high fidelity and has potential for scalability, acceptability testing informed by the Obesity-Related Behavioral Intervention Trials model for intervention development, and predetermined thresholds to ascertain intervention acceptability. Another strength of this project was the parsimony of design and low cost of the intervention. The study was conducted with minimal resource expenditure using in-house scripting or video and leveraging extant resources (eg, REDCap). This low-end development was used to achieve considerable positive impact and demonstrated the ability to compile meaningful, theory-based applications for increased reach, fidelity, and acceptability.

Conclusions
We conclude that electronically delivered acceptance- and mindfulness-based physical activity approaches to physical activity promotion represent potentially well-received and useful...
intervention option for insufficiently active survivors of breast cancer. Metrics pertaining to study retention, program adherence, and ratings of PEOU, usefulness, and intrinsic motivation all met the predetermined criteria for success. Receipt of the intervention was associated with increases in reported aerobic- and muscle strengthening–physical activity, physical activity acceptance, identified and integrated regulation of physical activity, and decreases in fatigue and sleep disturbance. More research is needed to further develop this approach to promote physical activity and formally evaluate its potential efficacy in pilot-testing with randomized designs.

Acknowledgments
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Conflicts of Interest
None declared.

References


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**Abbreviations**

ACT: Acceptance and Commitment Therapy  
BREQ-3: Behavioral Regulation for Exercise Questionnaire-3  
CONSORT: Consolidated Standards of Reporting Trials  
DBCI: digital behavior change intervention  
IMIiE: interest/enjoyment subscale of the Intrinsic Motivation Inventory  
IMTA: Integrated Model of Technology Acceptance  
PAAQ: Physical Activity Acceptance Questionnaire  
PEOU: perceived ease of use  
PROMIS-29: Patient-Reported Outcomes Measurement Information System-29 profile measure (version 2.1)  
PU: perceived usefulness  
REDCap: Research Electronic Data Capture

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Barriers to Clinical Trial Participation: Comparative Study Between Rural and Urban Participants

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Abstract

Background: The National Clinical Trials Network program conducts phase 2 or phase 3 treatment trials across all National Cancer Institute’s designated cancer centers. Participant accrual across these clinical trials is a critical factor in deciding their success. Cancer centers that cater to rural populations, such as The University of Kansas Cancer Center, have an additional responsibility to ensure rural residents have access and are well represented across these studies.

Objective: There are scant data available regarding the factors that act as barriers to the accrual of rural residents in these clinical trials. This study aims to use electronic screening logs that were used to gather patient data at several participating sites in The Kansas University of Cancer Center’s Catchment area.

Methods: Screening log data were used to assess what clinical trial participation barriers are faced by these patients. Additionally, the differences in clinical trial participation barriers were compared between rural and urban participating sites.

Results: Analysis revealed that the hospital location rural urban category, defined as whether the hospital was in an urban or rural setting, had a medium effect on enrolment of patients in breast cancer and lung cancer trials (Cohen d=0.7). Additionally, the hospital location category had a medium effect on the proportion of recurrent lung cancer cases at the time of screening (d=0.6).

Conclusions: In consideration of the financially hostile nature of cancer treatment as well as geographical and transportation barriers, clinical trials extended to rural communities are uniquely positioned to alleviate the burden of nonmedical costs in trial participation. However, these options can be far less feasible for patients in rural settings. Since the number of patients with cancer who are eligible for a clinical trial is already limited by the stringent eligibility criteria required of such a complex disease, improving accessibility for rural patients should be a greater focus in health policy.

Introduction

There are numerous barriers for rural residents to obtain health care. Some of the barriers include but are not limited to lack of facilities, lack of infrastructure, inability to travel, lack of specialists, financial barriers, and limited access to clinical trials [1]. Consequently, patients may avoid or delay care, resulting in more severe clinical outcomes [2,3].

Within this field, there are several environmental risk factors such as sun exposure, pesticide exposure, and risk of injury from farming equipment [4,5]. Among these risks, pesticides and other chemicals may lead to an increased cancer incidence among rural populations [6]. Given the nature of cancer, without early diagnosis, the patient might be left with fewer treatment options or may even run out of treatment options. Moreover, treatments for battling cancer are very expensive as they require...
multiple sessions over a long period of time [7,8]. The medications involved with cancer treatment are also expensive, and not all are covered through medical insurance leaving the patient to pay for it [9]. Given most of the rural residents are either self-employed or employed through small companies, typically their insurance coverage is very minimal [10]. A lack of insurance coverage or gaps in insurance coverage can add to the difficulty of the treatment process for rural patients. In many cases, these patients must choose between skipping treatment or taking on debt [9]. In consideration of these obstacles, clinical trials may represent an underutilized avenue of affordable treatment for rural patients. However, the availability of these trials to rural patients is limited by the logistic difficulty of bringing expensive medical devices involved in cancer treatment to isolated health centers in nonmetro areas.

The Masonic Cancer Alliance (MCA), which serves as the outreach network for the University of Kansas Cancer Center (KUCC), already has a great relationship with most of the rural hospitals and clinics in the catchment area. The KUCC launched this network to extend clinical trials at these hospitals and clinics in rural and health professional shortage areas. The majority of trials made available to the MCA sites are the National Cancer Institute’s National Clinical Trials Network studies. To better understand the volume and patient cohort availability, all of the screening information gathered at these locations was documented at each of the sites under a screening log database. These community sites span across the state of Kansas, covering the majority of KUCC’s catchment area.

The National Clinical Trials Network (NCTN) program is aimed to motivate like-minded people across North America and internationally to coordinate and support cancer clinical trials that are funded by the National Cancer Institute. The trials that were part of the NCTN program were used as potential trials available for patients who received care at 9 community sites. The community site information is summarized in Table 1, including the county and state these sites are located, as well as their Rural Urban Continuum Codes (RUCC) classification, which designates counties as rural or urban depending on population and urbanization.

KUCC, in collaboration with MCA, launched clinical trial screening at the 9 community sites that are located across the KUCC catchment area for the NCTN trials. Figure 1 provides a geographical representation of where these sites are located.

<table>
<thead>
<tr>
<th>Site name</th>
<th>County, state (population)</th>
<th>RUCC classification</th>
<th>Health professional shortage areas (primary care)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hays Medical Center</td>
<td>Ellis County, KS (28,553)</td>
<td>Rural (5)</td>
<td>No</td>
</tr>
<tr>
<td>Heartland Cancer Center</td>
<td>Finney County, KS (36,467)</td>
<td>Rural (5)</td>
<td>Yes</td>
</tr>
<tr>
<td>Newman Regional Center</td>
<td>Lyon County, KS (33,195)</td>
<td>Rural (4)</td>
<td>Yes</td>
</tr>
<tr>
<td>Olathe Medical Center</td>
<td>Johnson County, KS (602,401)</td>
<td>Urban (1)</td>
<td>No</td>
</tr>
<tr>
<td>Salina Regional Health Center</td>
<td>Saline County, KS (54,224)</td>
<td>Rural (5)</td>
<td>Yes</td>
</tr>
<tr>
<td>St. Catherine Hospital</td>
<td>Finney County, KS (36,467)</td>
<td>Rural (5)</td>
<td>Yes</td>
</tr>
<tr>
<td>St. Francis Comprehensive Medical Center</td>
<td>Shawnee County, KS (176,875)</td>
<td>Urban (3)</td>
<td>Yes</td>
</tr>
<tr>
<td>Truman Medical Center</td>
<td>Jackson County, MO (703,011)</td>
<td>Urban (1)</td>
<td>No</td>
</tr>
<tr>
<td>Via Christi Hospital</td>
<td>Crawford County, KS (38,818)</td>
<td>Rural (4)</td>
<td>Yes</td>
</tr>
</tbody>
</table>

*RUCC: Rural Urban Continuum Codes.
Methods

Screening Methodology

The MCA, in conjunction with the Biostatistics and Informatics Shared Resources, have built a screening log survey using REDCap (Research Electronic Data Capture) [11]. The screening log was targeted to capture high-level information about participants who were screened at these community sites. The screening log captured information such as whether there was a trial available based on the community cancer center’s clinical trials portfolio. If a potential trial was currently available for a participant’s cancer type, the participants were screened and screening information was documented. Documented screening information for these patients included cancer disease type, stage, and recurrence. The screening log is attached as a supplementary document listing all the questions that were captured during the screening. If a patient was found to be ineligible for a trial after screen, the corresponding reasons were also documented. If a patient was eligible for a trial but chose not to take part, their reasons were also documented. Multiple disease trials were considered to be available trials for both patients with lung cancer and patients with breast cancer.

The University of Kansas Medical Center Institutional Review Board’s approval was given to capture the participants screening information across the 9 community sites in October 2014. Since then, information has been captured under the REDCap screening log project. The data dictionary depicting the screening information that was captured has been attached as a supplementary document (Multimedia Appendix 1). The number of clinical trials that were available across these 9 sites is illustrated as a bar chart in Figure 2. These results are stratified by year, and different colors represent the type of disease the trial was targeting (breast, lung, or multiple disease). The multiple disease trials are broader studies that allowed screening for both breast and lung but also other common cancer types.

The 9 sites involved in the screening process span across the state of Kansas and are described in Table 1. Based on the RUCC, these sites were classified as Rural (RUCC 4-9) or Urban sites (RUCC 1-3). For the purposes of this study, we used hospital location to categorize rural or urban status to compare factors in breast cancer and lung cancer between the rural and urban groups. These factors include clinical trial availability, barriers to treatment, and disease characteristics.
Statistical Analysis

The data capture for screening were developed with a pure intention of operational goals, and consequently there was not a formal study design to determine the sample size for each of these sites. Moreover, the screening process of clinical trials is hard to predict, and there is always an ebb and flow with screening both in urban and rural areas. Due to these sampling issues, the Fisher exact test $P$ value was determined to be an insufficient method for comparing rural participants to urban participants. Additionally, in consideration of the fact that significant $P$ values are also likely to be found in large sample sizes even when the size of the effect is negligible, Cohen $d$ was used to calculate effect size instead [12]. To obtain the Cohen $d$, a log odds ratio was calculated and then converted [13]. A Cohen $d$ value of $[0.0,0.2)$ implies negligible effect; $[0.2; 0.5)$ implies small effect; $[0.5; 0.8)$ implies medium effect; and $[0.8; \infty)$ implies large effect [14].

Cohen $d$ Calculation

Cohen $d$ is calculated using the following standard formula:

Variables included for analysis included the rural-urban category, with outcomes including the disease-specific information gathered during the screening process. Among the disease-specific information, variables varied between patients who had breast cancer and those diagnosed with lung cancer.

Outcome variables for patients with breast cancer included clinical trial availability, whether they were a new or existing patient at diagnosis, tumor stage, histology of the breast, nodal breast status, metastatic status, recurrence status, stage of breast, and hormone of the breast. Clinical trial availability was recorded as yes or no depending on whether a clinical trial was available. Metastatic status was recorded as yes or no. Recurrence status was recorded as recurrent or nonrecurrent. Tumor stage was recorded as T1, T2, T3, or T4. Histology of the breast was recorded as ductal carcinoma in situ (invasive carcinoma), or inflammatory carcinoma. Nodal breast status was recorded as either positive or negative. Stage of breast was recorded as 0, I, II, III, or IV. Lastly, the hormone of the breast was recorded as ER/PR+ (estrogen receptor/progesterone receptor) HER2+ (human epidermal growth factor receptor 2), ER/PR+ HER2−, ER/PR− HER2+, or ER/PR− HER2−.

Outcome variables for patients with lung cancer included clinical trial availability, whether they were a new or existing patient at diagnosis, tumor stage, histology of the lung, nodal lung status, metastatic status, and recurrence status. Clinical trial availability was recorded as yes or no depending on whether a clinical trial was available. Metastatic status was recorded as yes or no. Recurrence status was recorded as recurrent or nonrecurrent. Lung histology was recorded as adenocarcinoma, bronchoalveolar, squamous cell carcinoma, small-cell carcinoma, or mesothelioma. Tumor stage was recorded as T0, T1, T2, T3, or T4. Lastly, nodal lung status was recorded either positive or negative.

Ethics Approval

The University of Kansas Medical Center granted approval under a central IRB with reliance by the other institutions (STUDY00002341).

Results

A total of 2258 patients with breast cancer and 1347 patients diagnosed with lung cancer were screened across 9 sites from October of 2014 to December of 2020. Some common reasons why patients were not able to participate in clinical trials are described in Multimedia Appendix 2. As stated previously, we sought to assess the relative availability of clinical trials between rural and urban patients. Additionally, we analyzed the relative incidence of certain cancer disease features between these two
populations. These results are detailed in Multimedia Appendix 3.

Among patients with breast cancer, we noted significant differences in clinical trial availability between rural-urban categories. For urban residents, 177 (18.7%) of the 945 patients with breast cancer were eligible for a clinical trial based on their portfolio. Compare this to rural residents, where 79 (6.01%) of 1313 patients were eligible for a clinical trial. A Cohen $d$ value of 0.7 represents a medium effect between the rural and urban groups when it comes to clinical trial availability. Using the Cohen $d$ calculation formula, this would mean that an urban patient who has breast cancer would be 3.56 more likely to have an available clinical trial for their cancer type compared to a rural patient with breast cancer. This suggests that an urban participant diagnosed with breast cancer had higher odds of finding a potential clinical trial compared to a rural patient diagnosed with the same condition. Hospital Location Rural-Urban Category (HLRUC) had a small effect on whether a patient was a new or existing patient at the time of diagnosis (Cohen $d=0.2$), suggesting slightly higher odds that a rural patient would be a new patient at the time of diagnosis. Health risk control did not display an effect on either the stage of breast cancer or breast histology. For both outcomes, the Cohen $d$ was 0.1. Health risk control displayed a small effect size ($Cohen d=0.2-0.4$) on nodal breast status, metastatic status, recurrence status, stage of breast, and hormone of breast. This suggests slightly higher odds for the incidence of these outcomes among rural patients diagnosed with breast cancer.

Among patients with lung cancer, there was a similar disparity in clinical trial availability. For rural patients with lung cancer, 84 (10.5%) of 798 patients had an available clinical trial. For urban patients with lung cancer, 140 (43%) of 325 patients had an available clinical trial. The residence category resulted in a Cohen $d$ of 0.8, which would mean that urban patients with lung cancer were 4.268 times more likely to have an available clinical trial. HLRUC had a small effect on the incidence of lung histology categories including adenocarcinoma, bronchoalveolar, small-cell carcinoma, and mesothelioma. HLRUC did not influence the lung histology category of squamous cell carcinoma. HLRUC had a small effect on incidence of the T1 stage of lung cancer (Cohen $d=0.2$) but had no effect on the incidence of other stages. HLRUC had no effect on nodal status (Cohen $d=0.1$), and a small effect on metastatic status (Cohen $d=0.2$). HLRUC had a medium effect on recurrent status of patients with lung cancer (Cohen $d=0.6$), suggesting a higher odds of recurrent lung cancer among rural patients.

**Discussion**

**Key Findings**

Our results suggest that clinical trial availability was greater for urban patients with breast cancer and lung cancer than it was for their rural counterparts. It stands to reason that the benefit of expanding clinical trial availability to rural patients could be significant for an already underserved population. Since the screening was a part of the data gathering process, the effect size could also potentially be due to fewer study options that are available at the rural sites. Stringent eligibility criteria are a long-standing barrier in cancer trial participation, and there have been recent initiatives to reevaluate and broaden clinical trial availability [15,16]. Broadening the criteria has multiple benefits such as improved clinical trial participation, reflecting larger patient population and increasing patient access to new investigational treatment [17]. Even after initial prescreening, the participants might have to undergo a set of labs before they are officially enrolled into the clinical trial. Costs for these additional labs or exams might not be covered by the clinical trial sponsor and might discourage participants from even entertaining the idea of participation into these trials [18]. Subsequent studies should consider barriers to clinical trial participation in the context of cancer stage as well as current factors. In cases where the participants’ diagnosis is in an advanced stage, they have very fewer clinical trial opportunities because of fewer advanced stage trials and the aggressive nature of the disease [19]. The time-sensitive nature of advanced stage cancer incentivizes physicians to begin treatment as quickly as possible instead of searching for potential clinical trials. When there are additional barriers complicating clinical trial participation, this could make clinical trials particularly unavailable for patients in an advanced cancer stage.

Apart from the clinical trial availability metric, our keen focus was to assess if patients who seek care in rural areas might differ in care, which could potentially lead to malignancy of cancer or a diagnosis of a late stage. Our analysis indicated that the prevalence of certain cancer features was similar between populations seeking care at rural and urban centers. However, the limited sample size of patients at rural locations could affect the interpretation of these results. More data from rural populations, as well as the inclusion of additional factors in the screening process, will be required for future analysis.

Recent studies suggest that involving primary care physicians in the conversation of clinical trial participation can encourage rural patients to see cancer trials as a treatment option [20]. For rural participants who are diagnosed with cancer for the first time, they may lack the experience and information to decide what treatment options suit them. This can exacerbate the already present barriers to clinical trial participation for these patients. If information on clinical trial options is provided to them by a primary care physician or other familiar health care worker, they may be more receptive to alternate treatment options such as clinical trial participation [21]. In this way, some of the individual and personal barriers to clinical trial participation can be alleviated.

Multimedia Appendix 2 illustrates some of the common reasons why participants were not able to find an appropriate clinical trial that suits their profile. Additionally, if they were qualified for study participation and decided not to participate, those reasons have been documented as well. Among both the breast and the lung cancer group, the major screening failure reason has been the performance status or the ECOG (Eastern Cooperative Oncology Group) status. The ECOG status is a frequently used measure in clinical trial planning, which details a patient’s ability to care for themselves, as well as their mobility and activity levels. Typically, most trials under their inclusion criteria look for participants who have a lower performance
status; a higher performance status would mean they are limited self-care or need additional support [22].

As mentioned previously, multiple disease trials were considered to be available trials for patients with lung cancer and those with breast cancer. While the lack of specificity in these trials allows for greater accessibility, the broadness of their typical premise means the potential benefits of participation are limited. Some of the common reasons why the patient decided not to participate includes “time concern,” “travel concern,” “insurance denial,” “study logistics,” “language barrier,” “social,” and “physician didn’t offer.” One of the low hanging fruits that can be easily addressed from the above barriers is to educate the physicians at these sites and provide them with a comprehensive list of studies that suits their patient’s profile. For this very reason, KUCC has developed a mobile app also known as “Clinical Trial Finder App” that can be used by any physician to easily screen or refer a patient while the patient is in the clinic with them [23,24].

Limitations
Due to the data limitation, we are unable to assess if the screening rate varies by site or based on race or ethnicity. As a future project, our team proposes to find ways to collaborate with these sites to gain additional demographics and clinical information to dive deeper into understanding the various trends. Another major limitation of the study was that hospital location was used as a surrogate for patient residence. In future studies, it would be beneficial to gather data on actual patient residence in order to determine urban or rural residence categories. The screening estimates might be on the lower end, as some of the screened patients who did not follow the standard screening procedures could have been excluded from the data capture system.

Conclusion
Even in this day and age, we continue to observe barriers that discourage participants from participating in clinical trials. Additionally, the health care availability gap between rural and urban participants is widening, which limits the generalizability of clinical trials for rural participants. Technological, therapeutic, and medical practice advances have had very little impact on reducing these barriers. A few of the notable barriers include lack of personnel to screen participants, lack of technology, commuting issues, and differences among the population characteristics. We as a cancer center strive to continue educating our clinical teams at the rural sites about the potential referral opportunities. Future policy makers must consider more targeted programs that facilitate the participation of rural patients. This approach must be multifaceted, involving earning the trust of rural patients, providing resource to facilitate clinical trial participation, disseminating the right information, and continuing to engage and adapt to the dynamic rural environment. Additional support must be provided to encourage clinical trial participation through resources such as transportation, childcare, and tax credits, among others.

Acknowledgments
Development of the Clinical Trial Finder App was supported by the National Cancer Institute (NCI) Cancer Center Support Grant P30 CA168524 and used by the Biostatistics and Informatics Shared Resource (BISR).

Conflicts of Interest
None declared.

Multimedia Appendix 1
Survey template.
[PDF File (Adobe PDF File), 56 KB - cancer_v8i2e33240_app1.pdf ]

Multimedia Appendix 2
Screen failure reason and qualified participants reason to decline trial participation.
[DOCX File, 17 KB - cancer_v8i2e33240_app2.docx ]

Multimedia Appendix 3
Comparison of rural versus urban participants based on the participants' screening characteristics.
[DOCX File, 40 KB - cancer_v8i2e33240_app3.docx ]

References


Abbreviations

ECOG: Eastern Cooperative Oncology Group
ER/PR: estrogen receptor/progesterone receptor
HER2: human epidermal growth factor receptor 2
HLRUC: Hospital Location Rural-Urban Category
KUCC: University of Kansas Cancer Center
MCA: Masonic Cancer Alliance

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Patient and Provider Perspectives on Enrollment in Precision Oncology Research: Qualitative Ethical Analysis

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Abstract

Background: The genomic frontier continues to revolutionize the practice of oncology. Advances in cancer biology from tumorigenesis to treatment resistance are driven by the molecular underpinnings of malignancy. The framing of precision oncology as both a clinical and research tool is constantly evolving and directly influences conversations between oncologists and their patients. Prior research has shown that patient-participants often have unmet or unrealistic expectations regarding the clinical utility of oncology research and genomic sequencing. This indicates the need for more in-depth investigation of how and why patients choose to participate in such research.

Objective: This study presents a qualitative ethical analysis to better understand patient and provider perspectives on enrollment in precision oncology research.

Methods: Paired semistructured interviews were conducted with patient-participants enrolled in a prospective head and neck precision oncology research platform, along with their oncology providers, at a National Cancer Institute–designated academic cancer center.

Results: There were three major themes that emerged from the analysis. (1) There are distinct and unique challenges with informed consent to precision medicine, chiefly involving the ability of both patient-participants and providers to effectively understand the science underlying the research. (2) The unique benefits of precision medicine enrollment are of paramount importance to patients considering enrollment. (3) Patient-participants have little concern for the risks of research enrollment, particularly in the context of a low-burden protocol.

Conclusions: Patient-participants and their providers offer complementary and nuanced perspectives on their motivation to engage in precision oncology research. This reflects both the inherent promise and enthusiasm within the field, as well as the limitations and challenges of ensuring that both patient-participants and clinicians understand the complexities of the science involved.

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KEYWORDS
oncology research platform; precision oncology; head and neck oncology; academic cancer center; semistructured interview; patient-provider dyads; oncology; interview; ethical analysis; patient; provider
**Introduction**

The genomic frontier continues to revolutionize the practice of oncology. Advances in cancer biology from tumorigenesis to treatment resistance are driven by the molecular underpinnings of malignancy, and the framing of precision oncology as both a clinical and research tool is constantly evolving. Introspection is warranted to examine how conversations between oncologists and their patients may be affected.

Studies have assessed the motivations of research participants enrolling in genome sequencing research, such as the HealthSeq [1] and ClinSeq [2] projects, and reflected the tension between the risk and potential reward that these platforms offer. Additional studies have explored the perspectives of patient-participants enrolled in precision oncology studies, many of whom reported unfulfilled expectations [3]. These patient-participants also reported a higher level of perceived utility of the study at the time of enrollment than after enrollment. Specifically, their expectations that participation in a genome sequencing study would affect future health and medication decisions were not frequently met [4].

These studies all indicate the need for more nuanced questions and perspectives. As one study states, “Further evaluation of whether and how family members and close contacts were involved in the patient’s decision to pursue or decline sequencing, and any discussion with family members and friends preceding sequencing, may help to elucidate how these dynamics affect decision-making” [5]. A key component when asking these questions is to address the unique concerns in this field of research. For example, precision oncology has a more established clinical utility in certain cancers than others. Moreover, the role of germline mutations is de-emphasized in many cancers, which may confuse how patients consider the issues of heritability and familial risk. In addition, cancer stage, prognosis, and recurrence will all invariably impact how patients, many of whom are affected by cancers considered to be terminal, will consider the prospect of using “cutting edge science” to save their lives. This is particularly true when most precision oncology platforms to date have, at best, modest impact on survival outcomes.

