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Contents

Review

Original Papers

Corrigenda and Addenda

Review

Scientific Publications on Nursing for COVID-19 in Patients With Cancer: Scoping Review

Vivian Cristina Gama Souza Lima[1,2*], MSN; Raquel de Souza Soares[1], MSN; Willian Alves dos Santos[1*], MSN; Paulo Alves[3], PhD; Patricia dos Santos Claro Fuly[1], PhD

[1]Academic Program in Health Care Sciences, Fluminense Federal University, Niterói - RJ, Brazil

[2]National Cancer Institute, Rio de Janeiro, Brazil

[3]Interdisciplinary Health Research Centre, Institute of Health Sciences, Catholic University of Portugal, Porto, Portugal

[*]these authors contributed equally

Corresponding Author:
Vivian Cristina Gama Souza Lima, MSN
Academic Program in Health Care Sciences
Fluminense Federal University
Rua Doutor Celestino, 74 - Centro
Niterói - RJ, 24020-091
Brazil
Phone: 55 21 2629 5215
Fax: 55 21 2629 5215
Email: vcgslima@gmail.com

Abstract

Background: The needs of patients with cancer must be met, especially in times of crisis. The advent of the pandemic triggered a series of strategic actions by the nursing team to preserve the health of patients and professionals—hence the importance of studies on nursing care actions provided to patients with cancer during the COVID-19 pandemic. It is known that these patients are susceptible to severe COVID-19. However, no previous review has summarized the findings of scientific studies on nursing for COVID-19 in patients with cancer.

Objective: This study aims to map the topics addressed in scientific studies on nursing for COVID-19 in patients with cancer.

Methods: A scoping review was conducted using the methodology described in the *Joanna Briggs Institute Reviewers' Manual 2015*. The research question was elaborated using the population, concept, and context framework: What topics have been studied in nursing publications about COVID-19 in adult patients with cancer? The searches were carried out in 8 databases between April and November 2021 without time restrictions.

Results: In total, 973 publications were identified using the search strategies in the databases, and 12 papers were retrieved by consulting the references. A total of 31 (3.2%) publications were included in the final analysis, generating 4 thematic categories on the subject: “restructuring the services: how oncology nursing was adapted during the pandemic,” “experiences of patients and performance of the nursing team during the COVID-19 pandemic,” “protocols and recommendations for dealing with the COVID-19 pandemic,” and “challenges and the role of oncology nurses facing the COVID-19 pandemic.”

Conclusions: Several strategies used by oncology nurses to face the COVID-19 pandemic in the international scenario were identified. Reports about the restructuring of services and the team's reactions to the pandemic predominated. However, there is a lack of reports regarding emotional support strategies for health care professionals. Another gap identified was the scarcity of clinical studies on the activities developed by oncology nurses. Therefore, there is a need for clinical research in the oncology area and emotional coping strategies to support oncology nurses.

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KEYWORDS

COVID-19; review; nursing; coronavirus infection; oncology nursing

Introduction

Cancer is 1 of the main public health issues in the world, especially in developing countries, and it is already among the 4 main causes of death before the age of 70 years in most countries. The incidence and mortality from cancer have been increasing considerably, whether due to aging, population growth, or the change in the distribution and prevalence of risk factors, especially those associated with socioeconomic development [1].

In this context, it is noteworthy that patients with cancer are susceptible to developing infections. Despite the benefits of cancer treatment, it may cause the expansion of immunosuppression, making these patients more vulnerable to bacterial, fungal, and viral infections [2].

The world has been affected by the outbreak of COVID-19, a public health emergency. Since the emergence of SARS-CoV-2 in late 2019 in China, the worldwide spread has been rapid, with over 395 million confirmed cases and over 5.7 million deaths reported worldwide as of January 2022 [3-6]. It is observed that infected patients can present different manifestations and results, especially when considering the oncological disease. Therefore, it is essential to identify, through studies, the main characteristics of those infected in order to help allocate the right resources and improve the quality of care [7].

The SARS-CoV-2 infection has a mild course in most people, but in a significant portion of the population, the condition progresses to a severe respiratory disease characterized by hyperinflammatory syndrome, multiple-organ dysfunction, and death [8]. This is because some patient subgroups, such as the elderly and individuals with chronic conditions, such as hypertension, diabetes, and chronic lung diseases, have been shown to have an increased risk of morbidity and mortality when affected by COVID-19 [9].

Literature data indicate that patients with cancer undergoing active treatment are at greater risk of developing serious events related to COVID-19, requiring admission to an intensive care unit [10]. There are reports of early studies from China that demonstrated a 2- to 4-fold increase in COVID-19 mortality among patients with cancer compared to those without cancer, while other smaller studies reported a 29% case fatality rate and worse outcomes among patients with cancer infected with COVID-19 [9].

In this way, it is understood that the needs of patients with cancer must be met, especially in times of crisis. The advent of the pandemic triggered a series of strategic actions by the nursing team to preserve the health of patients and the team—hence the importance of studies to guide the nursing care provided to patients with cancer in the context of the COVID-19 pandemic [11].

The role of nursing has undergone significant changes, mainly due to the need for changes in the nursing education process. Currently, nurses are increasingly trained to promote and improve the quality of clinical practice and provide support in patient and community care in all aspects. With the pandemic, new opportunities and threats have emerged due to the introduction of new technologies in the health area, which requires the nursing team to develop new digital skills [12].

It is noteworthy that the nursing team is of fundamental importance in patient care in the face of the pandemic. Within health services, nurses are the main direct caregivers providing vital services and, in this way, are considered the system's backbone. It is a fact that the pandemic has shown that many health environments are also workplaces where these professionals face high risks of occupational exposure to physical and mental illnesses [13]. Instead of absenteeism, during the pandemic, an increase in presenteeism—the problem of workers being on the job but, because of illness (in this case COVID-19), not fully functioning—has been observed in a hospital in Australia. Frontline nurses were more affected by SARS-CoV-2 than all other health care professions [13].

To find the publications on the subject, a preliminary search was carried out in the International Prospective Registry of Systematic Reviews (PROSPERO), Cochrane Systematic Review, and Medical Literature Analysis and Retrieval System Online (MEDLINE). We searched the literature for protocols and reviews on the topic and identified 30 studies by using the descriptors "COVID-19," "nursing," and "cancer" connected by the Boolean operator AND. Only 2 studies related to the topic were found, a review about home care and palliative care [14] and a research protocol published as a conference proceeding [15], indicating the existence of a gap in the literature. Such limitations may compromise the understanding of actions aimed at nursing care for patients with cancer and COVID-19.

Thus, it is recognized that a broad literature review can bring new knowledge to the subject. Therefore, this scoping review's objective was to map the topics addressed in scientific publications on nursing for COVID-19 in patients with cancer.

Methods

Design

A scoping review was carried out using the Joanna Briggs Institute's (JBI) [16] method that provides an overview of the evidence, being recommended to authors who intend to answer specific research questions about the nature and diversity of evidence on a given topic or identify existing gaps [17]. The following 5 steps were completed: selection of the research question, identification of relevant publications, study selection, data extraction, and data synthesis and discussion of findings [17-19]. The protocol for this scoping review has been registered with the Open Science Framework [20].

Selecting the Research Question

The research question was created using the Population, Concept, and Context (PCC) framework as follows:

- Population: adult patients (defined by the World Health Organization [WHO] as 18 years or over) with any type of cancer
- Concept: nursing care in the different scenarios of the nursing activity

- Context: the COVID-19 pandemic

Therefore, the following research question was explored: What topics have been studied in nursing publications on COVID-19 in adult patients with cancer?

Identifying Relevant Publications

The following databases were used to retrieve publications: the Cumulative Index to Nursing and Allied Health Literature (CINAHL), the National Center for Biotechnology Information (NCBI/PubMed), the Latin American and Caribbean Health Sciences Literature (LILACS), Scopus, and the Excerpta Medica Database (Embase). The gray literature was searched for additional relevant publications using Mednar and the *Gray Literature Report*. Subsequently, the search was extended to the Virtual Health Library (VHL) and the Brazilian Digital Library of Theses and Dissertations (BDTD, in Portuguese). The search was restricted to studies published from March 11, 2020, to date, considering the date on which the pandemic state was declared [5]. No language restrictions were used.

The descriptors “coronavirus infections,” “oncology,” and “nursing” were combined using the Boolean operators AND and OR to construct the search strategy, which was defined considering the specificities of each database.

Primary and secondary studies were included regardless of their methodological approach. Therefore, original papers, literature reviews, term papers, theses, and dissertations were eligible if they were available for free or through subscriptions made by the authors' institution. The following exclusion criteria were used: duplicates, errata, commentary papers, research protocols, booklets, studies not addressing the research question, and papers not available in full text.

Study Selection

The study selection was carried out from April to November 2021. After the search strategy was used in the databases, the results were exported to EndNote, through which the papers were grouped, and duplicates were removed before title and abstract screening. Two different reviewers conducted this step guided by pre-established inclusion criteria and the research question to systematize the review and reduce the risk of bias. Disagreements between the reviewers were resolved through discussion with a third reviewer. The selection process is depicted in a Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flowchart [16].

Data Extraction

The data extraction was developed using a form created based on the review's objective and research question, with the following variables: bibliographic information (origin, type of publication, title, authors, descriptors, year, country, and language), objectives, study design, methodological approach (data collection, period, location, analytical method, and treatment of data), conclusions, and recommendations. The authors pilot-tested the form before the data extraction, making the necessary adjustments.

Two steps were conducted to reach the final sample. First, the titles and abstracts of the publications were screened based on the eligibility criteria. In the second round of screening, the full texts were read to ensure their congruence with the research question and 2 independent reviewers validated the process. After these steps, the retrieved publications were listed and numbered according to the chronological order of the data collection and sorted in an electronic spreadsheet.

Data Synthesis and Discussion of Findings

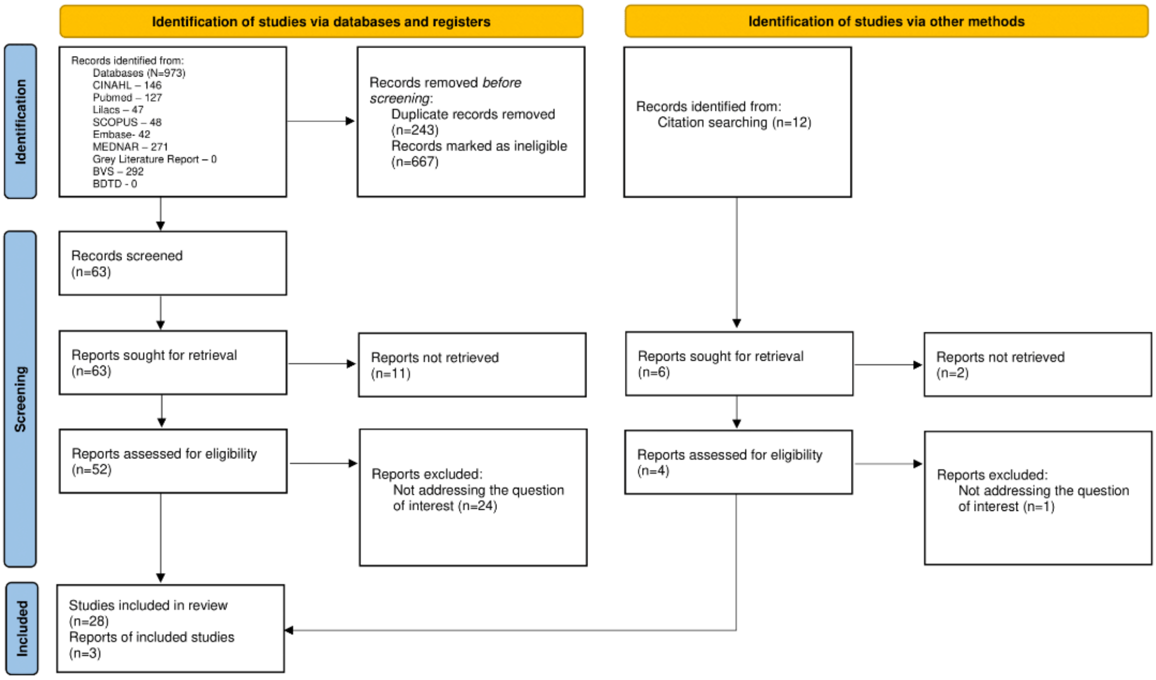
The studies were synthesized using a chart with the main characteristics and points of interest of each study. A figure was created to synthesize information about the studies' countries, years of publication, and designs. A discussion of findings was conducted using descriptive statistics and narrative synthesis.

Results

Identifying Relevant Publications

The search strategies allowed us to identify 973 records, from which 243 (25%) duplicates were removed. After the title and abstract screening, 63 (6.5%) documents remained and were read in full. After applying the exclusion criteria, 29 (46%) documents remained. After reading the references of these documents, 12 additional records were identified, of which 3 were selected, resulting in 31 publications, as shown in Figure 1.

Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flowchart of study selection.



Selection of Studies

The main characteristics of the included studies are presented in Tables 1 and 2 and Figure 2. A narrative summary was prepared using categories that emerged from the results found, and the JBI Appraisal Tool was adopted to assess the methodological quality and risk of bias.

Table 1. Synthesis of the characteristics of the included studies (N=31).

Study ID	Title	Journal	Authors	Level of evidence
S1	A COVID-19 Screening Tool for Oncology Telephone Triage	*Supportive Care in Cancer*	Elkin et al [21]	4a
S2	A New Proactive Virtual Resource Center Navigation Model Identifies Patient Risk Factors to Reduce Barriers to Cancer Care During the COVID-19 Pandemic	*Supportive Care in Cancer*	Bigelow et al [22]	4b
S3	The Role of Patient Safety Service in the Fight Against COVID-19 in a Hospital	*Enfermagem em Foco*	Cardoso et al [23]	5c
S4	First Case of COVID-19 in an Oncological Palliative Care Unit: Experience Report	*Enfermagem em Foco*	Santiago et al [24]	5c
S5	Defining Moments: A Nurse's Touch	*Heath Communication*	Baglia [25]	5c
S6	Comment on "Pathways to Psychological Wellbeing for Patients With Bladder Cancer and Their Partners-in-Care" and Contextualization in the COVID-19 Pandemic	*European Journal of Oncology Nursing*	Caruso et al [26]	5c
S7	COVID-19 and Cancer Nursing: Challenges and Opportunities	*Canadian Oncology Nursing Journal*	Booker [27]	5c
S8	COVID-19's Implications for People With Cancer and Oncology Nurses Oncology Nurses	*News and News - ONS*[a] *Voice*	Sheldon [28]	5c
S9	Editorial: The Critical Role of Nurse Practitioners in the Care of Cancer Patients	*European Journal of Cancer Care*	Weller [29]	5c
S10	Infusion of Antineoplastic therapies in the Home	*Oncology Nursing Forum*	ONS [30]	5c
S11	Managing the Journey of Patients Under Chemotherapy in a Pandemic Era: A Nursing Perspective	*Chemotherapy*	Gualandi et al [31]	4a
S12	Mitigating Strategies and Nursing Response for Cancer Care Management During the COVID-19 Pandemic: An Italian Experience	*International Council of Nurses*	Zeneli et al [32]	4a
S13	Nursing Navigation in Breast Cancer Care During the Pandemic: An Experience Report	*Journal of Nursing and Health*	Osorio et al [33]	5c
S14	Navigating a Global Pandemic: How Nurses in Florida Responded	*The Florida Nurse*	Marshall [34]	4a
S15	Nurses' Role in Providing Comprehensive Communication, Prognostication, and Palliative Care During the COVID-19 Pandemic	*Journal of Hospice & Palliative Nursing*	Koch et al [35]	4d
S16	Oncology Nursing Challenges During COVID‐19 Outbreak: Precautions and Guidance	*Asia‐Pacific Journal of Oncology Nursing*	Shankar et al [36]	5c
S17	Oncology Nursing During a Pandemic: Critical Reflections in the Context of COVID-19	*Seminars in Oncology Nursing*	Paterson et al [37]	4a
S18	Oncology Nursing Workforce: Challenges, Solutions, and Future Strategies	*The Lancet Oncology*	Challinor et al [38]	4a
S19	Palliative Care Challenges and Strategies for the Management Amid COVID-19 Pandemic in India: Perspectives of Palliative Care Nurses, Cancer Patients, and Caregivers	*Indian Journal of Palliative Care*	Pai et al [39]	5c
S20	Patient Satisfaction With Nurse-Led End of Treatment Telephone Consultation for Breast Cancer During COVID-19 Pandemic	*The Breast Journal*	Schuster-Bruce et al [40]	5c
S21	Nurse Navigators' Telemonitoring for Cancer Patients With COVID-19: A French Case Study	*Supportive Care in Cancer*	Ferrua et al [41]	4d
S22	Primary Palliative Care Clinical Implications: Oncology Nursing During the COVID-19 Pandemic	*Clinical Journal of Oncology Nursing*	Rosa et al [42]	4d
S23	The Psychological Pressures of Breast Cancer Patients During the COVID-19 Outbreak in China: A Comparison With Frontline Female Nurses	*Frontiers in Psychiatry*	Cui et al [43]	4a
S24	The Role of the Oncology Nurse Navigator in Establishing an Epic Workflow for Virtual Multidisciplinary Clinics During Covid Restrictions	*LVHN Scholarly Works*	Beaupre et al [44]	5c
S25	COVID-19 and Cancer Care	*The British Journal of Nursing*	Foulkes [45]	5c
S26	Sarah Cannon Virtual Breast Cancer Support Group	*Journal of Oncology Navigation & Survivorship*	Sarah Cannon [46]	5c
S27	Colorectal Cancer Surgery in the Coronavirus (COVID-19) Pandemic	*Gastrointestinal Nursing*	Taylor et al [47]	5c

Study ID	Title	Journal	Authors	Level of evidence
S28	Fighting Cancer in Coronavirus Disease Era: Organization of Work in Medical Oncology Departments in Emilia Romagna Region of Italy	*Future Oncology*	Brandes et al [48]	5c
S29	The Cancer Nurse as Primary Palliative Care Agent During COVID-19	*Cancer Nursing*	Rosa et al [49]	5c
S30	Nurse’s Roles in Protecting Cancer Patients During COVID-19 Pandemic	*Jurnal Bedah Nasional*	Nuryani et al [50]	5c
S31	Navigating the COVID-19 Pandemic as an Oncology Nurse	*Oncology Times*	Nalley [51]	5c

[a] ONS: Oncology Nursing Society.

Table 2. Synthesis of the topics of the included studies (N=31).

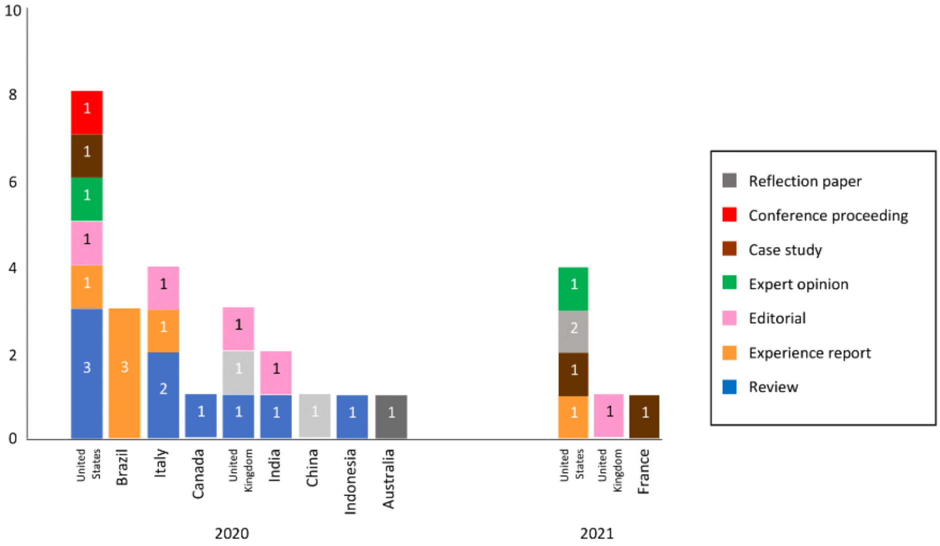
Study ID	Subject
S1	Development and implementation of a COVID-19–screening tool for oncology telephone service. The tool was developed and implemented in clinical practice, facilitating patient triage and patient tracking in various outpatient settings.
S2	Implementation, associated interventions, and results of the proactive navigation model of a virtual resource center. Successfully transitioned to a new proactive, virtual outreach program to educate, advocate, resource, and support patients with cancer during the COVID-19 pandemic.
S3	Experience of the Patient Safety Center, in the face of COVID-19, in a hospital unit. The lived experience shows the importance of the Patient Safety Center, which aims to promote a safe health service.
S4	Report on nursing care to the first patient in oncological palliative care with COVID-19 in a hospital in Rio de Janeiro. The rapid worsening of the disease, isolation, absence of a caregiver/family member, and risk of contamination of the team in the context of the pandemic made nursing care more specific and careful.
S5	Report on the relationship between a patient, the nurse, and the physician who accompanied the patient with lymphoma during treatment and differences between the moments before and during the COVID-19 pandemic.
S6	Continuous psychological assessment of patients with cancer, especially in unusual health conditions, such as COVID-19, can improve nursing practice and patient outcomes.
S7	Discuss the role of nurses in disseminating information during the pandemic.
S8	Implications of the COVID-19 pandemic for oncology nurses and patients with cancer.
S9	Performance of nurse-led clinics in supporting patients with cancer during the COVID-19 pandemic. The services led by nurses showed good performance and quality, and the teleservice performed by nurses indicated a high level of patient satisfaction.
S10	Guidelines to be followed by any health care organization offering systemic anticancer therapy at home, established by the ONS[a] to avoid interruption of patient care.
S11	Update on the needs, experiences, and responses to treating patients treated with chemotherapy in a context of high risk of contagion due to the COVID-19 pandemic. New solutions to emerging problems are implemented, even without scientific evidence.
S12	Description of a cancer center's COVID-19 emergency response to allow other nursing organizations to determine what elements might help manage an increase in patients in their own environment.
S13	Navigator nurses' role in assisting patients with breast cancer during the new coronavirus pandemic in a private hospital in Southern Brazil.
S14	Florida nurses' response to the COVID-19 pandemic: changes in academia and research during the pandemic, the negative consequences of COVID-19 on cancer care, and the innovative model created by perioperative services to care for patients with COVID-19.
S15	Case report of assistance to the mother of a child with end-stage cancer with whom providers had not discussed care goals and prognosis during the COVID-19 pandemic.
S16	Challenges for oncology nursing during the COVID-19 outbreak: supporting patients with cancer during treatment, managing case care amid the COVID-19 crisis, and assessing the risk of exposure to coronavirus infection in the face of cancer treatment to avoid anxiety and panic among patients with cancer.
S17	Critical reflection on COVID-19 in the context of oncology nursing with recommendations for caring for people affected by cancer during this pandemic. Nurses participate in the development and implementation of policies regarding standards of care and play a key role in the management of COVID-19 in the year marked as the International Year of Nursing.
S18	A narrative review on challenges faced by oncology nurses during the COVID-19 pandemic, including shortages of nurses and specialized staff, occupational safety and burnout concerns, and possible solutions to address these challenges.
S19	Palliative care challenges and strategies for management during the COVID-19 pandemic in India.
S20	Benefits of teleconsultation carried out by nurses to patients with breast cancer during the COVID-19 pandemic.
S21	The use of a new application effectively monitored patients with cancer and reduced contact with other people.
S22	Integrating palliative care into the practice of oncology nursing helps health organizations and cancer centers be better equipped to meet the holistic needs of patients with cancer and their families.
S23	Psychological status of patients with breast cancer and female nurses at the peak of the COVID-19 outbreak.
S24	Safe options for conducting multidisciplinary clinics remotely, maintaining the same level of quality, during a time when at least half of providers and browsers were working remotely during COVID-19 restrictions.
S25	Challenges for oncology nurses in treating patients with cancer facing the COVID-19 pandemic.
S26	Experience of a virtual group with women with breast cancer in the face of the COVID-19 pandemic.
S27	Guidance for specialist nurses to help patients decide whether to proceed with or delay colorectal cancer surgery during the COVID-19 pandemic, guide them along new paths, address their concerns, and provide preoperative assessment and support.

Study ID	Subject
S28	Various topics about the current pandemic. COVID-19 will continue to disrupt society and cancer care in 2021, but the arrival of vaccines brings hope for a decrease in serious infections.
S29	Measures applied to reduce the spread of COVID-19 in clinical oncology departments.
S30	The role of oncology nurses in strategic roles during the pandemic includes educating the patient's family, coordinating with other health teams, triaging patients by phone, and caring for their own mental health.
S31	Challenges for health professionals and oncology nurses in coping with the pandemic: protocols for chemotherapy administration, patient protection, and guarantee of PPE[b] to health professionals.

[a] ONS: Oncology Nursing Society.

[b] PPE: personal protective equipment.

Figure 2. Distribution of papers by year of publication, country, and type (N=31).



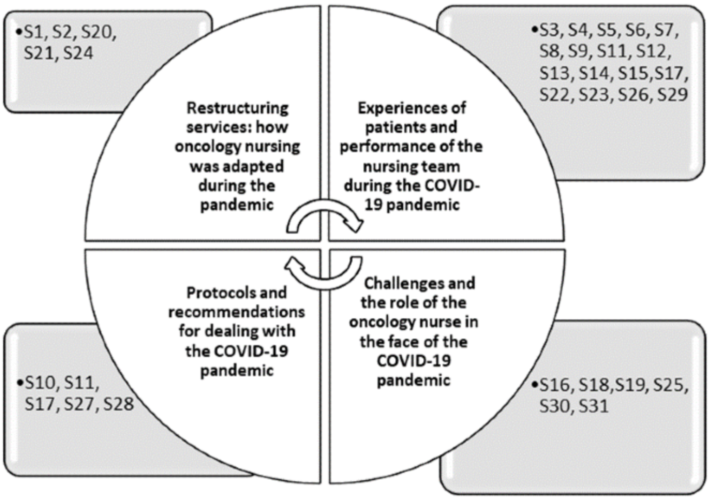
Data Extraction

All publications were retrieved from databases or citations search, and no documents were selected from the gray literature. Regarding the language and type of publication, 28 (90%) of the 31 studies were written in English and most were published in scientific journals (n=28, 90%). With regard to research design, 9 (29%) were literature reviews, 6 (19%) experience reports, 6 (19%) editorials, only 3 (10%) original papers, 3 (10%) case studies, and 1 (3%) publication in a conference proceeding. Almost half of the studies were developed in the United States, with a total of 13 (42%) publications, followed by Italy with 4 (13%) and the United Kingdom also with 4 (13%) publications. Of the 31 publications, 25 (80%) were published in 2020.

Data Synthesis and Discussion of Findings

From the analysis of the papers, 4 categories emerged, as shown in Figure 3.

Figure 3. Distribution of papers by thematic category (N=31).



Restructuring the Services: How Oncology Nursing Was Adapted During the Pandemic

This category includes how certain services have been reinvented to provide quality care remotely, given the need for social distancing during the pandemic. Of the 31 studies, 2 (6%) addressed nursing care through telephone monitoring and 2 (6%) others outlined different strategies for remote care. The development and implementation of a telephone tool included questions about patients' cancer history and current treatments and an emphasis on asking patients about their symptoms (which may be related to COVID-19 or cancer and treatment) [19]. In this way, nurses made informed decisions and assertive triage. Similarly, a tertiary cancer center in Paris, France, rapidly reorganized cancer treatment pathways to protect patients with cancer from severe COVID-19 and ensure that these patients continue receiving optimal cancer care [41].

To deal with the increasing barriers, another specialized oncology center has adopted a new navigation strategy based on virtual resources targeting the needs of the most vulnerable patients with cancer [22]. The model, led by nurse navigators, is patient centered and prioritizes visits carried out by telephone or video. With the partial closure of the service in March 2020, the previous navigation model could not meet the needs of patients with cancer and their families. Therefore, the decision to restructure this virtual model was efficient and effective. The navigation model provided support and improved care and safety for patients and family members who could not get these services during the pandemic [22].

In another paper, the navigation team of the Lehigh Valley Health Network [44] needed to create safe options to carry out its multidisciplinary consultations remotely, maintaining the same level of quality during a period in which at least half of the providers were working remotely [44]. Due to the pandemic, the demand for virtual clinical experiences required several clinical and administrative tasks from nurses. Despite the restrictions, patients and providers have appreciated the opportunity to safely continue their multidisciplinary efforts, which remains an option for off-site patients and providers.

The authors of another study evaluated the benefits of teleconsultation during COVID-19 and found that although some patients were satisfied with this approach, at least half of the sample still preferred face-to-face appointments [40].

Experiences of Patients and Performance of the Nursing Team During the COVID-19 Pandemic

An experience report was identified about the experiences lived by a patient during the pandemic. The patient mentions noticeable differences between the pre- and postpandemic periods in the appointments with nurses and physicians, emphasizing changes in social behaviors, such as lack of hugs or handshakes and the need to have the face constantly hidden behind a mask [25].

Studies examining the experiences lived by nurses were also found, discussing patient safety issues in the hospital scenario [23], the management of the nursing team, and the challenges that arose along with the first case of COVID-19 in a palliative care setting [24], the implementation of a remote approach to monitor and assist patients with breast cancer in palliative care [33], and the experience of carrying out a virtual group for women with breast cancer in the face of the pandemic [46].