Our aim is to better understand patient and provider perspectives related to the decision to enroll in a low-burden precision oncology protocol. In this study, we employed a qualitative embedded ethics protocol involving semistructured interviews of both adult patients with head and neck cancer enrolled in precision medicine research and their clinicians. This study was nested within a prospective precision oncology study at one institution, a National Cancer Institute–designated academic cancer center. Two other articles have been derived from the interview data set, one focused on patient and provider perspectives on enrolling in head and neck cancer research [6] and the other on commercialization of cancer genomic data [7]. Herein, we focus specifically on patient and provider perspectives on enrollment in precision oncology itself.

**Methods**

**Overarching Study Design**

This inquiry ran alongside the overarching study, “Developing Precision Medicine Protocols for Head and Neck Cancer MiOtoSeq (Michigan Otolaryngology and Translational Oncology Sequencing Center),” an institutional review board–approved precision medicine study in the Michigan Medicine Department of Otolaryngology–Head and Neck Surgery [8]. Patient-participants enrolled in MiOtoSeq were adults with biopsy-confirmed cancer of the head and neck who were counseled and consented to participate in upfront, targeted genomic research sequencing of their tumors and germline tissues. In conjunction with the MiOtoSeq study, we embedded this qualitative ethics protocol to better understand and compare perspectives on their involvement in precision oncology research. Specifically, we were interested in the motivations of patients and providers to enroll in the research.

**Interviews**

A subset of the MiOtoSeq patient-participants were purposively sampled for interviews based on demographic and clinical factors to ensure a diverse variety of experiences. All patients participated in a 1-hour interview conducted by researchers trained in semistructured interviewing techniques [9]. All interviews were conducted in 2018.

The interviews were audiorecorded, transcribed by a third-party service, and deidentified. All interview files were stored on an institutionally supported secure storage platform. In these interviews, participating patients and clinicians were asked a variety of questions related to the goals of precision medicine research, the risks and benefits as they perceived them, and their experience with the MiOtoSeq enrollment and consent process.

This analysis includes responses from a total of 20 interviews from 10 patients and 8 clinicians. In the cases of 2 physicians, each had treated 2 patients and we conducted 2 separate interviews with the physicians to focus on each patient. Patient-participants were recruited until thematic saturation was achieved [10] and then their physician was recruited for comparison purposes. One of the clinicians is an author of this analysis, and his interview responses were excluded from quotation. Once the interviews were underway, team members (KSB and MK) iteratively developed the codebook [9]. Transcripts were inductively and deductively double-coded (by MK and CK) and discords were reconciled (KSB). Please refer to our previous publication for more detail regarding these methods [6]. For the purposes of this article, gender pronouns for clinicians and patient-participants were randomly selected for additional privacy.

**Ethics Approval and Consent to Participate**

Approval was obtained from the ethics committee of the University of Michigan (HUM00085888). The procedures used in this study adhere to the tenets of the Declaration of Helsinki. Informed consent was obtained from all individual participants included in the study.
Results

Theme 1: Challenges With Informed Consent to Precision Medicine

Many patient-participants stated that their background knowledge of genetics came from media or television. For example, several patient-participants cited the movie Jurassic Park, coverage of “test tube babies,” or the Discovery Channel as their main source of genetic information. As one patient-participant put it, their awareness began “when Francis (or was it Crick?) first started the Human Genome Project” (Patient [P] 05). As one clinician aptly joked, “I think most patients don’t understand [genetics], because I barely do in a lot of ways” (Clinician [C] 10).

Many clinicians were concerned that the patients’ lack of understanding of genetics, and research in general, might lead to confusions between clinical care and enrollment in a precision medicine protocol. For patients without a strong grasp of the basics of genetics, the nuanced potential benefit of precision oncology—where clinical care and research may be blurred—was complex to understand. For example, the doctor of one of the patient-participants who said he had learned about genetics from Jurassic Park admitted that although he explained to the patient that this was not a therapeutic trial, “…maybe he didn’t get that. I don’t know [laughs]” (C02). Another doctor added, “I don’t know if [my patient] actually understood, because patients express understanding of almost everything I say…” (CO3). Other clinicians seemed reassured that patients at least understood that the research would not change their clinical care or help them directly. However, despite one clinician stating that he thinks “the personal reward for any individual patient is very low” (C11), his patient stated that her expectation from participating in the study was that it “might save my life” (P11).

Other clinicians emphasized the inherent vulnerability of patients in a clinical oncology visit and how that might compound confusion or inadvertent exploitation. Of note, although the clinicians were MiOtosq coinvestigators, consent for enrollment into the study was obtained by a dedicated study coordinator. One clinician described her realization that “most patients don’t understand genetic sequencing and simply sign something because we give [it to] them in a very vulnerable situation” (C07). She went on to describe asking patients to enroll in research during a clinical care visit as “really not an informed consent process.” Another clinician agreed that his patients were “more worried about not passing away from [the cancer] as opposed to having their sequencing done” (C10). As a patient affirmed, “In the whirlwind of things…I really didn’t think about [enrolling in research] too much…I just consented” (P11). However, a different patient-participant described the benefit of learning about precision medicine in the clinical context: “Wow, you know, I’d like to know more about myself…and my genetic makeup and kind of what went wrong…” (P08).

Theme 2: Unique Benefits of Precision Medicine Enrollment

Many patient-participants were excited about the promise of precision medicine research specifically, referring to current cancer treatment options as “archaic.” They described precision medicine as “the future,” and several expressed hope for finding a cure for cancer.

“I think that we have no idea of what we’re doing right now. We’re dabbling a foot in the pool, but once we get all the way into that pool, I think we’re going to have some serious answers. [P07]

Patient-participants were less clear about potential benefits to themselves in enrolling in precision medicine research. Although the majority noted that they realized the research was not primarily for their own benefit, many held out hope for the “teeny, teeny, teeny, teeny possibility that it could help me” (P07). Several patient-participants specifically described hoping that the research could help them if their cancer came back in the future. Clinicians appeared generally aware of their patients’ aspirations to have their cancer cured, which one described as a “common coping strategy” (C07). Although, as one clinician said, he explains to patients that the research could not possibly affect their clinical course, “when it takes 14 months to get the sequencing back!” (C02).

More uniquely related to a precision medicine protocol than other types of clinical research, many patient-participants also described that research participation might help their blood relatives in the future and protect them from “what is inside me that came from my ancestors…” (P04). Almost all spoke about protecting their family and children through research enrollment, with one patient-participant stating that they “would do anything to make sure they [their children] don’t go through this” (P08). Another described this altruistic legacy as “a way for me watching out for my family later on when I’m gone” (P07). Another added: “I would hope that this could help, you know, my family first and then out into other people” (P09). Notably, some of these themes might relate to other novel cancer research platforms and are not necessarily specific to precision oncology itself.

Theme 3: Risks of Research Enrollment

Although patient-participants overwhelmingly spoke of hope and the potential benefits of precision medicine research, the majority of those who spoke of risks only brought them up to dismiss them. Many discussed how enrolling in a precision medicine protocol had no additional risk or burden to themselves and did not involve much effort or downside: “If there’s something that really doesn’t cause you any…discomfort, really takes up very little of your time, if down the road 30 or 40 years from now, that could really affect peoples’ lives, you know, why wouldn’t you want to do that?” (P09). One patient-participant also discussed the convenience of being able to complete everything in the same visit; he said that if the trial required extra visits, he probably would not have enrolled.

If patient-participants or their clinicians mentioned specific risks that concerned them, the most common was finding out information that the patients might not want to know. One
patient-participant described these potential secondary findings as both “a shield and a sword” (P05). She added, “I can’t see that ignorance could possibly benefit you…other than a bit of bliss I suppose.” Another patient-participant dismissed the risk of finding out unwanted information this way: “Life has twists and turns. We don’t have a clue what’s going to happen, but are we going to hold back positive for the thought of a negative?” (P07). Another concluded that he was already 70 years old, so he did not need to worry about genetic discrimination or being fired from his job. This common dismissal of the risks of research enrollment might relate to the general lack of understanding of genetics as highlighted in Theme 1.

Interestingly, the most common risk described by clinicians was not related to stumbling upon an affirmative genetic finding that patients might not want to know about, but quite the opposite—that of not understanding what an abnormal variant meant for their patients in the first place. This relates to an altogether different category of risk related to transgressions of professional duty. One clinician described precision medicine research as having to be “comfortable with that uncertainty” (C08). Another clinician bemoaned that scientific advancement regrettably may lead to recognition of missed diagnoses, if they “look back in 5 years, and you didn’t even know the germline mutation that was bad was a bad one then, right?…Even if you didn’t know it was bad, should you have told them that something could be there?” (C10).

Discussion

This analysis uniquely matches the perspectives of patient-participants with their corresponding clinicians, offering insight into the influence of the doctor-patient relationship on precision oncology research enrollment and satisfaction. Our findings highlighted nuanced challenges with informed consent to precision medicine, uniquely perceived benefits of precision oncology, and relatively discounted risks related to genomic discovery.

One key component of our findings relates to ensuring that patients have the capacity to fully understand the research to which they are being asked to consent. Specifically, although many patient-participants stated that they understood the basics of the science, the background they cited was limited to popular media and fictionalized interpretations, indicating low true genomic health literacy (defined as “the capacity to obtain, process, understand, and use genomic information for health-related decision making” [11]). The relative lack of genomic health literacy among patient-participants raises concerns for the maintenance of their underlying autonomy throughout the enrollment process and beyond.

A component of this genomic health literacy important to the process of informed consent is understanding the limitations of genome sequencing, a competency that has been associated with high levels of education [12]. For example, there is still a lack of common understanding of the term “actionable,” and there are differences in understanding “between patients and clinicians, with patients expecting more personal benefits to come from actionable results” [13]. Actionability generally relates to recognition of a germline mutation with implications for relatives, as well as identifying clinically prognostic biomarkers and biological targets to be used in the patient’s treatment. In head and neck precision oncology both remain rather rare; thus, there are more nebulous outcomes than direct benefits of enrollment at this stage.

Of the patients that do experience decisional conflict when enrolling in genomic sequencing, this phenomenon is associated with lower health literacy and a lack of experience with prior genetic testing [14]. Unfortunately, disparities in baseline genomic knowledge often persist longitudinally, despite the offering of educational materials and genetic counseling opportunities [15]. In this study, clinicians noted several times that the inherent vulnerability of their patients to both structural and individual coercion, or at least undue influence, to enroll in research was tied closely to clinical caregiving. Past research has demonstrated that framing potential benefits as aspirational, direct, and collateral can help clarify the otherwise complex relationship between research and clinical care in this space [16,17]. Our findings are consistent with these, confirming the need for better strategies to educate and counsel patients and participants alike.

The benefits of obtaining high genomic health literacy are that greater baseline knowledge of genomics has been associated with lower levels of distress related to participating in a genome sequencing study and higher levels of understanding of the study. Ensuring that both clinicians and patient-participants understand the risks and benefits of research participation can serve to clarify decisions and better enable prospective participants to honor their autonomy.

Although informed consent has been shown to improve knowledge about both the limitations and benefits of genome sequencing in a variety of settings [4,12], many oncologists have little familiarity with newer genetic technologies and have a low level of genomic literacy themselves, as several of our clinician interviewees admitted [18]. Clinicians without backgrounds in genetics also report difficulty understanding and communicating genomic terminology and the volume of complex information yielded from genomic sequencing studies [19]. If clinicians have a limited understanding of genetic sequencing studies, they may be uncomfortable communicating the goals or results of these studies to their patients. This could lead to lower levels of physician satisfaction and less participation in future studies [18]. This tension was noted by the clinicians interviewed herein as well, despite the fact that they are all engaged in academic research in this field.

The theme of altruism is also prominent in studies exploring subjects’ motivations to engage in genetic research [20]. In the broadest lens, this reflects contributing to the generation of generalizable knowledge to help future patients—the cornerstone of clinical research itself. However, this concept is far more nuanced when considering the distinctions between germline and somatic mutations [21]. In this study, in which somatic mutations are far more common than germline mutations in a head and neck cancer cohort, the likelihood of family members benefiting directly from the research is lower. An intriguing ethical analysis reconceptualizes participation in precision
medicine “as inextricable from social relationships and their ongoing ethical obligations. Going beyond altruism, reframing biospecimen and data collection in terms of socially regulated gift-giving recovers questions of responsibility and care…and underscores ethical commitments to reciprocity and responsibility” [22].

In summary, patient-participants and their providers offered complementary and nuanced perspectives on their motivation to engage in precision head and neck oncology research. It is important to note that the findings reported here represent the views of a specific group of clinicians and their patient-participants. Further research is warranted to generalize their experiences. Nevertheless, this study reflects the participants’ excitement to be a part of cutting-edge research, as well as their inherent altruistic tendencies. This enthusiasm should still be tempered with realistic expectations, and better systems should be created to educate cancer patients turned participants about the precision medicine.

Acknowledgments

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Authors’ Contributions

AGS, JCB, and PLS substantially contributed to conception and design. MK and CB substantially contributed to the acquisition of data. All authors substantially contributed to the analysis or interpretation of data. KSB and AGS drafted the article. All authors revised the article critically for important intellectual content and granted final approval of the version to be published.

Conflicts of Interest

None declared.

References


Abbreviations

C: clinician
MiOtoSeq: Michigan Otolaryngology and Translational Oncology Sequencing Center
P: patient

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A Cancer Exercise Toolkit Developed Using Co-Design: Mixed Methods Study

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Abstract

Background: Access to exercise therapy for cancer survivors is poor. Professional development to support exercise professionals in delivering these interventions is needed. Few online resources exist for exercise professionals to address this issue.

Objective: To develop and evaluate a freely available online toolkit to support exercise professionals working with cancer survivors.

Methods: A 2-phase, experience-based co-design approach was used to develop and evaluate the online toolkit. The two phases were as follows: 1) needs identification and co-design of resources and platform and 2) pilot evaluation. Four co-design workshops were conducted, transcribed, and thematically analyzed to identify key elements for the toolkit. For the pilot evaluation, a customized survey (the Determinants of Implementation Behavior Questionnaire) was distributed to exercise professionals at baseline and 3 months after launch of the online toolkit to determine its usability, utility, and effectiveness in improving their knowledge, confidence, and behavior. Results were reported as the median and interquartile range and changes were calculated using non-parametric tests. Website analytics described site usage after the initial evaluation.

Results: Twenty-five exercise professionals participated in co-designing 8 key elements of the online Cancer Exercise Toolkit: the homepage and pages for getting started, screening and safety, assessment, exercise prescription, education, locations, and resources. For the pilot evaluation, 277/320 respondents (87% of whom were physiotherapists) from 26 countries completed the survey at baseline, with 58 exercise professionals completing follow-up surveys at 3 months. Exercise professionals’ knowledge, skills, and confidence in delivering exercise therapy to cancer survivors increased 3 months after baseline (items 1, 6, and 8: median score 5, IQR 3 to 6) to follow-up (items 1 and 6: median score 6, IQR 5 to 6; item 8: median score 5, IQR 5 to 7; P<.001) on a 1 to 7 Likert scale. Most participants (35/44, 80%) agreed or strongly agreed they would recommend the toolkit to colleagues. In the 6 months following the pilot evaluation, the toolkit received an average of 866 views per month.

Conclusions: The co-designed online Cancer Exercise Toolkit was a useful resource for exercise professionals that may increase their knowledge, skills, and confidence in providing exercise therapy to cancer survivors.

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KEYWORDS
cancer; website; online learning; professional development; physiotherapy; exercise; cancer survivorship; cancer survivor; digital health; online health; online toolkit

Introduction

International guidelines support the integration of exercise into cancer care to improve cancer outcomes [1,2]. Well-established evidence shows exercise therapy can reduce cancer-related impairments such as fatigue and improve the health-related quality of life of cancer survivors [1]. Exercise may prevent development of chronic disease, prolong survival, and prevent cancer recurrence in some cancer cohorts, such as breast, colorectal, and prostate cancer [3,4]. Despite compelling evidence that exercise is important for cancer survivors, access to specialized exercise therapy programs for people with cancer is poor, with just 1 in 200 cancer survivors able to participate in an exercise-based rehabilitation program in Australia [5,6].

Skilled exercise professionals are critical for the implementation and delivery of exercise therapy to cancer survivors [7]. Exercise professionals, including physiotherapists and exercise physiologists, are well placed to provide exercise therapy given their expertise in prescribing exercise and behavior change for people with chronic health conditions [8,9]. In Australia alone, there are over 40,000 registered exercise professionals who could provide services to people with cancer [10,11]. Despite their professional training, recent surveys of Australian and Irish physiotherapists found they lack confidence in providing care, including exercise therapy, to cancer survivors [12,13]. Education and practical support are required for exercise professionals to safely and effectively prescribe exercise and monitor progress according to current cancer guidelines [1].

Exercise professionals may be able to develop and consolidate their knowledge through attendance of in-person courses and lectures and passive text-based resources. However, these knowledge sources may be less effective at improving knowledge and skills than active approaches such as e-learning, which provide greater flexibility to cater for individual learning needs [14]. Online material has been shown to be feasible for educating clinicians about exercise, with multimedia innovations, such as video, infographics, quizzes, and podcasts, enhancing clinician engagement [15]. For example, the online Pulmonary Rehabilitation Toolkit [16], developed in Australia over 10 years ago, is now considered an essential reference for physiotherapists and students working in pulmonary rehabilitation [17]. Currently, few similar resources exist to facilitate professional development for exercise professionals working in cancer rehabilitation. With a rapid rise in exercise and cancer research [18,19], it can be challenging for clinicians to keep up with best practices. Online resources may overcome time and cost barriers to professional development and offer convenience for time-poor clinicians [20].

The primary aim of this study is to develop an online toolkit, based on experience-based co-design [21] methods, to provide support to exercise professionals by delivering evidence-based exercise interventions to cancer survivors. A secondary aim is to evaluate the initial use of the online toolkit and explore its effect on exercise professionals’ knowledge, confidence, and behavior.

Methods

Study Design

An online toolkit called the Cancer Exercise Toolkit was developed with an experience-based co-design approach [21] using mixed methods between May 2020 and October 2021. Qualitative interviews, workshops, and online surveys informed the toolkit development. The study procedure (Multimedia Appendix 1) was based on the experience-based co-design (EBCD) toolkit [21] and a published study using EBCD to develop a cancer prehabilitation program [22]. EBCD is a collaborative approach to service improvement completed in partnership with end users [21]. Co-design helps researchers build meaningful relationships with research participants [23], whereby users are recognized as experts in their own experiences [24]. The study was completed in two phases: (1) needs identification and co-design of resources for the online platform and (2) pilot evaluation (Figure 1).
Participants

Two groups of participants were included in the co-design workshops for toolkit development. Group 1 included “generalist” exercise professionals, defined as physiotherapists and exercise physiologists working in other areas who may have occasional contact with cancer survivors. Group 2 included “expert” or experienced cancer exercise professionals, defined as physiotherapists and exercise physiologists who had worked specifically in cancer for at least 2 years. The workshops did not include patients, as exercise professionals were intended to be the end users of this resource. However, patients who had been diagnosed with cancer and participated in exercise-based cancer rehabilitation were invited to participate in a brief video shown to clinicians in the co-design workshops, setting the scene and direction for the session. Snowball sampling was undertaken to recruit participants over a 2-week period. Exercise professionals were invited to participate in the study through

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Figure 1. Participant recruitment procedure for the creation and evaluation of the Cancer Exercise Toolkit.
an invitation email distributed by a health service and through local professional networks (eg, the Australian Physiotherapy Association). For workshops 1 and 2, it was estimated that 8 to 10 participants in each group would be sufficient to provide varied experiences and contribute to new knowledge [21].

For the pilot evaluation phase of the toolkit, a third group of exercise professionals was recruited. We aimed to recruit a convenience sample of at least 100 exercise professionals over a 3-month period. This sample size assumed that 50% of participants would be confident enough to prescribe exercise therapy to cancer survivors and that this would be sufficient for estimating the expected proportion of sufficiently confident participants with 10% absolute precision and 95% CI [25]. Recruitment was not capped, as participants received recognition for continuing professional development as part of participation.

**Procedure**

**Phase 1: Needs Identification and Co-Design**

One-hour semi-structured interviews (Multimedia Appendix 2) were completed via teleconference (Zoom Video Communications) with 3 patients who had participated in cancer rehabilitation in a public subacute hospital in Australia. Interviews were conducted by a member of the research team who had previous experience in conducting qualitative interviews and did not have any prior involvement in the treatment of these patients. The interviews included questions exploring the patients’ journey in participating in an exercise-based cancer rehabilitation program. The videos were independently analyzed by 2 research team members (AD and CT) using an inductive approach to identify key touchpoints of the overall cancer rehabilitation experience [21]. The videos were edited into a short video clip and used at the start of workshops 1 and 2 to set the scene for the sessions.

Separate workshops (workshops 1 and 2, each 1 hour long) with the generalist and expert exercise professionals were conducted to explore areas for health care improvement and identify therapist learning needs. Learning needs identified from the workshop formed the content outline of the new online toolkit. A combined workshop (workshop 3; 1.5-2 hours long) was then held with all the participating exercise professionals to design key content elements and the overall layout of the online toolkit. A prototype online toolkit was developed based on findings from the combined workshop and key cancer rehabilitation literature [1,26,27]. A weblink was sent to exercise professionals attending the workshops to trial the toolkit for 1 month.

Following 1 month of access to the prototype, a second joint workshop (workshop 4; 1.5 hours long) was conducted to facilitate feedback. In this workshop, participant perceptions regarding the strengths and limitations of the new resource were explored. Further refinements to the toolkit were made by the research team following this workshop before it was formally evaluated by the broader exercise community (Phase 2).

Workshops were facilitated by a researcher with experience in EBCD (CT). Two members of the study team (AC and AD) generated field notes to assist in triangulation and data trustworthiness. Project team members acted as observers and additional facilitators for the larger joint workshops. Immediately after each workshop, project team members debriefed with the workshop facilitator and discussed their reflections.

Recordings from all workshops were transcribed, stored, and managed using Microsoft Word and NVivo (version 12). Transcripts were coded independently by 2 reviewers (AD and CT), who used an inductive thematic analysis approach to identify touchpoints from the workshops [28]. The team then came together to discuss and reach consensus on the key touchpoints, which informed the structure and design of the online toolkit. All but 1 team member had experience in conducting qualitative research (Multimedia Appendix 3).

**Phase 2: Pilot Evaluation**

The online toolkit was formally piloted and evaluated with a broader, international sample of exercise professionals, including co-design participants (February 2021 to April 2021). An open online survey, Research Electronic Data Capture (RedCap) [29], was distributed to a large health service and via local professional networks (eg, the Australian Physiotherapy Association and Exercise and Sports Science Australia), as well as international ones (eg, the Canadian Physiotherapy Association and the University of British Columbia Clinical Exercise Physiology Lab) through email and social media pages.

Participants gained access to the website after completion of the survey. The survey was completed twice: (1) prior to accessing the website (T0) and (2) 3 months after initially gaining access to the website (T1). The T1 surveys were sent only to participants who provided contact details at the end of the T0 survey. Reminder emails were sent at 7 and 14 days after distribution of the T1 survey. A free professional development event held via webinar was also conducted at follow-up to promote survey completion.

This anonymous online survey (Multimedia Appendix 4) aimed to explore the website’s effectiveness in addressing knowledge gaps, confidence, and behavior in prescribing exercise according to guidelines [1] along with the usability and utility of the toolkit [16]. It comprised 3 sections and took approximately 10 minutes to complete. Section 1 included demographic data. Section 2 included questions derived from the Determinants of Implementation Behavior Questionnaire (DIBQ), which is based on the theoretical domains framework [30]. Domains in the DIBQ show high discriminant validity, reliability, and internal consistency [30]. The 45-item instrument assessed the impact of continuing professional development activities on health professionals’ knowledge, confidence, and implementation behaviors. Each item was measured on a 7-point Likert scale (ranging from 1, “strongly disagree” to 7, “strongly agree”). Item 45 was reverse scaled. Section 3 related to the usability and utility of the website [31] and was included in the follow-up survey only. This survey was tested by members of the research team (AD, CB, and CO) for readability and functionality prior to its distribution. A short quiz created by the researchers was also embedded as a learning tool within the toolkit to test user knowledge related to published recommendations on exercise and cancer [1,26]. Website views at the end of the 3-month trial period (May to October 2021) were reported to identify engagement with the website.
Data analysis
Survey and website metadata were described using proportions, medians, and interquartile ranges. Content analysis was conducted on open-ended survey questions by 2 researchers (AC and CO) independently. Following recommendations for the analysis of anonymous survey data that cannot be paired [32], differences in DIBQ scores between baseline and follow-up were analyzed using the Mann Whitney U test with Bonferroni adjustment for multiple comparisons. A sensitivity analysis was applied to account for dependence in the follow-up survey. This involved using the same sample size at baseline and follow up in a random sample of data from the baseline survey [32]. Data were analyzed using SPSS version 27 (IBM Corp).

Ethics Approval
This study was reported in accordance with the Consolidated Criteria for Reporting Qualitative Studies [33] and Good Reporting of A Mixed Methods Study [34] checklists and approved by the hospital and university ethics committees (LR 20-020). Workshop participants provided written informed consent. Consent for the online surveys was implied by survey completion.

Results
Phase 1: Needs Identification and Co-Design
Twenty-five exercise professionals (13 experts and 12 generalists) participated in the co-design workshops. The co-design group included 21 physiotherapists and 4 exercise physiologists. Thirteen co-design participants worked in hospital settings in Australia. On average, the exercise professionals had 15 years of total experience (Table 1).

<table>
<thead>
<tr>
<th>Characteristics, n (%)</th>
<th>All (N=25)</th>
<th>Expert (n=13)</th>
<th>Generalist (n=12)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Profession</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physiotherapist</td>
<td>21 (84)</td>
<td>11 (85)</td>
<td>10 (83)</td>
</tr>
<tr>
<td>Exercise physiologist</td>
<td>4 (16)</td>
<td>2 (15)</td>
<td>2 (17)</td>
</tr>
<tr>
<td><strong>Setting</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospital</td>
<td>12 (48)</td>
<td>10 (77)</td>
<td>3 (25)</td>
</tr>
<tr>
<td>Community</td>
<td>9 (36)</td>
<td>1 (8)</td>
<td>8 (67)</td>
</tr>
<tr>
<td>Both</td>
<td>1 (4)</td>
<td>1 (8)</td>
<td>0 (0)</td>
</tr>
<tr>
<td><strong>Funding</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Public</td>
<td>14 (56)</td>
<td>8 (62)</td>
<td>7 (58)</td>
</tr>
<tr>
<td>Private</td>
<td>2 (8)</td>
<td>0 (0)</td>
<td>2 (17)</td>
</tr>
<tr>
<td>Both public and private</td>
<td>6 (25)</td>
<td>3 (23)</td>
<td>3 (23)</td>
</tr>
<tr>
<td>Years of total experience, mean (SD)</td>
<td>14.8 (8.6)</td>
<td>17.2 (8.0)</td>
<td>12.3 (8.6)</td>
</tr>
</tbody>
</table>

Workshops 1 and 2 identified 5 key touchpoints describing successful cancer rehabilitation programs (Table 2). These touchpoints highlighted the knowledge exercise professionals required to be included in the toolkit for implementation in cancer rehabilitation programs. Overall, touchpoints were similar between the expert and generalist exercise professionals.

*Need easy access to latest guidelines for general knowledge...often difficult to keep up to date... [Expert group participant]*

*[Need] access [to] article(s), training... [to be] more confident to safely advocate...to other health professionals.* [Generalist group participant]

When compared to the generalist group, the experts identified more nuanced, disease-specific knowledge, such as the need for strict infection control procedures and cancer-specific assessments. The importance of practical considerations, understanding the impact of cancer treatment and side effects, and education provision and access were common themes forming the foundational content of the toolkit prototype. These touchpoints informed 8 key sections of the toolkit: the homepage; getting started; screening and safety; assessment; exercise prescription; education; locations; and resources (Multimedia Appendix 5).

In the joint workshop (workshop 3), the exercise professionals agreed the toolkit needed to be simple, practical, and not duplicate existing resources. Participants provided suggestions for existing resources that could be linked or embedded in the toolkit and described a need for templates that could be used in their clinical practice. Website monitoring and updating were identified as critical for the website’s sustained success. At the conclusion of this workshop, the research team drafted the toolkit content. Freely available multimedia resources (videos, infographics, patient handouts, and podcasts) were sourced to supplement information provided on the website rather than creating new multimedia content.
Table 2. Key touchpoints from workshops 1 and 2.

<table>
<thead>
<tr>
<th>Elements of cancer rehabilitation</th>
<th>Common themes</th>
<th>Expert only</th>
<th>Generalist only</th>
</tr>
</thead>
<tbody>
<tr>
<td>Getting started</td>
<td>Setting up the environment, including social support, space, equipment, and group dynamics; communicating with patients how to get started with cancer rehabilitation</td>
<td>Importance of infection control due to work with immunocompromised patients</td>
<td>Whether to deliver therapy one-to-one or in groups; uncertainty as to how to integrate cancer patients with other disease populations; standardized templates and letters</td>
</tr>
<tr>
<td>Screening and safety; assessment</td>
<td>Understanding impact of cancer treatment; precautions and contraindications</td>
<td>Discussion of impairment, performance, and quality of life measures used for assessment, including cancer-specific measures</td>
<td>Emphasis on importance and challenges of goal setting</td>
</tr>
<tr>
<td>Exercise prescription</td>
<td>Individualization; modification and progression/regression; monitoring fatigue</td>
<td>More emphasis on guidelines and optimal dosage</td>
<td>Patient-centered approach to tailor exercise based on needs and symptoms</td>
</tr>
<tr>
<td>Education</td>
<td>Requirement for multidisciplinary input, including psychological and nutritional support and fatigue management; need for resources for both patients and clinicians; inclusion of patient testimonials</td>
<td>N/A(^a)</td>
<td>N/A</td>
</tr>
<tr>
<td>Access</td>
<td>Poor access to cancer rehabilitation</td>
<td>Acknowledgement of lack of sufficient suitable programs</td>
<td>Difficulty of generating and managing referrals; low confidence of other health professionals to refer patients to cancer rehabilitation</td>
</tr>
</tbody>
</table>

\(^a\)N/A: Not applicable. There were no differences in the themes related to education between the 2 groups.

At the second joint workshop (workshop 4), further refinements were made (Multimedia Appendix 6) including changing the website name to the Cancer Exercise Toolkit [35] and creating a logo. The main feedback was related to navigation and the addition of content. More content was added on special cancer populations, including exercise modifications for specific cancers and side-effects of treatment. The final website was, and still is, a freely available web-based resource that can be self-navigated by users. At the time of evaluation, it comprised 8 sections including relevant information related to implementing exercise-based rehabilitation for cancer survivors (Multimedia Appendix 5 and Multimedia Appendix 7).

**Phase 2: Pilot Evaluation**

The website [31] was launched on World Cancer Day (February 4, 2021) and the baseline survey was accessed by 414 people, 37 of whom did not identify as exercise professionals; the survey was terminated. An additional 57 participants did not complete the survey. Respondents who were exercise professionals included 320 clinicians from 26 countries, with most having 5 years or less of cancer-specific experience (Table 3). The majority were physiotherapists (277/320, 87%). Just 120 of the 320 clinicians (38%) worked exclusively in cancer, palliative care, or lymphedema care. The main motivations for accessing the website were for professional development (142/320, 44%) and to improve patient care (17/320, 22%) (Figure 2).

Contact details for follow-up surveys were provided by 160 respondents, of whom 58 completed the follow-up survey (for a response rate of 36%). There were no differences in demographics between those who completed the baseline and follow-up surveys (Table 3).
Table 3. Participant characteristics at baseline and in a 3-month follow-up survey.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Baseline (N=320)</th>
<th>3-month follow-up (n=58)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Discipline, n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physiotherapy</td>
<td>277 (87)</td>
<td>51 (88)</td>
</tr>
<tr>
<td>Exercise physiology</td>
<td>43 (13)</td>
<td>7 (12)</td>
</tr>
<tr>
<td><strong>Country or region, n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Australia</td>
<td>249 (78)</td>
<td>50 (86)</td>
</tr>
<tr>
<td>Europe/United Kingdom</td>
<td>38 (12)</td>
<td>3 (5)</td>
</tr>
<tr>
<td>Americas</td>
<td>15 (5)</td>
<td>3 (5)</td>
</tr>
<tr>
<td>Asia/Pacific</td>
<td>8 (3)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Africa</td>
<td>7 (2)</td>
<td>2 (3)</td>
</tr>
<tr>
<td>Middle East</td>
<td>1 (0.3)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>City-based, n (%)</td>
<td>228 (71)</td>
<td>41 (71)</td>
</tr>
<tr>
<td><strong>Setting, n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Public</td>
<td>159 (50)</td>
<td>29 (50)</td>
</tr>
<tr>
<td>Private</td>
<td>116 (36)</td>
<td>21 (36)</td>
</tr>
<tr>
<td>Both public and private</td>
<td>36 (11)</td>
<td>7 (12)</td>
</tr>
<tr>
<td>Other</td>
<td>9 (3)</td>
<td>0 (0)</td>
</tr>
<tr>
<td><strong>Years of experience, mean (SD)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;1</td>
<td>82 (26)</td>
<td>9 (16)</td>
</tr>
<tr>
<td>1-2</td>
<td>60 (19)</td>
<td>12 (21)</td>
</tr>
<tr>
<td>3-5</td>
<td>60 (19)</td>
<td>12 (21)</td>
</tr>
<tr>
<td>6-10</td>
<td>29 (9)</td>
<td>9 (15)</td>
</tr>
<tr>
<td>&gt;10</td>
<td>25 (8)</td>
<td>7 (12)</td>
</tr>
<tr>
<td><strong>Primary area of clinical practice, n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cancer/palliative care/lymphedema</td>
<td>118 (37)</td>
<td>23 (40)</td>
</tr>
<tr>
<td>Other</td>
<td>200 (63)</td>
<td>35 (60)</td>
</tr>
<tr>
<td><strong>Proportion of caseload cancer, n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>76-100%</td>
<td>61 (19)</td>
<td>14 (24)</td>
</tr>
<tr>
<td>51-75%</td>
<td>26 (8)</td>
<td>5 (9)</td>
</tr>
<tr>
<td>26-50%</td>
<td>55 (17)</td>
<td>14 (24)</td>
</tr>
<tr>
<td>≤25%</td>
<td>174 (54)</td>
<td>25 (43)</td>
</tr>
<tr>
<td><strong>Highest level of qualification, n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Undergraduate degree</td>
<td>138 (43)</td>
<td>24 (41)</td>
</tr>
<tr>
<td>Post-graduate certificate</td>
<td>71 (22)</td>
<td>12 (21)</td>
</tr>
<tr>
<td>Masters by coursework</td>
<td>73 (23)</td>
<td>17 (29)</td>
</tr>
<tr>
<td>Masters by research</td>
<td>13 (4)</td>
<td>1 (2)</td>
</tr>
<tr>
<td>PhD</td>
<td>20 (6)</td>
<td>4 (7)</td>
</tr>
<tr>
<td><strong>Cancer-specific professional development completed</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Informal training</td>
<td>175 (55)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>External courses</td>
<td>173 (54)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Post-graduate education</td>
<td>42 (13)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Other</td>
<td>23 (7)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>
Usage, Usability, and Utility

After the 3-month pilot period, the toolkit received on average 866 views per month. Toolkit usage peaked in June 2021 at 1205 views and declined to 731 views in October 2021.

The most viewed pages were “Locations,” “Patient Education,” and “Precautions and Contraindications” (Multimedia Appendix 8).

Participants found the website useful, easy to understand, and easy to use (items 1 to 4: median score 6, IQR 5-7) (Table 4). Most participants (35/44, 80%) agreed or strongly agreed that they would recommend the Cancer Exercise Toolkit to colleagues. Open-ended feedback received from 11 participants was positive; the following are representative quotes:

Great source, filling a gap; like the pulmonary rehab toolkit.

I had difficulties accessing the toolkit and never got around to sorting out the issue.

Participants suggested some minor improvements to the website relating to accessibility (n=3), website function (n=2), increasing website scope (n=2), and dissemination (n=2).

Table 4. Website usability and utility.

<table>
<thead>
<tr>
<th>Question</th>
<th>Median rating, IQR</th>
<th>Rating 6 or 7 (“strongly agree”), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall, the Oncology Rehabilitation Toolkit website was easy to use</td>
<td>6, 5-7</td>
<td>30 (68)</td>
</tr>
<tr>
<td>(n=44)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The content of the Oncology Rehabilitation Toolkit website met my</td>
<td>6, 5-7</td>
<td>31 (70)</td>
</tr>
<tr>
<td>expectations (n=44)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall, it was easy to understand the organization of the Oncology</td>
<td>6, 5-7</td>
<td>28 (67)</td>
</tr>
<tr>
<td>Rehabilitation Toolkit website screens, especially the menu levels and</td>
<td></td>
<td></td>
</tr>
<tr>
<td>the flow of the screens (n=42)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How useful do you find the Oncology Rehabilitation Toolkit website to</td>
<td>6, 5-7</td>
<td>29 (66)</td>
</tr>
<tr>
<td>be? (n=44)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I would recommend the Oncology Rehabilitation Toolkit website to my</td>
<td>7, 6-7</td>
<td>35 (80)</td>
</tr>
<tr>
<td>colleagues (n=44)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

aNumbers are Likert scales ranging from 1 (“strongly disagree”) to 7 (“strongly agree”)
Determinants of Implementation Behavior Questionnaire

At baseline, participants rated themselves highest on items relating to their capability to deliver exercise rehabilitation according to guidelines and lowest on items relating to their training and ability to practice delivering exercise rehabilitation (Table 5, Multimedia Appendix 9).

At the 3-month follow-up, participants self-reported significantly higher scores on items related to knowledge and skills (items 1-7, \( P < .001 \)) and confidence to deliver exercise therapy according to guidelines (items 8 and 9, \( P < .001 \)) (Figure 3, Table 5).

Table 5. Determinants of Implementation Behavior Questionnaire. The significance level was set at \( P < .001 \) (Bonferroni adjustment). Italics indicate significance after the sensitivity analysis was applied. A total of 47 subjects did not complete this section of the survey at baseline. At follow-up, an additional 3 responses were excluded as participants indicated they never accessed the website.

<table>
<thead>
<tr>
<th>Question</th>
<th>Baseline (N=273)</th>
<th>Follow-up (n=55)</th>
<th>Between-group difference (P value)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Knowledge, median (IQR)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I know how to deliver Exercise Oncology Rehabilitation following the guidelines.</td>
<td>5 (3-6)</td>
<td>6 (5-6)</td>
<td>(&lt;.001)</td>
</tr>
<tr>
<td>Objectives of Exercise Oncology Rehabilitation and my role in this are clearly defined for me.</td>
<td>4 (3-6)</td>
<td>5 (5-6)</td>
<td>(&lt;.001)</td>
</tr>
<tr>
<td>With regard to Exercise Oncology Rehabilitation, I know what my responsibilities are.</td>
<td>5 (3-6)</td>
<td>6 (5-6)</td>
<td>(&lt;.001)</td>
</tr>
<tr>
<td>In my work with Exercise Oncology Rehabilitation, I know exactly what is expected from me.</td>
<td>4 (3-5)</td>
<td>6 (5-6)</td>
<td>(&lt;.001)</td>
</tr>
<tr>
<td><strong>Skills, median (IQR)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I have been trained in delivering Exercise Oncology Rehabilitation following the guidelines.</td>
<td>4 (1-5)</td>
<td>6 (4-6)</td>
<td>(&lt;.001)</td>
</tr>
<tr>
<td>I have the skills to deliver Exercise Oncology Rehabilitation following the guidelines.</td>
<td>5 (3-6)</td>
<td>6 (5-6)</td>
<td>(&lt;.001)</td>
</tr>
<tr>
<td>I am practiced to deliver Exercise Oncology Rehabilitation following the guidelines.</td>
<td>4 (2-5)</td>
<td>6 (4-6)</td>
<td>(&lt;.001)</td>
</tr>
<tr>
<td><strong>Confidence, median (IQR)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I am confident that I can deliver Exercise Oncology Rehabilitation following the guidelines.</td>
<td>5 (3-6)</td>
<td>5 (5-7)</td>
<td>(&lt;.001)</td>
</tr>
<tr>
<td>I am confident that I can deliver Exercise Oncology Rehabilitation following the guidelines even when other professionals with whom I deliver Exercise Oncology Rehabilitation do not do this.</td>
<td>4 (3-6)</td>
<td>5 (5-6)</td>
<td>(&lt;.001)</td>
</tr>
<tr>
<td>I am confident that I can deliver Exercise Oncology Rehabilitation following the guidelines even when there is little time.</td>
<td>4 (3-5)</td>
<td>5 (4-6)</td>
<td>(&lt;.001)</td>
</tr>
<tr>
<td>I am confident that I can deliver Exercise Oncology Rehabilitation following the guidelines even when participants are not motivated.</td>
<td>4 (3-5)</td>
<td>5 (4-6)</td>
<td>(&lt;.001)</td>
</tr>
</tbody>
</table>
Figure 3. Differences in Determinants of Implementation Behavior (DIBQ) scores between baseline and 3-month follow-up. Figure legend: Shaded data refer to Likert scales ranging from 1 (“strongly disagree”) to 7 (“strongly agree”), numbers refer to absolute number of participants who answered survey question.

Triangulation of Data
Qualitative data obtained from clinician workshops converged with quantitative survey data. Participants expressed a need to access information related to published exercise guidelines and described information related to exercise screening and safety as a priority. Areas of traffic on the toolkit were highest for pages related to safety and education (Multimedia Appendix 8). This aligned with survey item scores related to guidelines (“I know how to deliver Exercise Oncology Rehabilitation following the guidelines”; “I have been trained in delivering Exercise Oncology Rehabilitation following the guidelines”; “I have the skills to deliver Exercise Oncology Rehabilitation following the guidelines”; “I am confident that I can deliver Exercise Oncology Rehabilitation following the guidelines”) improving at follow-up.

Discussion
Principal Findings
This study identified key learning needs of exercise professionals related to cancer care and facilitated development of the co-designed online Cancer Exercise Toolkit. Learning needs included knowledge of practical considerations for starting a cancer rehabilitation program; how to perform assessment, screening, and safety; and how to prescribe exercise, including tailoring and monitoring. Other important elements described by participants were facilitating access to care, clinician and patient education, and inclusion of templates and forms to support practice. The toolkit had international reach and was described as useful and easy to navigate. The pilot evaluation suggests the Cancer Exercise ‘Toolkit may also improve exercise professionals’ knowledge, skills, and confidence to deliver exercise therapy to cancer survivors.

Knowledge, skills, and confidence of exercise professionals to provide exercise therapy according to guidelines were rated higher after access to the Cancer Exercise Toolkit. This finding indicates that online toolkits such as this could be a useful knowledge translation strategy, supporting previous research showing that online platforms can support delivery of evidence-based practice [36]. The areas of highest traffic on the website after initial piloting included sections related to education, safety, and access. This aligns with the learning needs identified in the co-design workshops and with previous research indicating that these are the areas exercise professionals most lack confidence when managing people with cancer [12]. Building workforce capacity through development of high-quality education and broad dissemination is high on the agenda for the “Moving Through Cancer” movement to embed exercise as part of standard care by 2029 [37]. By improving the knowledge and skills of exercise professionals, it is likely to lead to better quality of care for cancer survivors and improve access to specialized cancer rehabilitation programs.

Most toolkit users were exercise professionals who did not specialize in cancer but were motivated to obtain professional development and improve patient care. Initial survey respondents and users indicated that we achieved a global reach, with more than 400 health professionals from 26 countries accessing the toolkit. This reach is important considering that recent national [38] and international guidelines [1] call for increased access and uptake of exercise services for cancer survivors. Highlighting the need for resources like the Cancer Exercise Toolkit, very few exercise professionals registered in Australia have specialist qualifications or training in cancer care. Moreover, many exercise professionals feel underprepared to practice in cancer care after their entry-level training [12]. Many professional bodies have only started developing post-graduate career pathways in cancer care in the past 5 years.
This study found that most clinicians receive their professional development through informal training, which may reflect the scarcity of professional development opportunities traditionally available in this area [12]. The Cancer Exercise Toolkit developed in this study provides generalist and specialist clinicians new opportunities to improve their cancer-specific knowledge and skills to meet increasing demand.

The toolkit appeared to meet clinician needs, being described as easy and useful, with most survey respondents agreeing they would recommend it to their colleagues. Characteristics of the toolkit informed by the co-design process reflected effective web design, such as easy navigation; inclusion of images, logos, and multimedia content; optimal organization, including a hierarchical structure; and content utility, determined by sufficiency, relevancy, quality, and motivational power of the information [40]. While there was a high initial uptake of the website, usage decreased over time. It is possible that participants obtained what they needed from the website when they initially accessed it, and that they therefore did not need to continue visiting it. Planning for ongoing promotion of the toolkit and updates with new content may also be required to improve user engagement. Planned strategies for ongoing sustainability include sharing and promotion via social media and seeking endorsement by key professional bodies. Maintenance of the toolkit will be imperative to ensure its ability to disseminate up-to-date exercise and cancer knowledge and meet clinicians’ professional development needs in the future.

**Strengths and Limitations**

This is the first study to describe the development of a freely available toolkit to support exercise professionals working with cancer survivors. The co-design approach ensured end user learning needs were met through tailoring the toolkit based on clinician experience [23]. The effectiveness of co-design in health is not well established. However, qualitative reports indicate that participants in the co-design process have a positive experience, and materials derived from co-design projects are more applicable and acceptable to end users [23]. Co-design methods have commonly been used in curriculum design for secondary and tertiary education [41,42], but not for developing professional development toolkits in a health setting. Applicability of the toolkit was optimized by involving exercise professionals from a variety of clinical settings with a broad range of experience. Our broad dissemination approach, including engaging exercise professionals worldwide, also enhanced the generalizability of the end product.

There were limitations to this study. In the evaluation, only one-third of the original exercise professional participants completed the follow-up survey. Despite multiple attempts to improve engagement with the follow-up survey, including reminder emails and hosting a webinar where survey completion was promoted, the follow-up response rate remained low. This low response rate is consistent with other clinician surveys designed to evaluate physiotherapy professional development initiatives [43] and may be due to lack of time or motivation. To improve response rate, clinicians could be provided with further incentives to complete follow-up surveys, such as prizes, accredited professional development points, or certificates of completion. We were also unable to match participant responses due to the anonymous nature of the survey. It is also possible that the follow-up responses we did receive were from participants who were more interested and invested in cancer rehabilitation; these participants may have reported higher scores. However, the demographics of the participants who completed the follow-up survey were similar to the overall cohort. Additionally, a sensitivity analysis to account for the issue of dependence was conducted to increase the confidence in our results. Our inclusion of exercise professionals involved in the co-design of the toolkit during the evaluation phase also could have biased the outcome. However, we included this group to optimize the sample size available for evaluation, and to ensure that the changes made following the workshops were appropriate. Other health professionals, such as occupational therapists, dietitians, nurses, and doctors, were excluded, as they are not traditionally involved with specialist exercise prescription for cancer survivors. The website was developed for the Australian context. Health systems in other parts of the world may differ, and the content may need to be adapted to meet their needs. Despite this, positive feedback was received from participants from other countries, indicating that cross-cultural adaptation would likely be acceptable. Lastly, online resources may not be as effective at improving clinician behavior as more active learning strategies, such as workshops and mentoring [44].

**Conclusion**

This study described the development of the co-designed Cancer Exercise Toolkit. The toolkit was accessed by physiotherapists and exercise physiologists who described the website as valuable and easy to use. Exercise professionals rated their knowledge, skills, and confidence higher after accessing the website, indicating that it may be an effective alternative or complement to traditional professional development. The Cancer Exercise Toolkit may help improve access to exercise therapy and improve the effectiveness of care for cancer survivors through greater capability of the exercise professional workforce.