Another way of describing current experiences is through case studies and the publication of narrative reviews, as in a paper that discusses the benefits of psychological therapies for patients with cancer, increasing their well-being and favoring the performance of the nursing team [26]. A study in China showed that patients with breast cancer had better psychological adaptation than frontline nurses at the COVID-19 epicenter in Wuhan [43]. Other authors discuss the different roles and attributions given to nurses during the pandemic: dissemination of information, service leadership, and telehealth, all with a high level of responsibility and expectations, being extremely relevant in the current scenario [27-29]. In addition, 2 (6%) papers describe the “nursing response to COVID-19” and what would be the reaction of this team to the pandemic in the context of nursing work. The intention is to allow other nursing organizations, based on these reports, to determine which elements may be useful to manage the increased number of patients in nursing care settings. The top topics covered changes in academia and research during the pandemic, the negative consequences of COVID-19 on cancer care, and the innovative models created by health care institutions [32,34].

With regard to palliative care, nurses must be trained to deal with these cases during the pandemic. A case study [35] reports the case of a mother of a child with end-stage cancer with whom the team had not yet discussed the prognosis. The authors conclude that the early introduction of palliative care and greater efforts to train and encourage conversations about palliative care by nurses can improve the quality of life for these patients and their families. Another paper addresses topics aimed at training clinical oncology nurses working in all settings with primary palliative care skills during the COVID-19 pandemic [42].

In addition to these topics, other diverse topics are addressed through newsletters and papers, such as vaccines, death and contagion statistics, and measures to reduce the spread of COVID-19 in hospital and home environments [28,48]. It is worth mentioning that these publications were extremely important throughout the pandemic, as new protocols and recommendations were still being created.

Protocols and Recommendations for Dealing With the COVID-19 Pandemic

Of the 31 publications, 1 (3%) cites that to avoid interrupting the treatment of patients, the Oncology Nursing Society (ONS) established guidelines to be followed by any health organization providing systemic anticancer therapy at home [30]. These guidelines include assessment of the complexity and risk of complications, assessment of the home environment and patient and family readiness to receive care at home, handling of antineoplastic agents, the correct disposal of waste, and indications concerning personal protective equipment (PPE), among other recommendations. In addition, the study emphasizes the need for informed consent from the patient, the need for keeping a spill kit at home, and the prerequisites that nurses must meet to administer anticancer drugs at home.

Furthermore, 1 (3%) of the studies reinforces the importance of reviewing and following institutional recommendations from specialized, state, and governmental agencies [37]. The paper presents recommendations for identifying and tracking contacts, guidelines for using PPE according to WHO recommendations, and an algorithm that can be used to ensure core staff availability for specialty areas prior to the deployment of staff to a labor pool. Nurses are advised on whether to proceed or postpone colorectal cancer surgery during the pandemic and what issues should be addressed during preoperative cancer patient care [47]. It is noted that the National Health Service (NHS) Action Plan reinforces that national health services and local authorities must implement plans to ensure that people receive essential care and support during all phases of a future pandemic through educational materials to educate patients about the surgical treatment of cancer and prioritizing patients according to their severity.

Challenges and the Role of Oncology Nurses Facing the COVID-19 Pandemic

WHO declared 2021 the International Year of Nursing, recognizing the tremendous work carried out by these workers. In the same year, the world was hit by the pandemic, the great challenge for oncology nurses was delivering care during the COVID-19 pandemic and not getting sick [36]. Although oncology nurses routinely use PPE, shortages of this type of material have been reported in many countries. In addition, healthy people are at risk of spreading the infection. Therefore, maintaining a balance between exposure to the virus and delivery of cancer treatment should be a priority for nurses to avoid unnecessary anxiety and panic.

A worldwide oncology nursing workforce is critical to achieving the United Nations 2030 Agenda for Sustainable Development Goals: 3.4 (reduce premature mortality from noncommunicable diseases by one-third) and 3.8 (achieve universal health coverage) [38]. Unfortunately, challenges for a robust oncology nursing workforce include shortages, recruitment barriers, and burnout. The long-term effect of COVID-19 on cancer care worldwide is unknown, but the immediate interruptions of therapy, workforce consequences, and threats to standard cancer nursing practice are addressed in this paper.

The challenges faced by palliative care nurses have also been addressed. An Indian paper [39] reports the main causes of stress and suffering experienced by nurses during the COVID-19 outbreak. The fear of contracting the infection was the main concern that most nurses faced in direct contact with patients. In palliative care centers, nurses were anxious and concerned about the lack of staff, distancing from family members, and feeling alone in delivering care to dying patients and recognized other factors contributing to stress. For example, violence against COVID-19 heroes, such as physicians and other health care workers, has been reported in India, making the entire process of treating the COVID-19 pandemic infection more traumatic than ever.

The pandemic has made patients reluctant to seek help from health care services, reducing urgent referrals. Undoubtedly, this is due to a combination of the intention to avoid increasing the health care system's workload and the fear of contracting coronavirus. Another challenge mentioned in 1 (3%) of the studies reviewed [45] is the necessity to meet an influx of people with cancer in hospitals that also treat patients with COVID-19. Therefore, a consequence of the pandemic was the need to discuss risks that have never been addressed.

Health care workers are used to providing treatments to patients with advanced diseases, considering their quality of life and managing the associated risks. In the context of COVID-19, this was quickly rephrased. Treatments that expose patients to a greater risk of contracting the virus may no longer be viable in terms of outcomes and workload for services. Consequently, many treatments may not be initiated or are likely to be discontinued.

An open discussion of risks with patients is necessary and desirable, but they are difficult and inevitably lead to anguish, worry, and uncertainties. Authors report the need to associate the current challenges of this pandemic with the care of patients with cancer undergoing chemotherapy [31]. Another study [37] critically reflects the challenges faced in the pandemic, gives recommendations to the nursing team, and states that nurses are key stakeholders in developing and implementing policies regarding standards of care during the COVID-19 pandemic. This statement speaks a lot about the role of nurses in the current context. The different roles assumed by nurses in the pandemic complement each other. The complexities of COVID-19 revealed the importance of oncology nurses assuming their role as agents of primary palliative care in defense of the patient and protecting patients with cancer during the pandemic, with a focus on preventing transmission and providing support to patients and families [49-51].

Discussion

Principal Findings

The main issues addressed in the publications were the adaptation and restructuring of services. Several services reinvented themselves to provide quality assistance even remotely, as there was a need for social distancing during the pandemic. The focus of the service was telehealth, characterized by virtual consultations by video calls or by telephone and other remote approaches. The restructuring of the health service is a complex element, as it involves knowledge about where cases and deaths are concentrated [52]. It was not evidenced in this review, for example, the emergence of new positions or jobs or the duration of these adaptations. In addition, the emergence of clusters of COVID-19 cases and the dynamics of occurrence of these cases must be monitored, in addition to trend analysis, so that timely interventions or new adjustments are carried out.

Nurse navigation services were also adapted to the virtual model. Due to the high barriers to care during the pandemic, a new navigation strategy based on virtual resources has been adopted, targeting the needs of the most vulnerable patients with cancer. Navigator nurses generally lead the process, and most visits are done by telephone or video. Multidisciplinary teams have been challenged to carry out their approaches remotely, while keeping the same quality of service in a period when at least half of the providers and navigators were working remotely. It is concluded that adapting to a virtual model was efficient and effective, providing support and improved care for patients and family members who might not have received these services during the pandemic. The remote care model is characterized by devices, services, and interventions designed around the health and well-being needs of the patient, and related data are shared so that the patient can receive care as proactively and efficiently as possible [53].

The evidence shows that nursing teleconsultation has many benefits, and many patients were satisfied with this assistance modality during the COVID-19 pandemic. However, according to the findings of this research, a relevant part of the patients approached in some studies prefer face-to-face encounters. It was not evidenced in the findings that the teleservice has made the day-to-day activities of those involved difficult. Health professionals, patients, and their families were well adapted to the new reality, and this modality is considered a facilitator of assistance during the pandemic.

The experience reports revealed several aspects experienced in the pandemic scenario. The nursing team reports show experiences regarding the team's performance concerning patient safety issues in the inpatient and outpatient settings. Likewise, the team's management had to be adapted in the face of cases of COVID-19, as well as the role of nurse navigators and palliative care nurses who were required to conduct virtual approaches. Case studies and narrative reviews are useful to disseminate reflections and experiences via a singular and, simultaneously, plural history since they allow the creation of links between meanings and experiences lived in a given sociohistorical context [54].

The importance of support from the psychology service to patients with cancer and professionals facing important emotional problems during the pandemic is also highlighted. Nurses, seen as “heroes and heroines” in this context, needed to assume multiple roles and deal with new attributions and those notably known, such as disseminating information, carrying out leadership roles, and conducting telehealth encounters, all with responsibility and accountability. However, the reactions of this team of professionals are worrisome.

A study published in China [55] shows that health care workers have faced psychological consequences, such as anxiety, stress, and depression, since the beginning of the COVID-19 pandemic. Psychological impacts generated by the pandemic, already intense in the general population, are amplified in health professionals, especially those on the front line of care. In addition to being exposed to the virus, the nursing team is exposed to the lack of PPE and hospital supplies and the role of deciding which patients will receive further treatment. The author also states that after the outbreak of SARS, Japanese professionals started to consume more alcohol and tobacco due to the stress suffered, increasing posttraumatic stress. It is important to acknowledge that health care workers are 1 of the most vulnerable groups to burnout syndrome. This psychosocial phenomenon emerges as a response to chronic stressors present at work, characterized by emotional exhaustion, depersonalization, and reduced personal fulfillment at work.

Several recommendations and protocols were made to guide health teams and the population during the COVID-19 pandemic. The ONS has established guidelines to be followed by health care organizations that provide anticancer treatment at home. It is known that the health workforce was extremely demanded during the pandemic, with a large volume of work, changes in the workflow, and technological innovation. During the fight against COVID-19, health managers had to deal with several adversities, such as shortages of supplies, exhaustion of frontline professionals, technology implementations, and internal process changes [56].

During the pandemic, nurses needed to follow institutional recommendations. Several guidelines concerning the identification and tracking of contacts, the use of PPE, the organization of the workforce, and the allocation of personnel have been disseminated. In addition, specialist nurses were assigned roles such as assisting patients in decision-making regarding cancer treatment, addressing their concerns, and providing preoperative assessment and support [47].

Oncology nurses have faced major challenges in the COVID-19 pandemic. These challenges include managing patients with cancer, while preventing the risk of disseminating the coronavirus infection in a shortage of PPE and resources, which occurred worldwide. In this context, a study [57] states that nurses routinely face precariousness in the workplace and numerous problems in the health system, such as lack of infrastructure, scarcity of supplies, inadequate staffing, lack of PPE, work overload, low wages, and lack of training. All these factors contribute to the illness and stress of health care workers [57].

One of the groups most impacted by COVID-19 can be considered to be health professionals, as they have experienced measurable negative psychological impacts [58]. Nurses and multidisciplinary staff may have experienced a variety of stressors related to interruptions in routine work tasks, limited knowledge and data about the illness, and job security concerns. The various changes forced the team to learn and adopt new work tools quickly, and this unexpected need can cause stress to health professionals, as it requires the adoption of technology-based measures without the necessary knowledge or adequate training, generating extra pressure on the professional, above and beyond the stress levels experienced by the general public in the face of COVID-19. Parallel to this, the fear of exposure to SARS-CoV-2 at work can cause additional stress and anxiety, in addition to favoring harmful consequences on their psychological health and their performance in the care of patients with cancer [58].

Whether in cancer screening or cancer treatment, it is known that the impact of this pandemic was great. In the context of cancer screening, the impact of COVID-19 on health care systems can be illustrated in terms of loss as it causes loss of life, loss of talent and operational activity, and financial loss. Worldwide, it is estimated that approximately half of elective cancer surgeries have been canceled or postponed during service interruptions caused by the pandemic [58]. This scenario can worsen the cancer statistic in numbers, but still, it is difficult to know how 24–7 care services could impact the health of a patient with cancer even more negatively [58].

The immediate interruptions of cancer therapy generated consequences for the workforce and threats to standard cancer nursing practice. A literature review [59] shows that patients with cancer need specific strategies for cancer management during the current pandemic. In addition, patients with cancer have a higher risk of Sars-CoV-2 infection and unfavorable outcomes when acquiring the virus. The redistribution of health resources can make access to treatments difficult, so the management of patients with cancer must find the balance between benefit and risk [59]. The study also addresses the existence of significant difficulties in the construction of a universal protocol due to the various characteristics of each type of cancer, patients, and oncology services, which means that despite the construction of recommendations and guidelines, there is a need for a case-by-case evaluation.

With regard to palliative care, there are challenges related to the stress and suffering of the moment. In this context, the management of patients with cancer in palliative care questions the premise of generating optimal symptom control and patient comfort. Thus, despite the current scenario, efforts to promote the well-being of the patients must be made [59].

There is still the challenge of assisting patients with cancer in hospitals that are striving to deal with the new coronavirus properly. The risks associated with cancer treatment during the pandemic are not easily resolved. As a result, many patients are not being treated or managed appropriately. The saturation of the health system, which has had resources allocated to COVID-19, threatened the adequate treatment of oncological diseases. Thus, during the ongoing COVID-19 pandemic, it is expected that the mortality of patients with cancer will continue to increase either by the infection or by the failure to provide adequate cancer treatment [59].

The COVID-19 pandemic has presented several challenges for oncology services, and nurses play a key role in the care and management of COVID-19 worldwide. The “Nursing Now” campaign launched in London in February 2018 values the nursing profession, and in 2020, the world celebrated the bicentennial of the birth of Florence Nightingale, the mother of contemporary nursing. Florence Nightingale stood out for her work in the Crimean War, and so many years later, the nursing profession continues to stand out worldwide for being essential on the front line in the fight against the pandemic [57].

Limitations

The limitations of this study include the scoping literature review method, which may not have apprehended all potentially relevant studies, in addition to the constant appearance of new publications about COVID-19, making it difficult to include all relevant studies. The focus on scientific publications on nursing may also have excluded some relevant studies with implications for the generalization of the conclusions. We adopted the inclusion of a third reviewer as a strategy to strengthen the research design and overcome the limitations.

Conclusion

The knowledge produced in this research made it possible to identify several strategies used by oncology nurses to face the COVID-19 pandemic in the international scenario. Reports concerning the restructuring of services and the team's reactions to the pandemic predominated. The findings show great appreciation and recognition of nurses' role, especially in managing institutions, restructuring hospital and home care services, and follow-up of patients with cancer during the pandemic.

Difficulties experienced in the daily lives of health professionals and the emotional issues of being a nurse amid the pandemic were discussed, but there was a lack of studies on strategies to support these professionals. Another gap identified was the scarcity of clinical studies on the activities developed by oncology nurses. Therefore, there is a need for clinical research in the oncology area and emotional coping strategies to support oncology nurses.

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Conflicts of Interest

None declared.

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Abbreviations

JBI: Joanna Briggs Institute
ONS: Oncology Nursing Society
PPE: personal protective equipment
WHO: World Health Organization

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Original Paper

Supporting Shared Decision-making About Surveillance After Breast Cancer With Personalized Recurrence Risk Calculations: Development of a Patient Decision Aid Using the International Patient Decision AIDS Standards Development Process in Combination With a Mixed Methods Design

Jet Wies Ankersmid[1,2], MSc; Sabine Siesling[1,3], PhD; Luc J A Strobbe[4], MD, PhD; Johanna M Meulepas[5], PhD; Yvonne E A van Riet[6], MD; Noel Engels[2,7,8], MD; Janine C M Prick[2,9], MD; Regina The[10], MSc; Asako Takahashi[10], MSc; Mirjam Velting[11], MA; Cornelia F van Uden-Kraan[2], PhD; Constance H C Drossaert[12], PhD

[1]Department of Health Technology and Services Research, University of Twente, Enschede, Netherlands
[2]Santeon, Utrecht, Netherlands
[3]Department of Research and Development, Netherlands Comprehensive Cancer Organisation, Utrecht, Netherlands
[4]Department of Surgery, Canisius Wilhelmina Hospital, Nijmegen, Netherlands
[5]Department of Quality and Safety, Catharina Hospital, Eindhoven, Netherlands
[6]Department of Surgery, Catharina Hospital, Eindhoven, Netherlands
[7]Department of Internal Medicine, Maasstad Hospital, Rotterdam, Netherlands
[8]Department of Internal Medicine, Leiden University Medical Centre, Leiden, Netherlands
[9]Department of Neurology, OLVG, Amsterdam, Netherlands
[10]ZorgKeuzeLab, Delft, Netherlands
[11]Dutch Breast Cancer Society, Utrecht, Netherlands
[12]Department of Psychology, Health & Technology, University of Twente, Enschede, Netherlands

Corresponding Author:
Jet Wies Ankersmid, MSc
Department of Health Technology and Services Research
University of Twente
TechMed Centre
Hallenweg 5
Enschede, 7522 NH
Netherlands
Phone: 31 303073906
Email: j.w.ankersmid@utwente.nl

Abstract

Background: Although the treatment for breast cancer is highly personalized, posttreatment surveillance remains one-size-fits-all: annual imaging and physical examination for at least five years after treatment. The INFLUENCE nomogram is a prognostic model for estimating the 5-year risk for locoregional recurrences and second primary tumors after breast cancer. The use of personalized outcome data (such as risks for recurrences) can enrich the process of shared decision-making (SDM) for personalized surveillance after breast cancer.

Objective: This study aimed to develop a patient decision aid (PtDA), integrating personalized risk calculations on risks for recurrences, to support SDM for personalized surveillance after curative treatment for invasive breast cancer.

Methods: For the development of the PtDA, the International Patient Decision Aids Standards development process was combined with a mixed methods design inspired by the development process of previously developed PtDAs. In the development, 8 steps were distinguished: establishing a multidisciplinary steering group; definition of the end users, scope, and purpose of the PtDA; assessment of the decisional needs of end users; defining requirements for the PtDA; determining the format and implementation strategy for the PtDA; prototyping; alpha testing; and beta testing. The composed steering group convened during regular working-group sessions throughout the development process.

Results: The “Breast Cancer Surveillance Decision Aid” consists of 3 components that support the SDM process: a handout sheet on which personalized risks for recurrences, calculated using the INFLUENCE-nomogram, can be visualized and which contains an explanation about the decision for surveillance and a login code for a web-based deliberation tool; a web-based deliberation tool, including a patient-reported outcome measure on fear of cancer recurrence; and a summary sheet summarizing patient preferences and considerations. The PtDA was assessed as usable and acceptable during alpha testing. Beta testing is currently ongoing.

Conclusions: We developed an acceptable and usable PtDA that integrates personalized risk calculations for the risk for recurrences to support SDM for surveillance after breast cancer. The implementation and effects of the use of the “Breast Cancer Surveillance Decision Aid” are being investigated in a clinical trial.

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KEYWORDS

patient decision aid; PtDA; breast cancer; surveillance; risk information; shared decision-making; SDM

Introduction

Follow-up after curative treatment for breast cancer can be subdivided into *aftercare* and *posttreatment surveillance*. *Aftercare* focuses on information provision, guidance, identification, and dealing with complaints, symptoms, and the physical or psychosocial effects of the disease and treatment [1]. The primary aim of *posttreatment surveillance* is the early detection of locoregional recurrences (LRRs) or second primary tumors (SPs) [1]. In the Netherlands, surveillance is currently one-size-fits-all for all patients with curatively treated breast cancer. However, the risks for LRRs and SPs differ per patient [2,3], and surveillance can be personalized to reduce health care and patient burden. Annual physical examination and imaging are recommended for at least 5 years after treatment for a large group of women with a relatively low risk for recurrences. However, for these women, less intensive surveillance is as effective as more intensive surveillance in terms of diagnosis of LRRs and SPs, and overall survival [4,5].

A woman’s personalized 5-year risk for LRRs and SPs after treatment for breast cancer can be estimated using the INFLUENCE nomogram, a validated prediction model [2,3]. Furthermore, patient needs and preferences should be considered when personalizing surveillance. Patients describe trade-offs between burdens, such as the burden of going to the hospital, anxiety, discomfort, and pain because of the examination and benefits such as the reassurance that surveillance can offer [6]. Therefore, the decision regarding the organization of posttreatment surveillance (eg, frequency, duration, and examination) can be seen as a preference-sensitive decision for which shared decision-making (SDM) is identified as the preferred way of decision-making [7].

SDM can be seen as an indicator of quality of care and is being increasingly reported in breast cancer guidelines [8,9]. It can be defined as “an approach where clinicians and patients share the best available evidence when faced with the task of making decisions, and where patients are supported to consider options, to achieve informed preferences” [10,11]. Within the process of SDM, four steps can be distinguished: (1) the professional informs the patient that a decision is to be made and that the patient’s opinion is important, (2) the professional explains the options and their pros and cons, (3) the professional and the patient discuss the patient’s preferences and the professional supports the patient in deliberation, and (4) the professional and the patient discuss the patient's wish to make or defer the decision, and discuss follow-up [10]. Recent studies show that even though patients are open to SDM for personalized surveillance, it is only rarely applied and information needs remain unaddressed [6,12,13].

Patient decision aids (PtDAs) are evidence-based tools designed to help patients make specific and deliberate choices among various health care options. PtDAs provide evidence-based information and help patients recognize and clarify values that may play a role in decisions [14]. Clear and objective risk information is an essential component of PtDA. General risk information (about groups of patients) is often presented, but this information is difficult to translate to individual cases [15,16]. Nomograms are being increasingly developed to better estimate individual personal risks. However, these nomograms are rarely integrated into PtDAs [17].

This study aimed to develop a PtDA integrating personalized risk calculations regarding the risk of LRRs and SPs to support SDM for personalized surveillance after curative treatment for invasive breast cancer.

Methods

Overview

The development of the “Breast Cancer Surveillance Patient Decision Aid” was initiated by Santeon, a group of 7 collaborating top clinical hospitals in the Netherlands. ZorgKeuzeLab was the development and implementation partner. ZorgKeuzeLab has developed and implemented over 25 PtDAs and therefore has high expertise. For the development of the PtDA, the International Patient Decision Aids Standards (IPDAS) development process [18] was combined with a mixed methods design inspired by the development process of PtDAs previously developed in collaboration with ZorgKeuzeLab [19-21]. In the development, eight steps were distinguished: (1) establishing a multidisciplinary steering group, (2) definition of the end users and scope and purpose of the PtDA, (3) assessment of the decisional needs of end users, (4) defining requirements for the PtDA, (5) determining the format and implementation strategy for the PtDA, (6) prototyping, (7) alpha testing, and (8) beta testing.

Step 1: Steering Group

To start the development process, the initiators established a multidisciplinary steering group consisting of relevant experts, including patients that were curatively treated for invasive breast cancer and health care professionals (HCPs). To ensure broad acceptance and high implementation of the tool to be developed, members of the multidisciplinary steering group represented all stakeholders involved in the decision-making process, had expertise in breast cancer surveillance, and came from different institutions. Patient representation was ensured by inviting the Dutch Breast Cancer Society (BVN) and the Dutch Federation of Cancer Patient Organizations to participate in the steering group. A selection was made of potential steering group members, and approximately 25 potential steering group members were invited by email to participate. The steering group members were to convene during 5 steering group sessions from which the timing and content were determined based on the steps of the development process. The steering group sessions were prepared and led by a small group of steering group members (including authors JWA, RT, and JBM). The aim of each session was evaluated at the end of each session.

Step 2: End Users, Purpose, and Scope

The end users, purpose, and scope of the PtDA were determined based on consensus discussions among the steering group members, supported by input from decisional needs assessment studies among patients and HCPs. A small group of steering group members set up a proposal for the end users, purpose, and scope, which was presented and discussed in the first steering group session. Related results from decisional needs assessment studies among patients and HCPs were presented to support this discussion.

Step 3: Decisional Needs Assessment End Users

Two decisional needs assessment studies were set up and performed among 22 patients (patient needs assessment study) and 21 HCPs (HCP needs assessment study) according to the Ottawa Hospital Research Institute’s guidelines [22] to determine the needs regarding SDM about personalized posttreatment surveillance. For both the needs assessment studies, semistructured interviews were conducted between August 2019 and February 2020. The interviews lasted about one hour and were performed by one researcher (JA, PhD Candidate, MSc in Psychology) who was trained in conducting interviews. Female patients who received curative treatment for invasive breast cancer and had completed their primary treatment were eligible to participate in the patient needs assessment study. The interviews with patients focused on the following topics: (1) current information provision about surveillance, (2) current decision-making about surveillance, (3) preferences for decision-making about surveillance, (4) current use and perspectives on the use of information on personal risks for recurrences in decision-making about surveillance, and (5) perspectives on less intensive surveillance in case of low personal risk. HCPs involved in the follow-up after breast cancer were eligible to participate in the HCP needs assessment study. The interviews with HCPs focused on a broad range of preferences regarding decision-making concerning surveillance and the following topics: (1) perspectives on less intensive surveillance for women with low risks for recurrences, (2) attitudes regarding SDM about surveillance, and (3) perspectives on the use of information on personal risks for recurrences in decision-making about surveillance. Transcripts of all interviews were coded by independent coders (JA and CD) and analyzed using the “framework methodology” [23], which consists of a combination of inductive and deductive approaches: in each of the main topics, the coders inductively searched for themes that emerged from the data. Further details regarding the method of the needs assessment studies can be found in 2 previously published papers [6,24].

Step 4: Requirements

On the basis of the IPDAS minimum standard criteria [25], in combination with steering group discussions and the results of the needs assessment studies, a list of requirements for the PtDA was developed. This list of requirements was used to inform the format and implementation strategy for the PtDA (step 5), prototyping (step 6), and alpha testing (step 7).

Step 5: Format and Implementation Strategy

The format of the PtDA was determined in consultation with the steering group and was inspired by the 4 steps of SDM and the format of other existing PtDAs [10,19-21,26]. The implementation strategy was determined in the earlier stages of development (before prototyping) to enable optimization of the design and content of the PtDA and to adapt it to the workflow. Furthermore, it would allow for the early identification and addressing of potential implementation issues [27]. The results of an assessment of the follow-up care pathways in the Santeon hospitals [12], successful implementation strategies for existing PtDAs [28], and a web-based self-management app using patient-reported outcome measures (PROMs) to monitor the quality of life which focuses on awareness, willingness, and behavior of both HCPs and patients [29] were used as a basis for the implementation strategy for the PtDA. The final implementation strategy was determined through consultations with the steering group.

Step 6: Prototyping

On the basis of the results of the needs assessment studies and the determined format, several low-fidelity prototypes were developed during the three cocreative steering group sessions. ZorgKeuzeLab (the development and implementation partner) uses an approach in cocreative design and prototyping, consisting of the following steps: (1) designing the summary sheet, (2) determining the structure and content of the web-based deliberation tool, and (3) designing the handout sheet. The prototypes were discussed, evaluated, and improved (multiple times if needed) by the steering group members to the high-fidelity prototype used for testing. The presentation of personal risks for LRRs and SPs (including uncertainty) in our PtDA was based on the literature on the current best practices for risk presentation in PtDAs [30]. Various risk presentations for the personal risks of LRRs and SPs were considered, discussed, and adapted during consensus discussions in the steering group during the prototyping phase.

Step 7: Alpha Testing

Alpha testing of the PtDA consisted of (1) checking whether all determined requirements were met, (2) usability and acceptability testing with patients, and (3) usability and acceptability testing with HCPs. The PtDA was checked for all minimal requirements by the authors JA and CD using the list of requirements that were developed by the steering group.

Alpha testing with patients was conducted in May 2020. Eligible participants were female patients who were curatively treated for breast cancer and finished their primary treatment. We strived to include 6-8 patients [31]. The patients were invited to participate through the social media platform of the BVN. A total of 10 patients volunteered for whom 6 participated (all women, aged 44-75 years, mean 54 years). Owing to COVID-19, tests were performed virtually using Microsoft Teams. First, patients were given a handout sheet with a fictitious patient with a specific (fictious) illness, treatment characteristics, and personal risks for recurrences. They were asked to go through the web-based deliberation tool while thinking aloud about their experiences and thoughts. Any observed difficulties or expressed problems were noted by researchers (usability). After this, patients were interviewed about their satisfaction with the content, layout, and perceived usefulness of the PtDA (acceptability). Finally, we asked the patients whether they would recommend the tool to others (acceptability). Patients' understanding of the risk information was not included in the tests.

Alpha testing of HCPs was performed in May 2020. A total of 14 HCPs, involved in surveillance after breast cancer, participated (6 surgical oncologists, 4 nurse practitioners, 2 medical oncologists, 1 radiation oncologist, and one research nurse). They were selected and approached via email by steering group members. Our aim was to include more HCPs than patients because the PtDA was intended for use in several hospitals and therefore there was a need to explore routes for implementation (how it fits in the workflow) and potential barriers and facilitators for implementation. Alpha testing was conducted through telephone interviews, which were held after the HCPs had gone through the PtDA by themselves. During the interviews, all 3 components of the PtDA were discussed. Furthermore, HCPs were asked about suggestions for improvement regarding the workflow and content of the PtDA (usability), if they would use the PtDA themselves, and whether they would recommend it to others (acceptability).

The alpha testing sessions with patients and HCPs were summarized and analyzed by authors JA, RT, and AT using the framework methodology [20]. The results, including suggestions for improvement, were discussed in the last steering group session, in which decisions were made on the final adaptations.