**Acknowledgments**

We would like to thank our steering committee, the co-design participants, and the consumers who helped with the development of the Cancer Exercise Toolkit. Thank you to Joshua Stopper for his contribution to web design. This project was funded by a grant from the Pat Cosh Trust.

**Conflicts of Interest**

None declared.
Multimedia Appendix 1
Experience-based co-design (EBCD) steps.
[DOCX File, 22 KB - cancer_v8i2e34903_app1.docx ]

Multimedia Appendix 2
Patient interview schedule.
[DOCX File, 24 KB - cancer_v8i2e34903_app2.docx ]

Multimedia Appendix 3
Backgrounds of the research team.
[DOCX File, 12 KB - cancer_v8i2e34903_app3.docx ]

Multimedia Appendix 4
Evaluation survey.
[DOCX File, 338 KB - cancer_v8i2e34903_app4.docx ]

Multimedia Appendix 5
Description of website content.
[DOCX File, 12 KB - cancer_v8i2e34903_app5.docx ]

Multimedia Appendix 6
Website changes.
[DOCX File, 13 KB - cancer_v8i2e34903_app6.docx ]

Multimedia Appendix 7
Screenshot example of Cancer Exercise Toolkit.
[DOCX File, 2993 KB - cancer_v8i2e34903_app7.docx ]

Multimedia Appendix 8
Cancer Exercise Toolkit Visits.
[DOCX File, 13 KB - cancer_v8i2e34903_app8.docx ]

Multimedia Appendix 9
Full Determinants of Implementation Behavior Questionnaire (DIBQ) outcomes.
[DOCX File, 46 KB - cancer_v8i2e34903_app9.docx ]

References


Abbreviations

DIBQ: Determinants of Implementation Behavior Questionnaire
EBCD: experience-based co-design

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https://cancer.jmir.org/2022/2/e34903
Mobile-Based Self-management Application Requirements for Patients With Gastric Cancer: Quantitative Descriptive Study of Specialist and Patient Perspectives

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Abstract

Background: Gastric cancer is one of the most common gastrointestinal cancers. Patients with gastric cancer experience disabilities and complications that lead to reduced quality of life. Empowering these patients by providing them with information and self-management skills can help reduce side effects and improve their quality of life.

Objective: The aim of this study was to identify the user requirements for developing a mobile-based self-management app to support patients with gastric cancer.

Methods: Data were analyzed using descriptive statistics and frequency distribution reports using IBM SPSS Statistics software.

Results: All of the data elements and functional requirements except “data recording times” and “weight changes in graphs” were identified as essential by clinical experts and patients. Among the functional requirements required in a gastric cancer self-management app, the capabilities related to informing, announcing warnings, and reminders are included. In the demographic data section, most patients (14/26, 53%) did not comment on the importance of recording data such as name, surname, and place of residence, and the demographic data section was met with less agreement from patients than clinicians.

Conclusions: Applying the requirements mentioned in this study can improve the self-management of patients with gastric cancer. Such apps can play an important role in empowering patients and improving their quality of life. However, the apps need to be designed and implemented to see how they can meet users’ requirements.

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KEYWORDS
digital health, eHealth; telehealth; mHealth; mobile app; self-management; patient education; needs assessment, requirements analysis, stomach neoplasm, gastric cancer

Introduction

Cancer is one of the leading causes of death and disability worldwide, especially in developing countries. According to a report (GLOBOCAN), in 2020, 1 in 5 people were diagnosed with cancer during their lifetime, and 1 in 8 men and 1 in 11 women died due to the disease [1]. In some cases, cancer is caused not by a person’s physical and genetic characteristics but by the person’s living environment [2-4]. Stomach cancer is now the fifth most common malignancy worldwide, after...
cancers of the lung, breast, colorectal, and prostate, with 1,033,701 new cases (5.7% of the total) estimated in 2018. It is the third most common cause of cancer-related death, with 782,685 deaths (8.2% of the total) in 2018 [5]. According to the National Cancer Institute, gastric cancer is very common in Japan, Central Latin America, South America, Eastern Europe, and parts of the Middle East [6]. In Iran, gastric cancer has been reported as the deadliest cancer. The statistics of disease incidence rates show the high incidence of gastrointestinal cancer in the northern provinces of the country, especially Mazandaran and Golestan [5,7].

Treatment for gastric cancer includes surgery, chemotherapy, and radiation therapy, which are used based on the stage of the disease. Surgery is a major and effective treatment in the early and advanced stages of the disease [8]. After gastrectomy surgery, there are many complications related to nutrition and gastrointestinal function. The most common of these complications are premature dumping syndrome, late dumping syndrome, and fat malabsorption, which can lead to gradual weight loss, premature satiety, abdominal pain, postprandial pain, and chronic diarrhea. Other nutritional problems that occur gradually include anemia, hypoxemia, vitamin C deficiency, and calorie and protein malnutrition, which have a significant impact on all aspects of the quality of life of these patients [9]. Self-management refers to the ability and autonomy of the individual to accept responsibility for self-care and to manage the physical, mental, and social consequences of having a chronic condition [10,11]. Today, self-management is performed by health care professionals through training booklets, audio and videotapes, and group meetings.

Currently, in the clinical environment, the most common types of patient education are using educational pamphlets, audiotapes, videos, and also oral presentations in personal or group sessions. These methods have low efficiency because they provide a large amount of information and rely on the individual’s ability to recall information, which may lead to patient confusion. For example, about 40%-80% of oral information was immediately forgotten, and half of this information was not recalled correctly by patients [12]. Therefore, to solve these problems and limitations, new tools and approaches are needed, and smartphones are one of these suitable and well-known tools [13]. The advantages of using mobile health (mHealth) intervention include managing the improvement of the patient’s condition during treatment and afterward, improving patient knowledge, self-management, drug management, and receiving social support from patients with similar conditions [14].

Therefore, due to the importance of self-management by patients with gastric cancer, the ineffectiveness of educational pamphlets and oral information, the role of smartphones in facilitating education and management [12,15,16], and the high prevalence of this cancer [1,5], the purpose of this study was to identify the requirements of mobile-based self-management app for patients with gastric cancer and help them to improve disease management.

Methods

Overview

This research was conducted using the quantitative descriptive method in 2021. The data collection tool in this study was a questionnaire designed by the research group (Multimedia Appendix 1). It was used to assess information needs and determine the data elements and capabilities required for a self-management app for patients with gastric cancer based on library studies, global guidelines for gastric cancer management and treatment, and searches of valid databases and scientific articles. This questionnaire was considered equal for the two groups of clinical staff and patients. The questionnaire consisted of 41 closed questions in 5 sections that included patient data (1 item), patient clinical data (8 items), disease management (6 items) and educational information (12 items), and app capabilities and functions in 3 areas of notices, program alerts, and reminders and screen capabilities of the program (14 items).

At the end of the questionnaire, an open-ended question was asked to receive the participants’ opinions on their issues. This questionnaire was designed based on a 5-point Likert scale. To determine the questionnaire content validity, the opinions of 5 experts in the field of cancer and information management were obtained, and the relevant corrections were made.

To determine questionnaire reliability, we used Cronbach alpha and invited 5 physicians and 10 patients with gastric cancer to participate. Cronbach alpha was 83% for the patient’s individual data, 80% for the patient’s clinical data section, 87% for the disease management section, 97% for the educational information section, and 92% for the app capabilities and functions section. Data analysis was performed based on the calculation of frequency distribution (number and percentage), mean, and quarter deviation index of each questionnaire question in IBM SPSS Statistics software (version 22; IBM Corp). Thus, if a total of 75% of the participants in the study or more chose the first two options (very important and important) in the questionnaire, that data element was considered in the final model, the data elements that a total of 50%-75% of the study population chose the first two options or the last two options in the questionnaire, were questioned again in the second stage of Delphi and comments below 50% of the model were removed. Thus, if a total of 75% of the participants in the study or more chose the first two options (very important and important) in the questionnaire, that data element was considered in the final model. The data elements for which 50%-75% of the study population chose the first two options or the last two options in the questionnaire were considered. In the second stage of the Delphi process, comments below 50% of the model were removed. This study involved two rounds of the Delphi method. The scores of the questionnaire options were as follows: 5=very important, 4=important, 3=I have no opinion, 2=insignificant, and 1=very insignificant. In addition, if a new data element was suggested by at least 40% of the participants in the open question section of the questionnaire, the desired data element was used in the design of the program. Questionnaires were available to all medical specialists in the fields of cancer radiotherapy, blood and oncology, pathology, pharmacy, and head nurses of the chemotherapy department working in the hospitals of
Mazandaran University of Medical Sciences, which had an oncology department (Bouali Sina and Imam Sari) and by available sampling to 30 patients with gastric cancer who were admitted to the oncology department and met the criteria for inclusion in the study. Inclusion criteria were technological skills, gastric cancer, smartphones, and a minimum age of 30 years and maximum age of 65 years. Finally, the obtained data were analyzed using descriptive statistics and frequency distribution reports and using IBM SPSS Statistics software.

**Ethical Considerations**
This study was reviewed by Mazandaran University of Medical Sciences and provided with ethics code IR.MAZUMS.REC.1399.7855.

**Results**
In the first round, 50 questionnaires (20 for clinical experts and 30 for patients) were distributed, and 42 questionnaires (16 by clinical experts and 26 by patients) were completed. In the second round, 50 questionnaires (20 for clinical experts and 30 for patients) were distributed, and 35 questionnaires (15 by clinical experts and 20 by patients) were completed. Most participants in the clinical group were male (n=10, 62%) and in the age range of 40-49 years (Table 1). Most of them had medical subspecialists degrees (n=9, 56%), and most of them (n=8, 50%) specialized in radiotherapy. In addition, most participants in this round (n=9, 56%) had work experience between 6 and 10 years. Most of the patient participants in the study were male (n=15, 57%) with a range of 50-59 years (Table 2). Most of them had a diploma (n=20, 77%), and most of them had a freelance job (n=8, 31%). Tables 1 and 2 show participants’ characteristics in the first and second rounds of the Delphi study.

<table>
<thead>
<tr>
<th>Delphi study variables</th>
<th>Round 1, n (%)</th>
<th>Round 2, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>10 (62)</td>
<td>9 (60)</td>
</tr>
<tr>
<td>Female</td>
<td>6 (38)</td>
<td>6 (40)</td>
</tr>
<tr>
<td><strong>Age (years)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30-39</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>40-49</td>
<td>12 (75)</td>
<td>11 (73)</td>
</tr>
<tr>
<td>50-59</td>
<td>2 (12)</td>
<td>2 (13)</td>
</tr>
<tr>
<td>60-69</td>
<td>2 (12)</td>
<td>2 (13)</td>
</tr>
<tr>
<td><strong>Level of education</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BSc</td>
<td>2 (12)</td>
<td>2 (13)</td>
</tr>
<tr>
<td>MSc</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Medical specialty</td>
<td>5 (31)</td>
<td>5 (33)</td>
</tr>
<tr>
<td>Medical subspecialty</td>
<td>9 (56)</td>
<td>8 (33)</td>
</tr>
<tr>
<td><strong>Occupation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oncologist</td>
<td>2 (12)</td>
<td>2 (13)</td>
</tr>
<tr>
<td>Radiotherapist</td>
<td>8 (50)</td>
<td>7 (47)</td>
</tr>
<tr>
<td>Pathologist</td>
<td>3 (19)</td>
<td>3 (20)</td>
</tr>
<tr>
<td>Pharmacist</td>
<td>1 (6)</td>
<td>1 (7)</td>
</tr>
<tr>
<td>Nurse</td>
<td>2 (12)</td>
<td>2 (13)</td>
</tr>
<tr>
<td><strong>Work experience in cancer (years)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-5</td>
<td>2 (12)</td>
<td>2 (13)</td>
</tr>
<tr>
<td>6-10</td>
<td>9 (56)</td>
<td>8 (53)</td>
</tr>
<tr>
<td>11-15</td>
<td>2 (12)</td>
<td>2 (13)</td>
</tr>
<tr>
<td>≥16</td>
<td>3 (19)</td>
<td>3 (20)</td>
</tr>
</tbody>
</table>
Table 2. Patients characteristics in the first and second rounds of the Delphi study.

<table>
<thead>
<tr>
<th>Delphi study variables</th>
<th>Round 1, frequency (%)</th>
<th>Round 2, frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>15 (57)</td>
<td>12 (60)</td>
</tr>
<tr>
<td>Female</td>
<td>11 (43)</td>
<td>8 (40)</td>
</tr>
<tr>
<td><strong>Age (years)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30-39</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>40-49</td>
<td>8 (31)</td>
<td>4 (20)</td>
</tr>
<tr>
<td>50-59</td>
<td>10 (38)</td>
<td>10 (50)</td>
</tr>
<tr>
<td>60-65</td>
<td>8 (31)</td>
<td>6 (30)</td>
</tr>
<tr>
<td><strong>Level of education</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diploma</td>
<td>20 (77)</td>
<td>16 (80)</td>
</tr>
<tr>
<td>Associate degree</td>
<td>3 (12)</td>
<td>1 (50)</td>
</tr>
<tr>
<td>BSc</td>
<td>3 (12)</td>
<td>3 (15)</td>
</tr>
<tr>
<td>MSc</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>PhD or above</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td><strong>Occupation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clerk</td>
<td>3 (12)</td>
<td>3 (12)</td>
</tr>
<tr>
<td>Farmer</td>
<td>4 (15)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Freelance job</td>
<td>8 (31)</td>
<td>12 (60)</td>
</tr>
<tr>
<td>Retired</td>
<td>7 (27)</td>
<td>5 (25)</td>
</tr>
<tr>
<td>Unemployed</td>
<td>4 (15)</td>
<td>0 (25)</td>
</tr>
</tbody>
</table>

Table 3 and Table 4 show participants’ response distribution regarding data elements and functional requirements. Most of the data elements were identified as very important or significant by the majority of participants (Table 3).

Among the data elements required in the patient's clinical data part, the highest mean was the treatment types used (mean 4.3, SD 0.91), and appointment time with doctor had the lowest mean (3.3, SD 1.66). Among the data elements required in the disease management part, the treatment protocols (ie, surgery, radiotherapy, and chemotherapy) had the highest mean (4.6, SD 0.95), and complementary therapies had the lowest mean (3.8, SD 1.17). Among the data elements required by the educational information, the highest mean belonged to physical activity (mean 4.4, SD 0.91), and the lowest mean belonged to excretory substances (mean 3.6, SD 1.18). Moreover, medication reminders had the highest mean (4.2, SD 0.95), and the nutrition reminders had the lowest average of the functional requirements for mobile-based self-management apps (mean 3.3, SD 0.48). However, some data elements led to the second round of Delphi, such as medication, other diseases and medications, appointment time with a doctor, excretory substances, list of cancer treatment centers, hopeful quotes notification, nutrition reminder, the ability to display the date entry time and date, and weight changes graph (Table 4).

In the second round, 15 specialists and 20 patients participated. Most of the participants in the study were male (n=9, 60%) and in the age range of 40-49 years (n=11, 73%). Most of them had a subspecialty degree (n=8, 53%), and most of them specialized in radiotherapy (n=7, 47%). In addition, most participants in this round (n=8, 53%) had work experience between 6 and 10 years. In addition, most of the patient participants in the study were male (n=12, 60%) and in the age range of 50-59 years (n=10, 50%). Most of them had a diploma (n=16, 80%), and most of them had a free job (n=12, 60%).

These results show that in the demographic data section, most patients did not comment on the importance of recording data such as name, surname, and place of residence and were met with less agreement from patients compared to clinicians. Furthermore, the group of clinical specialists emphasized the importance of recording the type of treatments, paraclinical measures (eg, laboratory tests, sonography, mammography, radiography, endoscopy, and cytology), and their results as well as introducing the side effects of chemotherapy and their medication interactions. Patients emphasized the importance of educational information such as nutrition management, emotional support, health advice during chemotherapy, and wound care after surgery. In terms of functional requirements, the patient group paid more attention to the necessary reminders for medication, visiting a doctor, and performing paraclinical procedures in the app, while experts emphasized the need for reminders to screen the patient's first-degree family. Moreover, the experts stated as the main treatment for gastric cancer is related to chemotherapy and surgery, so the list of surgeons and medical subspecialists in hematology and oncology should be considered in the field of informing capabilities of the app.
Table 3. Participants’ response distribution regarding required data elements for mobile-based self-management app (round 1).

<table>
<thead>
<tr>
<th>Data elements</th>
<th>Patients, mean (SD)</th>
<th>Clinical specialists, mean (SD)</th>
<th>Total, mean (SD)</th>
<th>Agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Demographic data</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Demographic data</td>
<td>3.7 (0.82)</td>
<td>4.2 (0.93)</td>
<td>3.8 (1.15)</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Clinical patients data</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Occurrence of early symptoms (day/month/year)</td>
<td>3.92 (1)</td>
<td>4.4 (0.72)</td>
<td>4.1 (1.07)</td>
<td>✓</td>
</tr>
<tr>
<td>Diagnosis time (day/month/year)</td>
<td>3.9 (0.88)</td>
<td>3.8 (1.14)</td>
<td>3.8 (1.02)</td>
<td>✓</td>
</tr>
<tr>
<td>Paraclinical test history</td>
<td>3.9 (1.19)</td>
<td>4.36 (0.76)</td>
<td>4.1 (1.02)</td>
<td>✓</td>
</tr>
<tr>
<td>Treatments type (surgery, chemotherapy, radiotherapy)</td>
<td>4.1 (0.98)</td>
<td>4.46 (0.74)</td>
<td>4.3 (0.91)</td>
<td>✓</td>
</tr>
<tr>
<td>Medication</td>
<td>3.1 (1.57)</td>
<td>3.6 (1.66)</td>
<td>3.4 (1.59)</td>
<td></td>
</tr>
<tr>
<td>Other diseases and medications</td>
<td>3.1 (1.44)</td>
<td>3.7 (1.12)</td>
<td>3.4 (1.32)</td>
<td>—</td>
</tr>
<tr>
<td>Appointment time with a doctor</td>
<td>3.1 (1.55)</td>
<td>3.6 (1.66)</td>
<td>3.3 (1.66)</td>
<td>—</td>
</tr>
<tr>
<td>Time for paraclinical tests</td>
<td>3.85 (1.01)</td>
<td>4.6 (0.8)</td>
<td>4.2 (0.95)</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Disease management</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gastric cancer causes</td>
<td>4.0 (1.14)</td>
<td>4.5 (0.51)</td>
<td>4.2 (0.99)</td>
<td>✓</td>
</tr>
<tr>
<td>Gastric cancer symptoms</td>
<td>4.1 (0.94)</td>
<td>4.7 (0.34)</td>
<td>4.3 (0.94)</td>
<td>✓</td>
</tr>
<tr>
<td>Diagnostic methods (test, ultrasound, imaging, pathology)</td>
<td>3.7 (1.11)</td>
<td>4.1 (0.99)</td>
<td>3.9 (1.1)</td>
<td>✓</td>
</tr>
<tr>
<td>Treatment protocols (surgery, radiation therapy, chemotherapy, etc)</td>
<td>4.2 (1.06)</td>
<td>4.8 (0.34)</td>
<td>4.6 (0.95)</td>
<td>✓</td>
</tr>
<tr>
<td>Side effects and Medication interactions</td>
<td>4.1 (0.98)</td>
<td>4.4 (0.82)</td>
<td>4.3 (0.91)</td>
<td>✓</td>
</tr>
<tr>
<td>Complementary therapies</td>
<td>3.7 (1.21)</td>
<td>4.0 (0.96)</td>
<td>3.8 (1.17)</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Educational information</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nutrition management</td>
<td>4.5 (0.51)</td>
<td>4.1 (0.96)</td>
<td>4.3 (0.8)</td>
<td>✓</td>
</tr>
<tr>
<td>Risk factors</td>
<td>4.2 (1.04)</td>
<td>4.1 (1.32)</td>
<td>4.1 (1.10)</td>
<td>✓</td>
</tr>
<tr>
<td>Excretory substances</td>
<td>3.4 (1.09)</td>
<td>3.8 (1.36)</td>
<td>3.6 (1.18)</td>
<td>—</td>
</tr>
<tr>
<td>Rest</td>
<td>4.1 (0.99)</td>
<td>3.7 (1.11)</td>
<td>3.9 (1.13)</td>
<td>✓</td>
</tr>
<tr>
<td>Stress management</td>
<td>4.2 (0.98)</td>
<td>4.1 (1.2)</td>
<td>4.1 (1.1)</td>
<td>✓</td>
</tr>
<tr>
<td>Emotional support for patient and family</td>
<td>4.4 (0.82)</td>
<td>4.1 (1.02)</td>
<td>4.3 (0.91)</td>
<td>✓</td>
</tr>
<tr>
<td>Physical activity management</td>
<td>4.6 (0.82)</td>
<td>4.3 (1.02)</td>
<td>4.4 (0.91)</td>
<td>✓</td>
</tr>
<tr>
<td>Health advice during chemotherapy</td>
<td>4.1 (1.31)</td>
<td>3.7 (1.26)</td>
<td>3.9 (1.28)</td>
<td>✓</td>
</tr>
<tr>
<td>Warning/danger symptoms during treatment (jaundice, bloody stools, bloody vomit)</td>
<td>4.1 (0.99)</td>
<td>3.7 (1.17)</td>
<td>3.8 (1.13)</td>
<td>✓</td>
</tr>
<tr>
<td>Family education</td>
<td>4.0 (0.96)</td>
<td>3.9 (1.21)</td>
<td>3.9 (1.17)</td>
<td>✓</td>
</tr>
<tr>
<td>Wound care after surgery</td>
<td>4.4 (0.82)</td>
<td>4.1 (0.98)</td>
<td>4.3 (0.91)</td>
<td>✓</td>
</tr>
<tr>
<td>Frequently asked questions</td>
<td>3.9 (1.13)</td>
<td>4.4 (0.72)</td>
<td>4.0 (1.07)</td>
<td>✓</td>
</tr>
</tbody>
</table>

*No agreement reached.*
Table 4. Distribution of the participants’ responses regarding functional requirements for mobile-based self-management app (round 1).

<table>
<thead>
<tr>
<th>App functional requirements</th>
<th>Patients, mean (SD)</th>
<th>Clinical specialists, mean (SD)</th>
<th>Total, mean (SD)</th>
<th>Agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Notices</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>List of cancer treatment centers</td>
<td>3.6 (1.19)</td>
<td>3.3 (1.45)</td>
<td>3.5 (1.28)</td>
<td>a</td>
</tr>
<tr>
<td>List of cancer radiotherapists and hematologist-oncologist</td>
<td>4.3 (0.76)</td>
<td>3.9 (1.19)</td>
<td>4.1 (1.05)</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Alerts and reminders</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medication reminder</td>
<td>4.4 (0.81)</td>
<td>4.1 (1.09)</td>
<td>4.2 (0.95)</td>
<td>✓</td>
</tr>
<tr>
<td>Appointment reminder</td>
<td>4.0 (0.92)</td>
<td>3.9 (1.13)</td>
<td>3.9 (1.03)</td>
<td>✓</td>
</tr>
<tr>
<td>paraclinical test reminder</td>
<td>4.1 (0.99)</td>
<td>3.7 (1.17)</td>
<td>3.8 (1.09)</td>
<td>✓</td>
</tr>
<tr>
<td>Screening reminder</td>
<td>3.6 (1.26)</td>
<td>4.1 (0.96)</td>
<td>3.9 (1.12)</td>
<td>✓</td>
</tr>
<tr>
<td>Physical activity reminder</td>
<td>3.6 (1.26)</td>
<td>4.0 (0.92)</td>
<td>3.8 (1.15)</td>
<td>✓</td>
</tr>
<tr>
<td>Hopeful quotes notification</td>
<td>3.6 (1.19)</td>
<td>3.2 (1.45)</td>
<td>3.4 (1.23)</td>
<td>—</td>
</tr>
<tr>
<td>Nutrition reminder</td>
<td>3.0 (1.50)</td>
<td>3.6 (1.46)</td>
<td>3.3 (1.48)</td>
<td>—</td>
</tr>
<tr>
<td><strong>Display capabilities</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ability to display data entry date</td>
<td>3.4 (1.36)</td>
<td>3.7 (1.39)</td>
<td>3.6 (1.38)</td>
<td>—</td>
</tr>
<tr>
<td>Ability to display data recording time</td>
<td>3.3 (1.45)</td>
<td>3.7 (1.11)</td>
<td>3.5 (1.32)</td>
<td>—</td>
</tr>
<tr>
<td>Show weight changes graphically</td>
<td>3.1 (1.50)</td>
<td>3.7 (0.98)</td>
<td>3.5 (1.23)</td>
<td>—</td>
</tr>
<tr>
<td>Ability to record ultrasound images, test results, etc</td>
<td>3.9 (1.16)</td>
<td>3.8 (1.05)</td>
<td>3.8 (1.13)</td>
<td>✓</td>
</tr>
<tr>
<td>Reports</td>
<td>4.1 (0.99)</td>
<td>3.7 (1.11)</td>
<td>3.9 (1.05)</td>
<td>✓</td>
</tr>
</tbody>
</table>

aNo agreement reached.

**Discussion**

**Principal Findings**

The findings of this study showed that from the perspective of clinicians and patients, most components related to personal data, patient clinical data, disease management, and educational information, as well as app capabilities such as notices, alerts, and reminders, and screen-related capabilities other than “ability to display data recording hours and display weight changes in charts” were required. The findings of this study showed that most patients did not comment on the importance of recording data such as name, surname, and location, and personal data were met with less agreement from patients compared to clinicians. This may be due to concerns about privacy and confidentiality. Therefore, the results of this study are in line with the results of Neobek et al [17], who expressed users’ concerns about privacy as the main obstacle in using health-related self-management programs. In addition, the study of Malmi et al [18] also mentioned the importance of security and access to identity information in the design of apps. Therefore, due to the possibility of data transfer and communication with clinical specialists in apps, the existence of demographic information in self-management apps is essential.

In similar studies, the importance of recording patient clinical data was reported. In this regard, Sicotte et al [19] has shown that recording patient data and using electronic medical records led to improved flow of information, increased quality of care, and reduced the average waiting time in cancer outpatient centers. In addition, Yazdanian et al [20] stated it is possible to record patients’ clinical data electronically and manage the course of cancer from screening and prevention to treatment and beyond, despite the breadth of data elements related to cancer patient care. Levy et al [21] also created a form to collect data related to the chemotherapy protocol, assess pretreatment symptoms and provide chemotherapy training in the electronic health record. This form included data elements such as name, dose, and method of injection, as well as the expiration date of the medication. Mukai et al [22] also designed the Advanced Medical Information Database System (AMIDAS) to record clinical data and archive radiotherapy information. The data required by the AMIDAS system included patient demographic information, tumor data, radiotherapy treatment plan, follow-up (tumor complications, disease progression reactions, mortality, etc), laboratory results, and treatment delivery. Therefore, it seems that designing an app with a mobile phone will provide a complete view of patients with cancer by considering the types of data required by the oncology, chemotherapy, and radiotherapy departments, resulting in the integration of the data of patients with cancer, improving the quality of care, making more informed decisions, and reducing the time required to search for patient information.

The findings showed, due to the need for disease management, the presence of information on gastric cancer and its causes, symptoms, types of diagnostic methods, and treatment regimens are necessary. In a study conducted to develop a tablet-based app for patients with gastric cancer, Wu et al [15] found that patients had much less weight loss than the control group by providing sufficient information on the symptoms of the disease.
In addition, Wu et al [23] designed a smartphone-based app that reminded activities related to nutritional status, medical information management, drainage follow-up, and wound care in patients with gastric cancer after surgery. This app informed patients of severe weight loss or possible bleeding by including clinical decision support. Ultimately, it achieved the highest level of satisfaction in 93% of users. Therefore, it seems that patients with gastric cancer need sufficient information about the causes and symptoms of the disease, diagnostic methods, and types of treatment regimens to improve their knowledge about the pathology and the course of the disease and the role and importance of treatment regimens.

Educational information was another major topic that many patients and clinicians emphasized, including the importance of nutrition management, stress management, health advice during chemotherapy, and more. In a similar study, June and Park [24] conducted a self-management program with 22 items in 7 areas of management of dietary restrictions, avoidance of risk factors, attention deposits, stress management and psychological support, attention to rest, regular diet, and follow-up care for patients with gastric cancer after gastrectomy. In this regard, Davoodi et al [9] emphasized the important role of the effect of self-care program training on the quality of life of patients with gastric cancer after surgery, especially in the psychological dimension. Moreover, Xuan [25] emphasized the very positive effect of self-management training on weight changes and quality of life in patients with gastric cancer that undergoing chemotherapy. In a review study, Mehdizadeh et al [12] found that mobile apps can provide easy access to appropriate and reliable information for patients with cancer and their families. Therefore, it seems providing educational information for supporting self-management by using mHealth intervention and mobile app can help patients with gastric cancer. It could be useful for nutrition management, diet therapy, improved physical activity, psychological and social effects, and sharing patients’ experiences with others.

Functional requirements related to informing, warnings, and reminders were functional requirements identified by participants as essential features for a gastric cancer self-management app. Some studies have reported that timely use of medications can lead to reduced disease recurrence and progression, reduced risk of mortality, and increased quality of life in patients with colorectal cancer. In this regard, Slatter et al [26] helped patients and their families by designing the ONCO FAMILY APP app, which had a reminder module for taking medication and seeing a doctor. In another study, Kock and colleagues [27] designed a LESS app with a calendar and reminder module for children with cancer. This module automatically reminds users of their appointments and periodic tests by specifying points on the calendar. Therefore, it seems mHealth interventions could be used as a promotional tool for encouraging people to participate in self-management activities and improving patient adherence to treatment protocols and communication between health care providers and patients.

Limitations
This research had some limitations. First of all, although most medical specialists in the fields of cancer radiotherapy, blood and oncology, pathology, pharmacy, and head nurses of the chemotherapy department working in the teaching hospitals of Mazandaran University of Medical Sciences, which had an oncology department (Bouali Sina and Imam Sari), took part in the study, the number of the participants in the first and second rounds of the Delphi study was limited. However, as there is no well-defined rule for selecting a specific number of participants in a Delphi study and representation is assessed by the quality of the expert panel rather than its number, we can conclude that the participants were well-experienced clinicians in cancer care and the results might be generalized to larger sample sizes. The second issue might be related to the level of details associated with each data element. Although we reached a large number of data elements necessary for designing a mobile-based self-management app for patients with gastric cancer, it was not possible to include all of them in the questionnaire. Therefore, more details about other data elements, which might not be mentioned in this study, should be investigated before or during designing a real system.

Conclusions
The goal of this study was to identify app requirements for the self-management of patients with gastric cancer. The features provided included personal data, patient clinical data, disease management, educational information, and functional requirements such as notifications and reminders that could be used for developing software or apps and made available for users. These apps can play an important role in empowering patients and also improving their quality of life. However, the apps need to be designed and implemented to see how they can meet users’ requirements.

Acknowledgments
This paper is the result of an approved research project entitled “Design, Development, and Evaluation of Mobile Self-Management Application for Stomach Cancer Patients,” by Mazandaran University of Medical Sciences.

Conflicts of Interest
None declared.

Multimedia Appendix 1
Data elements and functional requirements questionnaire.
[DOCX File, 23 KB - cancer_v8i2e36788_app1.docx]


Abbreviations

AMIDAS: Advanced Medical Information Database System
mHealth: mobile health

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Evaluation of a Mobile Health App Offering Fertility Information to Male Patients With Cancer: Usability Study

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Abstract

Background: Cancer and its treatment can adversely affect male fertility. Although sperm banking is an effective fertility preservation method, there is an unmet need for information and support surrounding these issues.

Objective: This usability study evaluates a mobile health app providing male patients with cancer with credible information about the impact of cancer and its treatment on fertility and fertility preservation.

Methods: Participants were recruited by a market research firm. Eligibility criteria were men who were 18-45 years of age, identified as male, diagnosed with new or recurring cancer within 1 year, not in fertility treatment, able to read and write in English or French, and had internet access. App usage was tracked for 2 weeks. After app use, participants provided qualitative feedback about their experiences using the app as well as quantitative data regarding their sperm banking decisions, perceived change in fertility knowledge, evaluation of the app’s information on the Information Assessment Method, and the app’s quality on the user version of the Mobile App Rating Scale.

Results: The sample included 40 men aged 27-45 years. Approximately 68% (27/40) indicated that no one had previously spoken to them about the impact of cancer on fertility, and 85% (34/40) had not received information on fertility preservation. Approximately 83% (33/40) found the app’s information relevant, and 85% (34/40) said that it increased their fertility knowledge. Approximately 23% (9/40) made a decision about sperm banking after using the app. Participants rated the app’s quality highly, with mean scores (out of 5) of 4.14 for information, 4.06 for functionality, 3.84 for aesthetics, and 3.63 for engagement.

Conclusions: The app proved to be useful for male patients with cancer, suggesting that mobile health resources could be beneficial to incorporate into clinical care to enable shared decision-making about fertility.

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KEYWORDS
mobile app; eHealth; male; cancer; infertility; fertility preservation; psycho-oncology
Introduction

About 8600 Canadian boys and men aged 15-39 years are diagnosed with cancer yearly [1]. Cancer can adversely affect male fertility by damaging the reproductive organs, disrupting hormone levels, or impairing sperm production/release [2]. Male fertility can also be affected by cancer treatment, including chemotherapy, radiation, and surgery [3-6]. As survival rates improve [7], patients face long-term consequences of cancer and its treatment [8]. Psychological distress is common among men with cancer who may fear disease recurrence or feel inadequate and for whom cancer might interfere with career goals and family planning [9]. Cancer treatment may result in decreased libido, sexual dissatisfaction, erectile dysfunction [9], and cause difficulties in cultivating intimate relationships [10].

The most established method to preserve male fertility before cancer treatment is semen cryopreservation, also known as sperm banking [4,11]. For most patients, the semen sample is collected via masturbation [12]. However, in patients with difficulties providing a semen sample via ejaculation, there are a variety of alternative sperm retrieval techniques that can be used (eg, electroejaculation, aspiration of sperm from the testicle or epididymis) [12,13]. Banked sperm can then be used to achieve a pregnancy with the use of assisted reproductive techniques such as in vitro fertilization and intracytoplasmic sperm injection [4]. There are also options for men who do not have viable sperm, such as the use of donor sperm in conjunction with in vitro fertilization and intracytoplasmic sperm injection, as well as adoption [11].

Although sperm banking is an effective fertility preservation method [14], there is an unmet need for information and support surrounding these issues [15-17]. Most male patients with cancer view receiving fertility information as very important but are often dissatisfied with the information obtained [16]. The urgency to begin treatment or fear of passing cancer to offspring may act as barriers to sperm banking [15,18,19]. Factors that often prevent fertility preservation conversations include the potential distress from discussing infertility risk, limited access to educational materials, and clinicians’ lack of time and knowledge [20]. Additionally, men may not initiate these conversations since they are generally less likely than women to ask questions during medical appointments [21].

There is a need for fertility preservation resources to be better integrated into cancer care [4,15,18,22]. In a survey conducted by our team, 80% of male patients with cancer preferred receiving fertility information at the first oncology consult or at the time of diagnosis and treatment planning [15]. Loren et al [18] recommend that referrals to counselling services be incorporated into routine care for men with fertility concerns. Thus, it is imperative that clinicians discuss fertility preservation with patients as early as possible and refer them to reproductive specialists.

eHealth resources are viewed positively by cancer survivors [23] and are suitable for men who often value autonomy and anonymity when seeking information [24]. However, current web-based information for male patients with cancer is not comprehensive, less accessible than that for female patients [25], of inadequate readability and quality [26], and is not rigorously evaluated [27]. One study has assessed the feasibility of a web-based intervention targeting fertility distress after cancer, but their sample includes only 4 men [28,29]. Given the widespread use of smartphones [30], mobile health (mHealth) apps show promise as tools to improve the quality of life of patients with cancer [31].

To address the need for fertility information tailored to male patients with cancer, our team developed an mHealth app, Infertility XY, providing information on the impact of cancer and its treatment on male fertility and fertility preservation. In this study, we evaluate the app’s quality and information, as well as its potential to improve fertility knowledge and help patients make fertility preservation decisions.

Methods

App Study Design

The study design for the Infertility XY app adhered to the Medical Research Council guidelines for the development and evaluation of complex interventions [32]. The guidelines include 4 phases: development, feasibility and piloting, evaluation, and implementation [32].

In the development phase of the study, our team designed 3 versions of the Infertility/Infertilité XY app for 3 populations in collaboration with an app development company: men in the general public, male patients with infertility, and male patients with cancer. In this paper, only data from the sample of patients with cancer are presented.

The app content was written by our team and informed by extensive literature reviews and a needs assessment survey of the fertility-related informational and support needs of male patients with cancer [15]. Key stakeholders, including male patients with cancer, were included throughout the app development process, informing the app’s content and design elements. Content was vetted by health professionals and experts in patient-centered care. All content was available in English and French.

In addition to information about sperm banking, the app for male patients with cancer provided information on fertility treatment in general (eg, in vitro fertilization) as well as the use of donor sperm. The app also addressed common concerns among male patients with cancer such as the risk of passing their cancer onto future children, which was a concern that came up in the needs assessment survey among male patients with cancer [15].

Our research team collaborated with an app company to transform the informational content into a user-friendly app.

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(page number not for citation purposes)
The app company helped develop the look and feel of the app (eg, color scheme, graphics), the different features in the app (eg, map of fertility clinics, pop-up glossary definitions), and the navigation. The app company did not have access to users’ data.

In the feasibility/piloting phase of the study, an interactive prototype of the Infertility XY app was developed, which allowed the research team to make changes to the organization of the information before presenting the app to participants.

In the evaluation phase of the study, we assessed the uptake and usability of the app by using a pre-post study design. We determined our 2 main outcome measures (the user version of the Mobile App Rating Scale [uMARS] and the Information Assessment Method [IAM]) based on literature reviews of available tools to assess the quality and information of apps. The next phase of the study is implementation, which includes finding partners to disseminate the app and provide long-term follow-up and monitoring [32].

Ethics Approval and Recruitment
This study was approved by the Medical/Biomedical Research Ethics Committee of CIUSSS (Centre intégré universitaire de santé et de services sociaux) West-Central Montreal Research Ethics Board (MP-05-2016-344). Participants were recruited between August and October 2020 across Canada by a market research firm (“recruitment company”). The recruitment company was selected based on their experience in medical research, their ability to recruit a representative sample of participants from Canada, and their adherence to the highest standards in research methodology, ethical practices, respondent rights, and personal privacy. The recruitment company did not have access to participants’ data. In the communications between our team and the recruitment company, participants were referred to by their unique code, which did not identify them, to protect participants’ confidentiality. The recruitment company recruited patients with cancer via physicians and patient advocacy groups and contacted them via email and telephone. The recruitment company screened potential participants for the following criteria: identified as male, had internet access, able to read and write in English/French, aged 18-45 years, diagnosed with new/recurrent cancer within the past year, and not in fertility treatment. Individuals who met the eligibility criteria and provided written informed consent were enrolled in the study. Once the target sample of 40 participants was reached, recruitment was terminated.

Participants
Guidelines for this phase of the evaluation of web-based interventions suggest that a sample of at least 20 users is required for statistical significance [33]. To account for possible attrition, we aimed to recruit 40 men. The recruitment company contacted 586 patients with cancer; 63 agreed to be screened, 43 were eligible and consented, and 40 completed the study. Of these 40 men, 24 were recruited via referrals from health care providers, 11 via patient referrals, and 5 via the recruitment company’s database.

Procedures
After providing informed consent online, participants created an app account, completed pre–app usage questionnaires, and gained access to the app for 2 weeks. This period was selected based on our previous experience [34], where app usage tended to drop off after 2 weeks. After app use, participants were blocked from viewing the app and directed to post–app usage questionnaires. After completing the questionnaires, participants regained app access. To reduce attrition, participants were sent up to 3 reminder emails to complete questionnaires and use the app. Participants received CAD $150 from the recruitment company upon study completion. See Multimedia Appendix 3 for the study’s procedures.

Measures

Background Questionnaire
Participants provided information about their sociodemographic characteristics, including relationship status, age, ethnicity, immigrant status, education, income, religion, and parity. Participants were also asked whether anyone had spoken to them about the impact of cancer on fertility, whether they received information about fertility preservation, and if so, whether they received all the information they needed, their most recent cancer diagnosis, and the age at which they received it, and their current cancer status.

Fertility Knowledge and Preservation
After app use, participants were asked (1) whether the app increased their knowledge of fertility in relation to cancer, using a scale from 0 (“No, not at all”) to 3 (“Yes, quite a lot”); (2) whether they made a decision about sperm banking during the study (yes/no); and (3) if they selected “yes,” they were asked what decision they made (eg, I banked my sperm), and what factors helped them make the decision.

IAM
The IAM was used to evaluate participants’ ratings of the app’s information. The measure was developed to assess the relevance, cognitive impact, use, and health benefits of web-based health information and has been validated with patients and consumers of web-based health information [35,36]. Our team adapted the 8-item measure from the 2019 IAM version for Fertility and the IAM4All. All items are considered individually. No total scores or cutoffs exist.

uMARS
The uMARS was used to measure participants’ rating of the app’s quality. This 20-item measure consists of 4 subscales. The Engagement subscale measures whether the app is interesting, customizable, and interactive; the Functionality subscale asks about the app’s functionality and navigation; the Aesthetics subscale asks about the app’s visual appeal; and the Information subscale asks whether the app contains credible, high quality information. Each subscale is measured on a scale from 1-5; higher scores represent higher ratings. The mean score is obtained by averaging the 4 subscales’ scores. An additional 4 items measuring the app’s subjective quality can be averaged to obtain a subjective quality score. The uMARS was developed by Stoyanov et al [37] and tested in a sample of Australians.
aged 16-25 years. The Flesch-Kincaid readability test indicated that the uMARS required a grade 8 reading level [37]. The total score demonstrated excellent internal consistency (α=.90) and interrater reliability (intraclass correlation=0.79) [38]. Each subscale demonstrated satisfactory consistency, with Cronbach alpha ranging from .70 to .80 [37].

Qualitative and Quantitative Data on App Usage
To capture participants’ experiences using the app, our team developed open-ended questions.

1. Please describe any fertility topics or features that were not included in the app and that you would have liked to be included. Please tell us why you want those topics or features to be included.
2. Please tell us what you liked best about the app and why.
3. Please tell us what you liked least about the app and why.

We present quantitative data for the following app usage metrics: unique pageviews and thumbs-up/down assessments.

Quantitative Analyses
No questionnaire data were missing. Quantitative analyses were performed using SPSS (IBM Corp). Descriptive quantitative analyses were used to assess participants’ sociodemographic characteristics and informational needs, the influence of the app on treatment decisions and fertility knowledge, and evaluation of the app’s information and quality. Given the small sample size (N=40), we did not conduct multivariate analyses. However, descriptive statistics were sufficient in answering our overarching question regarding the usability of the app in conjunction with the qualitative feedback.

App Usage
The app company compiled the app usage metrics. For each participant, the numbers of unique pages viewed and thumbs-up/down assessments were extracted. These metrics were presented as totals and were also classified into categories: medical (11 articles), legal (3 articles), or psychosocial (5 articles; Multimedia Appendix 1). Developed for analytic purposes, these categories were not seen by participants. If a participant visited a page multiple times, it was only counted once. No app usage data were missing.

Qualitative Feedback
All participants responded to the open-ended questions assessed in the questionnaires delivered after using the app. Their feedback was analyzed by 2 researchers (KK and ENG) on a qualitative data analysis software (NVivo, QSR International) using directed content analysis with an iterative approach [39]. A directed content analysis approach allows researchers to use predetermined codes. The uMARS dimensions of aesthetics, functionality, engagement, and information guided analyses and were used as the pre-existing codes. These categories allowed researchers to understand participants’ qualitative feedback in relation to the quantitative data, which also looked at users’ perceptions of the app on these quality rating scales. After the first round of coding, discrepancies were discussed and resolved between 2 researchers.

Results
Sociodemographic Data
The sample consisted of 40 patients with cancer, all of whom accessed the app in English (see Multimedia Appendix 4 for sociodemographics). The age range was 27-45 years (mean 36.93 [SD 5.48] years). Most participants were in heterosexual relationships (27/40, 68%), followed by single (8/40, 20%), and in nonheterosexual relationships (5/40, 13%). More than half of the men had children (22/40, 55%), and most indicated that they would like to have children in the future (33/40, 83%). Most were White (25/40, 63%), born in Canada (35/40, 88%), had an income between CAD $50,000-CAD $89,999 (19/40, 48%), had a high school or CEGEP (Collège d'enseignement général et professionnel) education level (23/40, 58%), and were not religious (25/40, 63%). During the study, approximately 68% (27/40) of the participants were in cancer treatment, 25% (10/40) in partial remission, and 8% (3/40) in remission, with an average remission time of 1 year (SD 1.73, range 0-3). The most common diagnoses were prostate cancer (7/40, 18%), testicular cancer (7/40, 18%), skin cancer (5/40, 13%), and bladder cancer (4/40, 10%). The average age of diagnosis was 36.1 (SD 5.49) years (range 26-45 years).

Information Seeking
Of the 40 participants, 27 (68%) indicated that no one had ever spoken to them about the impact of cancer on fertility and 34 (85%) had not received information on fertility preservation. Of those who did receive this information, 67% (4/6) did not get all the information they needed.

App Usage
On average, participants viewed 99% (18.80/19) of the app’s articles (SD 0.97, range 13-19), and specifically 99% of the medical articles (10.93/11, SD 0.27, range 10-11), and 98% of the psychosocial articles (4.88/5, SD 0.79, range 0-5). All participants viewed each of the 3 lifestyle articles. Participants gave a thumbs-up to an average of 7.85 (SD 7.94, range 0-19) articles and specifically to an average of 4.53 (SD 4.59, range 0-11) medical articles, 1.40 (SD 1.39, range 0-3) lifestyle articles, and 1.93 (SD 2.24, range 0-5) psychosocial articles. No article received a thumbs-down.

Fertility Knowledge and Preservation
Of the 40 participants, 34 (85%) said the app increased their fertility knowledge. Prior to the study, 95% (38/40) of men had not banked their sperm. During the study, 23% (9/40) of the participants made a decision about sperm banking: 1 decided to bank his sperm, 7 are planning to do so in the future, and 1 decided not to. Of the 8 who decided to bank their sperm, 6 (75%) said the app helped them make the decision.

Evaluation of the App’s Information
80% (32/40) of the participants viewed the app to satisfy their curiosity about a health matter (Table 1). Approximately 83% (33/40) found the information relevant, 95% (38/40) understood the information well, and 83% (33/40) learned something new. Of the 78% (31/40) who used the information for themselves, 90% (28/31) said the information helped them better understand...
a particular health issue. Of the 85% (34/40) who benefited (or expect to benefit) from the information, 79% (27/34) said the information helped them feel less worried about a health problem and 53% (18/34) said it facilitated their communication with health professionals.
Table 1. Data on the app’s information evaluated by the Information Assessment Method (IAM) (N=40).