Step 8: Beta Testing

Beta testing (field testing) of the "Breast Cancer Surveillance Decision Aid" with patients and HCPs is ongoing in a large clinical trial. The effectiveness and implementation of shared decision-making supported by outcome information among patients with breast cancer (SHOUT-BC) trial is a multiple interrupted time-series design study in which 630 breast cancer patients will be included in 2 conditions (before or after implementation of the PtDA) in 7 top clinical hospitals (Santeon hospitals) over a period of 20 months. Data will be collected at 3 time points using questionnaires: after the consultation in which the decision for the organization of posttreatment surveillance was made and after 6 and 12 months. In addition, 230 consultations between HCPs and patients facing decisions about the organization of surveillance care will be audio recorded and analyzed. Additional data (eg, data on health care use) will be collected from patients' medical records. The primary outcome will be patient-reported SDM. The secondary outcomes include observed SDM, decisional conflict and regret, fear of recurrence, risk perception, disease perception, and quality of life. More details on the SHOUT-BC trial can be found in the published study protocol [32].

Ethical Considerations

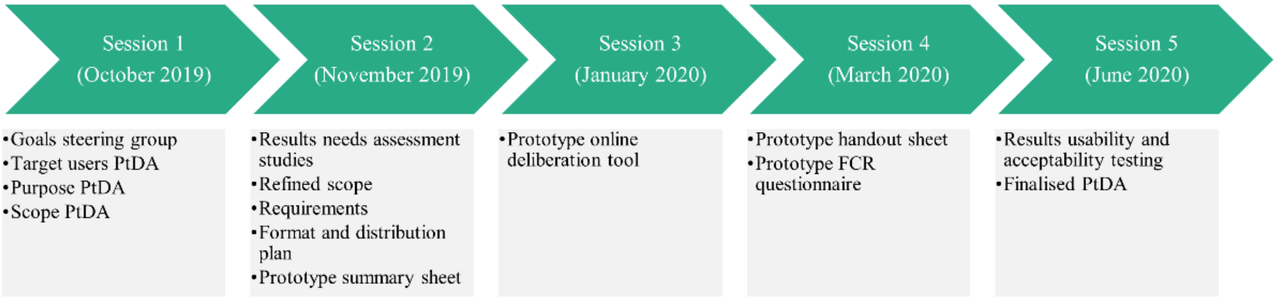
The studies carried out as part of the development of the PtDA were conducted in accordance with local laws and regulations. The Medical Research Ethics Committees United in Nieuwegein, the Netherlands, confirmed that the studies were not subject to the Medical Research Involving Human Subjects Act (WMO).

Results

Step 1: Steering Group

The established steering group consisted of 15 members: 3 surgical oncologists, 1 medical oncologist, 1 radiation oncologist, 2 nurse specialists, 2 patient advocates, 1 patient representative, 1 operational manager of an oncology department, 1 clinical epidemiologist, 2 health psychologists, and 1 communication scientist with experience in SDM. The development process was facilitated by 2 project leaders, the general director, and a user experience expert from ZorgKeuzeLab. An overview of all the steering group members is provided in Multimedia Appendix 1. The steering group convened during regular cocreative steering group sessions between October 2019 and June 2020. In Figure 1, the timing and topics of each steering group session are displayed. The predetermined aims were achieved for each session.

Figure 1. Timing and topics of cocreative steering group sessions. FCR: fear of cancer recurrence; PtDA: patient decision aid.



Step 2: End Users, Purpose, and Scope

The end users of the developed PtDA were women curatively treated for invasive breast cancer after finalizing their primary treatment. Women who were treated palliatively or those with a genetic disposition related to breast cancer were excluded as end users because of differing follow-up care pathways. Male patients, women diagnosed with noninvasive breast cancer, and women who received neoadjuvant systemic treatment were excluded because the risk prediction model (INFLUENCE nomogram) that is integrated within the PtDA is not suitable for calculating their risks for recurrences.

A discussion point regarding the purpose and scope of the PtDA was whether it should entail personalization of surveillance and aftercare (because of the intertwinement of both in clinical practice) or surveillance alone. The steering group eventually agreed that the PtDA should be specifically aimed at decision-making about surveillance and not aftercare after breast cancer because of the more dynamic nature of aftercare. Although regular surveillance moments can be planned according to the steering group, aftercare should be organized in a more flexible manner. For example, through monitoring of patients' needs through PROMs and by personalizing care on the outcomes of these PROMs. Therefore, the main purpose of the PtDA is to support patients and their HCPs in SDM for personalized surveillance. The decisions that are supported within the scope of the PtDA are the decisions about the frequency of surveillance, the duration of surveillance, the examination or examinations performed during surveillance, and the way of contact with the HCP (eg, face-to-face or teleconsultation).

Step 3: Decisional Needs Assessment End Users

The decisional needs assessment among patients revealed that SDM regarding posttreatment surveillance is not often practiced. Patients expressed a wish for more SDM and were open to the use of personalized information on risks for recurrences in this process. However, patients indicated that they sometimes experienced an "internal conflict" between rationale (eg, a low risk for recurrences) and feelings or emotions (fear of cancer recurrence [FCR]), resulting in a high need for reassurance. The HCP needs assessment study revealed that most HCPs supported SDM regarding surveillance and were also positive about using personalized information on risks for recurrences. HCPs indicated some common misconceptions among patients that should be addressed in the PtDA (eg, that patients think that surveillance is primarily aimed at the detection of distant metastasis and the overestimation of the value of physical examination during surveillance consultations). Specific information needs, preferences, and prerequisites for SDM about personalized posttreatment surveillance were gathered and translated into requirements for the PtDA (see *Step 4: Requirements*). More detailed results of the needs assessment studies can be found in 2 previously published papers [6,24].

Step 4: Requirements

The list of requirements for the PtDA developed by the steering group based on the IPDAS minimal criteria, steering group discussions, and the results of the needs assessment studies are displayed in Textbox 1.

Textbox 1. Requirements for the breast cancer surveillance patient decision aid (PtDA). Only the requirements that emerged from the needs assessment studies or steering group discussions are mentioned. More general International Patient Decision Aids Standards criteria were considered the baseline requirements.

Information on surveillance and options:

1. The PtDA informs on the difference between aftercare and surveillance after breast cancer.
2. The PtDA informs on the aim of surveillance including that surveillance is not aimed at active surveillance for distant metastasis.
3. The PtDA informs on the options for the organization of surveillance for each decision modality (frequency, duration, examinations, way of contact with the health care professional [HCP]) including the advantages and disadvantages.
4. The PtDA informs on the limited added value of physical examination in the detection of locoregional recurrence (LRRs) and second primary tumors (SPs).
5. The PtDA informs on the potential added value of self-examination in the detection of LRRs and SPs and on how to perform self-examination.
6. The PtDA informs patients that they can receive aftercare when the frequency of surveillance is less intensive.
7. The PtDA informs on who to contact in case of complaints or worries.

Probabilities:

1. The PtDA informs on personal risks for LRRs and SPs.
2. Personal risks for LRRs and SPs should be displayed both verbally (in words) and visually (in a diagram, including visual information about levels of uncertainty of the prediction).
3. The PtDA informs on the factors on which personal risks for LRRs and SPs depend.

Methods for clarifying and expressing patients' considerations and preferences:

1. The PtDA gives insight in the patients' own level of fear of cancer recurrence and facilitates conversations about experienced fear of cancer recurrence with HCPs.
2. Patients should be able to read about and reflect on other women's choices and experiences regarding surveillance.
3. The PtDA facilitates clarification of patient preferences and considerations for the organization of surveillance (value-clarification exercise).

Guidance in deliberation and communication:

1. HCPs should be able to indicate the available options for the maximum duration of surveillance and the options for examinations.
2. The PtDA facilitates for patients to test their knowledge on the most important aspects of surveillance.
3. The PtDA facilitates for patients to indicate their role-preference for the shared decision-making process regarding personalized surveillance.
4. The PtDA facilitates patients to list any remaining questions that they might have for their HCP.

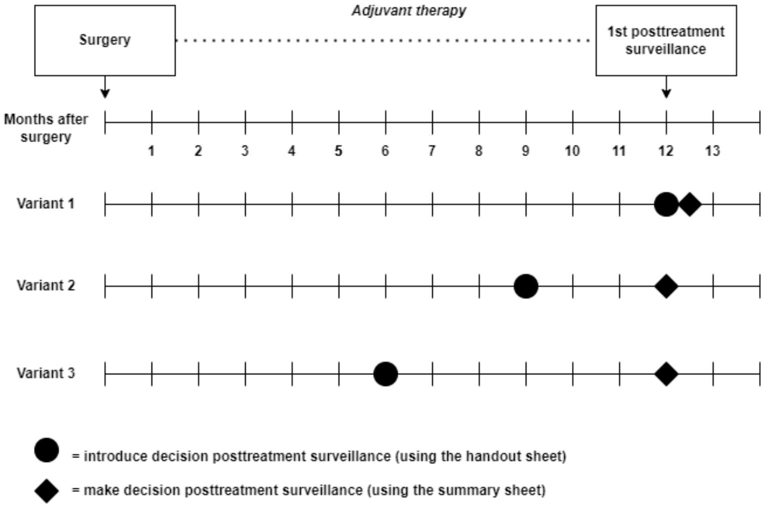
Step 5: Format and Implementation Strategy

The steering group determined that the PtDA would consist of 3 components supporting all 4 steps in the SDM process [10]. Each component is described in detail in *Step 6: Prototyping*." The results of an assessment of the organization of surveillance in the Santeon hospitals were used to determine how the PtDA would fit in the follow-up care pathways [12]. Three different variants for the integration of the PtDA into the care pathways were identified. An overview of the 3 variants is shown in Figure 2. The HCP who introduces the decision about surveillance and who makes the final shared decision about surveillance with patients differs per hospital.

An implementation strategy was developed to implement the PtDA in clinical practice. The implementation strategy consists of the following components:

- Creating support for using the PtDA by cocreation, including both HCPs and patients, and by customizing the PtDA for each hospital (eg, by applying the hospital logo);
- Documenting the current pathways in each hospital to find the best way to incorporate the PtDA [12];
- Informing and involving all HCPs in the care pathway by means of an information meeting, and by offering the possibility to follow the e-learning courses "SDM with patients" and "Applying outcome information in SDM";
- Giving HCPs the opportunity to practice conversational skills with actors in group training on "SDM and the use of outcome information";
- Providing an instructional meeting on the use of the PtDA in clinical practice (eg, on how to introduce and discuss it), including reports on experiences of other HCPs and patients who have used the PtDA before;
- Follow-up on the implementation by practical support in clinical practice, a reporting tool to keep track of the implementation rate of the PtDA, and a refresher module of the received conversational skills training program;
- Close monitoring of progress and stimulating implementation of the PtDA by a local ambassador.

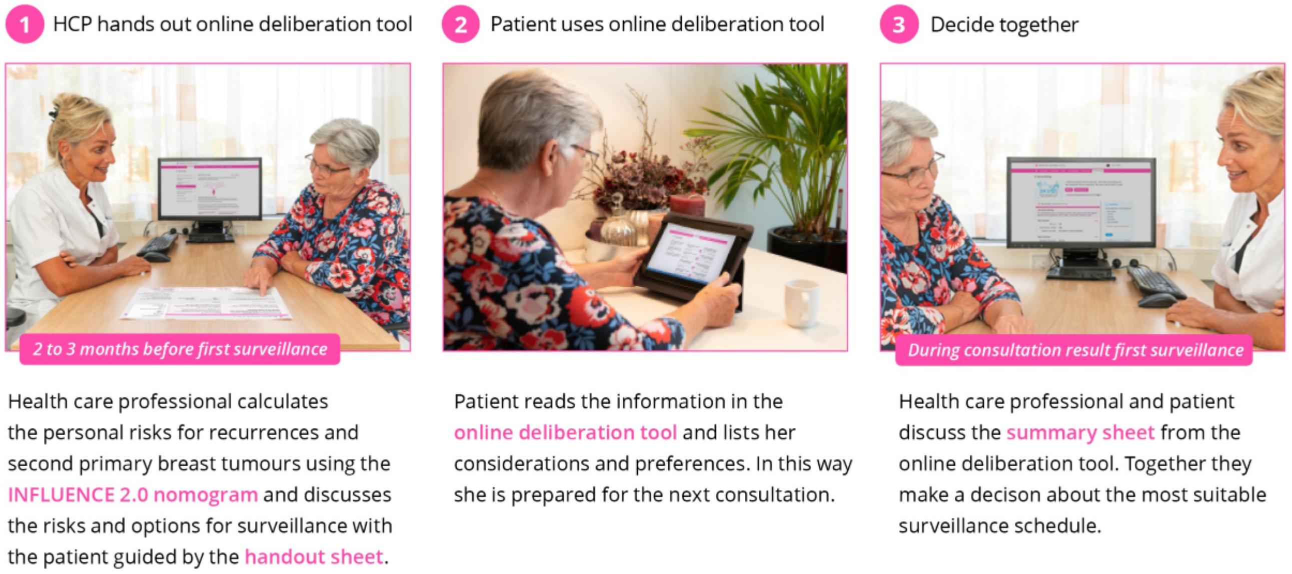
Figure 2. Overview of 3 variants for integration of “Breast Cancer Surveillance Decision Aid” in care pathways.



Step 6: Prototyping—the Three Components of the PtDA

Several low-fidelity prototypes were developed within the cocreative working group sessions. The high-fidelity prototype that was developed and used for alpha and beta testing consisted of 3 main components (Figure 3) that are described as follows: (1) a handout sheet, (2) a web-based deliberation tool, and (3) a summary sheet.

Figure 3. Three components of the Breast Cancer Surveillance Decision Aid. HCP: health care professional.



Health care professional calculates the personal risks for recurrences and second primary breast tumours using the INFLUENCE 2.0 nomogram and discusses the risks and options for surveillance with the patient guided by the handout sheet.

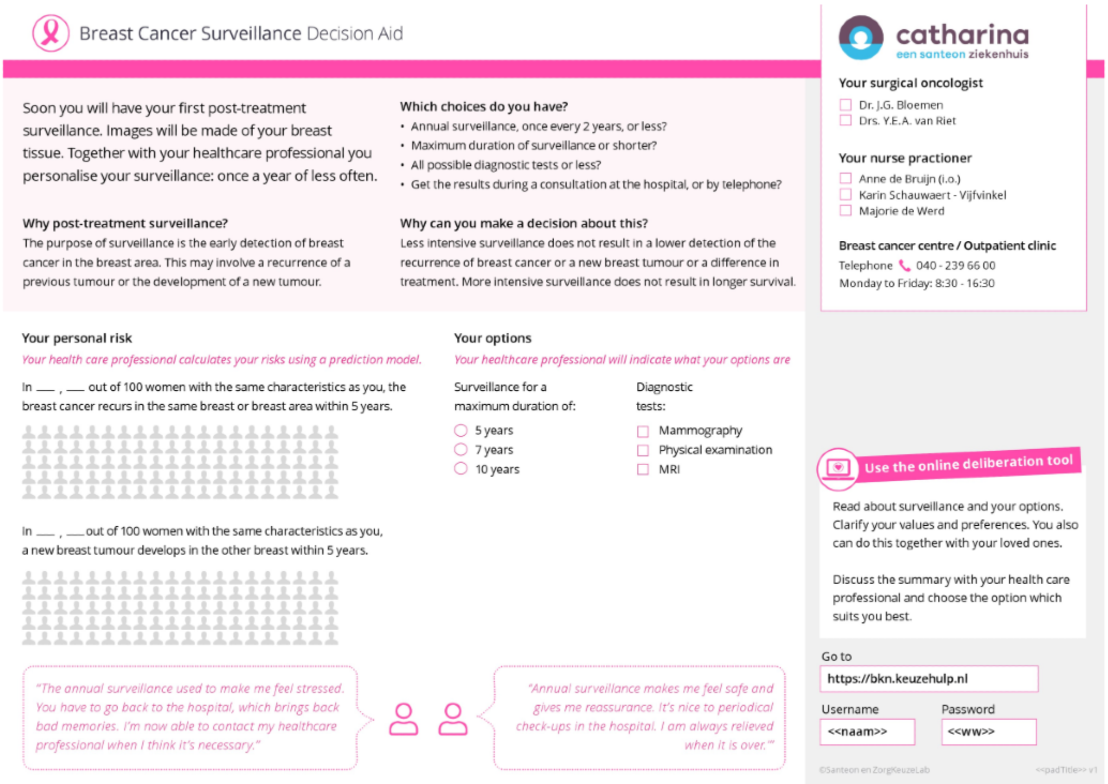
Patient reads the information in the online deliberation tool and lists her considerations and preferences. In this way she is prepared for the next consultation.

Health care professional and patient discuss the summary sheet from the online deliberation tool. Together they make a decison about the most suitable surveillance schedule.

Component 1: The Handout Sheet

Component 1 consists of a handout sheet with which the HCP explains why the patient can co-decide about surveillance and what the options are (eg, frequency, imaging, duration, and preferred contact with HCPs). The handout sheet supports step one and step 2 of the SDM process. The HCP enters the required patient, tumor, and treatment characteristics in the web-based INFLUENCE nomogram [2], which the 5-year risks for LRRs and SPs after treatment for breast cancer can be estimated. This risk is visualized on the handout sheet. The handout sheet also contained the login code and password for the web-based information and deliberation tool. In the PtDA, we make use of a personal login code for several reasons: (1) patients can decide with whom they share the information that they enter the PtDA, (2) patients can access the PtDA and the information that they entered at all times on any device without having to start over, and (3) the login code can be linked to a specific institution that enables implementation measurements (eg, the number of logins per institution). Figure 4 shows the handout sheet.

Figure 4. Handout sheet.



Breast Cancer Surveillance Decision Aid

Soon you will have your first post-treatment surveillance. Images will be made of your breast tissue. Together with your healthcare professional you personalise your surveillance: once a year of less often.

Which choices do you have?

- Annual surveillance, once every 2 years, or less?
- Maximum duration of surveillance or shorter?
- All possible diagnostic tests or less?
- Get the results during a consultation at the hospital, or by telephone?

Why post-treatment surveillance?
The purpose of surveillance is the early detection of breast cancer in the breast area. This may involve a recurrence of a previous tumour or the development of a new tumour.

Why can you make a decision about this?
Less intensive surveillance does not result in a lower detection of the recurrence of breast cancer or a new breast tumour or a difference in treatment. More intensive surveillance does not result in longer survival.

catharina
een santeon ziekenhuis

Your surgical oncologist
☐ Dr. J.G. Bloemen
☐ Drs. Y.E.A. van Riet

Your nurse practioner
☐ Anne de Bruijn (i.o.)
☐ Karin Schauwaert - Vijfvinkel
☐ Majorie de Werd

Breast cancer centre / Outpatient clinic
Telephone ☎ 040 - 239 66 00
Monday to Friday: 8:30 - 16:30

Your personal risk
Your health care professional calculates your risks using a prediction model.

In ___ , ___ out of 100 women with the same characteristics as you, the breast cancer recurs in the same breast or breast area within 5 years.

In ___ , ___ out of 100 women with the same characteristics as you, a new breast tumour develops in the other breast within 5 years.

Your options
Your healthcare professional will indicate what your options are

Surveillance for a maximum duration of:
○ 5 years
○ 7 years
○ 10 years

Diagnostic tests:
☐ Mammography
☐ Physical examination
☐ MRI

"The annual surveillance used to make me feel stressed. You have to go back to the hospital, which brings back bad memories. I'm now able to contact my healthcare professional when I think it's necessary."

"Annual surveillance makes me feel safe and gives me reassurance. It's nice to periodical check-ups in the hospital. I am always relieved when it is over.""

Use the online deliberation tool

Read about surveillance and your options. Clarify your values and preferences. You also can do this together with your loved ones.

Discuss the summary with your health care professional and choose the option which suits you best.

Go to
https://bkn.keuzehulp.nl

Username
<<naam>>

Password
<<ww>>

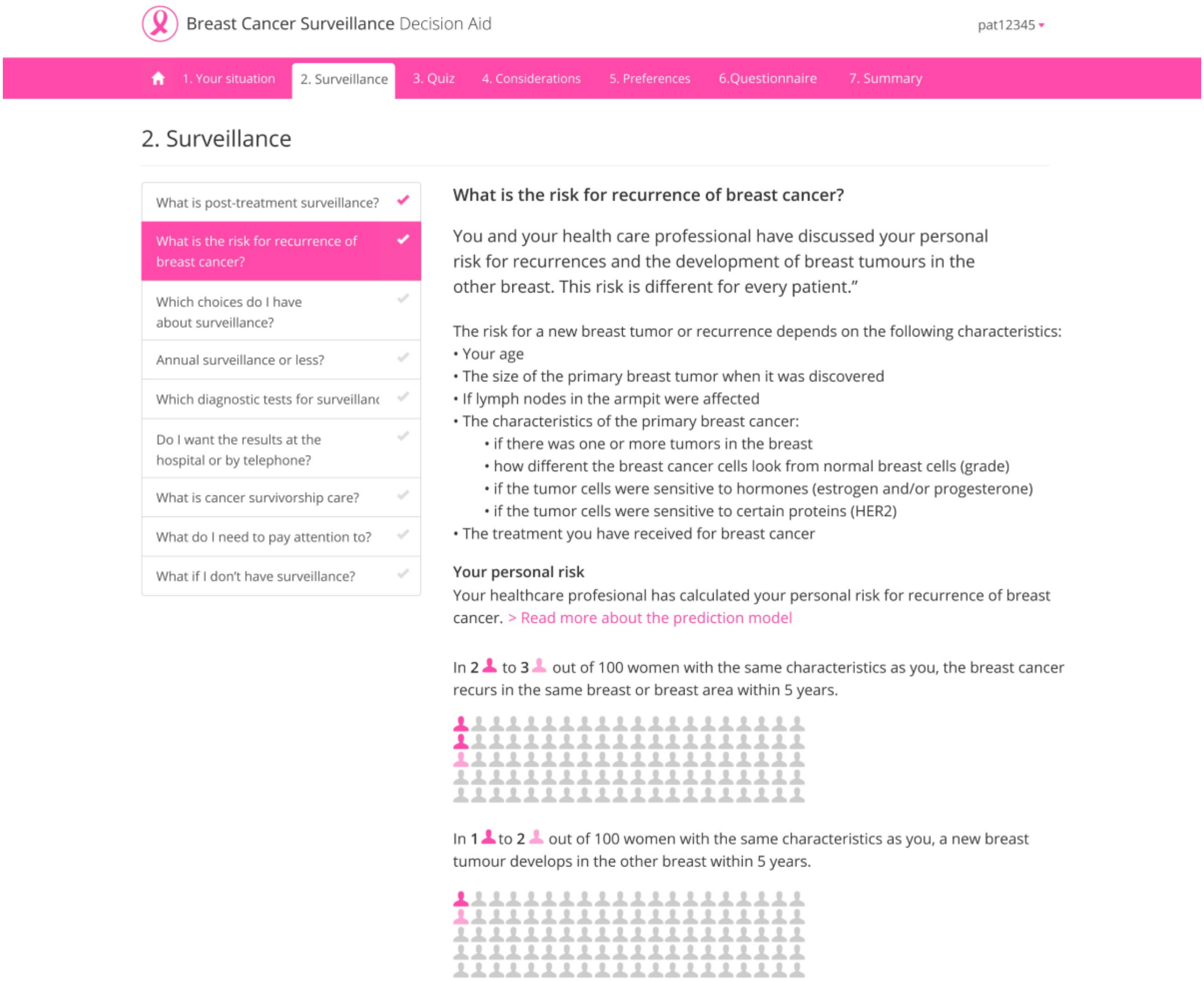
©Santeon en ZorgKeuzeLab
<<padTitle>> v1

Component 2: The Web-Based Deliberation Tool

Component 2 consists of a web-based information and deliberation tool for women and their caregivers to go through at home at their own pace and time. The web-based deliberation tool supports the second and third steps of the SDM process. The content of the web-based deliberation tool was written at the B1 level of the Common European Framework of Reference for Languages; therefore, it is comprehensible for most patients. The web-based deliberation tool consists of seven modules: (1) your situation, (2) information about surveillance, (3) a quiz, (4) your considerations, (5) your preferences, (6) a questionnaire, and (7) a summary.

In module 1, patients copy their risks for LRRs and SPs and options for the maximum duration and imaging modalities from the handout sheet to the web-based deliberation tool. Module 2 consists of several pages with information about surveillance (structured based on a set of frequently asked questions), the risks for LRRs and SPs, and different options for surveillance and aftercare after breast cancer. Module 3 consists of a knowledge quiz with 3 questions about misconceptions about surveillance with real-time feedback on the answers given. In module 4, patients are presented with a value-clarification assignment with 6 trade-offs on various aspects of surveillance. In module 5, patients can indicate their preference for the options applicable to them for surveillance. In module 6, women are asked to complete the 6-item Cancer Worry Scale questionnaire. This validated questionnaire is meant to assess and screen for FCR in patients that were curatively treated for invasive breast cancer [33]. The input is processed in real time and linked to tailored feedback on individual outcomes (based on validated cut-off scores), including comprehensive self-care advice (tips and tools). This questionnaire has been added to the web-based deliberation tool because the needs assessment studies and usability tests showed that patients regularly experience an "internal conflict" between rationale (low risk) and feelings or emotions (FCR). Because of this conflict, some patients indicated that they would still opt for more intensive surveillance than required for "reassurance." Many women with breast cancer experience FCR. By integrating the questionnaire, we aim that patients and HCPs can discuss any FCR and that HCPs can provide reassurance, tips for dealing with FCR, or refer the patient to another HCP (eg, a psychologist). In module 7, a summary is generated using the data that the patient has entered (patient preferences, considerations, and FCR score). Figure 5 displays a screenshot of the information on the risk for LRRs and SPs in module 2 of the web-based deliberation tool. Figure 6 shows the questionnaire on FCR in module 6 of the web-based deliberation tool.

Figure 5. Web-based deliberation tool—module 2 information on risks for locoregional recurrences and second primary tumors.



2. Surveillance

What is the risk for recurrence of breast cancer?

You and your health care professional have discussed your personal risk for recurrences and the development of breast tumours in the other breast. This risk is different for every patient.”

The risk for a new breast tumor or recurrence depends on the following characteristics:
- Your age
- The size of the primary breast tumor when it was discovered
- If lymph nodes in the armpit were affected
- The characteristics of the primary breast cancer:
  - if there was one or more tumors in the breast
  - how different the breast cancer cells look from normal breast cells (grade)
  - if the tumor cells were sensitive to hormones (estrogen and/or progesterone)
  - if the tumor cells were sensitive to certain proteins (HER2)
- The treatment you have received for breast cancer

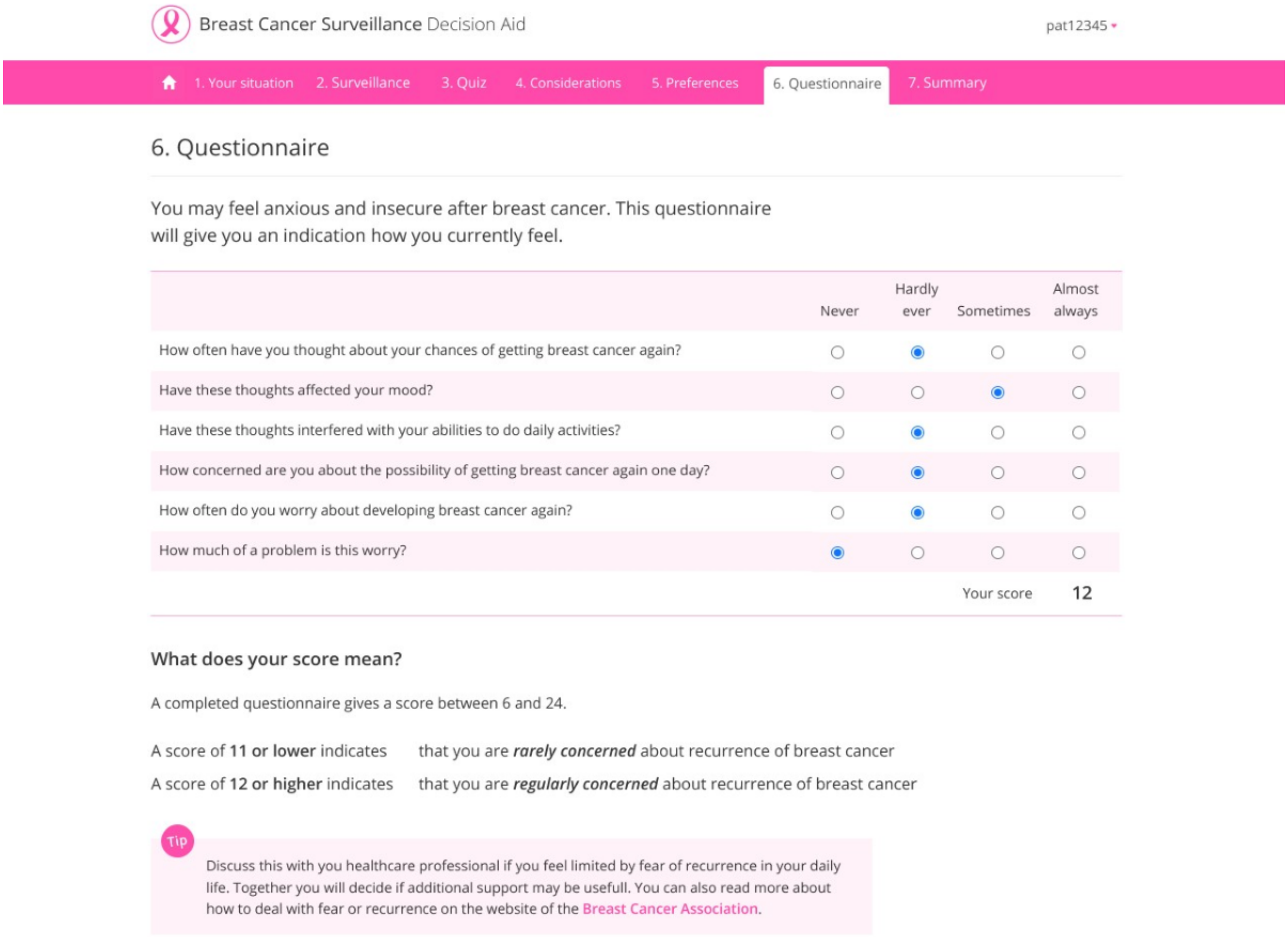
Your personal risk

Your healthcare profesional has calculated your personal risk for recurrence of breast cancer. > Read more about the prediction model

In 2 to 3 out of 100 women with the same characteristics as you, the breast cancer recurs in the same breast or breast area within 5 years.

In 1 to 2 out of 100 women with the same characteristics as you, a new breast tumour develops in the other breast within 5 years.

Figure 6. Web-based deliberation tool—module 6—fear of cancer recurrence questionnaire.



6. Questionnaire

You may feel anxious and insecure after breast cancer. This questionnaire will give you an indication how you currently feel.

	Never	Hardly ever	Sometimes	Almost always
How often have you thought about your chances of getting breast cancer again?	○	●	○	○
Have these thoughts affected your mood?	○	○	●	○
Have these thoughts interfered with your abilities to do daily activities?	○	●	○	○
How concerned are you about the possibility of getting breast cancer again one day?	○	●	○	○
How often do you worry about developing breast cancer again?	○	●	○	○
How much of a problem is this worry?	●	○	○	○
			Your score	12

What does your score mean?

A completed questionnaire gives a score between 6 and 24.

A score of **11 or lower** indicates	that you are ***rarely concerned*** about recurrence of breast cancer
A score of **12 or higher** indicates	that you are ***regularly concerned*** about recurrence of breast cancer

Tip

Discuss this with you healthcare professional if you feel limited by fear of recurrence in your daily life. Together you will decide if additional support may be usefull. You can also read more about how to deal with fear or recurrence on the website of the Breast Cancer Association.

Component 3: The Summary Sheet

Component 3 consists of a summary sheet containing women's preferences, considerations, and PROM results on fear of recurrence. The sheet can be used by the patient and HCP in the consultation to support step 3 and step 4 of the SDM process and contains all the information that the patients have given as input in the web-based deliberation tool. Figure 7 shows the summary sheet for a fictitious patient.

Figure 7. Summary sheet.

Breast Cancer Surveillance Decision Aid

pat12345

Your summary

This is the summary of your situation and preferences. Bring summary to your next consultation with your healthcare professional. Together you decide what surveillance options suit you best.

My situation

My risk for recurrences in the same breast or breast area	2.3 %
My risk for developing new breast tumours in the other breast	1.5 %
Surveillance for a maximum duration of	5 years
Options for diagnostic tests	Mammography, physical examination

My preferences about surveillance

How often?	Every year
How many years?	5 years
Which diagnostic tests?	Mammography, physical examination
Results at the hospital or by phone?	Consultation at the hospital
My remarks	- Argument
My role in decision making	I prefer that my healthcare professional and I make the decision together
My questions	- Question

My considerations

I don't mind going to the hospital for surveillance	I don't want to go to the hospital for surveillance
I want to go for surveillance, even though it makes me restless	I want as little surveillance as possible to avoid stress and unrest
Periodical surveillance makes me feel safe and reassured	I only want surveillance when I feel it is necessary
I want to have periodical surveillance, even if it takes time and effort	I prefer to spend as little time and effort as possible on surveillance
I want surveillance in the hospital, regardless of the costs	I don't want surveillance in the hospital, because of the costs
My loved ones thinks it is important that I have periodical surveillance	My loved ones understand if I don't have periodical surveillance

My score on the fear of recurrence questionnaire 12

Step 7: Alpha Testing

The "Breast Cancer Surveillance Decision Aid" was checked on the requirements established by the steering group (Textbox 1). All requirements were fulfilled.

The patients who were involved in the usability test were positive about the usefulness of the PtDA and would recommend it to other patients (acceptability). The patients indicated that they felt well informed and that they experienced the opportunity to clarify their considerations and preferences regarding surveillance as positive. The patients encountered very few usability issues and found that PtDA was easy to use. However, they found that some of the texts in the PtDA were too extensive.

The HCPs are also positive regarding the PtDA. Most of them indicated that the time was right for personalization of surveillance and that they saw the added value of the PtDA in informing patients and making them more conscious about their options for surveillance (acceptability). HCPs wanted to emphasize the value of self-examination and discuss the limited efficacy of physical examinations by HCPs in PtDA. They also felt that there should be more space to make notes on the discussion with the patient on the handout sheet.

On the basis of the collected feedback, several adaptations were made: (1) more space was created on the handout sheet to make notes, (2) texts within the web-based deliberation tool were shortened where possible, and (3) the descriptions of self-examination and physical examinations by HCPs in the web-based deliberation tool were altered.

Step 8: Beta Testing

The beta testing (field testing) of the "Breast Cancer Surveillance Decision Aid" is currently ongoing within the SHOUT-BC trial [32].

Discussion

Principal Findings

In cocreation, using a step-wise mixed method approach, we developed a PtDA integrating information on patients' personalized risks for LRRs and SPs to support SDM for personalized surveillance after curative treatment for invasive breast cancer. Development took place according to the IPDAS development process in combination with a mixed methods research design based on the development process of previously developed PtDAs [19-21]. Relevant experts, including patients and HCPs, were involved in development through steering group participation, participation in needs assessment studies, cocreative prototyping, and alpha and beta testing. Our studies revealed a list of requirements that were transferred to the prototype. Alpha testing revealed that all requirements (including the IPDAS minimum standard criteria) for the PtDA were met, and patients and HCPs found the PtDA acceptable and usable. Beta testing is currently ongoing. Throughout the development, we learned some lessons that will be discussed below.

Comparison With Previous Work

Our PtDA is one of the first to integrate outcome data. We integrated 2 types of outcome data: (1) individual PROMs data on FCR to support structural exploration and consideration of FCR levels and (2) personal risk information based on aggregated clinical data on LRRs and SPs. The results of our study showed that it is feasible to integrate outcome data into the 3-component structure of the PtDA, as both patients and HCPs were positive about the final prototype. Outcome data are expected to accelerate the implementation of SDM by strengthening the motivation of HCPs to apply SDM and empowering patients to engage in SDM [34]. During the steering group discussions, we debated whether a certain value of personal risk or FCR should prescribe a specified pathway in PtDA. However, for this time, we decided that the decision was only to be used as a source of information and not as a guideline because the evidence regarding the most adequate surveillance for specific risk groups needs to be extended. However, it remains interesting to examine whether such pathways are effective in PtDAs.

A challenge in supporting SDM using outcome data is to present data that are readily available to patients in a meaningful manner [16]. The presentation of personal risks for LRRs and SPs (including uncertainty) in our PtDA was based on the literature on the current best practices for risk presentation in PtDAs [30]. Various risk presentations for the personal risks for LRRs and SPs were considered, discussed, and adapted during consensus discussions in the steering group, in which both patients and HCP participated. Although the presentation of personal risks did not cause problems in the alpha testing phase, we did not measure the patients' understanding of the outcome data. In the beta testing phase, which is currently ongoing, we, therefore, decided to make audio recordings of consultations in which the PtDA is used, to examine how patients interpret and react to hearing their personal risks for recurrences, the FCR PROM score, and the questions they ask. For future research regarding the integration of outcome data into SDM support tools, we recommend testing patients' understanding of the outcome data during the alpha testing phase.

Within the development of the "Breast Cancer Surveillance Decision Aid," we have seen the importance of early development of an implementation strategy within the development process. Where (shared) medical decisions were made in one consultation, it is almost inherent to (the steps of) the SDM process, and thus the implementation of a PtDA to split the decision-making process into 2 consultations. This is especially true in the case of a complex decision that requires significant information processing or involves complex information such as outcome data. For successful implementation of PtDAs, it is important that the PtDA fits into the existing system or clinical pathway [35]. For our PtDA, the results of an assessment of the organization of surveillance in the Santeon hospitals were used to determine how the PtDA would fit in the follow-up care pathways [12]. Three different variants for the integration of the PtDA in the care pathways were identified. HCPs and decision support developers should realize that the implementation of PtDAs almost always requires a change in the flow of the care pathway. By assessing the care pathway in each hospital [12] and by determining the implementation strategy in the early stages of development, we could optimize the design and flow of the PtDA to the workflow in the hospitals. Furthermore, this allowed us to identify and anticipate potential implementation issues. In the original IPDAS development process model, attention to the implementation of PtDAs is limited [18,35]. However, recent research has shown that attention for and a successful implementation of are essential for the effectiveness of the developed PtDA [26,27]. We recommend considering implementation as a central part of the development of PtDAs.

During the development of the PtDA, we learned that dividing the steering group into multidisciplinary groups to perform rapid prototyping (during the steering group sessions), followed by a discussion of the prototypes with the complete steering group, enables all steering group members to actively participate in the design of the PtDA. Especially in the design of the outcome data in the PtDA (personal risks for LRRs and SPs and the PROM regarding FCR), this was beneficial for the development process as patients and HCPs were part of the steering group, and they could discuss how the outcome data would benefit them the most within the SDM process. Cocreation is not explicitly mentioned in the IPDAS criteria [18,25], but we recommend that it should be part of the development of every decision-support tool.

ZorgKeuzeLab uses an approach in the cocreative design and prototyping of PtDAs, consisting of the following steps: (1) designing the summary sheet, (2) determining the structure and content of the web-based deliberation tool, and (3) designing the handout sheet. This means that we started designing the last component of the PtDA. This made it easier to stay focused on the scope and relevant content requirements of the PtDA (see also *Step 6: Prototyping* under *Methods*). Therefore, we recommend using this approach for the development of future PtDAs in a similar format.

Limitations

However, the developmental process of the PtDA has some limitations. First, because we recruited patients for usability and acceptability testing through the social media platform of the BVN, we encountered relatively young patients who may have had more experience with computers and potentially the use of risk information. Second, because of COVID-19, usability and acceptability testing was performed digitally, during which we may not have been able to observe all relevant usability and acceptability aspects, such as the use of the handout sheet and the summary sheet in clinical practice. However, patients and HCPs were satisfied with the web-based deliberation tool and the linkages with the handout and summary sheets in general. Finally, we did not measure patients' understanding of the outcome data provided during alpha testing. However, in the beta testing phase, audio recordings of consultations in which the PtDA is used are analyzed, and specific attention is given to how patients interpret and react to the provided outcome data and to the questions that they have.

Conclusions

In conclusion, we developed an acceptable and usable PtDA to support SDM for personalized posttreatment surveillance after breast cancer. The implementation and effects of the use of the "Breast Cancer Surveillance Decision Aid" are being investigated in a clinical trial [32].

Acknowledgments

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Conflicts of Interest

RT and AT work for ZorgKeuzeLab; the company contracted by Santeon to support the development and implementation of the "Breast Cancer Surveillance Decision Aid." The authors declare that they have no conflicts of interest.

Multimedia Appendix 1
Steering group members.
[DOCX File , 15 KB - cancer_v8i4e38088_app1.docx]

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Abbreviations

BVN: Dutch Breast Cancer Society
FCR: fear of cancer recurrence
HCP: health care professional
IPDAS: international patient decision aids standards
LRR: locoregional recurrence
PROM: patient-reported outcome measure
PtDA: patient decision aid
SDM: shared decision-making
SHOUT-BC: shared decision-making supported by outcome information among patients with breast cancer
SP: second primary tumor

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Original Paper

Using Wearable Inertial Sensors to Assess Mobility of Patients With Hematologic Cancer and Associations With Chemotherapy-Related Symptoms Before Autologous Hematopoietic Stem Cell Transplant: Cross-sectional Study

Meghan B Skiba[1,2], MS, MPH, PhD, RDN; Graham Harker[3], MPH; Carolyn Guidarelli[4], MPH; Mahmoud El-Gohary[5], PhD; Fay Horak[3,5], PhD, PT; Eric J Roeland[4,6], MD; Rebecca Silbermann[4,6], MD, MMS; Brandon Hayes-Lattin[4,6], MD; Kerri Winters-Stone[4], PhD

[1]Biobehavioral Health Science Division, College of Nursing, University of Arizona, Tucson, AZ, United States
[2]The University of Arizona Cancer Center, University of Arizona, Tucson, AZ, United States
[3]Department of Neurology, School of Medicine, Oregon Health & Science University, Portland, OR, United States
[4]Division of Oncological Sciences, Knight Cancer Institute, Oregon Health & Science University, Portland, OR, United States
[5]APDM, Inc, a division of Clario International, Portland, OR, United States
[6]Division of Hematology and Medical Oncology, School of Medicine, Oregon Health & Science University, Portland, OR, United States

Corresponding Author:
Kerri Winters-Stone, PhD
Division of Oncological Sciences
Knight Cancer Institute
Oregon Health & Science University
3181 SW Sam Jackson Park Rd
KCRB-CPC
Portland, OR, 97239
United States
Phone: 1 503 494 0813
Fax: 1 503 346 8296
Email: wintersk@ohsu.edu

Abstract

Background: Wearable sensors could be a simple way to quantify and characterize mobility in patients with hematologic cancer scheduled to receive autologous hematopoietic stem cell transplant (autoHSCT) and how they may be related to common treatment-related symptoms and side effects of induction chemotherapy.

Objective: We aimed to conduct a cross-sectional study comparing mobility in patients scheduled to receive autoHSCT with that in healthy, age-matched adult controls and determine the relationships between patient mobility and chemotherapy-related symptoms.

Methods: Patients scheduled to receive autoHSCT (78/156, 50%) and controls (78/156, 50%) completed the prescribed performance tests using wearable inertial sensors to quantify mobility including turning (turn duration and number of steps), gait (gait speed, stride time, stride time variability, double support time, coronal trunk range of motion, heel strike angle, and distance traveled), and balance (coronal sway, coronal range, coronal velocity, coronal centroidal frequency, sagittal sway, sagittal range, sagittal velocity, and sagittal centroidal frequency). Patients completed the validated patient-reported questionnaires to assess symptoms common to chemotherapy: chemotherapy-induced peripheral neuropathy (Functional Assessment of Cancer Therapy/Gynecologic Oncology Group–Neurotoxicity subscale), nausea and pain (European Organization for Research and Treatment of Cancer Quality of Life Questionnaire), fatigue (Patient-Reported Outcomes Measurement Information System Fatigue Short Form 8a), vertigo (Vertigo Symptom Scale–short form), and depression (Center for Epidemiological Studies–Depression). Paired, 2-sided *t* tests were used to compare mobility between patients and controls. Stepwise multivariable linear regression models were used to evaluate associations between patient mobility and symptoms.

Results: Patients aged 60.3 (SD 10.3) years had significantly worse turning (turn duration; *P*<.001), gait (gait speed, stride time, stride time variability, double support time, heel strike angle, stride length, and distance traveled; all *P*<.001), and balance (coronal sway; *P*<.001, range; *P*<.001, velocity; *P*=.02, and frequency; *P*=.02; and sagittal range; *P*=.008) than controls. In patients, high nausea was associated with worse stride time variability (ß=.001; *P*=.005) and heel strike angle (ß=−.088; *P*=.02). Pain was associated with worse gait speed (ß=−.003; *P*=.003), stride time variability (ß=.012; *P*=.02), stride length (ß=−.002; *P*=.004), and distance traveled (ß=−.786; *P*=.005). Nausea and pain explained 17% to 33% and 14% to 36% of gait variance measured in patients, respectively.

Conclusions: Patients scheduled to receive autoHSCT demonstrated worse mobility in multiple turning, gait, and balance domains compared with controls, potentially related in part to nausea and pain. Wearable inertial sensors used in the clinic setting could provide granular information about mobility before further treatment, which may in turn benefit from rehabilitation or symptom management. Future longitudinal studies are needed to better understand temporal changes in mobility and symptoms across the treatment trajectory to optimally time, design, and implement strategies, to preserve functioning in patients with hematologic cancer in the long term.

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KEYWORDS

wearable inertial sensor; mobility; gait; induction chemotherapy; autologous hematopoietic stem cell transplant; autoHSCT; chemotherapy-related symptoms

Introduction

Background

The increasing frequency of autologous hematopoietic stem cell transplant (autoHSCT) to treat hematologic malignancies, especially among older adults, has contributed to increased survival [1,2]. AutoHSCT is preceded by myeloablative induction chemotherapy [3], which often leads to deconditioning and worsening of symptoms before transplant [4,5]. These pretransplant treatment-related impacts could predispose patients to altered mobility (ie, altered gait and balance) that could worsen after transplant and threaten patient's functioning and quality of life [6,7]. Mobility declines have broad health implications, as patients undergoing transplants who report low physical functioning are at high risk for morbidity and mortality following transplant [8,9]. Over the past few years, a few studies have evaluated the feasibility and potential clinical utility of wearable sensors in the oncology setting [10-12]. Wearable sensors could describe specific patterns of mobility impairment and their potential attribution to treatment-related symptoms and potentially identify patient risk at discrete intervals along the treatment trajectory. In turn, this information could be used to inform timing and design of rehabilitation and symptom management strategies to positively affect clinical outcomes for the patient with hematologic cancer [13].

Before transplant, patients undergo conditioning therapy, which can include any combination of radiation therapy, immunotherapy, or induction chemotherapy [3], all of which cause treatment-related symptoms and side effects that may linger into transplant [14]. Induction chemotherapy, in particular, can cause symptoms known to affect mobility including fatigue, neuropathy, vestibular dysfunction, dizziness, and pain [15]. Symptom clusters in patients undergoing transplant include fatigue, weakness, and anorexia; anxiety and depression; and nausea and vomiting [16]. These symptom clusters are associated with decreased self-reported physical functioning during autoHSCT and increased fall risk [17,18]. Current knowledge has relied on patient-reported measures of physical functioning, which can be less sensitive and informative and more prone to bias than objective measures of mobility and functioning [19,20]. It is also possible that using self-report may underestimate the degree of functional limitation among patients before autoHSCT. In addition, identifying the potential influence of treatment-related symptoms that are present at the time of transplant on mobility could identify patients at high risk for further decline after autoHSCT and who could benefit from appropriately timed rehabilitation and symptom management.

Objective mobility measurements can assess turning, gait, and balance during prescribed tasks, such as walking at a usual pace, walking while turning, and standing in place. Using technology to capture mobility measures can provide greater precision, sensitivity, and granularity of information than clinical or field tests [21-23]. Characterizing the mobility characteristics of turning, gait, and balance using indices of support, stance, swing, spatial temporal patterns, stability, and range of motion typically requires advanced laboratory techniques (ie, motion cameras) that limit their application in nonresearch settings. Advancements in wearable sensors to quantify the same laboratory-based assessments in a clinic or home setting widen the scope of objective mobility assessment to include clinical populations undergoing intensive treatment and requiring hospitalization, such as patients undergoing autoHSCT. So far, a single study using insole sensors to measure gait patterns in patients after receiving allogeneic hematopoietic stem cell transplant (HSCT) reported slower walking speeds and shorter stride times than healthy matched controls, suggesting that treatment may have altered gait [24]. However, as gait was measured after treatment, it remains unknown whether patients already experienced some mobility limitations from treatments before transplant and whether and which persistent symptoms may be associated with mobility in patients receiving autoHSCT.

Objectives

We conducted a cross-sectional study using wearable inertial sensors to measure mobility in patients with hematologic cancer after induction chemotherapy and before autoHSCT to identify (1) differences in mobility between patients and age-matched controls and (2) whether and which symptoms typically related to chemotherapy may be associated with pretransplant mobility in patients.

Methods

Study Design

We used a case-control design to compare the mobility of 78 patients with hematologic cancer before transplant with that of healthy age-matched controls and a cross-sectional design to identify chemotherapy-related symptoms associated with mobility in patients.

Participants and Setting

Eligible patients were recruited through the Oregon Health & Science University Knight Cancer Institute Center for Hematologic Malignancies HSCT unit. Eligible patients were those who were scheduled to receive autoHSCT for a hematopoietic or lymphatic malignancy, were aged ≥21 years at the time of enrollment, had no cognitive difficulties that precluded completing surveys, were participating in performance testing, provided informed consent, and had no preexisting medical conditions that significantly affect mobility (ie, severe dystrophy, severe spasticity, epilepsy, seizures, Alzheimer disease, dementia, severe balance disorder, and inability to ambulate independently). Patients completed assessments after the completion of initial induction chemotherapy and within 2 weeks before hospitalization for autoHSCT.

Age-Matched Controls

Age-matched controls were selected from a preexisting sample of healthy adults recruited from the local community for 2 study protocols [25,26]. Eligible controls had no history of falls, chronic diseases including cancer, significant neurological or musculoskeletal impairment, or medication use that affects mobility or limits their ability to follow instructions or provide informed consent. Controls were age-matched to participants according to age at the time of assessment within 1 year.

Ethics Approval

The Oregon Health & Science University institutional review board approved the study (16760), and informed consent was obtained from all participants before data collection. Participant data were deidentified using individual code numbers assigned upon enrollment. Participants were not compensated for participating in the study. The survey and mobility assessment took approximately 30 to 45 minutes to complete and thus was not considered to pose a significant burden to participants.

Demographic Measurements

Patient demographics (age, sex, ethnicity or race, education, marital status, employment, and history of falls in the previous year) were self-reported. Comorbidities were determined using the Functional Comorbidity Index, a self-administered 18-item checklist of chronic conditions that affect physical functioning [27]. Self-reported cancer diagnosis and treatment history were adjudicated by the research staff. Height and weight were measured in the clinic, and BMI was calculated as kg/m^2. The control group’s self-reported demographic data included age, sex, height, weight, health history, and education.

Objective Mobility Assessment

Objective mobility measures were assessed using Mobility Lab (APDM, Inc), a portable system of unobtrusive, body-worn, wireless, inertial sensors that quickly and automatically provide objective mobility measures, including turning, gait, and balance [28-30]. Patients’ Mobility Lab assessments were collected in the clinic using available space (eg, hallways) during a single appointment. Participants wore inertial sensors (Opal; APDM, Inc), placed at the sternum, lumbar spine, wrists, and ankles (Figure 1), and performed 2 standard physical functioning assessments—a 6-minute walk test (6MWT) and a 30-second quiet stance [19]. The 6MWT assesses distance walked over 6 minutes and is one of the most established outcome measures of functional mobility in clinical trials [31,32]. Participants walked at their usual pace for 6 minutes on a 20-meter course. Each full lap provided gait and turns averaged together, considerably reducing variability and performance bias compared with a single walk [33,34]. For controls, if a 6MWT was not performed owing to differences in protocol at the time of consent, a 400-meter walk was completed [25,26], which provides similar estimates of turning and gait [35]. Balance was measured using a 30-second quiet stance test, where participants stood as still as possible for 30 seconds with eyes open, feet together, and hands on their hips. Measures specific to turning, gait, and balance selected for these analyses (Table 1) have been previously used to assess fall risk, including dynamics during turning, postural adjustments associated with step initiation, spatial and temporal components of gait, and postural sway during standing balance [25,36-38]. Data processing was performed using Mobility Lab (version 2; APDM, Inc) and established algorithms [28,39]. The algorithms account for difference in physical stature (eg, height) of participants and in physical functioning assessment protocols for samples recruited at different times, allowing for a large sample of community-dwelling healthy adults with valid mobility data to select age-matched controls.

Figure 1. Inertial sensor placement (Mobility Lab Opal; APDM, Inc). In total, 6 sensors are placed—sternum (1 sensor; centered just below the collar bones, on the flat part of the chest), lumbar spine (1 sensor; centered at the base of the spine), wrist (2 sensors; on the wrist, similar to a watch), and ankles (2 sensors; centered on the front of the ankle). The figure was reproduced with permission from APDM, Inc.

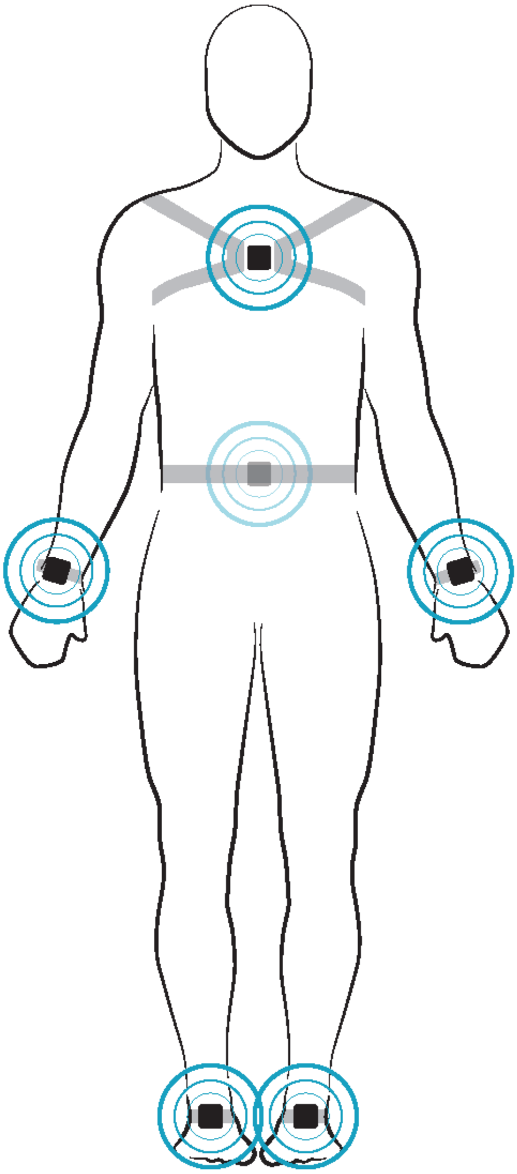

Table 1. Definitions of selected Mobility Lab mobility measures of turning, gait, and balance.

Measure	Definition
Turning (6MWT[a])	
Turn duration (s)	Duration of 180° turn
Number of steps	Number of steps during 180° turn
Gait (6MWT)	
Gait speed (m/s)	Forward speed of the individual, measured as the forward distance traveled during the gait cycle divided by the gait cycle duration
Stride time (s)	Duration of a full gait cycle, measured from the left foot's initial contact to the next initial contact of the left foot
Stride time variability (%)	Coefficient of variation stride length (SD/mean)
Double support time (%)	Rate of gait cycle while both feet are on the ground
Coronal trunk ROM[b] (°)	Angular range of the lumbar spine in the coronal plane
Heel strike angle (°)	Angle of the foot at the point of initial contact; the pitch of the foot is 0 when flat and positive when the heel contacts first
Stride length (m)	Forward distance traveled by a foot during a gait cycle
Distance (m)	Total distance traveled during the timed test, at usual walking speed
Balance (30-second quiet stance)	
Coronal sway RMS[c] (m/s^2)	Amplitude of lateral sway
Coronal range (m/s^2)	Angular range of the lateral thoracic spine (roll)
Coronal velocity (m/s)	Mean velocity of lateral sway
Coronal centroidal frequency (Hz)	Frequency of centroidal lateral sway
Sagittal sway RMS (m/s^2)	Amplitude of anterior-posterior sway
Sagittal range (m/s^2)	Angular range of the anterior-posterior thoracic spine (pitch)
Sagittal velocity (m/s)	Mean velocity of anterior-posterior sway
Sagittal centroidal frequency (Hz)	Frequency of centroidal anterior-posterior sway

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

[b] ROM: range of motion.

[c] RMS: root mean square.

Patient-Reported Symptoms

Overview

For patients scheduled for autoHSCT, validated, patient-reported outcomes on symptoms typically associated with chemotherapy were collected using the following instruments and administered electronically in REDCap (Research Electronic Data Capture; Vanderbilt University) [40]. High scores indicate high level of symptoms for all questionnaires, unless otherwise described. Symptoms were not assessed for controls.

Chemotherapy-Induced Peripheral Neuropathy

Numbness, tingling, or uncomfortable sensations in hands and feet over the previous 7 days were measured using the 4-item Functional Assessment of Cancer Therapy/Gynecologic Oncology Group–Neurotoxicity subscale, a reliable and valid measure of chemotherapy-induced peripheral neuropathy (score range 0-16, where high scores indicate less-severe chemotherapy-induced peripheral neuropathy; minimally clinically important difference [MCID] 1.38-3.68) [41].

Nausea and Pain

Symptoms during the previous week were assessed using the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–nausea or vomiting and pain symptom subscales (score range 0-100; MCID 2.4-15.5 [nausea] and 14.4-28.5 [pain]) [42,43]. This questionnaire is an acceptable measure of chronic pain [44].

Fatigue

Fatigue over the previous week was determined using the Patient-Reported Outcomes Measurement Information System Fatigue Short Form 8a (score range 0-100; MCID 3-5) [45,46].

Vertigo

The Vertigo Symptom Scale–short form was used to measure vertigo, dizziness, and somatic anxiety over the past month (score range 0-60; MCID 3) [47,48].

Depression

Depressive symptoms over the past week were assessed using the Center for Epidemiological Studies–Depression scale (score range 0-16; MCID 9-11) [49,50].