<table>
<thead>
<tr>
<th>Information Assessment Method question</th>
<th>Values, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Why did you look on this app for information?</strong></td>
<td></td>
</tr>
<tr>
<td>To answer a question about my health</td>
<td>27 (68)</td>
</tr>
<tr>
<td>To answer a question about the health of someone else</td>
<td>12 (30)</td>
</tr>
<tr>
<td>To satisfy my curiosity about a health matter</td>
<td>32 (80)</td>
</tr>
<tr>
<td>To help me decide if I should see a health professional</td>
<td>13 (33)</td>
</tr>
<tr>
<td>To prepare myself before talking to a health professional</td>
<td>8 (20)</td>
</tr>
<tr>
<td>To follow up on the information given by a health professional</td>
<td>5 (13)</td>
</tr>
<tr>
<td>To find choices different from those given by a health professional</td>
<td>6 (12)</td>
</tr>
<tr>
<td><strong>Is the app’s information relevant?</strong></td>
<td></td>
</tr>
<tr>
<td>Very little relevant</td>
<td>3 (8)</td>
</tr>
<tr>
<td>Somewhat relevant</td>
<td>4 (10)</td>
</tr>
<tr>
<td>Relevant</td>
<td>19 (48)</td>
</tr>
<tr>
<td>Very relevant</td>
<td>14 (35)</td>
</tr>
<tr>
<td><strong>Did you understand the app’s information?</strong></td>
<td></td>
</tr>
<tr>
<td>Very poorly</td>
<td>0</td>
</tr>
<tr>
<td>Poorly</td>
<td>2 (5)</td>
</tr>
<tr>
<td>Well</td>
<td>23 (58)</td>
</tr>
<tr>
<td>Very well</td>
<td>15 (38)</td>
</tr>
<tr>
<td><strong>What do you think about the app’s information?</strong></td>
<td></td>
</tr>
<tr>
<td>Now I know something new</td>
<td>33 (83)</td>
</tr>
<tr>
<td>This information says I did or I am doing the right thing</td>
<td>21 (53)</td>
</tr>
<tr>
<td>Now I am reassured</td>
<td>22 (55)</td>
</tr>
<tr>
<td>I am reminded of something I already knew</td>
<td>10 (25)</td>
</tr>
<tr>
<td>Now I want to learn more about this health matter</td>
<td>16 (40)</td>
</tr>
<tr>
<td>I am not satisfied with this information</td>
<td>3 (8)</td>
</tr>
<tr>
<td>I think there is a problem with this information</td>
<td>0</td>
</tr>
<tr>
<td>I think this information could be harmful</td>
<td>0</td>
</tr>
<tr>
<td><strong>Did you or will you use the app’s information for yourself?</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>31 (78)</td>
</tr>
<tr>
<td>No, not for myself, but I used this information for someone else</td>
<td>6 (15)</td>
</tr>
<tr>
<td>No, I did not use this information for myself or for someone else</td>
<td>3 (8)</td>
</tr>
<tr>
<td><strong>If yes, how did you or will you use it?</strong></td>
<td></td>
</tr>
<tr>
<td>This information helped (will help) me to better understand a particular issue about my health.</td>
<td>28 (90)</td>
</tr>
<tr>
<td>I did not know what to do, and this information helped (will help) me make a decision about my health.</td>
<td>16 (52)</td>
</tr>
<tr>
<td>I knew what to do, and I used (will use) this information to be more certain about my health care.</td>
<td>12 (39)</td>
</tr>
<tr>
<td>I was doing (going to do) something concerning my health, and I used (will use) this information to do it differently</td>
<td>4 (13)</td>
</tr>
<tr>
<td>I used (will use) this information in a discussion with a health professional</td>
<td>2 (7)</td>
</tr>
<tr>
<td><strong>Did you (do you expect to) benefit from the app’s information?</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>34 (85)</td>
</tr>
<tr>
<td>Information Assessment Method question</td>
<td>Values, n (%)</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------------------------------------</td>
<td>---------------</td>
</tr>
<tr>
<td>No</td>
<td>6 (15)</td>
</tr>
<tr>
<td><strong>If yes, how did you (do you expect to) benefit?</strong></td>
<td></td>
</tr>
<tr>
<td>This information helped (helps) me feel less worried about a health problem</td>
<td>27 (79)</td>
</tr>
<tr>
<td>This information made (makes) me more satisfied with health care I receive</td>
<td>16 (40)</td>
</tr>
<tr>
<td>This information allowed (will allow) me to better communicate with a health professional</td>
<td>18 (53)</td>
</tr>
<tr>
<td>Because of this information, I was (will be) more involved in decisions about my health</td>
<td>14 (41)</td>
</tr>
<tr>
<td>This information helped (will help) me to better handle a problem with my health</td>
<td>9 (27)</td>
</tr>
<tr>
<td>This information helped (will help) me prevent a health problem or the worsening of a health problem</td>
<td>2 (6)</td>
</tr>
<tr>
<td>This information helped (will help) to improve my health</td>
<td>1 (3)</td>
</tr>
</tbody>
</table>

**Evaluation of the App’s Quality**

Participants rated the app’s quality highly (Table 2). The average quality rating was the highest for information, followed by functionality. The lowest rated subscale was engagement, though it was still rated 3.63/5.00 on average. Most men would recommend the app.
Table 2. App quality analysis using the user version of the Mobile App Rating Scale (uMARS) (N=40).

<table>
<thead>
<tr>
<th>uMARS item</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Objective quality subscale, mean (SD)</strong></td>
<td></td>
</tr>
<tr>
<td>Engagement (range 2.20-4.80)</td>
<td>3.63 (0.75)</td>
</tr>
<tr>
<td>Functionality (range 2.25-5.00)</td>
<td>4.06 (0.74)</td>
</tr>
<tr>
<td>Aesthetics (range 2.67-5.00)</td>
<td>3.84 (0.65)</td>
</tr>
<tr>
<td>Information (range 3.00-5.00)</td>
<td>4.14 (0.61)</td>
</tr>
<tr>
<td>Objective quality total score (range 3.02-4.84)</td>
<td>3.92 (0.62)</td>
</tr>
<tr>
<td>What is your overall (star) rating of the app? (range 2.00-5.00), mean (SD)</td>
<td>3.75 (0.54)</td>
</tr>
<tr>
<td><strong>App rating, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>1 (One of the worst apps I’ve used)</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>1 (3)</td>
</tr>
<tr>
<td>3 (Average)</td>
<td>9 (23)</td>
</tr>
<tr>
<td>4</td>
<td>29 (73)</td>
</tr>
<tr>
<td>5 (One of the best apps I’ve used)</td>
<td>1 (3)</td>
</tr>
<tr>
<td><strong>Would you recommend this app to people who might benefit from it? n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Not at all</td>
<td>0</td>
</tr>
<tr>
<td>Very few people</td>
<td>3 (8)</td>
</tr>
<tr>
<td>Maybe</td>
<td>12 (30)</td>
</tr>
<tr>
<td>Many people</td>
<td>17 (43)</td>
</tr>
<tr>
<td>Definitely</td>
<td>8 (20)</td>
</tr>
<tr>
<td><strong>How many times do you think you would use this app in the next 12 months? n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>3 (8)</td>
</tr>
<tr>
<td>1-2</td>
<td>7 (18)</td>
</tr>
<tr>
<td>3-10</td>
<td>20 (50)</td>
</tr>
<tr>
<td>10-50</td>
<td>9 (23)</td>
</tr>
<tr>
<td>&gt;50</td>
<td>1 (3)</td>
</tr>
<tr>
<td><strong>Would you pay for this app? n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>1 (Definitely not)</td>
<td>7 (18)</td>
</tr>
<tr>
<td>2</td>
<td>8 (20)</td>
</tr>
<tr>
<td>3</td>
<td>15 (38)</td>
</tr>
<tr>
<td>4</td>
<td>8 (20)</td>
</tr>
<tr>
<td>5 (Definitely yes)</td>
<td>2 (5)</td>
</tr>
<tr>
<td><strong>Subjective quality total score (range 2.00-4.75), mean (SD)</strong></td>
<td>3.30 (0.696)</td>
</tr>
</tbody>
</table>

Qualitative Feedback

*Engagement*

Participants liked the videos because they were “interesting” (participant #24) and “informative” (participant #14), and they suggested including more videos. Men would have also liked the ability to connect with others, for example, to obtain “…feedback from people who have banked sperm…” (participant #4).

*Functionality*

Participants liked the app’s functionality, finding it “extremely easy to use and navigate” (participant #8) and that it had a “very intuitive design” (participant #9). Apart from being “neatly organized” (participant #29), men appreciated that the app allowed the user to “read at [his] own pace” (participant #29).

*Information*

Participants found the app “very educational and very useful” (participant #36) and appreciated that it was a “one stop shop for fertility info” (participant #23), which helped prevent information overload: “The link to detailed information is
available on demand, it prevents from unnecessary information burden…” (participant #38). Participants liked that the information was “very comprehensive” (participant #26) and “…was applicable for different scenarios” (participant #39). However, some thought there was “too much information” (participant #22).

Participants appreciated that the app included “a lot of good links and honest information about [where to go for help]” (participant #19). They particularly liked the sperm banking resources, saying that the app “helped locate sperm banks near me” (participant #5). Participants wanted “more cost-based information” (participant #16), including the “average cost of each procedure” (participant #27) and “if [each procedure is] covered by health care…” (participant #19). Participants also wanted more in-depth information about the effects of cancer on fertility, for example, about “…certain types of cancers and how it affects each one differently” (participant #10).

Participants valued that the app had a “wealth of useful info from very trustworthy sources” (participant #17). They also thought the information “was very easy to read” (participant #11), and “not too complicated or jargon heavy” (participant #7). However, 1 man would have liked if the information was “less wordy” (participant #30).

The app’s information made participants feel “reassured” (participant #25): “This app really made me feel comfortable about how I was feeling about my diagnosis and how to go about my family’s future” (participant #2). Men also mentioned that the information “made [him] feel safe and confident to look at donating sperm and how to do it” (participant #36). Though some found the information “depressing at times” (participant #6), overall men appreciated the “very supportive tone” of the app (participant #31).

Discussion

Principal Findings

Overall, participants valued Infotility XY as a source of comprehensive, relevant, and accessible information. Most participants had not received information about the impact of cancer on fertility or fertility preservation prior to the study. Those who did receive this information did not receive all the information they needed. After app use, most men felt that their fertility knowledge increased and that the information promoted better communication with clinicians, indicating that an mHealth app may be useful in clinical practice to address the fertility-related informational needs of male patients with cancer. Providing patients with written information may help initiate fertility discussions with medical staff, leading to a referral to a reproductive specialist [40].

The fact that most participants had not received fertility information prior to the study might have contributed to the high engagement level. Men seemed to be motivated to learn about fertility and sperm banking. Most participants found the information relevant, credible, and easy-to-read. Given the lack of oncology educational materials suitable for patients with varying health literacy levels [41], our study highlights the possibility of presenting scientific content in simple terms that is accessible to diverse patient groups.

Furthermore, although almost all men had never banked sperm prior to the intervention, 8 decided to bank during the study. Owing to lack of information, patients with cancer may not fully participate in decision-making regarding their future fertility, which can prevent them from banking sperm [42]. Our results indicate that an mHealth app can empower patients to feel more in control of their reproductive health and be proactive in preserving fertility. Furthermore, the information helped participants feel comforted and reassured that they were making the right decisions about their fertility. Thus, our study demonstrates the potential of an mHealth app to help address the fertility concerns of patients with cancer by providing evidence-based information in a supportive manner. Additionally, based on participants’ feedback, future mHealth apps should present a significant proportion of content in video format to help users with different health literacy levels understand and retain the material. A chat option may also benefit patients by allowing them to seek social support [43].

Study Limitations and Strengths

This study has several limitations. First, there may have been selection bias since participants volunteered to enroll in the study. Thus, our sample may not fully reflect the broader population of male patients with cancer. As we remunerated participants in appreciation of their involvement in the research, they may have felt more inclined to complete the study or provide more positive feedback about the app, which may have introduced bias into our results. Second, since our sample was small and did not include Francophones, French content was not evaluated, potentially limiting the generalizability of results. Third, our sample did not include men aged 18-26 years. This subgroup might not be concerned with family building yet but should nevertheless be informed about the impact of cancer on fertility, and thus, it is an important group to include in future research.

Despite these limitations, our study has notable strengths. We used quantitative methods and content analysis, allowing for a nuanced understanding of participants’ experiences using the app. Our sample was socioeconomically diverse with respect to income and education. There was also variation in participants’ relationship and fatherhood statuses, suggesting generalizability of results to patients at different life stages. Recruiting people at the hospital bedside who were in active cancer treatment for a psychosocial research project may have been challenging, especially given that recruitment took place during the COVID-19 pandemic. Therefore, using a recruitment company who could recruit participants remotely allowed for us to successfully recruit our target sample size (N=40).

Conclusions

This usability study provides preliminary support that an mHealth app may be valuable in clinical practice by assisting in educating patients about the impact of cancer on fertility, thereby helping them make fertility preservation decisions and providing comfort. To our knowledge, this study is the first to evaluate an mHealth app providing male patients with cancer...
with evidence-based information about the impact of cancer on fertility and fertility preservation. We are in contact with professional organizations and patient advocacy groups to engage in knowledge transfer and to plan future studies. Randomized controlled trials with larger samples are warranted to assess the effectiveness of mHealth interventions in improving patients’ fertility knowledge and influencing their sperm banking decisions. Further efforts are needed to increase the availability of evidence-based mHealth apps for patients with cancer.

Acknowledgments
This study was funded by the Canadian Institutes of Health Research grant (MOP 138296).

Conflicts of Interest
None declared.

Multimedia Appendix 1
Categories and articles of the Infotility XY app.
[DOCX File , 16 KB - cancer_v8i2e33594_app1.docx ]

Multimedia Appendix 2
Design and features of the Infotility XY app.
[DOCX File , 1351 KB - cancer_v8i2e33594_app2.docx ]

Multimedia Appendix 3
Study procedures.
[PNG File, 66 KB - cancer_v8i2e33594_app3.png ]

Multimedia Appendix 4
Sociodemographic characteristics of our sample.
[DOCX File, 19 KB - cancer_v8i2e33594_app4.docx ]

References


27. McCann L, McMillan KA, Pugh G. Digital Interventions to Support Adolescents and Young Adults With Cancer: Systematic Review. JMIR Cancer 2019 Jul 31;5(2):e12071 [FREE Full text] [doi: 10.2196/jmir.65440] [Medline: 31368438]


Abbreviations
IAM: Information Assessment Method
mHealth: mobile health
uMARS: user version of the Mobile App Rating Scale
The Experiences of Patients With Adjuvant and Metastatic Melanoma Using Disease-Specific Social Media Communities in the Advent of Novel Therapies (Excite Project): Social Media Listening Study

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Abstract

Background: Immunotherapy and targeted therapy treatments are novel treatments available for patients with metastatic and adjuvant melanoma. As recently approved treatments, information surrounding the patients’ and caregivers’ experience with these therapies, perceptions of treatments, and the effect the treatments have on their day-to-day life are lacking. Such insights would be valuable for any future decision-making with regard to treatment options.

Objective: This study aims to use health-related social media data to understand the experience of patients with adjuvant and metastatic melanoma who are receiving either immunotherapy or targeted therapies. This study also included caregivers’ perspectives.

Methods: Publicly available social media forum posts by patients with self-reported adjuvant or metastatic melanoma (and their caregivers) between January 2014 to October 2019 were programmatically extracted, deidentified, cleaned, and analyzed using a combination of natural language processing and qualitative data analyses. This study identified spontaneously reported symptoms and their impacts, symptom duration, and the impact of treatment for both treatment groups.

Results: Overall, 1037 users (9023 posts) and 114 users (442 posts) were included in the metastatic group and adjuvant group, respectively. The most identified symptoms in both groups were fatigue, pain, or exanthema (identified in 5%-43% of patients dependent on the treatment group). Symptom impacts reported by both groups were physical impacts, impacts on family, and impacts on work. Positive treatment impacts were reported in both groups and covered the areas of work, social and family life, and general health and quality of life.

Conclusions: This study explored health-related social media to better understand the experience and perspectives of patients with melanoma receiving immunotherapy or targeted therapy treatments as well as the experience of their caregivers. This exploratory work uncovered the most discussed concerns among patients and caregivers on the forums including symptoms and their impacts, thus contributing to a deeper understanding of the patient/caregiver experience.

(JMIR Cancer 2022;8(2):e34073) doi:10.2196/34073

KEYWORDS
health-related social media; patient-centric; melanoma; adjuvant; metastatic; immunotherapy; targeted therapy; natural language processing; patient experience; cancer; cancer therapy; patient perspective; social media; patient experience; caregiver experience
Introduction

Background

Melanoma is a skin cancer that arises from uncontrolled proliferation of melanocytes. It is the fifth most common cancer in the United Kingdom, accounting for nearly 5% of all new cancer cases [1]. In the last 10 years, the incidence of melanoma has increased by more than 50% in the United Kingdom and is further projected to increase by 7% between 2014 and 2035 [2,3]. The worldwide incidence of melanoma has also steadily increased over the last decades, ranging between 4% and 6% in North America, Australia, and New Zealand [4].

Survival rates for melanoma depend on the disease stage; for example, 1-year net survival at stage I is similar to that of the general population; however, survival at stage IV is historically much lower [5], with the median reported at just 6 to 10 months [6]. Surgery, while effective for early stages of melanoma, is a less effective treatment option for patients with metastatic or late-stage disease [7]. Newer therapies such as immunotherapy treatments and targeted therapies (TTs) have shown good efficacy in the treatment of metastatic melanoma and have shifted the treatment paradigm [8,9]. TTs block the growth and spread of cancer by interfering with specific molecules that are involved in the growth, spread, and progression of cancer. These, however, are limited to patients who carry the BRAF V600E/K mutations, the prevalence of which in melanoma is estimated to be ~40% to 50% [10-12]. Dabrafenib plus trametinib combination therapy is routinely used as a TT and was licensed for use in metastatic melanoma with BRAF V600E or V600K mutations in August 2015 [13]. Dabrafenib with trametinib has also been recommended for adjuvant treatment of adults with resected stage III BRAF V600 mutation-positive melanoma [14]. The European Society for Medical Oncology 2019 guidelines for metastatic melanoma suggest that patients be treated with nivolumab, nivolumab/ipilimumab, or pembrolizumab in the first-line setting, and for patients with BRAF V600 mutation, vemurafenib/cobimetinib (not recommended by the National Institute for Health and Care Excellence in the United Kingdom). Dabrafenib/trametinib and encorafenib/binimetinib can also be considered [15].

While trial data on these therapies are shown to have survival benefit, there are few reports regarding patients’ experiences while undergoing treatment. Social media provides an opportunity to unveil a more personal and firsthand view on patients’ and caregivers’ perspectives and experiences with melanoma receiving treatment.

Health-related social media has substantial potential as a sizeable real-world data source due to available posts from thousands of patients and caregivers that would be hard to capture in traditional data sources. These experiences are reported in a setting with no researcher or medical professional present. Furthermore, in June 2018 the US Food and Drug Administration (FDA) encouraged the use of social media to understand the patient perspective [16]. Studies have also suggested that real-world data from social media can provide a better understanding of the patient’s behavior, quality of life, adverse events, and any episodes [17,18].

Objectives

The objective of this study was to use publicly available health-related social media data (ie, discussions on melanoma-specific patient online forums) to understand the experience of patients with adjuvant and metastatic melanoma receiving immunotherapy or TTs and their caregivers. The reported symptoms and their associated burden such as physical impacts, impacts on family, and impacts on quality of life were of specific interest in this study.

Methods

This was a retrospective analysis of existing publicly available discussions posted from January 2014 to October 2019 (study period) in social media forums for patients with self-reported adjuvant or metastatic melanoma and their caregivers.

Data Source

To determine the feasibility of addressing the study objectives and to select the forums for inclusion in the study, a feasibility evaluation was conducted via a manual search and inspection of existing social media forums (finalized in May 2019). The search strategy focused on identifying melanoma-specific patient forums using relevant search terms such as “melanoma patient forums” and “melanoma discussion boards.” Generic social media forums (eg, Facebook and Twitter) were not considered due to the high level of noise (ie, irrelevant material).

Searches for social media forums were conducted using the Google Search engine for both the United Kingdom and the United States to get a complete picture of the available melanoma forum landscape. The first five pages of results were screened by title, and relevant forums were summarized. Disease-specific social media forums were selected based on their relevance to disease experience, user profile (melanoma patients or caregivers), being currently active (ie, multiple posts in recent months to accurately reflect the most up-to-date discussions among parents/caregivers), posts in the English language, and material being freely available for anyone to access and read, with no registration required. No geographical restrictions were applied when selecting the social media forums.

Based on these criteria, forums from the following social media forums were included: Melanoma International Foundation, Melanoma Research Foundation, MacMillan Cancer Support, Cancer Compass, and Cancer Survivors Network.

Data Preprocessing and Subsetting

Posts in the public domain on the included forums were programmatically extracted using validated algorithms in the R Programming Language. Upon extraction, data were deidentified by removal of identifiable personal information (ie, name, post or zip code, place names, email addresses, phone numbers, social security numbers, and conversion of raw usernames to unique identifiers). Data were also processed to correct for misspellings, remove non–Unicode Transformation Format-8 text, remove duplicate posts, and standardize all drug names to generic names.
Data were restricted to posts of users who began posting on or after the start of the study period and who mentioned at least one of the following treatments in their posts: binimetinib, dabrafenib, encorafenib, ipilimumab, nivolumab, pembrolizumab, or trametinib. Machine learning (ML) methods were used to predict whether posts contained actual treatment experiences as opposed to noise. Supervised ML algorithms were trained and tested on a random sample of over 1000 sentences from the collected data, which were manually labelled as “treatment experience related” or “not treatment experience related” to distinguish posts of interest and those containing noise. The best performing model was selected and applied to the data for subsequent analyses so that only users whose posts were predicted to contain actual treatment experiences were retained.

Natural language processing (NLP) methods (eg, inspection of clusters and n-grams) were used to stratify users into mutually exclusive adjuvant or metastatic groups based on lexical terms within posts. Terms derived from users’ posts were combined with those determined a priori (ie, “I had surgery” or “received adjuvant”) to generate the final list of terms for the population identification. The adjuvant group contained users with a mention of having surgery and no indication of metastatic disease, and the metastatic group consisted of users with terms relating to metastatic disease or treatments indicated at the metastatic setting. Users who could not be assigned to one of the groups were excluded from analyses. NLP methods using mentions of treatments in posts were used to further classify users into one of the following treatment subgroups:

- **TT**: dabrafenib/trametinib, encorafenib/binimetinib (metastatic group only)
- **Immunotherapy**: Pembrolizumab, ipilimumab/nivolumab (metastatic group only), or nivolumab

Treatment subgroups were not mutually exclusive, and posts were restricted to those containing the respective treatment to ensure the specificity of the data analyzed.

**Data Analysis**

**Symptom Identification**

Symptoms were captured using the Apache Clinical Text Analysis Knowledge Extraction System (cTAKES) [19], a NLP tool that maps concepts from the Unified Medical Language System to clinical terms mentioned within posts. cTAKES was supplemented with custom lexicons to capture lay terms used by patients and caregivers (ie, nonclinical events). The custom lexicons were initially compiled by using the FDA Adverse Event Reporting System reports and further expanded upon inspection of the most frequently occurring lay terms used by users.

The output was manually inspected, and revisions were made where necessary to remove clinical terms incorrectly captured as symptoms a patient experienced. Rates of symptom occurrence were calculated as users with a co-occurrence of a symptom mention and treatment in the same post over the number of users with a mention of the treatment.

**Qualitative Data Analyses**

Manual qualitative data analysis (QDA) was performed to capture the impacts of symptoms and treatment discussed in the forum. Due to the large volume of posts, random samples of users were generated from the overall population included. Full posting histories from those users were qualitatively reviewed. This exercise was conducted separately for each treatment group. A random sampling strategy was used to include a holistic view of the experience of forum users. Qualitative coding was conducted in ATLAS.ti (version 8.4.4) by two researchers following thematic analysis principles, and codes were assigned to data-driven themes, categories, and subcategories [20,21]. The posts were coded until saturation was reached. Saturation was defined as the point at which no new categories of codes were generated by reviewing additional data. Codes and themes were reviewed by a researcher who did not code the data.

**Ethical Conduct**

At the time of conducting the study, no strict guidelines on the appropriate use of health-related social media data had been developed. However, this study followed the recently published ethics framework from the University of Sheffield [22]. Only public open-access forums were used, where contents were openly visible and there was no requirement to register or to create a profile to view content. Terms and conditions of included forums were carefully reviewed to ensure compliance. To protect user privacy, no quotations are provided verbatim, and the original post cannot be traced in search engines using the text presented.