Statistical Analysis

Distributions were inspected for normality; balance measures were log transformed to improve normality, but model results were consistent; therefore, nontransformed variables and parametric tests were used for all analyses. Demographic characteristics were assessed using descriptive statistics, and paired, 2-sided *t* tests were used to determine the differences in mobility between patients and matched controls.

Linear regression models were used to determine the association between symptoms and mobility. Univariate linear regression models with α≤.05 were used to determine the model demographic control variables. The final models were adjusted for age, sex, and BMI. Symptom selection criteria for linear regression models were determined using Pearson correlations to mobility characteristics, with cutoff points ρ≥0.3 and α≤.10 [51]. Final stepwise multivariable linear regression models were built using α≤.05 with any mobility characteristic to symptoms and were externally validated with 1000 bootstrap replications. Variability of symptoms in mobility characteristics was estimated using standardized ß coefficients. Post hoc Benjamini-Hochberg false discovery rate adjustment [52] with α=.05 was completed for paired *t* tests and linear regression models. Analyses were completed using STATA (version 16.1; StataCorp, LLC), with α≤.05 for statistical significance.

Results

Participants

Between August 2017 and May 2019, 78 patients completed the Mobility Lab assessments before autoHSCT. The average age of patients before transplant was 60.3 (SD 10.3; range 31-76) years, and the most common cancer diagnosis was multiple myeloma (Table 2). The mean time since diagnosis to the scheduled autoHSCT was 9.9 (SD 11) months. All patients (78/78, 100) received induction chemotherapy before autoHSCT, with the average induction chemotherapy regimen lasting 4.7 (SD 3.2) months. In the year before the transplant, 17% (13/78) of the patients experienced a fall. The average age of matched controls (78/156, 50%) was 60.2 (SD 10.4) years. Most patients were men (50/78, 64%), whereas most controls were women (57/78, 73%). Controls had lower BMI and attained higher level of education than patients, and the control group had a high proportion of women compared with the patient group.

Table 2. Demographics and clinical characteristics of patients with hematologic cancer scheduled for autoHSCT[a] compared with that of healthy, age-matched controls (N=156).

Characteristics	Patients scheduled for autoHSCT (n=78, 50%)	Healthy controls (n=78, 50%)
Age (years), mean (SD)	60.3 (10.3)	60.2 (10.4)
Sex, n (%)		
Female	28 (36)	57 (73)
Male	50 (64)	21 (27)
Ethnicity, n (%)		
Non-Hispanic	69 (88)	N/A[b]
Declined to answer	9 (12)	N/A
Race, n (%)		
White	63 (81)	N/A
Non-White[c]	5 (6)	N/A
Declined to answer	10 (13)	N/A
Education, n (%[d])		
High school diploma or equivalent	20 (26)	2 (3)
Some college or associate degree	18 (23)	8 (10)
Bachelor’s degree or higher	31 (40)	68 (87)
Declined to answer	9 (12)	N/A
Marital status, n (%)		
Married or living with partner	53 (68)	N/A
Divorced or separated	7 (9)	N/A
Single	11 (14)	N/A
Declined to answer	7 (9)	N/A
Employment, n (%)		
Full time	23 (29)	N/A
Part time	6 (8)	N/A
Not working[e]	39 (50)	N/A
Declined to answer	10 (13)	N/A
BMI (kg/m^2), mean (SD)	29.8 (5.7)	25.2 (3.5)
Height (m), mean (SD)	1.7 (0.1)	1.6 (0.1)
Weight (kg), mean (SD)	88.9 (21.2)	66.3 (15.1)
Cancer diagnosis, n (%)		
Multiple myeloma	53 (68)	N/A
Hodgkin lymphoma	6 (8)	N/A
Non-Hodgkin lymphoma	19 (24)	N/A
Cancer stage[f], n (%)		
I	11 (14)	N/A
II	21 (27)	N/A
III	21 (27)	N/A
IV	12 (15)	N/A
Missing or unknown	13 (17)	N/A
Time since diagnosis (months), mean (SD)	9.9 (11)	N/A

Characteristics	Patients scheduled for autoHSCT (n=78, 50%)	Healthy controls (n=78, 50%)
Received induction chemotherapy, n (%)	78 (100)	N/A
Duration of induction chemotherapy (months), mean (SD)	4.7 (3.2)	N/A
Time since last induction chemotherapy (days), mean (SD)	20.2 (91.9)	N/A
Received radiation treatment, n (%)	14 (18)	N/A
Functional Comorbidity Index score[g], mean (SD)	1.3 (1.3)	N/A
History of fall in past year, n (%)	13 (17)	N/A

[a] autoHSCT: autologous hematopoietic stem cell transplant.

[b] N/A: not available; data were not collected for controls.

[c] Collapsed category including individuals who self-reported as being Asian, Black, or American Indian or Alaska Native or having >1 race.

[d] Percentages may not add up to 100% owing to rounding.

[e] Collapsed category including individuals who self-reported as being retired, unemployed, or homemaker. Disability status was not captured.

[f] Staging for multiple myeloma included International Staging System, Revised International Staging System, and Durie-Salmon staging classifications.

[g] Missing data <10%.

Objective Mobility

Mobility was significantly worse across most measures among patients than among controls (Table 3). In the 6MWT, turn duration was 0.28 (SD 0.54) seconds longer for patients than for controls (*P*<.001). Patients demonstrated an altered gait pattern, as exhibited by significantly slower gait speed (mean −0.32, SD 0.25 seconds), longer stride time (mean 0.13, SD 0.13 seconds), higher stride time variability (mean 1.07%, SD 1.42%), longer double support time (mean 5.91%, SD 4.23%), shallower heel strike angle (mean 0.81°, SD 3.56°), shorter stride length (mean −0.18, SD 0.19 m), and shorter distance traveled (mean −60.01, SD 93.49 m) than controls (*P*<.001). During standing balance, patients had significantly larger coronal sway (mean 0.02, SD 0.03 m/s^2; *P*<.001), longer coronal range (mean 0.10, SD 0.16 m/s^2; *P*<.001), higher coronal velocity (mean 0.03, SD 0.10 m/s; *P*=.02), lower coronal centroidal frequency (mean −0.11, SD 0.39 Hz; *P*=.02), and longer sagittal range (mean 0.08, SD 0.27 m/s^2; *P*=.008) than controls. Sensitivity analyses restricting the analytical sample to controls with gait data from the 6MWT (31/78, 40%) or who were both age-matched and sex-matched (44/78, 56%) yielded results consistent with those obtained using the full sample of controls.

Table 3. Comparison of mobility measures of turning, gait, and balance between patients with hematologic cancer scheduled for autoHSCT[a] and age-matched healthy controls.

Measures	Patients scheduled for autoHSCT, mean (SD)	Healthy controls, mean (SD)	Difference, mean (SD)	*P* value[b]
Turning				
Turn duration (s)	2.43 (0.37)	2.15 (0.40)	0.28 (0.54)	<.001
Number of steps	4.04 (0.68)	4.07 (0.78)	−0.03 (0.97)	.82
Gait				
Gait speed (m/s)	1.11 (0.19)	1.43 (0.15)	−0.32 (0.25)	<.001
Stride time (s)	1.14 (0.11)	1 (0.08)	0.13 (0.13)	<.001
Stride time variability (%)	3.55 (1.25)	2.48 (0.71)	1.07 (1.42)	<.001
Double support time (%)	23.24 (3.62)	17.33 (2.99)	5.91 (4.23)	<.001
Coronal trunk ROM[c] (°)	7.14 (2.68)	6.33 (2.66)	0.81 (3.56)	.06
Heel strike angle (°)	23 (5.57)	26.32 (4.23)	−3.32 (6.47)	<.001
Stride length (m)	1.25 (0.16)	1.43 (0.13)	−0.18 (0.19)	<.001
Distance (m)	375.76 (64)	435.78 (55.91)	−60.01 (93.49)	<.001
Balance				
Coronal sway RMS[d] (m/s^2)	0.06 (0.02)	0.04 (0.02)	0.02 (0.03)	<.001
Coronal range (m/s^2)	0.33 (0.13)	0.23 (0.09)	0.10 (0.16)	<.001
Coronal velocity (m/s)	0.10 (0.06)	0.07 (0.07)	0.03 (0.10)	.02
Coronal centroidal frequency (Hz)	1.05 (0.32)	1.16 (0.26)	−0.11 (0.39)	.02
Sagittal sway RMS (m/s^2)	0.08 (0.04)	0.07 (0.04)	0.01 (0.05)	.06
Sagittal range (m/s^2)	0.43 (0.22)	0.34 (0.16)	0.08 (0.27)	.008
Sagittal velocity (m/s)	0.15 (0.08)	0.13 (0.14)	0.02 (0.15)	.26
Sagittal centroidal frequency (Hz)	0.95 (0.22)	0.96 (0.24)	−0.01 (0.32)	.83

[a] autoHSCT: autologous hematopoietic stem cell transplant.

[b] Paired, 2-sided *t* test, with Benjamini-Hochberg false discovery rate adjustment set at α=.05, and all significant *P* values remained significant.

[c] ROM: range of motion.

[d] RMS: root mean square.

Mobility and Chemotherapy-Related Symptoms

Of the 78 patients with mobility data, 69 (88%) completed the patient-reported chemotherapy-related symptom questionnaires (Table 4). Reasons for missing questionnaires included incomplete responses, refusal, or acute illness. Patients with missing symptom data did not significantly differ from those with complete data on age (*P*=.73), BMI (*P*=.97), sex (*P*=.57), or Functional Comorbidity Index (*P*=.91); therefore, complete case analysis was conducted. Models were built for symptoms associations with gait only, because prespecified criteria for building regression models were met for symptoms and gait but not for turning or balance measurements. Symptoms that remained significantly associated with any gait metric were nausea and pain (Table 5). High nausea was associated with great stride time variability (ß=.023, 95% CI −0.007 to 0.039) and shallow heel strike angle (ß=−.088, 95% CI −0.160 to −0.017). High pain was associated with slow gait speed (ß=−.003, 95% CI −0.004 to –0.001), short stride length (ß=−.002, 95% CI −0.003 to −0.001), short distance (ß=−.786, 95% CI −1.321 to −0.252), and great stride time variability (ß=.012, 95% CI −0.002 to −0.023). Nausea better explained the variance in stride time variability (33%) and heel strike angle (31%), whereas pain better explained the variance in gait speed (36%), stride length (35%), and distance (34%).

Table 4. Chemotherapy-related symptom intensity among patients with hematologic cancer scheduled for autoHSCT[a] (n=69).

Chemotherapy-related symptom	Measure possible score, range	Measure MCID[b], range	Sample score, mean (SD)	Sample score, range
CIPN[c]	0-16	1.38-3.68	13.01 (3.63)	0-16
Nausea	0-100	2.4-15.5	11.35 (18.63)	0-100
Pain	0-100	14.4-28.5	27.05 (29.02)	0-100
Fatigue	0-100	3-5	53 (7.84)	33.1-69.8
Vertigo	0-60	3	4.81 (5.74)	0-31
Depression	0-60	9-11	9.19 (7.81)	0-39

[a] autoHSCT: autologous hematopoietic stem cell transplant.

[b] MCID: minimally clinically important difference.

[c] CIPN: chemotherapy-induced peripheral neuropathy.

Table 5. Associations between chemotherapy-related symptoms and gait characteristics among patients with hematologic cancer scheduled for autoHSCT[a] (n=69).

Gait characteristics	Nausea			Pain		
	ß coefficient (95% CI)	Standardized ß coefficient	*P* value[b]	ß coefficient (95% CI)	Standardized ß coefficient	*P* value[b]
Gait speed (m/s)	−.002 (−0.005 to 0.0003)	−.189	.09	−.003 (−0.004 to −0.001)	−.355	.003
Stride time (s)	.001 (−0.001 to 0.002)	.127	.28	.001 (−0.0001 to 0.002)	.221	.07
Stride time variability (%)	.023 (−0.007 to 0.039)	.331	.005	.012 (−0.002 to 0.023)	.275	.02
Double support time (%)	.018 (−0.028 to 0.064)	.09	.43	.014 (−0.017 to 0.044)	.104	.38
Coronal trunk ROM[c] (°)	.027 (−0.011 to 0.066)	.165	.16	−.033 (−0.058 to 0.007)	−.310	.16
Heel strike angle (°)	−.088 (−0.160 to −0.017)	−.305	.02	−.026 (−0.074 to 0.021)	−.141	.28
Stride length (m)	−.001 (−0.003 to −0.0005)	.174	.13	−.002 (−0.003 to −0.001)	−.349	.004
Distance (m)	−.662 (−1.464 to 0.140)	−.184	.10	−.786 (−1.321 to −0.252)	−.340	.005

[a] autoHSCT: autologous hematopoietic stem cell transplant.

[b] Linear regression models adjusted for age, sex, and BMI, with Benjamini-Hochberg false discovery rate adjustment set at α=.05, and all significant *P* values remained significant.

[c] ROM: range of motion.

Discussion

Principal Findings

To the best of our knowledge, this study is the first to measure pretransplant mobility in patients with hematologic cancer using an innovative system of wearable inertial sensors to characterize patients' mobility compared with that of healthy adults and determine whether symptoms may identify patients with altered mobility characteristics. Mobility was significantly worse for patients than for controls, indicating that chemotherapy may directly or indirectly alter systems that control turning, gait, and balance. Among patients, those with high levels of nausea and pain before transplant had worse gait characteristics, demonstrating a conservative gait pattern of slow shuffled walking associated with functional limitations and fall risk [53-55].

Comparison With Previous Studies

Wearable inertial sensors that measure multiple characteristics of turning, gait, and balance could better describe the mobility patterns affected by induction chemotherapy than self-report or field tests. Although other studies have only assessed gait, typically using a timed single walk test, our wearable sensor detected an aggregate of gait alterations in patients, along with differences in turning and balance. Gait parameters in our sample of patients were similar to those in a previous analysis using insole-worn sensors in a small sample of patients several months after allogenic HSCT [24]; however, our study provided great sensitivity by including additional gait metrics. These findings are consistent with slow and conservative gait patterns comparable with adults who are 20 years older [24,56], suggesting that patients may experience accelerated aging from induction chemotherapy [57]. The slow gait speed observed in our sample, consistent with previous findings in patients undergoing transplant [24], is concerning, given that slow gait speed at diagnosis is associated with subsequent hospitalizations and worse survival in older patients with hematologic malignancies [58]. Patients had a longer turn duration than controls, a measure associated with increased fall risk [59]; however, patients and controls took, on average, the same number of steps per turn. Increased double limb support time associated with falls [60] is a compensatory mechanism to make walking more secure with less time spent in single limb support. Gait may compensate for impaired balance [61,62], and thus, increased variability of gait characteristics could be owing to both compensatory mechanisms for balance deficits and multijoint incoordination. Control of balance while walking involves adjusting foot placement. Both variability in foot placement and double support time while walking also reflect impaired balance.

Postural sway during normal, quiet standing has long been shown to be a sensitive measure of balance control, with large, fast sway being associated with increased fall risk [63]. Consistent with other studies, primarily in survivors of breast cancer, patients exhibited worse balance, likely exacerbated by chemotherapy [26,64,65]. Sagittal and coronal sway values observed in our sample were worse than those previously associated with falls in elderly populations [66]. Chemotherapy can have neurologic and musculoskeletal impacts affecting mobility including distal sensory loss, ototoxicity, myelopathy, weakness, atrophy, and sarcopenia [67,68]. In addition, glucocorticoids coadministered during chemotherapy and deconditioning from hospitalization for cancer treatment lead to muscle loss that could also underpin decline in mobility [69,70]. These findings suggest that patients planning to receive autoHSCT may undergo a pretransplant mobility risk assessment to identify patients at the highest risk for falls and functional decline throughout their treatment trajectory. Moreover, pretransplant mobility assessment may allow clinical teams to prioritize limited rehabilitation expertise and resources for patients at the highest risk of functional decline and more extended hospital stays.

Symptoms may contribute to and co-occur with changes in mobility. Therefore, poorly controlled symptoms may help to identify patients at risk and those who may benefit from optimal symptom management and early palliative care integration [71]. We assessed multiple treatment-related symptoms previously associated with mobility and physical function in survivors of hematologic cancer [15-18]. In our sample, high nausea was significantly associated with great stride time variability and shallow heel strike angle. The pattern was also similar for pain, where high pain was significantly associated with slow gait speed, short stride length, great stride time variability, and less distance traveled. Persistent and severe nausea and pain clustering have been associated with poor performance status and limited physical function after cancer treatment [72]. Central nervous system disturbances owing to certain chemotherapies can affect cognition and movement, causing a sequela of symptoms comprising nausea and pain [73]. Chemotherapy can cause vestibular toxicity, resulting in nausea that intensifies over the transplant phase [74,75], which could directly or indirectly affect gait and balance [76]. Chronic pain is prevalent among survivors of hematologic cancer [77], has been associated with gait deficits in older adults [78], and is a significant risk factor for falls in survivors of cancer [79]. Persistent control of symptoms, including nausea and pain management, may be important for preserving physical functioning throughout the full treatment trajectory.

Integration of Wearable Inertial Sensors in Clinical Care

Providers subjectively assess a patient's functional status before autoHSCT using the Karnofsky Performance Status assessment—a tool with good reliability and validity, but which is subjective and prone to clinician bias [80-82]. Until recently, characterizing mobility was only possible with complex and expensive laboratory-based systems, making it difficult to assess patients at the point of care. Introduction of wearable inertial sensors to assess mobility in the clinic setting widens the scope of what can be learned and implemented in clinical practice [83]. Mobility Lab is an affordable (comparable with other mobile gait assessment platforms) and time-effective approach to assess patients for aspects associated with risk for functional decline including postural sway, spatial and temporal components of gait, and dynamic balance during common movement such as turning [36]. The average time for an in-clinic assessment is 15 minutes, and it provides clinically relevant and accurate mobility evaluation that could be integrated into patient care and inform clinical decision-making.

Detecting dynamic and potentially reversible gait changes during pretransplant appointments may minimize future health care use by directing resources to patients at high risk of treatment-associated disability or falls. Interventions to promote physical activity and exercise before or during treatment would improve physical function and mobility [84]. Exercise is feasible and can safely be initiated after induction chemotherapy [85]. Exercise interventions before autoHSCT have shown to improve quality of life and functional capacity, as measured by the 6MWT [86]. Symptom management itself may also lead to increased activity level in patients, and exercise has also been used to manage chemotherapy-related symptoms [87-89].

Strengths and Limitations

A significant strength of our study was the use of wearable inertial sensors to obtain objective measures of mobility characteristics before autoHSCT. We were able to collect high-quality mobility data in the domains of turning, gait, and balance using wearable inertial sensors in a clinic setting, which may have future utility in patient care. Wearable inertial sensors have additional benefits including low cost and portability for assessment outside laboratory settings [90]. This study also has limitations. Our case-control analysis used a previously collected set of data on controls, causing the patient and control samples to be unbalanced on some characteristics such as sex and body composition (eg, height, weight, and BMI), which may influence mobility measures; thus, future studies should prospectively enroll a matched control cohort. Our sample size was modest for linear regression; thus, findings should be interpreted accordingly. We did not have access to data from previous induction chemotherapy (eg, chemotherapy drug or classification, dose, number of cycles, and weight change) and concurrent medication use (eg, antiemetics and pain medications); thus, we are limited in what can be inferred about symptoms assessed before transplant. Similarly, we did not collect data on physical activity levels, but it is possible that there may be interactions between symptoms, mobility, and physical activity. For example, patients with low symptom severity may be more physically active and therefore demonstrate better mobility. In contrast, patients experiencing nausea or pain may require increased need for rest, which negatively affects their mobility. Similarly, we did not have information about symptom management interventions that may have similar interactions. In addition, our cross-sectional analysis could not establish causality between gait characteristics and patient-reported chemotherapy-related symptoms. Thus, they may be co-occurring problems. However, it is possible that symptoms could serve as a surrogate indicator of developing mobility deficits. As the average time from induction chemotherapy to enrollment was approximately 3 weeks, patient-reported pretransplant symptoms may be related to chemotherapy or comorbidities. Future studies could better establish the temporality of symptom onset and progression regarding mobility using longitudinal serial assessment.

Conclusions

Patients with hematologic cancer who have completed induction chemotherapy experience multiple alterations in mobility, as detected by a system of wearable inertial sensors. These altered gait patterns, which may have resulted from cancer treatment, place older patients with hematologic cancer at an elevated fall risk [91,92], which could ultimately increase morbidity and mortality risk [93,94]. Patients experiencing great nausea and pain at the time of autoHSCT may be at high risk of experiencing mobility limitations during and after transplant. Although this study could not infer whether chemotherapy-related symptoms directly alter gait, the findings highlight distinct mobility deficits in patients, which could not have been easily identified using standard mobility tests alone. Patients experiencing symptoms may warrant a more thorough assessment of their mobility using wearable sensors by the clinical team, including rehabilitation specialists, during routine appointments before hospitalization. Understanding these relationships could improve preventive care, symptom management, and rehabilitation efforts by identifying patients scheduled for autoHSCT who are at risk for further functional decline or falls after induction chemotherapy.

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Data Availability

The data that support the findings of this study are not publicly available owing to privacy or ethical reasons but may be provided from the corresponding author upon reasonable request. Restrictions apply to the availability of some data, which were used with permission of APDM, Inc for this study.

Authors' Contributions

KWS, FH, and MEG contributed to the study design. KWS, MEG, and FH were involved in protocol development. CG was involved in participant recruitment and data collection. MBS and GH contributed to data analysis plan and execution. MBS, GH, FH, MEG, and KWS were involved in interpretation of results. MBS and KWS wrote the manuscript. GH, FH, MEG, CG, BHL, RS, and EJR edited the manuscript. MEG, FH, and KWS were involved in obtaining the funding. All the authors approved the final version of the manuscript.

Conflicts of Interest

MEG is an employee of APDM, Inc, and is required to complete training and disclosure regarding financial conflicts of interest before engaging in research conducted at Oregon Health & Science University. FH is a part-time employee and has significant financial interest in APDM, Inc. APDM, Inc may have commercial interest in the application of the results of this study. This potential conflict of interest has been reviewed and managed by Oregon Health & Science University.

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Abbreviations

6MWT: 6-minute walk test
autoHSCT: autologous hematopoietic stem cell transplant
HSCT: hematopoietic stem cell transplant
MCID: minimally clinically important difference
REDCap: Research Electronic Data Capture

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Original Paper

Esophagogastroduodenoscopy Screening Intentions During the COVID-19 Pandemic in Japan: Web-Based Survey

Takemi Akahane[1], MD, PhD; Yasuhiro Nakanishi[2], PhD; Hitoshi Yoshiji[1], MD, PhD; Manabu Akahane[2], MD, PhD

[1]Department of Gastroenterology, Nara Medical University, Kashihara, Japan

[2]Department of Health and Welfare Services, National Institute of Public Health, Wako, Japan

Corresponding Author:
Takemi Akahane, MD, PhD
Department of Gastroenterology
Nara Medical University
840 Shijo-cho
Kashihara, 634-8522
Japan
Phone: 81 744223051
Email: stakemi@naramed-u.ac.jp

Abstract

Background: The number of people undergoing cancer screening decreased during the COVID-19 pandemic. The pandemic may have affected the willingness and motivation of undergoing cancer screening by those eligible for it.

Objective: This study aims to clarify the effect of the COVID-19 pandemic on the intention to undergo cancer and esophagogastroduodenoscopy (EGD) screening.

Methods: We performed a web-based survey on the intention to undergo screening among 1236 men and women aged 20-79 years. The numbers of participants by sex and 10-year age groups were equal. The survey was conducted in January 2021, during which the government declared a state of emergency because of the third wave of the COVID-19 pandemic in Japan. Emergency declarations were issued in 11 prefectures among all the 47 prefectures in Japan.

Results: In total, 66.1% (817/1236) of the participants felt anxious about undergoing screening due to COVID-19. More women than men were anxious about undergoing screening. By modality, EGD had the highest percentage of participants with anxiety due to COVID-19. Regarding the intention to change the participants' appointment for screening, the most common strategies were to book an appointment for a time during nonpeak hours, postpone the appointment to a later date, and change the mode of transportation. In addition, 35.8% (442/1236) of the participants were willing to cancel this year's screening appointment. Among the 1236 participants, 757 (61.2%) were scheduled for screening in 2020. Of the 757 participants in this subgroup, 68% (n=515) did not change the schedule, 6.1% (n=46) cancelled, and 26% (n=197) made some changes, including changing the appointment date, hospital, or mode of transportation. Among the 296 participants scheduled for EGD screening, 18.9% (n=56) made some changes, 5.7% (n=17) cancelled on their own, and 2.7% (n=8) cancelled on the hospital's order. Based on the previous screening results, the percentage of participants who felt anxious about EGD due to the COVID-19 pandemic was higher in the order of those who had not undergone screening and those who were judged to be in need of further examination in screening but did not visit a hospital for it. In the logistic regression analysis, the factors associated with anxiety about EGD screening due to the COVID-19 pandemic were "viral infection prevention measures," "waiting time," "fees (medical expenses)," "mode of transportation," "worry about my social position if I contracted COVID-19," and "perceived the risk of gastric cancer." However, "residence in declared emergency area" was not associated with EGD anxiety due to COVID-19.

Conclusions: Excessive anxiety about COVID-19 may lead to serious outcomes, such as a "decreasing intention to undergo EGD screening," and it is necessary to thoroughly implement infection prevention measures and provide correct information to examinees.

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KEYWORDS

COVID-19; cancer screening; esophagogastroduodenoscopy; EGD; intention; survey; cancer; Japan; screening; men; women; anxiety; information; infection

Introduction

The COVID-19 pandemic has led to severe restrictions in almost all countries and has affected many health care services worldwide. It disrupted the use of preventive health care services. In the United States, the American College of Radiology supported the postponement and rescheduling of nonurgent care, including cancer screening [1]. Screening for cancer is a proven and recommended approach to prevent deaths owing to cancer. The number of people undergoing cancer screening decreased during the COVID-19 pandemic [2]. Although there was an increase in the number of cancer screening tests beginning in late 2020, screenings remained between 29% and 36%, lower than those in the prepandemic era [3]. Coma et al [4] reported that during the pandemic, the number of malignant neoplasms decreased in all age groups, and the number of colonoscopies and mammograms also decreased. However, the number of chest radiographies increased. Another study conducted in north-eastern United States during the COVID-19 pandemic revealed a significant decrease in the number of patients undergoing screening tests for cancer and in the number of ensuing diagnoses of cancerous and precancerous lesions [5]. According to a survey conducted by the Japan Cancer Society, the number of people undergoing cancer screening in 2020 decreased by 30.5% compared with the number of screenings in the previous year. Consequently, the COVID-19 pandemic could disrupt oncology care by delaying the diagnosis and surgical treatment of cancer owing to reduced screening, thereby leading to the long-term consequence of projected increases in cancer-related deaths [6]. The reduction in the number of cancer screenings has been attributed to health care providers. Health care provider constraints included restrictions on elective procedures and shortages of health care staff owing to redeployment to help with pandemic-related care [7]. At the start of the pandemic, elective medical procedures, including cancer screening, were put on hold to conserve medical resources and reduce the risk of spreading COVID-19 in health care settings. However, health systems are now back to scheduling cancer screening tests and examinations. Even when health care providers have increased the availability of preventive care and cancer screenings, many patients face constraints such as loss of income and employer-based insurance coverage [2] and fear of contracting COVID-19 during in-person health care visits [8]. To increase the number of people who receive screening while the COVID-19 pandemic continues, it is necessary to survey the intention to be screened. However, to our knowledge, no studies have investigated the causes of refraining from undergoing cancer screening because of the effect of the COVID-19 pandemic.

This study aimed to examine the predictors of anxiety around cancer screening owing to the COVID-19 pandemic, with a focus on esophagogastroduodenoscopy (EGD).

Methods

Survey Method and Participants

All participants were recruited using an internet panel survey company, as we have previously reported [9-11]. All participants were registered as panel members with the company. The participants of this study included registered panel members aged between 20 and 79 years. First, to recruit participants, the survey company created a list using random sampling across all registers. Next, an email that gauges interest in survey participation was sent to all the individuals on this list. Registration was ended when the number of participants in each group reached the target sample size to ensure that the number of participants by sex and 10-year age groups was similar. Participants completed and provided their responses via mail. After completing the survey, participants received a small cash reward. This study comprised 1236 participants aged 20-79 years. Each group was balanced for age and sex. Assuming a confidence level of 95%, a margin of error of 5%, and an expected response rate of 50%, the required sample size was calculated to be 384. When the margin of error was assumed to be 3%, the required sample size was calculated to be 1067. Therefore, the sample size of 1236 was considered sufficient for the analysis. The survey was conducted in January 2021, when the Japanese government declared a state of emergency during the third COVID-19 pandemic. Emergency declarations were issued in the following 11 prefectures among all the 47 prefectures in Japan: Tochigi, Saitama, Chiba, Tokyo, Kanagawa, Gifu, Aichi, Kyoto, Osaka, Hyogo, and Fukuoka.

Survey of Intention to Undergo Screening During the COVID-19 Pandemic

We conducted an internet survey to assess selected measures of interest, that is, sex, age, place of residence, plans to undergo screening or EGD screening in 2020, results of previous screening, anxiety about undergoing screening due to the COVID-19 pandemic, concerns about undergoing EGD screening due to the COVID-19 pandemic, things to be concerned about if you have COVID-19, and whether you feel you are at risk of having gastric cancer (Multimedia Appendix 1).

Statistical Analyses

Continuous variables were compared between study groups using the *t* test (2-tailed). Categorical variables were compared using a chi-squared test. Logistic regression analysis was performed with anxiety regarding EGD screening due to the COVID-19 pandemic as the dependent variable. The independent variables included anxiety about viral infection control measures, waiting times, fees (medical expenses), mode of transportation, crowdedness, worry about own social position in case of contracting COVID-19, worry about own health in case of contracting COVID-19, worry about family member’s social position in case of contracting COVID-19, worry about health risk to family members in case of contracting COVID-19, perceived risk of contracting gastric cancer, and residence in a declared emergency area.

All statistical analyses were performed using SPSS version 27.0 (IBM Corp). Statistical significance was set at *P*<.05.

Ethics Approval

This study was approved by the Ethics Committee of the National Institute of Public Health, Japan (NIPH-IBRA#12302, approval date: November 17, 2020). All participants provided informed consent for data collection and storage. Written informed consent for participation in the study was obtained at the time of registration.

Patient and Public Involvement Statement

Patients or the public were not involved in the design, conduct, reporting, or dissemination plans of our research.

Results

Baseline Characteristics of Participants Concerning Anxiety About Screening Due to COVID-19

The background characteristics of the participants are shown in Multimedia Appendix 2. The average age of the participants was 49.4 (SD 16.5) years, with equal numbers in each 10-year age group and both sexes. Moreover, of the 1236 participants, 63.3% (n=783) resided in a declared emergency area. Furthermore, 66.1% (n=817) responded that they were anxious about undergoing screening due to the COVID-19 pandemic. There were more women than men in the group who were anxious about undergoing screening, but there were no significant differences in age or the percentage of people who resided in a declared emergency area (Table 1).

Participants who were anxious about receiving screening due to COVID-19 were significantly more likely to worry about their own health, the health risk of their family members, their own social position, or the social position of their family members if they had COVID-19 compared with those who were not anxious (Figure 1).

Excessive crowdedness was the most common concern regarding screening (n=1036, 83.8%), followed by waiting time (n=966, 78.2%), viral infection control measures (n=958, 77.5%), transportation (n=786, 63.6%), and fees (n=734, 59.4%; Table 2). By modality, the percentage of participants who felt anxious because of COVID-19 was higher for EGD and colonoscopy (Table 3).

Regarding the intention to change the screening, the most common strategies were to book an appointment for a time during nonpeak hours, postpone the appointment to a later date, and change the mode of transportation. In addition, 35.8% (442/1236) of the participants were willing to cancel this year's checkup (Table 4).

Among the 1236 participants, 757 (61.2%) were scheduled for screening in 2020. In this subgroup of 757 participants, 68% (n=515) did not change the schedule, 6.1% (n=46) cancelled, and 26% (n=197) made some changes, such as booking an appointment for a time during the nonpeak hours, postponing the appointment to a later date, or changing the hospital or mode of transportation (Table 5).

Among participants scheduled for screening, 18.9% (56/296) of those scheduled for EGD and 19.6% (37/189) of those scheduled for colonoscopy screening made some changes. Among participants scheduled for EGD, 5.7% (17/296) cancelled on their own, and 2.7% (8/296) cancelled on the hospital's order (Table 6).

Table 1. Anxiety about receiving a screening due to COVID-19 (N=1236).

Characteristics	Anxiety		*P* value
	Yes (n=817)	No (n=419)	
Sex, n (%)			<.001
Male	372 (45.5)	246 (58.7)	
Female	445 (54.5)	173 (41.3)	
Age (years), mean (SD)	49.2 (16.2)	49.8 (17.0)	.56
Declared emergency area, n (%)	528 （64.6）	255 (60.9)	.21

Figure 1. Association between anxiety due to having COVID-19 and intention of screening. A. The question was as follows: If you have COVID-19, are you concerned about your health? B. The question was as follows: If you have COVID-19, are you concerned about the health of your family members? C. The question was as follows: If you have COVID-19, are you concerned about your social status? D. The question was as follows: If you have COVID-19, are you concerned about the social status of your family members?

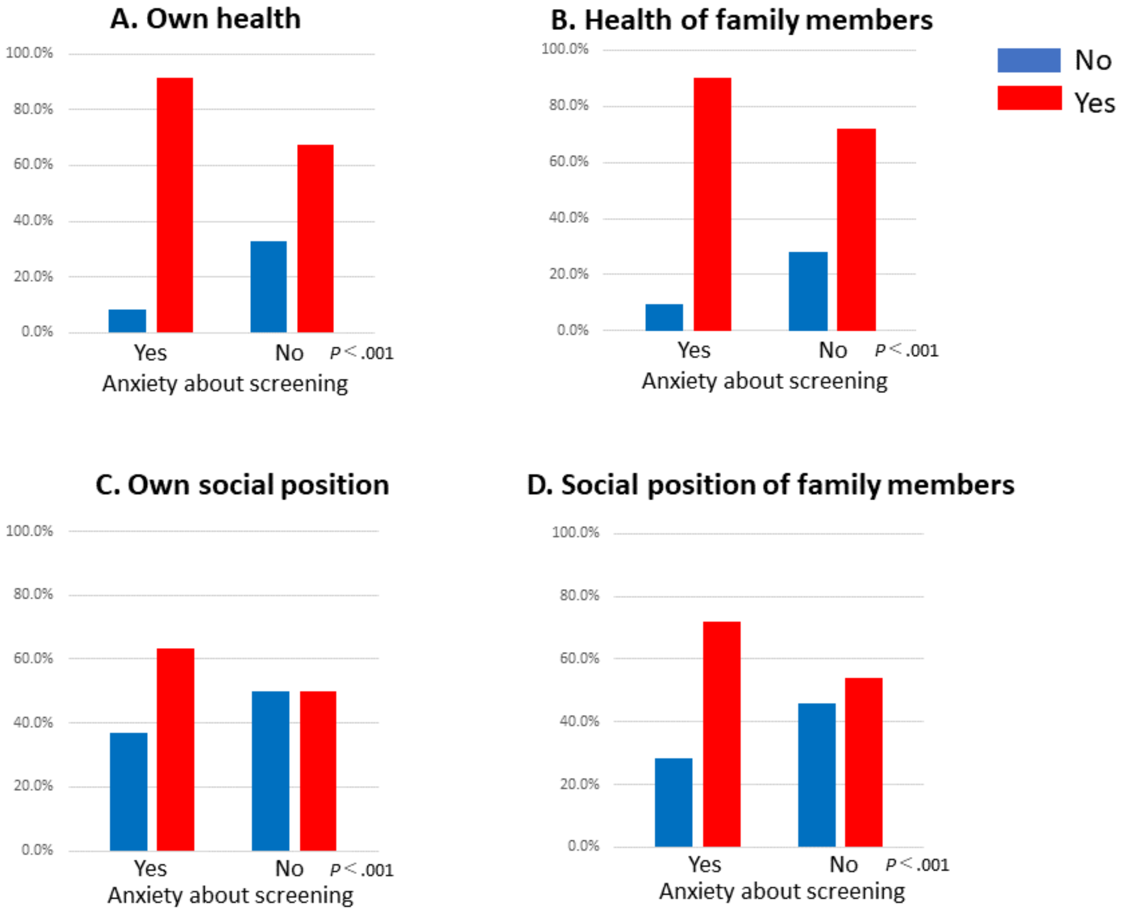


Table 2. Concerns due to the effect of the COVID-19 pandemic in screening.

Concerns	Yes, n (%)	No, n (%)
Crowdedness	1036 (83.8)	200 (16.2)
Waiting time	966 (78.2)	270 (1.8)
Viral infection control measures	958 (77.5)	278 (22.5)
Transportation	786 (63.6)	450 (36.4)
Fees (medical expenses)	734 (59.4)	502 (40.6)

Table 3. Anxiety due to the effect of COVID-19 by modality.

Modality	Yes, n (%)	No, n (%)
EGD[a]	510 (41.3)	726 (58.7)
Colonoscopy	485 (39.2)	751 (60.8)
CT[b]	413 (33.4)	823 (66.6)
MRI[c]	409 (33.1)	827 (66.9)
Ultrasonography	402 (32.5)	834 (67.5)

[a] EGD: esophagogastroduodenoscopy.

[b] CT: computed tomography.

[c] MRI: magnetic resonance imaging.

Table 4. Intentions to change screening due to the COVID-19 pandemic.

Variable	Yes, n (%)	No, n (%)
Book an appointment for a time during the nonpeak hours	973 (78.7)	263 (21.3)
Postponement	592 (47.9)	644 (52.1)
Change of transportation	577 (46.7)	659 (53.3)
Change to a nearby hospital	546 (44.2)	690 (55.8)
Cancel this year's screening	442 (35.8)	794 (64.2)
Change to a large hospital	213 (17.2)	1023 (52.8)

Table 5. Changes made regarding screening (n=757; multiple answers).

Variable	Value, n (%)
Nothing changed	515 (68)
Book an appointment for a time during the nonpeak hours	95 (12.5)
Postponed	63 (8.3)
Changed to a nearby hospital	45 (5.9)
Changed the mode of transportation	32 (4.2)
Changed to a large hospital	9 (1.2)
Others	7 (1)
Cancelled this year's screening	46 (6.1)

Table 6. Changes made regarding examinations for screening.

Modality	Total participants scheduled for testing, n	Postponed at own will, n (%)	Postponed on hospital order, n (%)	Cancelled at your own will, n (%)	Cancelled on the hospital's orders, n (%)	No change
EGD[a]	296	20 (6.8)	11 (3.7)	17 (5.7)	8 (2.7)	240 (81.1)
Colonoscopy	189	9 (4.8)	10 (5.3)	14 (7.4)	4 (2.1)	152 (80.4)
CT[b]	216	14 (6.5)	12 (5.6)	8 (3.7)	3 (1.4)	179 (82.9)
MRI[c]	205	8 (3.9)	11 (5.4)	10 (4.9)	6 (2.9)	170 (82.9)
Ultrasonography	341	18 (5.3)	10 (2.9)	17 (5.0)	8 (2.3)	288 (84.5)

[a] EGD: esophagogastroduodenoscopy.

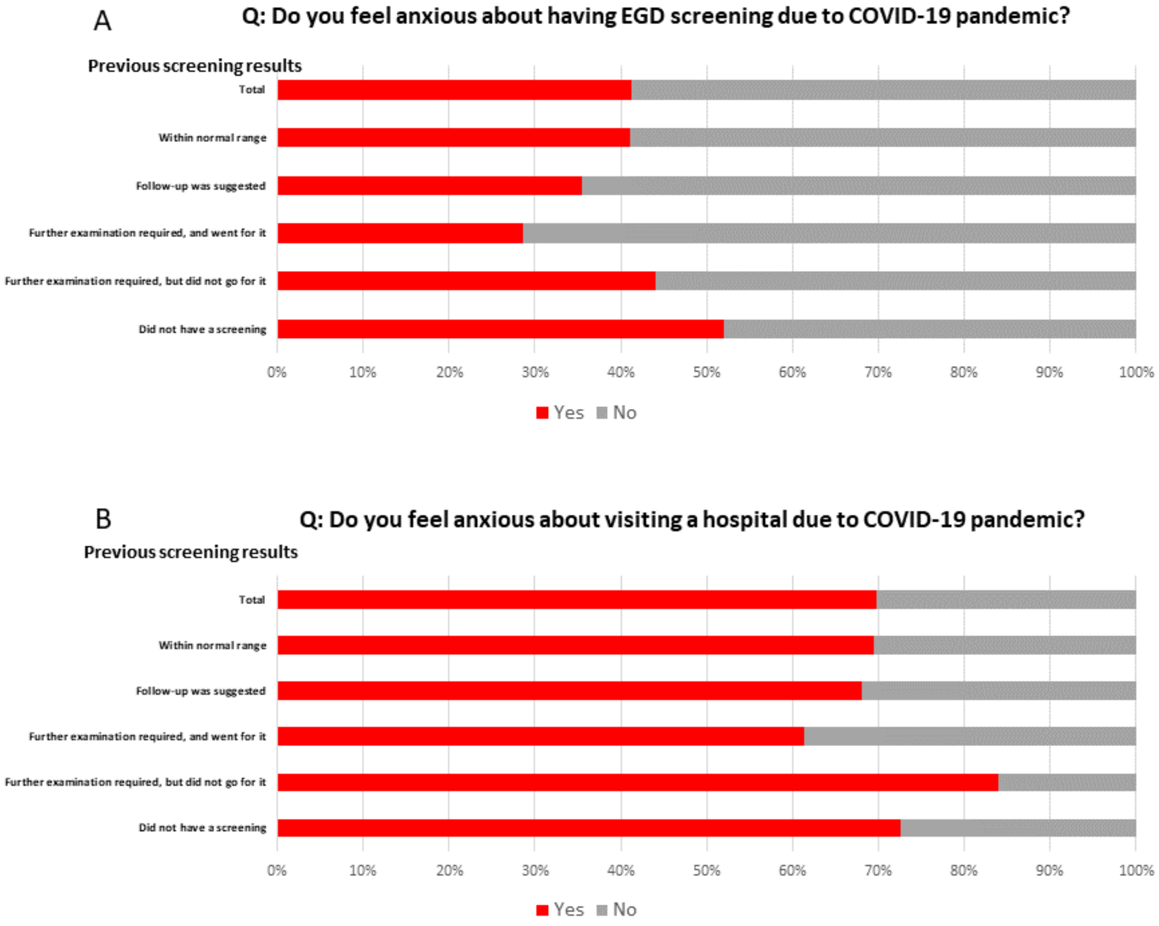
[b] CT: computed tomography.

[c] MRI: magnetic resonance imaging.

Percentage of Anxiety Stratified by Previous Screening Result

The proportion of "anxiety about EGD due to the COVID-19 pandemic" responses was analyzed according to the results of the previous screening. Based on previous screening results, participants who had not undergone prior screening had the highest amount of anxiety about EGD screening due to the COVID-19 pandemic (52%). Participants who were judged as needing extended examination but did not go for it had the second highest rate of anxiety about EGD (44%) (Figure 2, section A). Participants who were judged as needing extended examination but did not go for further screening had the highest amount of anxiety about visiting the hospital due to the COVID-19 pandemic (84%). Participants who had not undergone prior screening had the second highest rate of anxiety about visiting the hospital (73%) (Figure 2, section B).

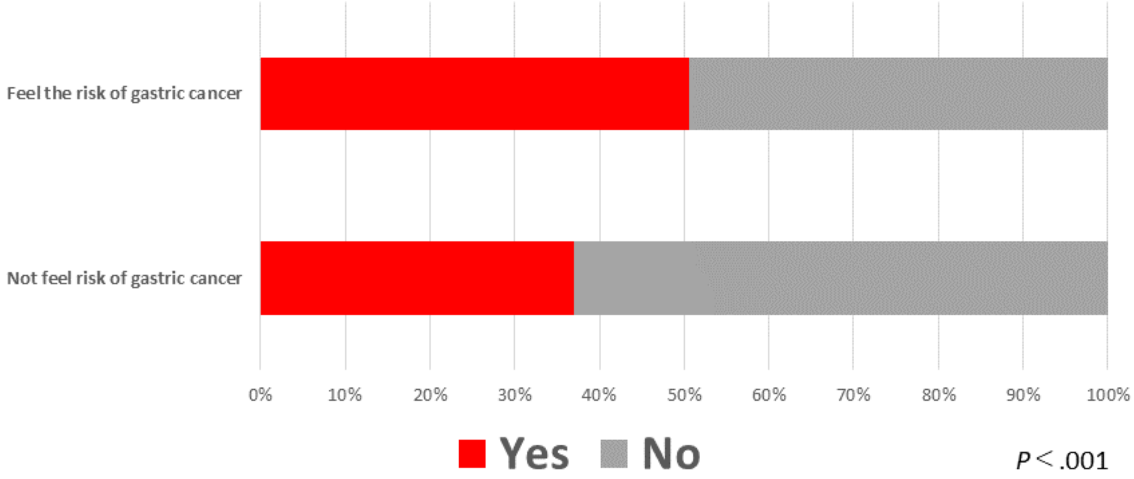
Figure 2. Percentages of respondents reporting anxiety stratified by previous screening result. A. The question was as follows: Do you feel anxious about having EGD screening due to the COVID-19 pandemic? B. The question was as follows: Do you feel anxious about visiting a hospital due to the COVID-19 pandemic? EGD: esophagogastroduodenoscopy.



Feeling at Risk of Developing Gastric Cancer and Anxiety About EGD Screening Due to the COVID-19 Pandemic

We compared “anxiety about EGD screening due to the COVID-19 pandemic’”between participant subgroups classified based on whether or not they felt at risk of contracting gastric cancer. There were 385 participants who felt that they were at risk of contracting gastric cancer, of whom 195 (50.6%) were anxious about EGD screening due to the COVID-19 pandemic. There were 851 patients who did not feel at risk for gastric cancer, of whom 315 (37.0%) were anxious about EGD due to the COVID-19 pandemic. The percentage of “anxiety about EGD screening” was significantly higher in the “feel the risk of contracting gastric cancer” group compared to the “do not feel the risk of contracting gastric cancer” group (Figure 3).

Figure 3. Percentages of respondents with “anxiety about EGD screening” in the “feel the risk of contracting gastric cancer” and the “do not feel the risk of contracting gastric cancer” groups. EGD: esophagogastroduodenoscopy.



Factors Associated With Anxiety About EGD Screening Due to the COVID-19 Pandemic

The factors associated with anxiety concerning EGD screening due to COVID-19 were examined using logistic regression analysis (Table 7).

The following factors were related to anxiety regarding EGD screening anxiety due to the COVID-19 pandemic: “viral infection prevention measures,” “waiting time,” “fees (medical expenses),” “mode of transportation,” “worry about my social position if I contracted COVID-19,” and “perceived the risk of gastric cancer.” However, the following responses were not associated with anxiety about EGD due to the COVID-19 pandemic: “residence in declared emergency area,” “worry about my health if I contracted COVID-19,” “crowdedness,” “worry about health risk of my family members if I contracted COVID-19,” or “worry about social position of my family members if I contracted COVID-19.”

Table 7. Factors associated with anxiety about esophagogastroduodenoscopy screening due to the COVID-19 pandemic.

Variables	Values	
	Odds ratio (95% CI)	*P* value
Viral infection control measures	3.7 (2.2-6.3)	<.001
Waiting time	2.7 (1.6-4.6)	<.001
Fees (medical expenses)	1.8 (1.4-2.4)	<.001
Mode of transportation	1.7 (1.2-2.3)	.002
Worry about my social position if I contracted COVID-19	1.5 (1.1-2.0)	.008
Perceived the risk of gastric cancer	1.4 (1.1-1.8)	.01
Residence in a declared emergency area	1.2 (0.9-1.6)	.19
Worry about my health if I contracted COVID-19	1.1 (0.73-1.8)	.54
Crowdedness	0.92 (0.51-1.7)	.79
Worry about the health risk of my family members if I contracted COVID-19	0.99 (0.61-1.6)	.98
Worry about the social position of my family members if I contracted COVID-19	1.2 (0.84-1.7)	.32

Discussion

Principal Findings

In this study, we conducted a web-based survey on the intention to undergo cancer and EGD screening. In total, 66.1% of participants responded that they felt anxious about undergoing screening owing to the pandemic. With respect to modality, the percentage of participants who felt anxious about screening was the highest for EGD. Factors associated with anxiety around EGD owing to the COVID-19 pandemic were “viral infection prevention measures,” “waiting time,” “fees (medical expenses),” “mode of transportation,” “worry about my social position if I contracted COVID-19,” and “perceived the risk of gastric cancer.” However, residing in a declared emergency area was not associated with anxiety around EGD screening owing to the COVID-19 pandemic. According to a previous screening result, the percentage of “concerned about EGD due to the COVID-19 pandemic” was higher in the groups who had not undergone screening or who needed extended examination but did not undergo it.

The World Health Organization declared the COVID-19 pandemic on March 11, 2020. Plans were put in place to reserve capacity for the surge in COVID-19 clinical care, including the suspension of elective care. In Japan, the Ministry of Health, Labour and Welfare issued a notification, stating that in areas where a state of emergency has been declared, only mass screenings should be postponed during the period the emergency declaration is in effect, and that those who are unable to receive screenings due to postponement will be given another opportunity to receive screening. Hospitals and clinics reduced appointments for cancer screening and nonemergency care to prepare for the diagnosis and treatment of patients with COVID-19 and to prevent the spread of the infection during the periods of emergency declaration, that is, from April to May 2020, and again from January to March 2021. The Japan Cancer Society reported that the number of people receiving cancer screenings in 2020 decreased by 30.5% compared to 2019, and that the number of cancer diagnoses in 2020 was 9.2% lower compared to the previous year (2019). This suggests that the decrease in the number of cancer diagnoses can be attributed to the temporary suspension of cancer screening due to the COVID-19 pandemic and the decrease in the number of people receiving screening due to refraining from visiting hospitals and going outside. In Taiwan, the number of mammography screening examinations decreased in 2020, although the medical system was not disrupted due to the COVID-19 pandemic, likely due to the influence of the population's perceived risk on their willingness to attend screening [12]. In our survey, 66.1% of the participants felt anxious about undergoing cancer screening regardless of whether they resided in a prefecture where a state of emergency was declared. With the spread of COVID-19, the deterioration of public mental health has become a major global and social problem. A web survey conducted in August 2020 among Japanese participants revealed that 73.2% of the respondents experienced perceived stress related to the COVID-19 pandemic, 34.9% felt intense stress associated with COVID-19, 17.1% were depressed, and 13.5% had severe anxiety symptoms [13]. Therefore, the psychological burden caused by COVID-19 could have affected the intention to undergo screening.

Various factors such as sex, age, marital status, education, occupation and income, place of residence, contact history with patients with COVID-19, and comorbidities were associated with mental health problems such as stress, depression, and anxiety [14-16]. During the COVID-19 pandemic, psychiatric disorders such as depression and anxiety were more prevalent in women than in men [13,17,18]. In this study, more women than men were anxious about undergoing screening. Epidemiological sex differences in anxiety disorders and major depression are well characterized. Anxiety and major depressive disorders are more common in women than in men [19,20]. Besides psychological and cultural factors, biological factors contribute to these sex differences [21]. Therefore, it is likely that there are sex differences in anxiety about undergoing screening owing to COVID-19.

By modality, the percentage of participants who felt anxious due to the COVID-19 pandemic was highest for EGD and colonoscopy, respectively. Malignant neoplasms are the leading cause of death in Japan. Colorectal cancer was the most common cancer type in 2018, followed by gastric cancer. In 2019, colorectal cancer was the second most common cause of cancer-related mortality, followed by gastric cancer. Delays in screening will increase the number of advanced cancers and deaths in the near future.

In a French study investigating the effect of the COVID-19 pandemic on EGD screening in France, 98.7% of endoscopists had cancelled endoscopies, and 73.6% of them had closed the endoscopy outpatient clinic [22]. COVID-19 spreads primarily through droplets of saliva, although airborne transmission and fecal excretion have been documented [23,24]. Severe acute respiratory syndrome coronavirus 2 can survive in the air for several hours [25]. Health care professionals in endoscopy are exposed to COVID-19 through contact with saliva droplets on their face and in airways, via touch contamination, and through contact with a patient's stool [26,27]. Aerosol infections around endoscopes have also been reported, making EGD among the major aerosol-generating procedures [28,29]. In EGD, where the risk of droplet diffusion and aerosol generation is high, careful measures, such as patient triage and thorough infection protection, are required [30]. Guidelines for endoscopy during the COVID-19 pandemic have been developed [31]. The Japan Gastroenterological Endoscopy Society has published a proposal on its website regarding gastrointestinal endoscopic care for COVID-19. In this survey, we did not ask about the risk for COVID-19 infection from aerosol in EGD, but it is hypothesized that the participants felt anxious about EGD because it is a face-to-face examination compared to other modalities.

In a Japanese study, the Comprehensive Survey of Living Conditions reported a 39% participation rate in gastric cancer screening in 2019. Cancer screening rates in Japan are lower than those in other countries, such as the United Kingdom and Korea. In this study, the percentage of "concerned about EGD due to the COVID-19 pandemic" was higher compared to "haven't undergone screening" and "needed further examination but did not go for it" based on previous screening results. It is a concern that those who do not undergo screening or visit hospitals for further examination will become increasingly reluctant to do so. In addition, one of the factors associated with EGD screening anxiety due to the COVID-19 pandemic was "perceived to be the risk of gastric cancer." These results suggest a decrease in the number of gastric cancer screenings and a delay in the detection of gastric cancer. Other factors associated with anxiety around EGD screening due to the COVID-19 pandemic were "viral infection prevention measures," "waiting time," "fees (medical expenses)," and "mode of transportation." Medical institutions and the government must reassure citizens by informing them that appropriate infection prevention measures are being taken during cancer screening.

This study had several limitations. First, we used an internet panel survey company to collect data. While we could obtain responses regarding a wide range of demographic factors such as age, occupation, and income, these groups were not representative of the general population in Japan. However, web surveys have recently become a common method for conducting studies [32,33]. Second, the spread of infection changes daily and varies across regions; however, the survey did not consider this effect. Third, because we did not ask respondents whether they ever had COVID-19, we do not know the effect of the respondents' personal experiences with previous infection on their anxiety. Finally, the cross-sectional design of this study made it difficult to assess causality.

Conclusions

This is the first survey-based study to examine the effects of the COVID-19 pandemic on the intention to undergo cancer screening. Most participants were anxious about undergoing screening owing to COVID-19 regardless of whether they resided in a prefecture where a state of emergency was declared, and the percentage of anxiety was higher for EGD than for other modalities. "Viral infection prevention measures," "waiting time," "fees (medical expenses)," "mode of transportation," "worry about my social position if I contracted COVID-19," and "perceived the risk of gastric cancer" were associated with anxiety about EGD screening anxiety owing to the COVID-19 pandemic. Excessive anxiety about COVID-19 leads to serious outcomes such as delayed detection of cancer and increased cancer-related deaths. Thus, it is necessary to thoroughly implement infection prevention measures and provide correct information to examinees.

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Data Availability

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

Authors' Contributions

TA and MA were responsible for the conception and design of the study and for the analysis of data. MA and YN contributed to acquisition of data. TA, YN, MA, and HY were responsible for the interpretation of data as well as drafting and revising the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Questionnaire survey.
[DOCX File , 20 KB - cancer_v8i4e40600_app1.docx]

Multimedia Appendix 2
Background characteristics of the participants.
[PPTX File , 56 KB - cancer_v8i4e40600_app2.pptx]

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Abbreviations

EGD: esophagogastroduodenoscopy

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Original Paper

Role for a Web-Based Intervention to Alleviate Distress in People With Newly Diagnosed Testicular Cancer: Mixed Methods Study

Ciara Conduit[1,2,3], MBBS; Christina Guo[4,5], MBBS; Allan B Smith[6], PhD; Orlando Rincones[6], MRes; Olivia Baenziger[1], BBMED, MPH, MD; Benjamin Thomas[7], MBBS, PhD; Jeremy Goad[8], MBBS; Dan Lenaghan[9], MBBS; Nathan Lawrentschuk[7,8], MBBS, PhD; Lih-Ming Wong[10], MBBS; Niall M Corcoran[7,11], MBBS, PhD; Margaret Ross[12], PsyD; Peter Gibbs[1], MBBS, PhD; Sophie O'Haire[1,3,13], BBSC, Grad Cert (App Stat); Angelyn Anton[1,14], MBBS; Elizabeth Liow[1,15], MBBS; Jeremy Lewin[2,3,16], MBBS; Ben Tran[1,2,3], MBBS

[1]Personalised Oncology, Walter and Eliza Hall Institute of Medical Research, Parkville, Australia
[2]Medical Oncology, Peter MacCallum Cancer Centre, Melbourne, Australia
[3]Sir Peter MacCallum Department of Oncology, University of Melbourne, Parkville, Australia
[4]The Institute of Cancer Research, London, United Kingdom
[5]The Royal Marsden NHS Foundation Trust, London, United Kingdom
[6]Ingham Institute for Applied Medical Research & University of New South Wales, Liverpool, Australia
[7]Department of Surgery, Royal Melbourne Hospital, University of Melbourne, Melbourne, Australia
[8]Cancer Surgery, Peter MacCallum Cancer Centre, Melbourne, Australia
[9]Urology, St Vincent's Hospital Melbourne, Fitzroy, Australia
[10]Epworth Healthcare, East Melbourne, Australia
[11]Victorian Comprehensive Cancer Centre, Parkville, Australia
[12]Psychosocial Cancer Care and Palliative Care, St Vincent's Hospital Melbourne, Fitzroy, Australia
[13]Cancer Health Services Research Unit, Peter MacCallum Cancer Centre, Melbourne, Australia
[14]Medical Oncology, Eastern Health, Melbourne, Australia
[15]Medical Oncology, Monash Health, Melbourne, Australia
[16]ONTrac at Peter Mac, Victorian Adolescence and Young Adult Cancer Service, Melbourne, Australia

Corresponding Author:
Ben Tran, MBBS
Personalised Oncology
Walter and Eliza Hall Institute of Medical Research
1G Royal Parade
Parkville, 3052
Australia
Phone: 61 393452555
Email: ben.tran@petermac.org

Abstract

Background: Distress is common immediately after diagnosis of testicular cancer. It has historically been difficult to engage people in care models to alleviate distress because of complex factors, including differential coping strategies and influences of social gender norms. Existing support specifically focuses on long-term survivors of testicular cancer, leaving an unmet need for age-appropriate and sex-sensitized support for individuals with distress shortly after diagnosis.