**Results**

**Study Population**

A total of 1037 users (9023 posts) and 114 users (442 posts) were included in the metastatic group and adjuvant group, respectively. A breakdown by treatment subgroup for each group is provided in Tables 1 and 2. As expected, given the timeline of treatment approvals, the largest treatment subgroups were nivolumab and pembrolizumab, and the smallest was encorafenib/binimetinib.
Table 1. Users included in the metastatic group by treatment group and analyses.

<table>
<thead>
<tr>
<th>Treatment subgroup</th>
<th>Symptom identification</th>
<th>Qualitative data analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Users, n</td>
<td>Posts, n</td>
</tr>
<tr>
<td>Encorafenib/binimetinib</td>
<td>20</td>
<td>36</td>
</tr>
<tr>
<td>Dabrafenib/trametinib</td>
<td>215</td>
<td>659</td>
</tr>
<tr>
<td>Ipilimumab/nivolumab</td>
<td>499</td>
<td>2723</td>
</tr>
<tr>
<td>Nivolumab</td>
<td>443</td>
<td>3751</td>
</tr>
<tr>
<td>Pembrolizumab</td>
<td>451</td>
<td>3171</td>
</tr>
</tbody>
</table>

The treatment groups are not mutually exclusive.

Table 2. Users included in the adjuvant group by treatment group and analyses.

<table>
<thead>
<tr>
<th>Treatment subgroup</th>
<th>Symptom identification</th>
<th>Qualitative data analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Users, n</td>
<td>Posts, n</td>
</tr>
<tr>
<td>Dabrafenib/trametinib</td>
<td>18</td>
<td>41</td>
</tr>
<tr>
<td>Nivolumab</td>
<td>63</td>
<td>263</td>
</tr>
<tr>
<td>Pembrolizumab</td>
<td>45</td>
<td>209</td>
</tr>
</tbody>
</table>

The treatment groups are not mutually exclusive.

**Identified Symptoms**

In both groups, fatigue, pain, or exanthema were the most mentioned symptoms by patients with metastatic melanoma or their caregivers in the forums (Figures 1 and 2).

In the metastatic group, fatigue was the most mentioned symptom for patients taking nivolumab (189/443, 42.7%), ipilimumab/nivolumab (163/499, 32.7%), and dabrafenib/trametinib (46/215, 21.4%), and pain was the most common symptom in pembrolizumab (144/451, 31.9%) and encorafenib/binimetinib (6/20, 30%). In the adjuvant group, fatigue and pain were the most common symptoms experienced by users in the nivolumab (n=18, 29%, and n=9, 14%, of 63 users, respectively) and pembrolizumab (n=7, 16%, and n=11, 24%, of 45 users, respectively) treatment groups, and chills and fever were the most common symptoms experienced in the dabrafenib/trametinib (n=5, 28%, and 4, 22%, of 18 users, respectively) treatment group.
**Figure 1.** Heat map of the most mentioned symptoms, metastatic group, by treatment group.

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Nivolumab</th>
<th>Pembrolizumab</th>
<th>Ipilimumab/Nivolumab</th>
<th>Dabrafenib/Trametinib</th>
<th>Encorafenib/Binimetinib</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fatigue</td>
<td>42.7%</td>
<td>30.2%</td>
<td>32.7%</td>
<td>21.4%</td>
<td>5.0%</td>
</tr>
<tr>
<td>Pain</td>
<td>28.9%</td>
<td>31.9%</td>
<td>26.3%</td>
<td>20.5%</td>
<td>30.0%</td>
</tr>
<tr>
<td>Exanthema</td>
<td>23.3%</td>
<td>14.9%</td>
<td>19.8%</td>
<td>12.6%</td>
<td>10.0%</td>
</tr>
<tr>
<td>Swelling</td>
<td>14.5%</td>
<td>12.6%</td>
<td>10.8%</td>
<td>14.0%</td>
<td>10.0%</td>
</tr>
<tr>
<td>Fever</td>
<td>12.0%</td>
<td>9.8%</td>
<td>11.6%</td>
<td>20.9%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Nausea</td>
<td>14.9%</td>
<td>9.1%</td>
<td>12.8%</td>
<td>9.8%</td>
<td>10.0%</td>
</tr>
<tr>
<td>Tired</td>
<td>14.7%</td>
<td>10.0%</td>
<td>10.8%</td>
<td>6.1%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Spots on skin</td>
<td>12.6%</td>
<td>11.5%</td>
<td>7.6%</td>
<td>7.4%</td>
<td>5.0%</td>
</tr>
<tr>
<td>Pruritus</td>
<td>15.1%</td>
<td>8.2%</td>
<td>11.6%</td>
<td>2.8%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>13.8%</td>
<td>6.2%</td>
<td>13.2%</td>
<td>2.8%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Headache</td>
<td>12.4%</td>
<td>7.8%</td>
<td>10.2%</td>
<td>11.2%</td>
<td>10.0%</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>11.7%</td>
<td>10.4%</td>
<td>7.8%</td>
<td>6.5%</td>
<td>5.0%</td>
</tr>
<tr>
<td>Colitis</td>
<td>12.2%</td>
<td>8.9%</td>
<td>12.0%</td>
<td>0.9%</td>
<td>5.0%</td>
</tr>
<tr>
<td>Stomach diseases</td>
<td>12.9%</td>
<td>8.0%</td>
<td>8.6%</td>
<td>3.3%</td>
<td>5.0%</td>
</tr>
<tr>
<td>Weakness</td>
<td>7.7%</td>
<td>7.5%</td>
<td>5.6%</td>
<td>6.1%</td>
<td>5.0%</td>
</tr>
<tr>
<td>Ache</td>
<td>8.1%</td>
<td>7.8%</td>
<td>6.8%</td>
<td>5.6%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Bleeding</td>
<td>7.2%</td>
<td>5.5%</td>
<td>5.8%</td>
<td>7.0%</td>
<td>5.0%</td>
</tr>
<tr>
<td>Chills</td>
<td>5.9%</td>
<td>5.8%</td>
<td>5.4%</td>
<td>11.2%</td>
<td>5.0%</td>
</tr>
<tr>
<td>Malaise</td>
<td>7.9%</td>
<td>5.3%</td>
<td>5.8%</td>
<td>5.6%</td>
<td>5.0%</td>
</tr>
<tr>
<td>Stress</td>
<td>8.4%</td>
<td>7.1%</td>
<td>5.6%</td>
<td>2.8%</td>
<td>5.0%</td>
</tr>
<tr>
<td>Seizures</td>
<td>6.3%</td>
<td>5.8%</td>
<td>4.0%</td>
<td>6.5%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Fear</td>
<td>7.2%</td>
<td>6.0%</td>
<td>5.2%</td>
<td>4.7%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Inflammation</td>
<td>6.1%</td>
<td>7.1%</td>
<td>4.8%</td>
<td>3.7%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Influenza</td>
<td>7.2%</td>
<td>4.9%</td>
<td>4.8%</td>
<td>4.2%</td>
<td>5.0%</td>
</tr>
<tr>
<td>Vitiligo</td>
<td>9.0%</td>
<td>5.8%</td>
<td>5.8%</td>
<td>0.9%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Anxiety</td>
<td>7.2%</td>
<td>4.4%</td>
<td>5.0%</td>
<td>3.3%</td>
<td>5.0%</td>
</tr>
<tr>
<td>Coughing</td>
<td>6.3%</td>
<td>5.1%</td>
<td>4.2%</td>
<td>5.1%</td>
<td>0.0%</td>
</tr>
</tbody>
</table>
Symptom Impacts

Metastatic Group

Symptom impacts varied by treatment subgroup; however, physical and psychological effects were the most common negative impacts reported. Physical impacts included mobility issues, being unable to drive, and overall reduced activity. Psychological impacts included feelings of anxiety, depression, frustration, worry, and loss of dignity. Negative impact on social life was reported among the dabrafenib/trametinib and nivolumab treatment groups, and disturbed sleep was reported among the binimetinib/encorafenib, nivolumab, and ipilimumab/nivolumab treatment groups; however, they were reported less frequently. Patients in the immunotherapy and TT groups reported impacts on their physical ability, including their day-to-day tasks and ability to perform activities requiring mobility:

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Nivolumab</th>
<th>Pembrolizumab</th>
<th>Dabrafenib/Trametinib</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fatigue</td>
<td>28.6%</td>
<td>15.6%</td>
<td>11.1%</td>
</tr>
<tr>
<td>Pain</td>
<td>14.3%</td>
<td>24.4%</td>
<td>16.7%</td>
</tr>
<tr>
<td>Exanthema</td>
<td>11.1%</td>
<td>11.1%</td>
<td>5.6%</td>
</tr>
<tr>
<td>Headache</td>
<td>9.5%</td>
<td>6.7%</td>
<td>11.1%</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>7.9%</td>
<td>4.4%</td>
<td>11.1%</td>
</tr>
<tr>
<td>Pruritus</td>
<td>9.5%</td>
<td>8.9%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Tired</td>
<td>12.7%</td>
<td>6.7%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Chills</td>
<td>3.2%</td>
<td>2.2%</td>
<td>27.8%</td>
</tr>
<tr>
<td>Swelling</td>
<td>9.5%</td>
<td>6.7%</td>
<td>5.6%</td>
</tr>
<tr>
<td>Anxiety</td>
<td>6.4%</td>
<td>11.1%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Spots on skin</td>
<td>7.9%</td>
<td>8.9%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Ache</td>
<td>4.8%</td>
<td>11.1%</td>
<td>5.6%</td>
</tr>
<tr>
<td>Colitis</td>
<td>3.2%</td>
<td>11.1%</td>
<td>5.6%</td>
</tr>
<tr>
<td>Fever</td>
<td>3.2%</td>
<td>2.2%</td>
<td>22.2%</td>
</tr>
<tr>
<td>Lymphedema</td>
<td>11.1%</td>
<td>2.2%</td>
<td>5.6%</td>
</tr>
<tr>
<td>Stomach diseases</td>
<td>9.5%</td>
<td>6.7%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Common cold</td>
<td>4.8%</td>
<td>6.7%</td>
<td>5.6%</td>
</tr>
<tr>
<td>Nausea</td>
<td>4.8%</td>
<td>2.2%</td>
<td>5.6%</td>
</tr>
<tr>
<td>Weakness</td>
<td>9.5%</td>
<td>0.0%</td>
<td>5.6%</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>9.5%</td>
<td>2.2%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Malaise</td>
<td>7.9%</td>
<td>8.9%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Muscle cramp</td>
<td>4.8%</td>
<td>2.2%</td>
<td>5.6%</td>
</tr>
<tr>
<td>Ulcer</td>
<td>3.2%</td>
<td>4.4%</td>
<td>5.6%</td>
</tr>
<tr>
<td>Myalgia</td>
<td>3.2%</td>
<td>6.7%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Dizziness</td>
<td>3.2%</td>
<td>2.2%</td>
<td>5.6%</td>
</tr>
</tbody>
</table>

His quality of life has extremely deteriorated and he is now unable to perform physical activities [Caregiver]

As treatment continues, I have developed panic attacks [Patient]

Adjuvant Group

Findings for the adjuvant group were limited due to the small sample size; however, adverse impacts on family life (“She is too weak to enjoy spending time with her” [caregiver]) and physical impacts (“heel pain wasn’t bad at the start, but now I sometimes feel I can barely walk” [patient]) were identified. In addition, reduction of perceived quality of life (“the fatigue is really bothering the husband” [caregiver]) and impact on work (“I changed my work schedule as I was worried about side effects” [patient]) was reported [Table 3].
Table 3. Impacts of symptoms by group.

<table>
<thead>
<tr>
<th>Impacts of Treatment</th>
<th>Metastatic group</th>
<th>Adjuvant group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical impacts</td>
<td>• Bedridden</td>
<td>• Inability to walk</td>
</tr>
<tr>
<td></td>
<td>• Less active</td>
<td>• Taking a break from running</td>
</tr>
<tr>
<td></td>
<td>• Difficulty doing physical activity</td>
<td>• Unable to exercise as before</td>
</tr>
<tr>
<td></td>
<td>• Difficulty exercising</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Difficulty getting out of bed</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Difficulty moving</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Difficulty walking</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• General impact on quality of life</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Unable to drive</td>
<td></td>
</tr>
<tr>
<td>Psychological impacts</td>
<td>• Anxiety</td>
<td>• Annoyance</td>
</tr>
<tr>
<td></td>
<td>• Concern</td>
<td>• Frustration</td>
</tr>
<tr>
<td></td>
<td>• Conflicted</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Depression</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Frustration</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Loss of dignity</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Nervous</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Panic attack</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Worried</td>
<td></td>
</tr>
<tr>
<td>Impacts on sleep</td>
<td>• Difficulty sleeping</td>
<td>• NR&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>• Inability to stay awake for long</td>
<td></td>
</tr>
<tr>
<td>Impacts on social life</td>
<td>• Needing to plan social outings</td>
<td>• NR</td>
</tr>
<tr>
<td></td>
<td>• Stopped socializing</td>
<td></td>
</tr>
<tr>
<td>Family/caregiver burden</td>
<td>• Feeling angry with patient</td>
<td>• Inability to enjoy time with grandchildren</td>
</tr>
<tr>
<td></td>
<td>• Emotional impact to family</td>
<td></td>
</tr>
<tr>
<td>Impacts on work</td>
<td>• Interruption to work</td>
<td>• Changing work schedule</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Taking time off from work</td>
</tr>
</tbody>
</table>

<sup>a</sup>NR: not reported.

Symptom Duration

**Metastatic Group**

Symptoms lasting less than a week appeared most common among patients receiving dabrafenib/trametinib, and longer-term sequelae appeared most common among patients receiving ipilimumab/nivolumab. Short-term symptoms (i.e., those lasting up to 1 week) included fever, headache, fatigue, and soreness. Longer-term ones (i.e., lasting longer than 1 week) included liver issues, nausea, diarrhea, and fatigue.

**Adjuvant Group**

More than one-third of patients receiving dabrafenib/trametinib or nivolumab mentioned symptom duration. Similar to the metastatic group, short-term symptoms appeared more frequently in patients receiving dabrafenib and trametinib, while longer-term issues were most commonly mentioned by patients receiving nivolumab. Examples of longer-term symptoms included liver problems, headache, colitis, and joint issues.

Impacts of Treatment

**Metastatic Group**

In the metastatic group, the positive impacts mentioned by forum users included effects on their general health and quality of life, physicality, work, and social life or family. Patients mentioned feeling better and happier, and being able to continue life as normal because of their treatment. Positive physical effects included gaining weight, looking better, being able to exercise, and feeling stronger. Examples of the positive influences for TTs include:

*I can work and complete tasks as usual [patient]*

*This is the first time in months that I have felt like myself [patient]*

For immunotherapy:

*As time progresses, he is getting stronger and gaining some weight. He is also doing some physical activity everyday [caregiver]*

*I am able to spend time with friends and family as I now believe I have several more years to live [patient]*

Negative effects of treatments on social/family aspects and work included not being able to travel with family, partners wanting time off from job, and the patient having to work less.

**Adjuvant Group**

In the adjuvant group, forum users had discussions on improvements in general health and quality of life, work, and social/family. Patients reported they felt better, worked as usual, and spent more time with family. A user treated with TT expressed their personal family experience:
my grandson will be born soon. This treatment has made it possible for me to appreciate moments that I didn’t think I would see.

In addition, a user who underwent immunotherapy reported the positive impact going to work had on their well-being: “I was still able to work, which made things seem normal.” Figure 3 illustrates the positive impacts of treatment in both groups.

**Figure 3.** Positive impacts of treatment. QoL: quality of life.

### Discussion

#### Principal Findings

This exploratory work uncovered the most common concerns discussed on social media forums among patients with adjuvant and metastatic melanoma receiving immunotherapy or TTs and their caregivers. Symptoms and related physical impacts (e.g., inability to perform usual activities) were the most frequently reported issues in both cohorts, while psychological impacts (e.g., anxiety) were also discussed among metastatic patients. Where discussed, treatment preferences were primarily focused on reduced risk of adverse events.

To the best of our knowledge, no published research has investigated experiences of patients with adjuvant or metastatic melanoma with immunotherapy or TT using health-related social media data.

Among the metastatic group, the most common symptom reported was fatigue in all treatment groups except for pembrolizumab and encorafenib/binimetinib, where pain was most common. Treatment included perceived improvements in general health, quality of life, physicality, ability to work, and patient’s social and family life. In the adjuvant group, comments reflected enhancements of general health, quality of life, work, and social/family interactions.

This study provides a unique perspective on patients’ experiences receiving immunotherapy or TTs. It is crucial to consider patient perspectives to ensure that real-life experiences and expectations are understood, especially as new therapies for melanoma become available. Social media not only allows patients to share their story but also provides a platform for patients and caregivers to seek support from others with similar experiences. This creates a sense of community that allows users to share positive experiences and burdens. Symptom impacts varied by treatment subgroups; however, the negative discussions generally featured work, family, and the physical aspects. The patients’ and caregivers’ point of view is not often incorporated in research but does play a large role in patients’ and their families’ well-being.

#### Comparison to Prior Literature and Interpretation

A study that examined the extent to which social media health data could provide insight for relative effectiveness assessment concluded that, within oncology, these real-world data sources can be used to assess adverse events and evaluate quality of life [18].

To the best of the authors’ knowledge, this is the first published study examining the impacts of immunotherapy and TT among patients with melanoma and their caregivers using social media forums. The most commonly reported symptoms by patients with metastatic melanoma self-reporting taking pembrolizumab were pain, fatigue, and exanthema, which aligns with some of the common side effects previously reported [23,24]. Fatigue and skin problems are some of the common side effects of Nivolumab, which aligns with the first and third most common symptoms identified in this study, respectively [25]. The same common side effects were identified with ipilimumab-nivolumab again mapping to those symptoms identified in this study [26]. Fatigue, nausea, diarrhea, vomiting, and abdominal pain have been previously identified as common side effects of binimetinib in combination with encorafenib [27,28]; however, our study identified pain as the most mentioned symptom by patients with metastatic melanoma who self-reported receiving this treatment.
Strengths and Limitations

Patients’ and caregivers’ firsthand experiences are potentially likely to reflect the true opinions of the users as they are provided spontaneously. Comments are possibly less likely to be impacted by information bias than traditional interview studies with no research or medical professionals present. This exploratory analysis provides insights as to which topics were most frequently discussed by patients with adjuvant or metastatic melanoma using forums receiving immunotherapy or TT. These are likely to reflect those of most importance to patients. The use of QDA allowed for further insight into factors of importance to patients and their caregivers, including those that may not have been considered at study conception.

The study was not free of limitations. First, due to the nature of the data and to respect patient privacy, the researchers were restricted by the amount of detail provided by users. Although all relevant detail on patients’ and caregivers’ experiences were coded during the qualitative review of posts, researchers could not ask for clarification in instances where users did not provide sufficient information; therefore, some detail may have been missed for a small number of users. Second, as the study was primarily exploratory in nature, all potentially relevant data were included in the analysis resulting in varied sample sizes across treatment groups. Thus, results from the QDA should be interpreted with caution as no statistical tests were conducted to assess differences between treatment groups. Findings were limited in the adjuvant group due to the small sample size, which is likely a result of recent approvals for the treatments of interest at this setting at the time of conducting the study. If repeated for a longer time after approval, a larger sample size could be achieved. Third, patients posting on forums cannot be considered representative of the entire melanoma patient population. Due to a lack of consistent reporting of patient attributes (eg, clinical and demographical characteristics), representativeness is challenging to assess in social media forums; however, this study was exploratory in nature with no comparative analyses. To capture a broad patient population and mitigate bias from nonrepresentativeness, multiple social media forums were included with no geographical restrictions. Finally, biases in health-related social media studies are not well understood, for example, the extent of information bias present in users’ posts. However, no study can be considered free of bias and such bias is not a limitation unique to this exploratory study.

Conclusions

This exploratory study uncovered the most discussed symptoms and their associated impacts among patients and caregivers using health-related social media forums. This suggests that these are the topics of utmost importance to patients and caregivers influencing their lives. Future research should aim to validate and investigate less frequently discussed topics and could include patient questionnaires, interviews, or focus groups. Such studies could be used to assess how important these topics are to patients and caregivers, and to validate the findings of this study.

Acknowledgments

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Authors' Contributions

All authors provided substantial contributions to the conception and design of the work, and interpretation of results and were involved in the review and approval of this manuscript for publication.

Conflicts of Interest

GF is an employee of University Hospitals of Leicester National Health Service Trust. AB, EM, and SH are employees of Evidera (London, UK), who were paid consultants to Novartis in connection with the development of this manuscript. HT, AN, and MS are employees of Novartis (London, UK).

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**Abbreviations**

**cTAKES**: Clinical Text Analysis Knowledge Extraction System
Communicating Treatment-Related Symptoms Using Passively Collected Data and Satisfaction/Loyalty Ratings: Exploratory Study

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Abstract

Background: Electronic patient-reported outcomes’ real time communication of treatment-related symptoms is increasingly associated with better outcomes including longer survival and less health care resource use, but the primary method of collecting this information, static questionnaires, has not evolved.

Objective: The aim of this paper is to describe the use of Noona’s three methods of communicating treatment-related symptoms, which are as follows: (1) Noona symptom questionnaires (NSQ), which incorporate branching logic; (2) a diary; and (3) secure messaging, the last two of which have NSQ reporting functionality. It also aims to explore, using multivariable analyses, whether patients find value using these features.

Methods: Noona users (N=1081) who have an active account for more than 30 days, who responded to the satisfaction/loyalty item, and who were undergoing active cancer treatment (systemic or radiotherapy) in the United States were included in this study. All study data were collected via software embedded within Noona code. This includes metadata, patient activities (measured in clicks), and responses to a satisfaction/loyalty question (“How likely are you to recommend Noona to another patient”) displayed on the Noona home page.

Results: Noona users expressed a high degree of satisfaction/loyalty when asked to rate how likely they would recommend Noona to another patient. Multivariable analyses indicate small but significant effects for some of the analyses. Use of NSQs were significantly related to satisfaction/loyalty, users of NSQs had significantly higher satisfaction/loyalty than those who did not use any, and secure communication use was significantly higher for those who rated the app highly compared to those who did not. These relationships will likely be further explicated with the use of satisfaction/loyalty questions that focus specifically on feature use.

Conclusions: Noona is well liked by respondents, and exploratory multivariable analyses demonstrate the potential for using passively and minimally invasive data to demonstrate value.

(Keywords: electronic patient-reported outcomes; ePRO; cancer; symptoms; health-related quality of life)

Introduction

For over 30 years, the systematic collection of patients’ experiences via electronic administration of static measures have been used to facilitate cancer treatment planning [1]. The current generation of devices are powerful, portable, internet accessible, and increasingly loaded with sophisticated capabilities and features. This has enabled real time patient-clinical care team communication of treatment-related symptoms. However, software interfaces have been described as “rudimentary” [2], and the primary method of collecting patient-reported data has been relatively static, which may impede patient engagement and long-term use.
Generally, research testing the electronic patient-reported outcomes (ePROs) impact can be divided into three groups. The first, randomized controlled trials, have consistently demonstrated the benefits of using this software. Basch et al [3] found those who used a web-based application and rated their treatment experiences using a 12-item questionnaire incorporating Common Terminology Criteria for Adverse Events (CTCAE) items remained on chemotherapy longer, reported significantly slower declines in health-related quality of life, used emergency department services less, and survived longer than those who used standard care. Two other studies have combined patient-reported treatment information with algorithms to improve functionality and better optimize clinical care. The first, a trial focusing on patients with lung cancer, found those in the treatment arm, which involved patients reporting symptoms via a weekly questionnaire, informed the computed tomography scan schedule. As a result, they lived longer and required fewer imaging tests compared to those receiving standard care (reporting symptoms to the family doctor or oncologist and attending regularly scheduled imaging appointments) [4]. The second study found that those who use an app that combines online symptom self-reporting with a clinical algorithm to generate automated advice to facilitate symptom self-management reported less decrement in physical well-being at 12 weeks and improved health-related quality of life in study participants at 18 weeks compared to standard care [5].