Objective: We evaluated a web-based intervention, Nuts & Bolts, designed to provide support and alleviate distress after diagnosis of testicular cancer.

Methods: Using a mixed methods design to evaluate the acceptability, feasibility, and impact of Nuts & Bolts on distress, we randomly assigned participants with recently diagnosed testicular cancer (1:1) access to Nuts & Bolts at the time of consent (*early*) or alternatively, 1 week later (day 8; *delayed*). Participants completed serial questionnaires across a 4- to 5-week period to evaluate levels of distress (measured by the National Comprehensive Cancer Network Distress Thermometer [DT]; scored 0-10), anxiety, and depression (Hospital Anxiety and Depression Score [HADS]–Anxiety and HADS-Depression; each scored 0-21). The primary end point was change in distress between consent and day 8. Secondary end points of distress, anxiety, and depression were assessed at defined intervals during follow-up. Optional, semistructured interviews occurring after completion of quantitative assessments were thematically analyzed.

Results: Overall, 39 participants were enrolled in this study. The median time from orchidectomy to study consent was 14.8 (range 3-62) days. Moderate or high levels of distress evaluated using DT were reported in 58% (23/39) of participants at consent and reduced to 13% (5/38) after 1 week of observation. *Early intervention* with Nuts & Bolts did not significantly decrease the mean DT score by day 8 compared with *delayed intervention* (early: 4.56-2.74 vs delayed: 4.47-2.74; $P=.85$), who did not yet have access to the website. A higher baseline DT score was significantly predictive of reduction in DT score during this period ($P<.001$). Median DT, HADS-Anxiety, and HADS-Depression scores reduced between orchidectomy and 3 weeks postoperatively and then remained stable throughout the observation period. Thematic analysis of 16 semistructured interviews revealed 4 key themes, “Nuts & Bolts is a helpful tool,” “Maximizing benefits of the website,” “Whirlwind of diagnosis and readiness for treatment,” and “Primary stressors and worries,” as well as multiple subthemes.

Conclusions: Distress is common following the diagnosis of testicular cancer; however, it decreases over time. Nuts & Bolts was considered useful, acceptable, and relevant by individuals diagnosed with testicular cancer, with strong support for the intervention rendered by thematic analyses of semistructured interviews. The best time to introduce support, such as Nuts & Bolts, is yet to be determined; however, it may be most beneficial as soon as testicular cancer is strongly suspected or diagnosed.

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KEYWORDS

testicular germ cell tumor; cancer survivors; emotional distress; anxiety disorders; depression

Introduction

Background

There have been significant advances in the treatment of testicular cancer in recent decades, such that >97% of individuals can expect a cure [1-3]. While being cancer free, survivors may experience physical, psychological, and social consequences that persist long after their diagnosis and treatment, including cardiovascular morbidity, hypogonadism, second malignancy, and residual chemotherapy toxicities [4-9]. Psychological distress is common immediately following diagnosis [10-13], with a large retrospective study of survivors of testicular cancer suggesting that distress was most significant at this time compared with other periods of their cancer journey [13]. Distress is multifactorial; however, it frequently stems from a perceived lack of information regarding treatment and prognosis [14] and is influenced by risk factors including education level, chronic illness, absence of paid employment, relationship status, and treatment-related factors, such as concomitant use of chemotherapy [6,9,15-18]. Importantly, some individuals may experience persistent symptoms leading to chronic anxiety and depression [19], such that the prevalence and severity of anxiety reported in long-term survivors of testicular cancer is higher than in the general population, with up to 21% of survivors reporting persistent symptoms [9].

Existing support for distress focuses on these long-term survivors, leaving individuals shortly after their diagnosis without adequate resources to support their distress, if required [13,20]. Multiple studies have demonstrated that psychosocial interventions or support help reduce anxiety and depression in people with cancer generally [21-23], and in long-term survivors of testicular cancer [24,25]. However, intervention uptake is variable, particularly in males and young adults [26-29], which may stem from differences in coping strategies and help-seeking behavior and the influence of social gender norms. In addition, there is a lack of age-appropriate and sex-sensitized support for younger people diagnosed with testicular cancer [30,31], further widening this gap and accentuating the need for support to help manage distress proactively and promote long-term psychological health. With this in mind, a pilot study of a web-based psychological intervention in long-term survivors of testicular cancer demonstrated promising acceptability; however, feasibility was limited by poor engagement with the intervention, as evidenced by low module completion rates over time [25]. Where survivors of testicular cancer frequently survive for many decades following curative treatment [32], it is integral to develop novel strategies to adequately address distress at the outset in those who need assistance.

Nuts & Bolts is a web-based intervention funded and operated by the Movember Foundation that could help address this unmet need in patients with recently diagnosed testicular cancer [33]. The intervention comprised the following three domains:

1. Information provision, where individuals can access accurate information about testicular cancer statistics, diagnosis, treatment, and prognosis.
2. “Ask an Expert,” where individuals access responses to frequently asked questions or pose new questions to specialized cancer clinicians and trained peers (with lived experience) and receive personalized responses.
3. “Connect with a Man,” where individuals can access one-on-one peer support from a trained survivor of testicular cancer.

The website requires individuals to self-navigate through the 3 domains according to their specific needs. It was not readily available to the public at the time this study was recruiting; however, the website has since been made available following an official launch.

Objectives

We undertook a prospective, multicenter, randomized controlled trial to evaluate the acceptability, feasibility, and impact of Nuts & Bolts on distress levels in the weeks following diagnosis of testicular cancer; however, because of poor accrual and anticipated impacts of the COVID-19 pandemic on research personnel, the trial closed early. We then evaluated the prevalence of distress, anxiety, and depression following a recent diagnosis of testicular cancer, changes in symptoms across a period of observation, and an exploration of the lived experience of individuals with newly diagnosed testicular cancer through thematic analysis of semistructured interviews.

Methods

Study Design and Participants

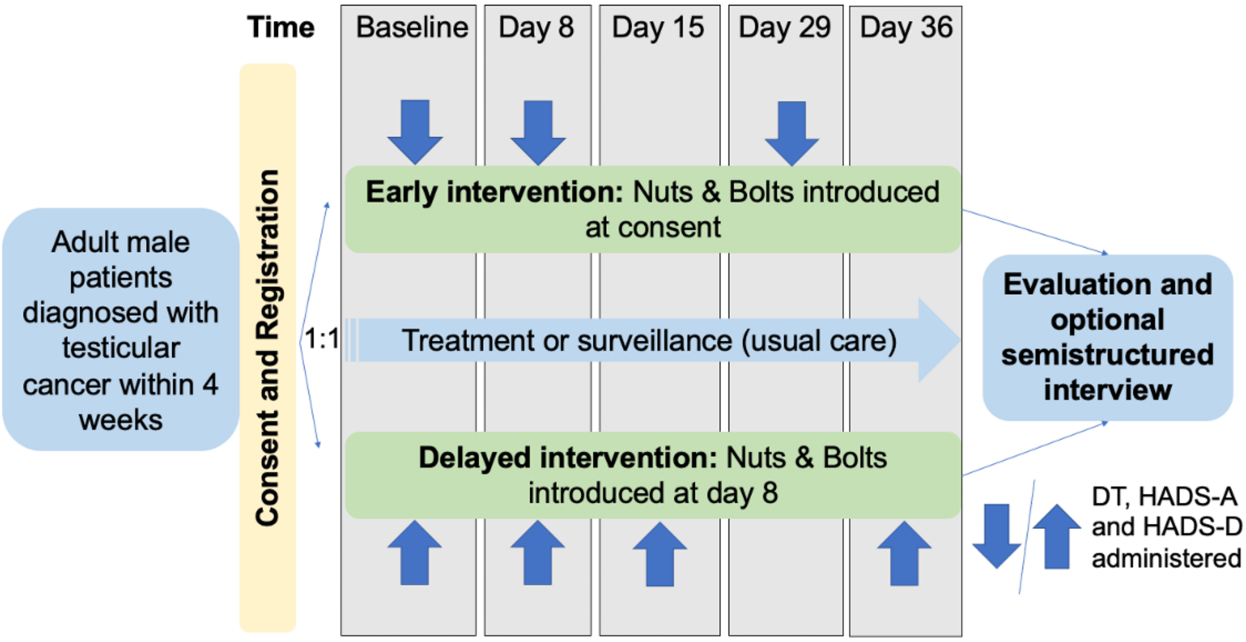
This study was designed as a mixed methods, convergent parallel, randomized controlled trial. Eligible participants were aged >18 years, had histologically confirmed testicular cancer within 4 weeks of study consent, were proficient in English and had access to the internet.

Eligible participants were assigned (1:1) to either *early intervention* with access to Nuts & Bolts at the time of study consent or *delayed intervention*, in which access was provided 1 week later. Once access was provided, participants were expected to self-navigate the website according to their specific needs.

Assessments and Outcomes

Quantitative data were collected using the National Comprehensive Cancer Network (NCCN) Distress Thermometer (DT) score (0-10) and problem list [34], as well as the Hospital Anxiety and Depression Scale–Anxiety (HADS-A) score (0-21), Hospital Anxiety and Depression Scale-Depression (HADS-D) score (0-21), and Hospital Anxiety and Depression Scale-Total score (0-42) [35]. Participants completed assessments on a web-based portal at study consent and after 1, 2, 4, and 5 weeks, which varied by the assigned study group (Figure 1).

Figure 1. Study scheme. DT: Distress Thermometer; HADS-A: Hospital Anxiety and Depression Scale–Anxiety; HADS-D: Hospital Anxiety and Depression Scale–Depression.



The primary end point was the change in DT score between study consent and day 8 in the *early intervention* group, compared with the control, *delayed intervention* group. Key secondary end points included changes in DT, HADS-A, and HADS-D scores between study consent and day 8 and introduction to Nuts & Bolts and 4 weeks later. Owing to poor accrual, a descriptive analysis of the results obtained from all enrolled participants, regardless of group assignment, was performed. In addition, the acceptability and usability of Nuts & Bolts were evaluated using a supplemental questionnaire delivered after the period of observation.

Qualitative data were collected after completion of the quantitative assessments. Participants were invited to undertake optional, ethically approved semistructured interviews, which were thematically analyzed [36] to explore the lived experiences of individuals following the diagnosis of testicular cancer. Consenting participants were invited to be interviewed using convenience sampling until data saturation was reached. Interviews were undertaken (interviewer was female, registered nurse and research coordinator; see the Acknowledgments section) in accordance with the consolidated criteria for reporting qualitative research recommendations [37]. Telephone interviews lasting 20 to 30 minutes were audio recorded. The interviewer had previous contact with all participants in her role as a research coordinator before the interview; no relevant biases were reported.

Analyses

We estimated that a sample of 86 participants, allowing for a 20% loss to follow-up, would provide ≥80% power to detect a mean difference of 1.8 between *early* and *delayed intervention* groups when a change in DT scores from baseline to day 8 were assessed using analysis of covariance where study arm and baseline DT score treated as covariates. In addition, linear regression was performed to explore the impact of the study arm and baseline DT score on the reduction in DT. Other quantitative data were analyzed using simple descriptive statistics. Odds ratios (ORs) were used to explore associations among categorical data, and the log method was used to calculate 95% CIs. For comparisons of mean scores between time points and subgroups, paired or independent 2-tailed *t* tests were used and are further outlined in the Results section. Statistical significance was defined as a 2-tailed *P* value of ≤.05. All statistical analyses were performed using Stata (version 14.2; IBM Corp) and Microsoft Excel for Mac (version 16.5).

Qualitative semistructured interview data were thematically analyzed, systematically identifying, organizing, and providing insight into patterns of meaning (themes) across the data set [36]. Interview transcripts were independently coded using NVivo (version 10; QSR International) by a member of the research team naïve to intervention allocation. A subset of the interviews (n=3) was coded by a second researcher to ensure concordance, and differences in coding were resolved through discussion. The themes were derived from the data. A constant comparative method involving moving back and forth between the interview transcripts, coded data extracts, and themes generated was used to ensure that the thematic hierarchy accurately reflected the interview data. Subthemes and themes were finalized in discussions with a second researcher to reduce the risk of individual biases affecting the results. The participants did not provide feedback on the findings.

Study data were collected and managed using REDCap (Research Electronic Data Capture; Vanderbilt University) [38,39], electronic data capture tools hosted by the Clinical Translation Centre, Walter and Eliza Hall Institute of Medical Research.

Ethical Considerations

This study was approved by the Melbourne Health Human Research Ethics Committee (MH-2018-157301). Local ethical and governance approval was obtained from all participating sites. All participants provided written informed consent based on the Declaration of Helsinki principles [40] and were not financially compensated for their involvement in the study. All data collected during the study were deidentified; participants were provided with a unique identification code at the time of registration.

Results

Participants

Between April 2019 and April 2020, of the 56 invited participants, 39 (70%) participants from 4 sites consented to the trial and were randomly assigned to *early intervention* (20/39, 51%) or *delayed intervention* (19/39, 49%; Figure 2). The accrual was closed early because of the anticipated impact of the COVID-19 pandemic on research personnel and hospital resources at coordinating and recruiting centers. Overall, 119 study questionnaires were completed during the observation period, and 95% (37/39) of the participants completed all study assessments. The median participant age was 32 (range 24-55) years, and the median time from orchidectomy was 14.8 (range 3-62) days at study consent (Table 1). In all, 5% (2/39) of the participants were enrolled >4 weeks after the diagnosis of testicular cancer (enrollment violation).

Figure 2. CONSORT (Consolidated Standards of Reporting Trials) diagram.

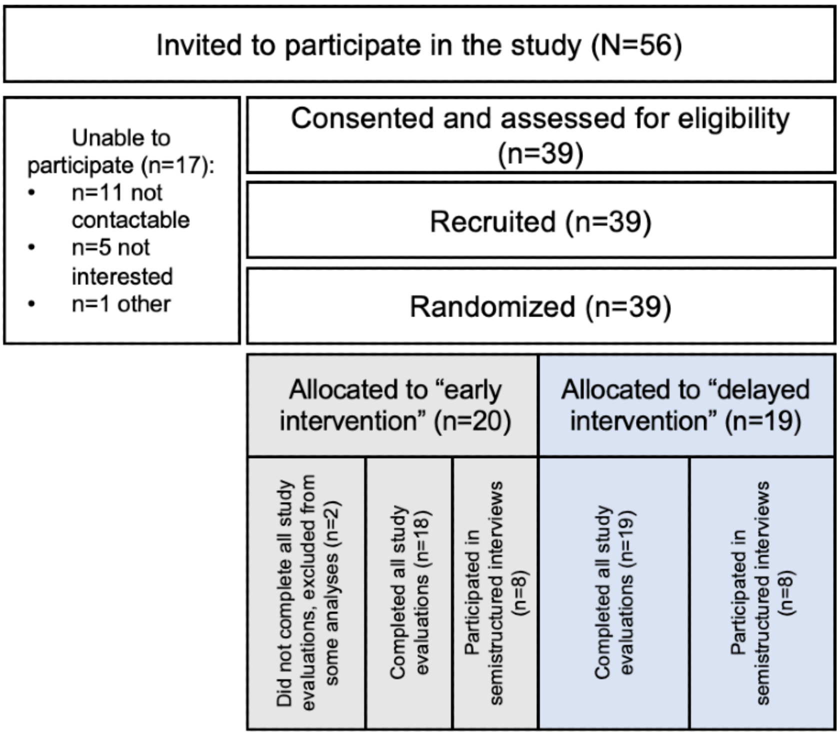


Table 1. Baseline characteristics (N=39).

	Eligible participants (n=39)
Age at consent (years), median (range)	32.4 (24-55)[a]
TNM[b] stage, n (%)	
I	32 (82)
II-III	4 (10)
Not stated	3 (8)
Ethnicity, n (%)	
White	34 (87)
Asian	4 (10)
Other	1 (3)
Relationship status, n (%)	
Single	12 (31)
Married or de facto	21 (54)
In a relationship	6 (15)
Highest level of education completed, n (%)	
High school	5 (13)
Apprenticeship	4 (10)
Tertiary	30 (77)
Paid employment, n (%)	36 (92)
Mental health history, n (%)	
Previous history of mental ill health	8 (21)
Currently receiving mental health support	9 (23)
Orchidectomy performed, n (%)	
Yes	36 (92)
Not stated	3 (8)
Time from orchidectomy (days), median (range)	14.8 (3-62)
Medical oncologist involvement at time of enrollment, n (%)	24 (62)
Planned treatment, n (%)	
Surveillance	30 (77)
Chemotherapy	5 (13)
Not stated	4 (10)
Baseline level of distress	
DT[c]	
Median score: all participants, median (range)	5 (0-8)
Mean score: consented <14 days since orchidectomy, mean (range)	5.2 (1-8)
Mean score: consented >14 days since orchidectomy, mean (range)	3.7 (0-7)
HADS-A[d]	
Median score: all participants, median (range)	5 (0-15)
Mean score: consented <14 days since orchidectomy, mean (range)	6.9 (2-15)
Mean score: consented 14 days since orchidectomy, mean (range)	4.4 (0-11)
HADS-D[e]	
Median score: all participants, median (range)	3 (0-10)

	Eligible participants (n=39)
Mean score: consented <14 days since orchidectomy, mean (range)	4.6 (0-9)
Mean score: consented >14 days since orchidectomy, mean (range)	3.1 (0-10)
Moderate or high levels of distress, n (%)	
DT≥5	23 (59)
HADS-T[f]≥11	15 (38)

[a] Excluding 2 participants in whose date of birth was incorrectly recorded.

[b] TNM: tumor, node, metastases.

[c] DT: Distress Thermometer.

[d] HADS-A: Hospital Anxiety and Depression Scale–Anxiety.

[e] HADS-D: Hospital Anxiety and Depression Scale–Depression.

[f] HADS-T: Hospital Anxiety and Depression Scale–Total.

Quantitative Results

Baseline Characteristics

Distress was reported by most participants at baseline on DT. The median DT score was 5 (range 0-8), with 53% (21/39) of all participants reporting moderate (DT score≥5 and <8) and 5% (2/39) reporting high-level (DT score≥8) distress. Baseline DT scores were not associated with key demographic risk factors for distress, including preexisting mental health history (moderate distress: OR 2.5, 95% CI 0.4-14.2), lower level of education (moderate distress: OR 0.8, 95% CI 0.3-3.9), or relationship status (moderate distress: OR 1.0, 95% CI 0.3-4.1) in our study (Table S1 in Multimedia Appendix 1). However, participants consenting to Nuts & Bolts <14 days following orchidectomy reported higher DT (5.2 vs 3.7; *P*=.04) and HADS-A (6.9 vs 4.4; *P*=.03) scores than participants who consented >14 days following orchidectomy in 2-tailed *t* test analyses.

Emotional and physical problems dominated the NCCN problem list at baseline, with nervousness, worry, fear, sadness, fatigue, feeling swollen, and pain reported by at least half of the participants (at least 22/39, 56%; Table S2 in Multimedia Appendix 1).

Difference Between Early and Delayed Intervention Groups Between Consent and Day 8

Early intervention with Nuts & Bolts did not significantly reduce mean DT scores on day 8 compared with those for delayed intervention after adjusting for baseline DT score (*P*=.85) when analyzed using an analysis of covariance (Tables S3 and S4 in Multimedia Appendix 1). The primary endpoint was not achieved. Using linear regression analysis, a higher baseline DT score was associated with a statistically significant reduction in DT across this period (*P*<.001) for all participants, but study arm was not.

Change in Distress, Anxiety, and Depression During Follow-up for the Whole Cohort

When analyzed as a whole, regardless of the group assignment, levels of distress evaluated using DT significantly declined between baseline evaluation and after 1 week in a paired 2-tailed *t* test analysis (4.6 vs 2.7; *P*<.001; Table S3 in Multimedia Appendix 1).

In contrast to the baseline evaluation, only 13% (5/38) of the participants reported moderate distress on DT after 1 week of observation, and none of the participants reported high levels of distress. Levels of anxiety evaluated using HADS-A did not change between baseline and 1-week later (5.7 vs 5.1; *P*=.26); however, depression scores reduced significantly across the same period (3.8 vs 3.1; *P*=.04; Table S4 in Multimedia Appendix 1).

When analyzed by time from orchidectomy rather than time from study entry, median DT, HADS-A, and HADS-D scores reduced most between 1 and 4 weeks following orchidectomy and then remained largely stable throughout the remainder of the observation period (Table 2).

Table 2. Median levels of distress, anxiety, and distress during observation.

Weeks following orchidectomy	Number of observations	DT[a] score, median (range)	HADS-A[b] score, median (range)	HADS-D[c] score, median (range)
≤1	10	5 (1-8)	6.5 (2-10)	4.5 (0-9)
>1 to ≤2	14	4.5 (1-8)	6.5 (0-15)	4.5 (1-9)
>2 to ≤3	20	2 (0-6)	4 (0-10)	2 (0-7)
>3 to ≤4	19	3 (0-7)	6 (2-11)	2 (0-10)
>4 to ≤5	24	2 (0-7)	5 (0-12)	2 (0-9)
>5 to ≤6	11	2 (0-5)	4 (0-11)	2 (0-10)
>6	21	1 (0-5)	4 (0-11)	2 (0-14)

[a] DT: Distress Thermometer.

[b] HADS-A: Hospital Anxiety and Depression Scale–Anxiety.

[c] HADS-D: Hospital Anxiety and Depression Scale-Depression.

Evaluation of Acceptability and Feasibility

Overall, 95% (37/39) of the participants completed the evaluation of acceptability and feasibility at the conclusion of the study. Most participants expressed that Nuts & Bolts was easy to use (37/37, 100%), relevant (36/37, 97%), and useful (31/37, 84%). Almost two-thirds (24/37, 65%) used the “Ask an Expert” module, with 87% (20/24) of responders agreeing that this module was useful, although some noted that their questions were not answered. A smaller proportion used the “Connect with a Man” module (5/37, 14%) and all agreed that this module was useful (5/5, 100%; Table 3). Participants who did not use “Connect with a Man” reported that other Nuts & Bolts domains and resources, such as family or friends, reduced the potential utility of this module. Many offered support for the idea of “Connect with a Man,” and some enrolled to become trained peers following the study (Table 3).

Table 3. Responses to poststudy questionnaire of acceptability and feasibility.

Statement asked	Response					
	Strongly disagree, n (%)	Disagree, n (%)	Unsure, n (%)	Agree, n (%)	Strongly agree, n (%)	Respondents, n (% of users)
Nuts & Bolts was useful to me	0 (0)	3 (8)	3 (8)	13 (35)	18 (49)	37 (95)
Nuts & Bolts was relevant to me	0 (0)	0 (0)	1 (3)	24 (65)	12 (32)	37 (95)
Nuts & Bolts was easy to use	0 (0)	0 (0)	0 (0)	11 (30)	26 (70)	37 (95)
I could understand the information provided by Nuts & Bolts	0 (0)	0 (0)	0 (0)	10 (27)	27 (73)	37 (95)
The length of the content on Nuts & Bolts was appropriate to me	0 (0)	1 (3)	3 (8)	9 (25)	23 (64)	36 (92)
I found the “Ask an Expert” section useful	0 (0)	1 (4)	2 (9)	14 (61)	6 (26)	23 (96)
I found the “Connect with a Man” section useful	0 (0)	0 (0)	0 (0)	2 (40)	3 (60)	5 (100)

Thematic Analysis

Overview

Over three-fourths of the participants (30/39, 77%) provided consent to participate in the optional, semistructured interviews, and using convenience sampling, 16 interviews were conducted. This group was representative of the studied population with a median age of 30.5 (range 24.1-54.5) years, and 50% (8/16) were assigned to each study group. Most participants were White (14/16, 88%), married or in a de facto relationship (11/16, 69%), and diagnosed with stage I testicular cancer (10/16, 63%; data not shown).

Thematic analysis of interviews generated 4 main themes regarding participants’ experiences following the diagnosis of testicular cancer and use of Nuts & Bolts (Figure 3). Additional illustrative quotes related to the subthemes are shown in Table 4.

Figure 3. Thematic map.

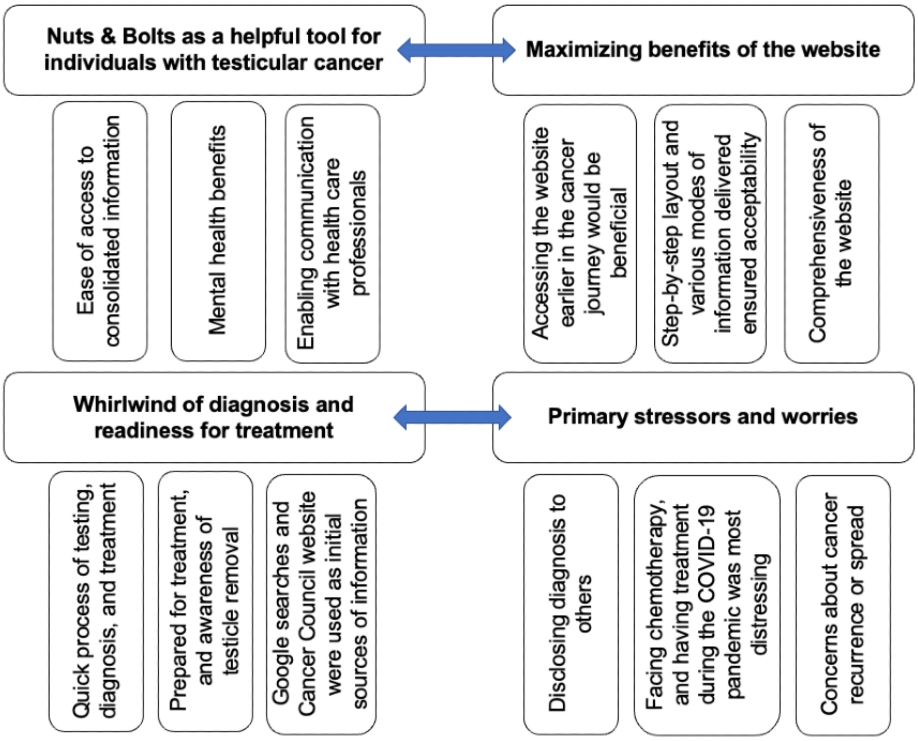


Table 4. Themes, subthemes, and illustrative quotes from thematic analyses.

Theme and subthemes	Illustrative quotes
1. Nuts & Bolts website as a helpful tool	
A. Ease of access to consolidated information	“The most helpful thing about the site is the fact that it consolidates the information that you’re after for this specific condition and that’s something that’s not readily available.” [Tertiary educated, in a relationship, aged 55 years]
B. Mental health benefits	“And I think...[the website] was good because when I was about to start to get a bit anxious so that like ‘Oh, God, what if, what if, what ifs,’ I could read the information to just reassure myself, I guess, with the general facts...” [Tertiary educated, in a relationship, aged 34 years]
C. Enabling communication with health care professionals	“...[The website] gave me the proper questions that I need to ask, not only the oncologist, but also the nurses when I went into chemo.” [High school educated, in a relationship, aged 49 years]
2. Maximizing the benefits of the website	
A. Accessing the website earlier in the testicular cancer journey would be beneficial	“I reckon...[the website] would be most useful pretty much as soon as you get diagnosed...Look, I would suggest probably once you’ve had some tests done with your GP, if it’s made available, then I think that would be beneficial...before going to see a urologist...” [Tertiary educated, single, aged 30 years]
B. Step-by-step layout and varied mode of information delivery ensured acceptability	“...[the website] has a step by step, and it explains each stage, and then you can drill down on the information...and then it explains as you go through the journey...And I think...[the website] is kind of like, ‘Here, we’ll help you’—like just a path. It just lays out the path that you need to go along.” [Tertiary educated, single, aged 33 years]; “I’d say definitely those videos, it just sort of put a human touch on the whole situation...” [High school educated, in a relationship, aged 30 years]
C. Comprehensiveness of the website	“I think everything is pretty good. I didn’t feel like anything was lacking.” [Tertiary educated, in a relationship, aged 30 years; “delayed intervention”]; “...some mental health support would have been good on the website...even if it was just like maybe a link or something like that to like—a support group...a psychologist or who to talk to...” [Tertiary educated, in a relationship, aged 33 years]
3. Whirlwind of diagnosis and readiness for treatment	
A. Quick process of testing, diagnosis, and treatment	“Yeah, it was quick. I didn’t expect it to be so soon, like it’s good that it was. So I saw her [his GP] on a Monday and then the Wednesday, it was the surgery booking...” [Tertiary educated, in a relationship, aged 30 years]
B. Prepared for treatment and awareness of testicle removal	“...once I found out they were gonna need to remove it, you sort of don’t really care. So, all that aesthetic stuff that normally comes with being a bloke, when you find out you have something like that in your body, you don’t really care. You just wanna get rid of it.” [High school educated, male, in a relationship, aged 30 years]; “I knew it had to be removed and, I suppose, I didn’t feel great about it.” [High school educated, in a relationship, aged 49 years]
C. Google searches and Cancer Council website were used as initial sources of information	“...both my partner and I did a bit of reading online. We didn’t do a lot because we didn’t wanna...scare ourselves...I had a brief read of the Cancer Council site, which was probably the most informative that I came across. And I sort of—after I got the general gist, I went, ‘Yep, all right, that’s enough.’” [High school educated, in a relationship, aged 30 years]
4. Primary stressors and worries	
A. Disclosing the diagnosis to others	“I found it really hard trying to control the people around me. I found that the biggest stress for me because they would hear the word cancer and kind of freak out a little bit.” [Tertiary educated, male, in a relationship, unknown age]
B. Facing chemotherapy and having treatment during the COVID-19 pandemic was most distressing	“I was quite worried about that and how my body was gonna handle [the chemotherapy].” [High school educated, in a relationship, aged 49 years]; “Honestly with the COVID-19 scenario at the moment, it’s a little bit hard to me as well. My parents are stuck over in Western Australia, so they can’t actually come here. So I’m, unfortunately, living on my own at the moment, so I’m having to look after myself a bit which is a little bit distressing but, look, you have to acclimatise and it is what it is.” [Tertiary educated, male, single, receiving chemotherapy, aged 30 years]
C. Concerns about cancer recurrence or spread	“I’ve got positive results and it looked good, there’s no point living in fear, I suppose, or whether it affects your life...But with that said, I do have a level of fear that it will come back, or it will manifest somewhere else.” [Tertiary educated, in a relationship, aged 38 years]

Nuts & Bolts Is a Helpful Tool

Nuts & Bolts was considered valuable throughout the journey with testicular cancer, including in participants with recurrent testicular cancer and those with high health literacy:

> *I think [Nuts & Bolts is useful at] every stage of the journey to be honest. Right from being given diagnosis through to any potential surgery and then post-surgery and the chemo and even recovery.* [High school educated, in a relationship, aged 49 years]

A total of 3 main subthemes were identified in this study. Participants reported that Nuts & Bolts provided consolidated access to reliable information (subtheme 1A). Specifically, many liked how the webpage explained what to expect for different disease stages (localized and advanced) and the role of various team members in their care. In addition, participants described feeling less anxious and distressed after accessing the resource (subtheme 1B), as the information provided offered them realistic expectations about treatment and prognosis. Some participants reported that Nuts & Bolts also helped lessen the fear of cancer recurrence and improved their baseline knowledge of testicular cancer, which made it easier to ask questions and communicate with their health care team (subtheme 1C).