Real-world studies have demonstrated that an ePRO can facilitate reporting of common treatment symptoms (eg, tiredness, fatigue, and anxiety) compared with standard medical records [6], and a separate study found population level benefit in patients with cancer, including improved 1-, 3-, and 5-year survival [7]. A third group, feasibility studies, has focused on testing ePRO solutions in various patient populations in which little or no ePRO evidence has been generated including radiotherapy [8], immunotherapy [9,10], surgery [11,12], and palliative care [13].

There has been an increasing recognition that ePRO-associated benefits can only be accrued through durable patient engagement [14] and that current methods can be improved [15]. However, more interactive, engaging, and personalized designs can only be achieved by understanding user behavior patterns [14]. Varian Medical System’s ePRO platform, Noona, is a United States Food and Drug Administration Class 1 device. It is a multifunction software that includes three modalities that can be used to communicate and track treatment-related symptoms via CTCAE-based [3] Noona symptom questionnaires (NSQ) to the clinical care team in real time. They are (1) questionnaires administered at regular intervals, which are also available for ad hoc reporting; (2) a diary; and (3) secure messaging, the last two of which incorporate NSQ tracking and reporting functionality. Between November 2020 and January 2021, Noona implemented a code within its software that collects objective app use information and assesses satisfaction and loyalty using a single, minimally invasive question, “How likely are you to recommend Noona to another patient.” The patients responded using an 11-point visual analog scale [16]. Variations of this question and the associated statistic, Net Promoter Score [16], are used by two-thirds of Fortune 1000 companies to measure customer satisfaction and loyalty [17]; they have also been used within the field of medicine to gauge the quality of various medical services [18-20], implementation of a telehealth system [21], and evaluation of software developed for patients with cancer [22,23] and cancer survivors [24].

Previous research has demonstrated the efficacy of using electronic devices to collect passive exercise data used by patients with cancer generally [25-27] and that such information is associated with self-reported treatment symptoms [28]. This information can be easily collected without inconveniencing patients or clinical staff; however, it is not clear whether such data, along with the minimally invasive collection of satisfaction/loyalty ratings, can be used to demonstrate ePRO value. Thus, the goal of this real-world study is to report how Noona users employ the three Noona communication and tracking features (scheduled and ad hoc CTCAE-based NSQs; a diary with NSQ tracking functionality; and secure messaging). This study also aims to rate app satisfaction/loyalty and explore, using multivariable analyses, whether patients find value using these features. Our hypotheses are that, regardless of app features or construction, users should value the most important component of communication/tracking of treatment-related symptoms. Thus, the first set of analyses will explore the association between communication and tracking features and satisfaction/loyalty. Next, analyses will test whether those who use these features report greater satisfaction/loyalty than those who do not. The last set will determine whether there is a difference between those who rate the app highly and those who do not, regarding using the three communication and tracking features.

Methods
Noona, Participants, and Procedure
Noona is an ePRO that has been installed in over 100 oncology clinics across 10 countries. It is currently available in 8 languages and has over 100,000 active users. Clinical staff at each site onboard patients and assist them with creating a patient profile. The participants (n=1081) in this study were experienced Noona users, which is defined as users who have an active account for more than 30 days, who responded to the satisfaction/loyalty item, and who were undergoing active cancer treatment (systemic or radiotherapy) in the United States between January 2021 (the first-day objective data and patient satisfaction/loyalty were both collected) and March 17, 2021 (when the data were downloaded and analyzed).

All study data (metadata, patient activities measured in clicks, and satisfaction/loyalty scores) were collected via software embedded within Noona code. Study information was passively collected. The satisfaction/loyalty question is administered randomly every 3 months. It pops up on the Noona home page, and users can either respond to it or opt out.

Ethical Considerations
Data were used for quality improvement purposes and thus not submitted for IRB approval; however, Noona clearly communicates patient rights when they sign on to use the app.
Specifically, when creating an account, they have the option of authorizing data sharing and are informed of those rights. This includes a statement that Noona collects information for several purposes including data analysis for resource optimization, which is the case for this study. Additionally, Noona ensures that the data used for any analyses will be deidentified. Further, patients are told that if they choose not to share their data, it will not affect the care received from the health care provider, eligibility for benefits, or payment for health care, and that they will still have access to the app. Patients are informed that they can revoke this authorization at any time prior to expiration by contacting Noona (info@Noona.com). Finally, users are informed that this authorization ends upon deletion of the Noona account. When this occurs, any data collected by Noona will remain with Noona, but the health care provider will not further disclose any health information concerning the patient to Noona.

Measures

Days Active
Noona reports the number of days since the patient activated an account. It is a continuous variable and is used as a covariate in this study.

Time on the App
Noona measures use in the number of total minutes the app was used since activation. It is a continuous variable and is used as a covariate in this study.

Age
Approximate patient age was calculated by subtracting the current year (2021) from the patient’s birth year, which was extracted as metadata.

Device
Noona captures the operating system of the device that the patients last used to log into the system (eg, Windows or iOS). This information was used to create a dichotomous item representing the device type—computer, smartphone, or tablet. This variable was used as a covariate in this study.

Satisfaction/Loyalty
Noona assesses satisfaction/loyalty by asking users to answer the question, “How likely are you to recommend Noona to another patient?” using an 11-point visual analog scale (ranging from 0 to 10) with the anchors “Unlikely” and “Very Likely” at opposite ends of the scale. The respondents click on the rating and then submit it. The information is often grouped into three categories. Patients who rated the app from 0 to 6 were categorized as “Detractors,” those who rated it 7 or 8 where considered “Passive,” and those who rated the app 9 or 10 were characterized as “Promoters” [16]. For this study, patient responses were reported using this taxonomy or the original 11-point scale.

Noona Symptom Questionnaires
NSQs were created by an advisory board of physicians who have clinical and research expertise within the specific treatment modality. NSQs are used to report treatment symptoms. The specific questionnaire is predicated on the treatment regimen. For example, patients receiving systemic therapy may receive the Chemotherapy-18 module, while those receiving radiotherapy for a pelvic cancer would be administered NSQs with that content. All NSQs include CTCAE-derived items in which patients can report 3 grades of severity (mild, moderate, and severe) and branching logic which reduces patient burden by eliminating the need to respond to items that are not relevant to the patient. Any responses that meet prespecified criteria will trigger alerts that can be viewed by the clinical care team. In turn, the team responds by suggesting an intervention, or in the case of an emergent concern, it instructs the patient to seek immediate medical attention. Some sites may assign a questionnaire by sending notifications asking patients to complete the questionnaire at prespecified times, though patients always have the option of using it any time. In this study, all clicks within this Noona feature are recorded and represent its use. Thus, a patient who clicked on this section once will have a score of 1, and another who clicked on this area 10 times will have a score of 10. Depending on the analysis, this variable was either an outcome or predictor variable.

Diary
Noona’s diary feature gives patients the opportunity to save personal clinical and nonclinical information that can be used for a range of purposes including symptom tracking over time. However, this study focuses on the symptom-reporting component, which can be used to communicate with the clinical team in specific circumstances. Thus, similar to the NSQs, every click within this portion of Noona is recorded and represents a single use. Therefore, a patient who clicked on that section once will have a score of 1, and another who clicked within this area 10 times will have a score of 10. Depending on the analysis, this variable was either an outcome or predictor variable.

Secure Messaging
This feature gives patients the ability to directly communicate with the clinical care team regarding clinically relevant and nonrelevant issues. Since this study focuses on clinically relevant issues, only those data are included. Similar to the other two features, every click is recorded and represents a single use. Thus, a patient who clicked on this section once will have a score of 1, and another who clicked on this area 10 times will have a score of 10. Depending on the analysis, this variable was either an outcome or predictor variable.

Feature Preference
The patients were sorted into 1 of 4 categories (“None,” “NSQ,” “Diary,” and “Secure messaging”) based on the feature they used most often (defined by number of clicks). Note that those who did not use any of the 3 specific features were included in the “None” category.

Analyses
Four sets of analyses are conducted for this study. The first set used descriptive statistics to report all study variables. Categorical variables were reported using count and percentage, and continuous variables are reported using means and standard deviations.
The remaining analyses are exploratory and used generalized linear models (GLMs), specifying a negative binomial distribution and a log link function, to test the relationship between the use of the three communication and tracking features and satisfaction/loyalty in accordance with a priori hypotheses. Additionally, the grand estimated marginal mean (the mean response for each factor, calculated as least-squares means presented at the mean of the covariates) and estimated marginal means were calculated using a maximum likelihood algorithm and are reported in their original metric.

The first hypothesis was tested by using separate GLMs to ascertain whether a symptom or tracking feature was associated with satisfaction/loyalty, controlling for Noona use (days active and time on app), age, and device. The next hypothesis, that patients who do not use any of the tracking features will report lower satisfaction/loyalty scores compared with those who have a feature preference, was assessed by testing the association between the categorical variable feature preference and satisfaction/loyalty scores, controlling for Noona use (days active and time on app), age, and device. The reference category for the feature preference variable was “None.” The final hypothesis was tested using separate GLMs to ascertain whether the hypothesis that Detractors use each of the three symptoms’ reporting and tracking features less than Promoters, controlling for Noona use (days active and time on app), age, and device. The covariates included in the analyses were not the primary focus of the study; thus, only those that were significant predictors across all models are reported at the end of the section to identify trends more easily.

### Results

The participants (Table 1 and Table 2) were generally older (mean age 65.16 years, SD 12.29), with active accounts for approximately three-quarters of a year (mean 285.22 days, SD 173.78), spent approximately 1 hour and 15 minutes using Noona (mean 76.41 minutes, SD 77.28), and were more likely to use smartphones or tablets (n=786; 72.4%) the last time they logged in. The overall satisfaction/loyalty rating was 8.05 (SD 2.91).

#### Table 1. Descriptive data of categorical variables.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Values, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Device</strong></td>
<td></td>
</tr>
<tr>
<td>Computer</td>
<td>295 (27.16)</td>
</tr>
<tr>
<td>Smartphone</td>
<td>786 (72.38)</td>
</tr>
<tr>
<td><strong>Satisfaction/loyalty groupings</strong></td>
<td></td>
</tr>
<tr>
<td>Detractors</td>
<td>227 (20.90)</td>
</tr>
<tr>
<td>Passive</td>
<td>187 (17.22)</td>
</tr>
<tr>
<td>Promoter</td>
<td>672 (61.88)</td>
</tr>
</tbody>
</table>

#### Table 2. Descriptive data of continuous variables.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), mean (SD)</td>
<td>65.16 (12.29)</td>
</tr>
<tr>
<td>Duration since activation (days), mean (SD)</td>
<td>285.22 (173.78)</td>
</tr>
<tr>
<td>Time on app (min), mean (SD)</td>
<td>76.41 (77.28)</td>
</tr>
<tr>
<td>Satisfaction/loyalty, mean (SD)</td>
<td>8.05 (2.91)</td>
</tr>
<tr>
<td>NSQa, mean (SD)</td>
<td>1.26 (2.64)</td>
</tr>
<tr>
<td>Diary, mean (SD)</td>
<td>0.78 (2.21)</td>
</tr>
<tr>
<td>Secure messaging</td>
<td>0.69 (1.80)</td>
</tr>
</tbody>
</table>

*aNSQ: Noona symptom questionnaires.

Of the total 1081 patients, 308 (28.36%) patients used the NQS, 312 (28.73%) used the diary, and 317 (29.19%) used secure communication modalities, respectively. Overall use ranged between 1 and 33 times (Figure 1). Patients tended to use NQS portions of the application most (mean 1.26 clicks, SD 2.64), followed by the diary (mean 0.78 clicks, SD 2.21), and secure messaging (mean 0.69 clicks, SD 1.80). Over half of the participants gave a satisfaction/loyalty rating to Noona. Promoters (scores of 9 or 10: n=672, 61.88%; Table 3) comprised more than 60% of the sample compared to Passives (scores of 7 or 8: n=187, 17.22%) and Detractors (scores between 0 and 6: n=277, 20.90%). The mean rating was 8.05 (SD 2.91).

The GLMs testing the relationship between NSQ use and satisfaction/loyalty were significant ($B=0.01$, $P=.05$; Table 4). This indicates that, for every NSQ module click, a 0.01 increase in satisfaction/loyalty score is predicted. The grand estimated marginal mean was 7.91. The confidence intervals were within a tenth of a point indicating a high degree of accuracy. The other
two models did not find a significant relationship between diary and secure messaging use and patient satisfaction.

The next analysis found that patients who used the NSQ most often reported significantly higher satisfaction/loyalty scores compared to those who did not use any of the three features \((B=0.71, P=.02; \text{Table } 5)\).

**Figure 1.** Patients’ use of symptom, diary, and secure communication modalities by clicks.

![Figure 1](image)

**Table 3.** Participants’ satisfaction/loyalty scores.

<table>
<thead>
<tr>
<th>Participants and NPS(^a)</th>
<th>Frequency</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Promoters</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>57</td>
<td>5.25</td>
</tr>
<tr>
<td>1</td>
<td>19</td>
<td>1.75</td>
</tr>
<tr>
<td>2</td>
<td>21</td>
<td>1.93</td>
</tr>
<tr>
<td>3</td>
<td>15</td>
<td>1.38</td>
</tr>
<tr>
<td>4</td>
<td>19</td>
<td>1.75</td>
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<tr>
<td>5</td>
<td>75</td>
<td>6.91</td>
</tr>
<tr>
<td>6</td>
<td>21</td>
<td>1.93</td>
</tr>
<tr>
<td><strong>Passive</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>53</td>
<td>4.88</td>
</tr>
<tr>
<td>8</td>
<td>134</td>
<td>12.34</td>
</tr>
<tr>
<td><strong>Detractors</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>99</td>
<td>9.12</td>
</tr>
<tr>
<td>10</td>
<td>573</td>
<td>52.76</td>
</tr>
</tbody>
</table>

\(^a\)NPS: Net Promoter Score.
Table 4. Generalized linear models testing the relationship between accessing new modules and satisfaction/loyalty.

<table>
<thead>
<tr>
<th>Modalities and variables</th>
<th>Values</th>
<th>SE</th>
<th>P value</th>
<th>Exp (B)</th>
<th>95% CI for odds ratios</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>B</td>
<td></td>
<td></td>
<td></td>
<td>Lower</td>
</tr>
<tr>
<td>NSQ&lt;sup&gt;a&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>App time</td>
<td>0</td>
<td>0</td>
<td>.47</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>Days since activation</td>
<td>0</td>
<td>0</td>
<td>.29</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>Age</td>
<td>0</td>
<td>0</td>
<td>&lt;.001&lt;sup&gt;b&lt;/sup&gt;</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>Device</td>
<td>−0.07</td>
<td>0.03</td>
<td>.01&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0.93</td>
<td>0.89</td>
</tr>
<tr>
<td>NSQ use</td>
<td>0.01</td>
<td>0</td>
<td>&lt;.001&lt;sup&gt;b&lt;/sup&gt;</td>
<td>1.01</td>
<td>1.00</td>
</tr>
<tr>
<td>Diary</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>App time</td>
<td>0</td>
<td>0</td>
<td>.20</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>Days active</td>
<td>0</td>
<td>0</td>
<td>.28</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>Age</td>
<td>0</td>
<td>0</td>
<td>&lt;.001&lt;sup&gt;b&lt;/sup&gt;</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>Device</td>
<td>−0.07</td>
<td>0.03</td>
<td>.01&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0.94</td>
<td>0.89</td>
</tr>
<tr>
<td>Diary</td>
<td>0</td>
<td>0.01</td>
<td>.66</td>
<td>1.00</td>
<td>0.99</td>
</tr>
<tr>
<td>Secure communication</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>App time</td>
<td>0</td>
<td>0</td>
<td>.26</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>Days since activation</td>
<td>0</td>
<td>0</td>
<td>.28</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>Age</td>
<td>0</td>
<td>0</td>
<td>.01&lt;sup&gt;b&lt;/sup&gt;</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>Device</td>
<td>−0.07</td>
<td>0.03</td>
<td>.01&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0.94</td>
<td>0.89</td>
</tr>
<tr>
<td>Secure messaging</td>
<td>0</td>
<td>0.01</td>
<td>.47</td>
<td>1.00</td>
<td>0.99</td>
</tr>
</tbody>
</table>

<sup>a</sup>NSQ: Noona symptom questionnaires.

<sup>b</sup>P<.05

Table 5. Generalized linear models testing the relationship between feature preference and satisfaction/loyalty (“None” was the reference group).

<table>
<thead>
<tr>
<th>Variables</th>
<th>Values</th>
<th>SE</th>
<th>P value</th>
<th>Exp (B)</th>
<th>95% CI for odds ratios</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>B</td>
<td></td>
<td></td>
<td></td>
<td>Lower</td>
</tr>
<tr>
<td>App time</td>
<td>0</td>
<td>0</td>
<td>.40</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>Days since activation</td>
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<td>0</td>
<td>.38</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>Age</td>
<td>0</td>
<td>0</td>
<td>.99&lt;sup&gt;a&lt;/sup&gt;</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>Device</td>
<td>−0.06</td>
<td>0.03</td>
<td>.02&lt;sup&gt;a&lt;/sup&gt;</td>
<td>0.94</td>
<td>0.89</td>
</tr>
<tr>
<td>Secure communication</td>
<td>0.03</td>
<td>0.03</td>
<td>.39</td>
<td>1.03</td>
<td>0.97</td>
</tr>
<tr>
<td>Diary</td>
<td>0.03</td>
<td>0.03</td>
<td>.40</td>
<td>1.03</td>
<td>0.96</td>
</tr>
<tr>
<td>NSQ&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0.07</td>
<td>0.03</td>
<td>.02&lt;sup&gt;a&lt;/sup&gt;</td>
<td>1.07</td>
<td>1.01</td>
</tr>
</tbody>
</table>

<sup>a</sup>P<.05

<sup>b</sup>NSQ: Noona symptom questionnaires.

The grand estimated marginal mean was 7.94. The estimated marginal means for NSQ (8.26) was 0.57 points higher than the “None” category (7.69). The two other features (diary=7.91; secure messaging=7.91) were also higher than “None.” The confidence intervals were within a tenth of a point, indicating a high degree of accuracy. The final set of analyses (Table 6) found that Detractors and Promoters significantly differ in their use of the secure communication feature (B=1.307, P=.04). The grand marginal mean was 0.11 clicks, and the estimated marginal mean was 0.13 clicks for Promoters and 0.11 for Detractors. The confidence intervals were within a tenth of a point, indicating a high degree of accuracy.
Examination of the covariates found a general trend for age; it was a significant predictor in all models, but the relationship was small. For example, in the model testing the relationship between NSQ and satisfaction/loyalty, for every minute of app use there was less than a 0.01 increase in clicks predicted. Additionally, the device patients used was also a significant predictor across all models, but the relationship differed depending on the model. For example, for all three models testing the relationship between communication and tracking features and satisfaction/loyalty, patients found consistent estimated marginal means were higher for smartphone or tablet use (8.14) compared with computers (7.81). In the analyses, testing whether Detractors and Promoters differentially predicted the use of the treatment symptom and tracking features, we found that for the models predicting NSQ and secure messaging, the estimated marginal means were higher for smartphone or tablet use (0.25 and 0.13, respectively) compared with computer (0.10 and 0.20, respectively). It was reversed for the model that included the diary (computer=0.11; tablet or smartphone=0.12).

Table 6. Generalized linear models comparing those with low and high satisfaction on communication and tracking features (Detractors was the reference group).

<table>
<thead>
<tr>
<th>Variables</th>
<th>Values</th>
<th>P value</th>
<th>Exp (B)</th>
<th>95% CI for odds ratios</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NSQ</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>App time</td>
<td>0.01</td>
<td>&lt;.001</td>
<td>1.01</td>
<td>1.01</td>
</tr>
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<td>Days since activation</td>
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<td>1.00</td>
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<tr>
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<td>1.02</td>
<td>1.01</td>
</tr>
<tr>
<td>Device</td>
<td>0.22</td>
<td>.04</td>
<td>1.25</td>
<td>1.01</td>
</tr>
<tr>
<td>Promoters</td>
<td>0.12</td>
<td>.28</td>
<td>1.13</td>
<td>0.91</td>
</tr>
<tr>
<td><strong>Diary</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>App time</td>
<td>0.01</td>
<td>&lt;.001</td>
<td>1.01</td>
<td>1.01</td>
</tr>
<tr>
<td>Days since activation</td>
<td>0</td>
<td>.01</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>Age</td>
<td>.03</td>
<td>&lt;.001</td>
<td>0.97</td>
<td>0.96</td>
</tr>
<tr>
<td>Device</td>
<td>.17</td>
<td>.21</td>
<td>0.85</td>
<td>0.65</td>
</tr>
<tr>
<td>Promoters</td>
<td>.11</td>
<td>.43</td>
<td>1.11</td>
<td>0.85</td>
</tr>
<tr>
<td><strong>Secure communication</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>App time</td>
<td>0.01</td>
<td>&lt;.001</td>
<td>1.01</td>
<td>1.01</td>
</tr>
<tr>
<td>Days since activation</td>
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<td>.23</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>Age</td>
<td>.03</td>
<td>&lt;.001</td>
<td>0.97</td>
<td>0.96</td>
</tr>
<tr>
<td>Device</td>
<td>0.22</td>
<td>.10</td>
<td>1.24</td>
<td>0.96</td>
</tr>
<tr>
<td>Promoters</td>
<td>0.23</td>
<td>.10</td>
<td>1.26</td>
<td>0.96</td>
</tr>
</tbody>
</table>

*aNSQ: Noona symptom questionnaires.

**P**<.05

**Discussion**

Real time reporting of treatment symptoms via ePROs will increasingly become a critical component of cancer treatment because patients better recognize symptoms compared with providers [29,30]. There is increasing evidence that ePRO use positively impacts critical outcomes (eg, mortality) [4,5,31], and it will eventually be required for some reimbursement [15]. Therefore, real-world evidence demonstrating patients’ use and satisfaction with ePRO software will be a necessary requirement for all stakeholders (patients, providers, and payers) who want to simultaneously mitigate patient distress and realize cost savings. Noona includes, among an array of features, three methods of communicating and tracking treatment-related symptoms that distinguish it among other ePROs and electronic platforms. The addition of capabilities to collect objective app use and satisfaction/loyalty with minimal patient burden is the veritable “win-win” scenario. Certainly, this information can be used descriptively, but its ability to produce real-world evidence, such as a demonstration that the use of these tracking features is associated with patient satisfaction/loyalty, can yield deeper understanding of how patients use and value the app.

An incontrovertible finding is that patients like the app; more than half (n=570, 52.76%) gave it the maximum score of 10,
and 61.98% (n=670) rated it a 9 or 10. The exploratory multivariate analyses demonstrate some small but significant relationships between objective data use of the three communication modalities in the form of clicks and responses to an item assessing Noona satisfaction/loyalty. They include the findings that NSQ use was a significant predictor of satisfaction/loyalty scores; patients using the NSQ reported significantly higher satisfaction/loyalty scores than those who did not use one of the three Noona communication features; and Promoters used the secure-messaging modality more than Detractors. In general, we think these exploratory analyses are successful because, by making some slight adjustments, it is relatively easy to refine the satisfaction/loyalty item so that respondents can focus on these features to guide ratings rather than other potential facets of the app. This will also likely resolve the obvious ceiling effect—patients rated the application so highly (over 50% reported a score of 10) that it reduced data variability, which also negatively impacting the analyses.

While we see great potential for the use of Net Promoter Scores, the data presented in our study have limitations. For example, we are not able to include more personal or clinically relevant data because they are not embedded within Noona. Additionally, we made some assumptions regarding the relationship between clicks and feature use, which future research may find to be suboptimal.

Conflicts of Interest
Varian, A Siemens Healthineers Company, owns Noona and employs both IK and TP.

References


Abbreviations

CTCAE: Common Terminology Criteria for Adverse Events
ePRO: electronic patient-reported outcomes
GLM: generalized linear model
NSQ: Noona symptom questionnaires