Maximizing the Benefits of the Website

All participants accessed Nuts & Bolts after study enrollment, with timing dependent on their group assignments. Most individuals had already commenced treatment, most commonly orchidectomy, when they first accessed the website:

> *...I discovered [Nuts & Bolts] sort of after my operation. So, the worst of it had sort of been over.* [High school educated, in a relationship, aged 30 years]

A total of 3 main subthemes were identified. Some participants assigned to either intervention groups perceived the timing of introduction to Nuts & Bolts as "late" with consensus that the optimal timing would be before seeing a urologist and orchidectomy (subtheme 2A). Despite this, participants considered Nuts & Bolts valuable and acknowledged the logistical barriers to providing earlier access because of the rapidity of diagnosis and treatment. The clear, step-by-step layout and varied mode of information delivery through images, videos, and patient testimonials was also highly acceptable (subtheme 2B). Nuts & Bolts was generally considered comprehensive (subtheme 2C); however, some participants suggested that additional information about the recovery time after treatment, chemotherapy, testicular cancer subtypes, and mental health support would be helpful.

"Whirlwind" of Diagnosis and Treatment Readiness

A total of 3 main subthemes were identified. Most participants perceived the diagnosis process and commencing treatment to be rapid (subtheme 3A), with some expressing "disbelief" or "shock" following their diagnosis. However, this rapid pace was valued by other participants, who were keen to *get rid of it* [tertiary educated, single, aged 30 years]. Only 1 participant indicated that they would have preferred more time to process the available information (subtheme 3B). In addition, most participants were aware that they would require orchidectomy and indicated that they felt prepared for this procedure. Some participants noted that they were not worried about their testicles being removed, while others felt *"devastated."*

Before study enrollment, Google searches and government-endorsed websites such as the Australian "Cancer Council" were commonly used to seek information (subtheme 3C). However, a few participants were hesitant because of concerns about negative anecdotes and information quality. Some participants accessed information from family, friends, or other physicians, others did not actively seek information before their diagnosis, citing a preference not to be overwhelmed by information. A participant voiced that they would seek out Nuts & Bolts as their first resource if they experienced recurrence or contralateral testicular cancer, obviating the need for broad Google searches.

Primary Stressors and Worries

The participants expressed that various emotions and stressors arose following their diagnosis of testicular cancer. The most distressing concerns were related to social impact following diagnosis and treatment-related concerns.

A total of 3 main subthemes were identified. Many participants described communicating information to friends and family and concerns about managing their emotional reactions as a significant source of distress (subtheme 4A). Some participants reported that investigations, particularly scans and chemotherapy treatments, added additional sources of stress during their journey. For participants enrolled in 2020, the impact of the COVID-19 pandemic and risk associated with attending hospitals for treatment during this period added further complexity to their experience (subtheme 4B). Finally, many participants reported fear of cancer recurrence or spread; however, this did not appear to cause sustained distress or functional impairment in most cases (subtheme 4C). Several participants indicated they were explicitly maintaining a "positive attitude" and avoiding thoughts about recurrence. Other concerns raised by the participants included the risk of infertility and contralateral testicular cancer in the future.

Discussion

Principal Findings

Distress identification is vital when caring for patients diagnosed with cancer [19]. Our study of individuals with recently diagnosed testicular cancer found that more than half of the participants reported moderate distress at the time of study enrollment, with the highest distress observed in participants within 14 days of orchidectomy, as in previous research [10-13]. Reassuringly, distress levels decreased over time, with a significant change in mean DT scores seen throughout the course of observation and as time increased from diagnosis, with only 13% (5/38) of the participants reporting moderate distress after 1 week of observation (approximately 3 weeks after orchidectomy). Notably, depressive symptoms were less common than anxiety in our cohort, which mirrors existing research [6,41].

Although the primary outcome of this study was not met and earlier introduction to Nuts & Bolts did not lead to a significant reduction in distress on day 8, thematic analysis of semistructured interviews occurring after completion of quantitative assessments emphasized a high level of perceived utility for Nuts & Bolts. Multiple participants indicated a strong preference for access to Nuts & Bolts at the time of diagnosis, when their distress was highest, while acknowledging its usefulness during and after treatment. Importantly, the introduction of Nuts & Bolts did not negatively affect distress, and thematic analysis and poststudy evaluations strongly endorse its ongoing role in supporting individuals following the diagnosis of testicular cancer. Partnerships between researchers and nongovernment and industry organizations are key to the sustained dissemination of web-based interventions in cancer care [42]. As this study was completed, Movember has formally launched and promoted the availability of Nuts & Bolts.

Making Nuts & Bolts available to individuals earlier in the process of diagnosing and treating testicular cancer may increase its clinical utility. The perceived "late" introduction to Nuts & Bolts may have lessened its clinical utility. A preference for earlier intervention, that is, before orchidectomy, was highlighted by participants in semistructured interviews and may be appropriate to help ameliorate the significant distress and whirlwind of diagnosis they experience in some individuals where a testicular cancer diagnosis is *strongly* suspected based on preoperative information. Other studies evaluating psychological interventions for the management of distress in patients with cancer, have similarly highlighted that earlier interventions lead to reduced stress, improved quality of life, and superior clinical outcomes [18]. With conflicting reports regarding the prevalence of long-term distress in survivors of testicular cancer [9,10,43], early intervention is important for those who wish to receive it. In addition, as a clinical trial requiring consent, the study may have introduced a potential selection bias for "active copers" rather than individuals with passive coping strategies [6], which may be reflected in the 70% (39/56) response rate for study involvement. These individuals are likely to seek additional information following their diagnosis as opposed to individuals with passive coping strategies. Sociodemographic information of nonconsenting individuals was not collected.

The potential sources of distress elicited from participants were wide ranging, with domains of emotional problems, such as nervousness, worry, fear and sadness and physical problems, such as pain, fatigue and "feeling swollen" dominating the NCCN problem list tool at study entry. Notably, these stressors reduced over time, with a comparatively small number of participants reporting these problems after 4 weeks of observation. This may relate to the resolution of postoperative symptoms, particularly pain and "feeling swollen," and adjustment to the new diagnosis over time. In addition, thematic analysis revealed important concerns regarding communicating with family and friends, fear of cancer recurrence or spread, potential toxicity from chemotherapy, and risks posed by the COVID-19 pandemic while undergoing treatment. Although only raised by a small number of participants in the semistructured interviews in our study, previous research has identified significant concerns about fertility and sexual health following a cancer diagnosis [44-47], which is relevant to survivors of testicular cancer. Regardless, Nuts & Bolts was able to address multiple sources of distress for some participants by providing accurate information about their diagnosis, treatment options, and prognosis, while others relied on their health care team, alternate resources, and family or friends to fill these gaps.

Overall, Nuts & Bolts was considered relevant, user-friendly, and acceptable by most participants. These findings are consistent with previous studies, which reported high levels of patient satisfaction with web-based and mobile-based psychosocial interventions [48-55], particularly those encouraging patient empowerment [56], such as Nuts & Bolts. This is significant for survivors of testicular cancer, given the barriers to engagement that this unique cohort faces over and above other populations with cancer [26-31]. As almost all individuals recruited in our study reported ethnicity, individuals from culturally and linguistically diverse backgrounds may require alternate support geared toward their needs in the future.

Strengths and Limitations

Our study had several strengths, including its prospective design with limited missing data and the inclusion of a mixed methods analysis derived from questionnaires and thematic analysis of semistructured interviews highlighting key issues for survivors after diagnosis. Unfortunately, owing to poor accrual and anticipated impacts of the COVID-19 pandemic on hospital resources and recruiting and coordinating centers, the study was closed early, and consequently, the primary end point was underpowered, and we were unable to draw firm conclusions about the differential impact of Nuts & Bolts on distress after 1 week. The instruments that have been validated in multiple clinical settings may also have been too crude to adequately evaluate changes over a short period, which may have also limited the interpretation [57].

In addition, our primary end point may have been inadvertently hampered by the study design. When designing the study, we felt that withholding access to a potentially valuable clinical resource from patients in the *delayed* group for more than 1 week was unethical. Although the baseline characteristics were balanced across both groups, our results showed that distress was highest in participants who were enrolled within 14 days of orchidectomy, and the baseline level of distress was the only covariate associated with a significant decline in DT score after 1 week of observation. Therefore, a 1-week delay in the introduction of Nuts & Bolts from the time of study consent was unlikely to have a significant impact on distress. Instead, prospectively enrolling participants before orchidectomy to ensure that questionnaires were completed at uniform periods postoperatively may have overcome this; however, this approach risked missing potential participants owing to the rapidity of diagnostic workup and delays in referral for the trial. Despite this limitation, the thematic analysis of semistructured interviews and observation over time of individuals' distress following a recent testicular diagnosis adds valuable data to the literature and remains a significant strength.

Conclusions

High levels of distress are observed following a diagnosis of testicular cancer; however, this decreases over time. Nuts & Bolts is an acceptable and feasible tool to help address distress in individuals recently diagnosed with testicular cancer, empowering them to seek information relating to their diagnosis and potentially improve preparedness for treatment using a model appropriate for its target population. The optimal timing of introduction remains unclear; however, early access to appropriate support appears to be key to maximizing benefit and ameliorating the whirlwind associated with diagnosis and treatment. On the basis of these outcomes, the intervention was rolled out in a broader community of individuals diagnosed with testicular cancer.

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Conflicts of Interest

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Multimedia Appendix 1
Baseline characteristics (N=39).
[DOCX File , 40 KB - cancer_v8i4e39725_app1.docx]

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Abbreviations

DT: Distress Thermometer
HADS-A: Hospital Anxiety and Depression Scale–Anxiety
HADS-D: Hospital Anxiety and Depression Scale-Depression
NCCN: National Comprehensive Cancer Network
OR: odds ratio
REDCap: Research Electronic Data Capture

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Original Paper

Identification and Potential Use of Clusters of Patients With Colorectal Cancer and Patients With Prostate Cancer in Clinical Practice: Explorative Mixed Methods Study

Maik J M Beuken[1], MEd; Iris M Kanera[2], PhD; Nicole Paulina Maria Ezendam[3,4], PhD; Susy Braun[2], PhD; Martijn Zoet[1], PhD

[1]Faculty of Financial Management, Research Centre for Future Proof Financials, Zuyd University of Applied Sciences, Sittard, Netherlands
[2]Faculty of Health, School of Physiotherapy, Zuyd University of Applied Sciences, Heerlen, Netherlands
[3]Department of Research, Netherlands Comprehensive Cancer Organization, Utrecht, Netherlands
[4]Center of Research on Psychology in Somatic Diseases, Department of Medical and Clinical Psychology, Tilburg University, Tilburg, Netherlands

Corresponding Author:
Maik J M Beuken, MEd
Faculty of Financial Management
Research Centre for Future Proof Financials
Zuyd University of Applied Sciences
Ligne 1
Sittard, 6231 MT
Netherlands
Phone: 31 682243809
Email: maik.beuken@zuyd.nl

Abstract

Background: A steady increase in colorectal and prostate cancer survivors and patients with these cancers is expected in the upcoming years. As a result of primary cancer treatments, patients have numerous additional complaints, increasing the need for cancer aftercare. However, referrals to appropriate cancer aftercare remain inadequate, despite a wide range of aftercare options. Caregivers and patients often do not know which aftercare is the most appropriate for the individual patient. Since characteristics and complaints of patients within a diagnosis group may differ, predefined patient clusters could provide substantive and efficient support for professionals in the conversation about aftercare. By using advanced data analysis methods, clusters of patients who are different from one another within a diagnosis group can be identified.

Objective: This study had a 2-fold objective: (1) to identify, visualize, and describe potential patient clusters within the colorectal and prostate cancer population and (2) to explore the potential usability of these clusters in clinical practice.

Methods: First, we used cross-sectional data from patients with colorectal cancer and patients with prostate cancer provided by the population-based PROFILES (Patient-Reported Outcomes Following Initial Treatment and Long-Term Evaluation of Survivorship) registry, which were originally collected between 2008 and 2012. To identify and visualize different clusters among the 2 patient populations, we conducted cluster analyses by applying the K-means algorithm and multiple-factor analyses. Second, in a qualitative study, we presented the patient clusters to patients with prostate, patients with colorectal cancer, and oncology professionals. To assess the usability of these clusters, we held expert panel group interviews. The interviews were video recorded and transcribed. Three researchers independently performed content-directed data analyses to understand and describe the qualitative data. Quotes illustrate the most important results.

Results: We identified 3 patient clusters among colorectal cancer cases (n=3989) and 5 patient clusters among prostate cancer cases (n=696), which were described in tabular form. Patient experts (6/8, 75%) and professional experts (17/20, 85%) recognized the patient clustering based on distinguishing variables. However, the tabular form was evaluated as less applicable in clinical practice. Instead, the experts suggested the development of a conversation tool (eg, decision tree) to guide professionals through the hierarchy of variables. In addition, participants suggested that information about possible aftercare initiatives should be offered and integrated. This would also ensure a good overview and seemed to be a precondition for finding suitable aftercare.

Conclusions: This study demonstrates that a fully data-driven approach can be used to identify distinguishable and recognizable (ie, in routine care) patient clusters in large data sets within cancer populations. Patient clusters can be a source of support for health professionals in the aftercare conversation. These clusters, when integrated into a smart digital conversation and referral tool, might be an opportunity to improve referral to cancer aftercare.

Trial Registration: Netherlands Trial Register NL9226; https://trialsearch.who.int/Trial2.aspx?TrialID=NL9226

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KEYWORDS

colorectal cancer; prostate cancer; referral to aftercare; patient clusters; cluster analysis; K-means cluster algorithm; multiple-factor analysis; expert panel group interviews; interview; cancer; patient; usability; clinical; colorectal; recovery

Introduction

Cancer represents one of the major global health care problems. In 2020, the incidence of all forms of cancer was higher than 18 million cases worldwide. Colorectal and prostate cancer are 2 of the top 4 most diagnosed cancers [1]. In 2020, approximately 11,500 new cases of colorectal cancer and over 12,000 new cases of prostate cancer were reported in the Netherlands alone [2]. Within the next 2 decades, these annual numbers in the Netherlands are expected to increase by 35% for colorectal cancer cases and 25% for prostate cancer cases. Fortunately, due to improved diagnostics and treatments, the 10-year survival rate of prostate cancer has risen to above 70% and that of colorectal cancer to almost 60% [2].

Cancer survivors are at a higher risk of developing new forms of cancer and comorbidities, as well as long-term physical, lifestyle, and psychosocial problems and difficulties with work. Consequently, an increasing number of survivors require information and support [3,4]. Earlier research has indicated that adequate cancer aftercare can support survivors to increase and maintain health, well-being, and quality of life [5-7].

Currently, cancer care in Dutch hospitals focuses on treatment by medical specialists, who do not always refer to additional (after)care interventions that match patients' wishes and needs [8]. Especially after intensive treatments, some patients do not know what to expect regarding their further recovery and how to resume a normal life. The general practitioner (GP) or specialist nurse in general practice could be in a position to monitor recovery and initiate a referral to appropriate aftercare tailored to survivors' needs. However, due to the lack of time, resources, and knowledge, family physicians also experience barriers to providing cancer aftercare. Moreover, patients may not perceive GPs and nurses as experts in cancer aftercare [9].

The European Academy of Cancer Sciences and other European organizations and cancer centers have emphasized the urgency of tailored aftercare in their published research agenda to reduce the major cancer burden and improve health-related quality of life by promoting cost-effective and evidence-based best practices in cancer prevention, treatment, care, and aftercare [10]. One of their recommendations for psychosocial oncology, rehabilitation, and survivorship research is to develop tools to enhance communication with patients and shared decision-making, such as the development and testing of decision aids for selecting aftercare. These are also key points in the recently published Dutch National Cancer and Life Action Plan [8].

In this paper, we explore the potential benefits of and barriers to patient clusters within the referral process. Referral to an aftercare option might be more appropriate and faster if distinguishing characteristics are considered. Clustering patient groups with similar characteristics may provide substantive and efficient support for professionals in the conversation about aftercare. Recently, researchers have explored new approaches to data analysis to identify patient clusters. Nicolet et al [11] used a clustering technique to highlight clinically relevant clusters and eventually identify profiles that use more health care and incur higher costs. The K-means algorithm is more commonly used to classify patients into clusters. Elbattah et al [12] used K-means to cluster elderly patients into groups. The K-means clustering technique is also frequently used in studies that focus on clustering patients with cancer. Florenca et al [13] recently used K-means to identify similar profiles of patients with colorectal cancer based on risk factors, and Kim et al [14] applied K-means to classify patients with breast cancer based on their level of adherence. In this study, we consider clustering variables related to long-term problems after cancer, including sociodemographic, health-related, psychosocial, lifestyle factors, and quality of life variables. The use of K-means to cluster patients into profiles based on a wide range of variables and the use of the multiple factor analysis (MFA) to interpret these profiles is a different approach from the aforementioned studies. To verify this fully data-driven approach in daily practice, we combined it with a qualitative evaluation among professionals and former and current patients with cancer.

This study had a 2-fold aim: (1) to identify, visualize, and describe potential patient clusters within colorectal and prostate cancer populations and (2) to explore the potential usability of these patient clusters in clinical practice.

Methods

Overview

This section is organized as follows. In part 1, we address the first aim of identifying, visualizing, and describing patient clusters. The clinical usability of the identified patient clusters is reported in part 2.

Ethics Approval

This study was carried out in accordance with the ethics committee Medisch Ethische ToetsingsCommissie Zuyderland at Zuyd Hogeschool (METCZ20200203). Ethical approval was obtained for the study samples from the certified medical ethics committee Maxima Medisch Centrum (0822). Informed consent was obtained from all individual participants included in the study, including consent for secondary data analysis. Data from the PROFILES (Patient-Reported Outcomes Following Initial Treatment and Long-term Evaluation of Survivorship) registry were used. These data are freely available for noncommercial scientific research, subject to the study question, privacy and confidentiality restrictions, and registration [15]. Data were deidentified and pseudonymized. Patients did not receive any financial compensation for study participation.

Part 1: Patient Clusters

Design

As previously mentioned, to identify patient clusters, we used cross-sectional data from the population-based PROFILES registry [16], which collects patient-reported outcomes in a large cohort to study the psychosocial and physical impacts of cancer and its treatment.

Study Population

From the PROFILES registry, we included 2 patient samples with colorectal cancer collected between 2008 and 2011 and 1 patient sample with prostate cancer collected between 2011 and 2012. A detailed description of the data collection method within the PROFILES registry has been reported elsewhere [16]. A population-based sampling frame was used, where patients were selected from the Netherlands Cancer Registry from a selected set of participating hospitals. In this study, we used the entire data set without sampling from it. Patients needed to be able to complete a Dutch questionnaire and be 18 years or older. Patients were invited by their treating oncology surgeon (colorectal cancer) or urologist (prostate cancer). There were no other inclusion or exclusion criteria to assure the population-based sampling.

Measurements

For the cluster analysis, we used all available variables from the PROFILES data set provided, including the following self-reported measures: sociodemographic information (regarding marital status, educational level, and employment), socioeconomic status [17], and emotional and cognitive functioning. We included all available patient-related outcome measurements in Multimedia Appendix 1 [16,18-26].

Statistical Analyses

Handling Data for Data Analysis

We conducted the data analyses on colorectal and prostate cancer samples separately. We merged both colorectal cancer samples and assessed all data for aberrant measurement data, missing data, and outliers.

Missing data were imputed by using the K-nearest neighbor (KNN) method (VIM package) [27]. All variables were used to impute missing values. In the KNN function, the distance computation was based on an extension of the Gower distance [28]. For continuous variables, we used the median to give a central measurement for the 5 nearest neighbors that were used to impute a missing value. For categorical variables, we used the mode to impute [27]. We used RStudio (version 4.0.3; R Foundation for Statistical Computing) as a programming language.

Further handling of missing data, including data imputation and the handling of outliers, as well as other used software packages, are described in Multimedia Appendix 2 [27,29-41].

Identification of Patient Clusters

To assign patients to clusters, we performed a K-means cluster algorithm. By using the K-means algorithm after data cleaning, we clustered individual cases into a k number of clusters using the squared Euclidean distance variable [42]. We minimized the distance between so-called centroids (1 centroid for each cluster) and the objects of each cluster. To evaluate the result of the K-means algorithm (number of clusters), we used the silhouette coefficient (SC), which measures the cohesion and segregation of each data point [43]. The closer the SC value gets to 1, the stronger the cohesion of data points within 1 cluster and the segregation between data points within 1 cluster relative to data points in another cluster. We determined the optimal number of patient clusters by the highest SC value for each diagnosis group.

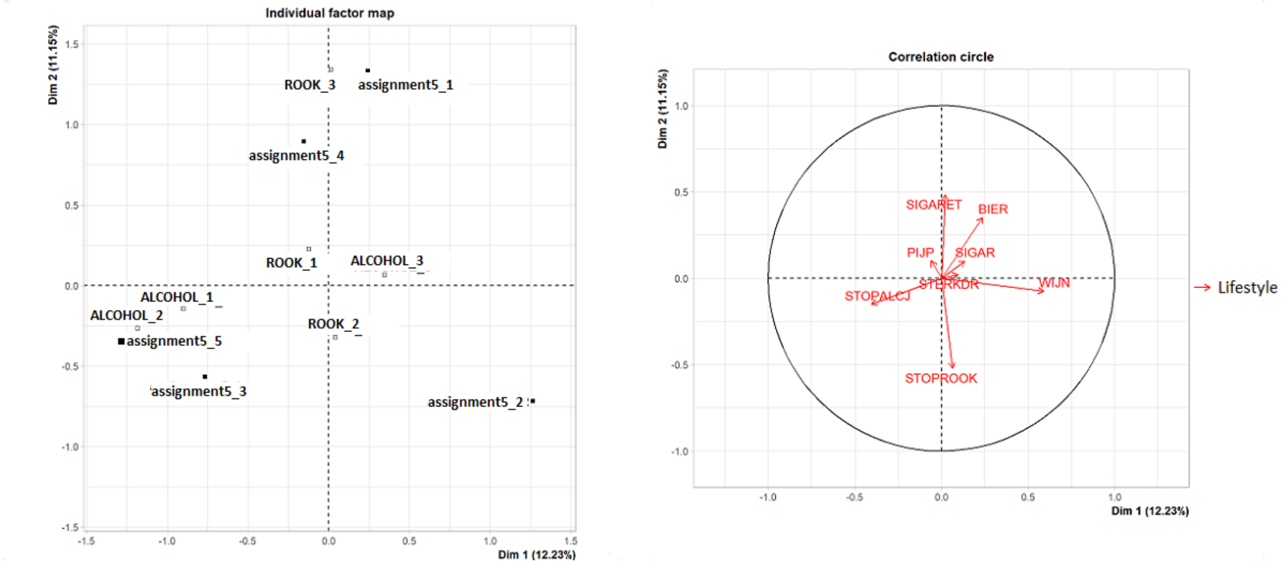
Visualization and Description of Patient Clusters

To enable visualization and to describe the characteristics of the identified patient clusters, we employed MFA [44]. Since the patient clusters consisted of quantitative and qualitative variables, we applied a factorial method to visualize the mutual relationships of the variables. We mapped quantitative variables by using the correlation circle based on principal component analysis. Qualitative variables, as well as cluster numbers, were visualized by using the individual factor map [45]. We grouped positively correlated variables in a correlation circle, which was visualized by arrows that lie together in the same direction in the correlation circle. Negatively correlated variables were presented opposite of each other. The further away the variables lay from the center of the correlation circle, visualized by longer arrows, the better these variables were represented within the concept. A particular topic is assessed by a few questions, which together illuminate a concept. For example, perception is a concept that is elucidated by 8 items of the Brief Illness Perception Questionnaire. For each concept, we performed this MFA analysis based on the prostate and colorectal cancer data (Figure 1, Multimedia Appendix 3).

To standardize, we used a cutoff point of 0.5 for the quality of the projection of a variable on 1 of the dimensions in the correlation circle. The same threshold was applied for the individual factor map when describing the characteristics of the clusters. We accounted for the variables drawn above these thresholds.

The variables that clustered together based on these procedures were described in different patient clusters for colorectal cancer and prostate cancer separately.

Figure 1. Multiple factor analysis plot. WIJN: Glasses of wine consumed per week; BIER: glasses of beer consumed per week; STERKDR: glasses of liquor consumed per week; SIGARET: number of cigarettes smoked per day; SIGAR: number of cigars smoked per day; PIJP: number of packages of pipe tobacco smoked per week; STOPALCJ: time since stopped drinking in years; STOPROOK: time since stopped smoking in years; ROOK_1: no, I do not smoke; ROOK_2: no, I do not smoke, but I used to; ROOK_3: yes, I do smoke; ALCOHOL_1: no, I do not drink alcohol; ALCOHOL_2: no, I do not drink alcohol, but I used to; ALCOHOL_3: yes, I do drink alcohol.



Part 2: Usability Study

Design

To assess the clinical usability of the identified patient clusters, we applied a qualitative approach by conducting expert panel group interviews. Due to the COVID-19 pandemic, the group interviews were held online.

Study population

Both patients with cancer and professionals formed the panel of experts. Eligible health care professionals were professionals from various care disciplines with expertise in the field of oncology, including prostate or colorectal cancer. Eligible participants for the patient-expert panel were adult former and current patients with colorectal or prostate cancer who completed primary cancer treatment and may still receive adjuvant therapy. Other inclusion criteria included having basic computer skills, internet access, and a digital device with a camera and speakers.

Procedure and Data Collection

Through an information letter, we recruited potential participating health care professionals from 2 regional hospitals: a GP society and an oncology physiotherapy network. These professionals approached other eligible health professionals and patients (snowball sampling). The researchers assessed the eligibility criteria, and detailed information was offered by phone. All participants provided informed consent before enrollment in the study.

We interviewed the professional expert panel, the expert panel of patients with colorectal cancer, and the expert panel of patients with prostate cancer separately. We held semistructured group interviews based on a topic list (Multimedia Appendix 4) with a maximum duration of 120 minutes to gain insight into the potential clinical usability of the identified patient clusters, as assessed by the health care professionals and patients with cancer. The group interviews followed a fixed structure. After a short introduction of the project, in which the purpose of the meeting was explained again, the patient clusters were presented to the panel, and the following topics were discussed: (1) the number of the patient clusters and recognizability of the content; (2) the forms of cancer aftercare that best fit each cluster; (3) the usefulness, meaningfulness, and opportunities of patient clusters concerning tailor-made aftercare referral; and (4) the preconditions for implementing patient clusters in clinical practice. Prior to the group interviews, the participants received information about the patient clusters and regional cancer aftercare possibilities. Additionally, they received a brief online questionnaire to gather information about personal characteristics. The participating health care professionals also received some preparation questions.

Data Analysis Expert Panels

We analyzed personal characteristics descriptively. Video recordings and additional notes from the online group interviews were analyzed based on an abridged transcript. We employed content-directed analysis [46] to describe and understand the collected qualitative data systematically [47]. We coded and categorized the data based on the structure of the topics and questions in line with the topic list. Three researchers (Pieter Eijgenraam, Alina Kramme, and author IMK) independently performed the coding and categorizing. To increase trustworthiness, 4 researchers (Willem Emons, Roy Jorissen, Pieter Eijgenraam, and author IMK) reviewed the codes and categories and reached an agreement on the results [48]. Subsequently, the participants received a summary of the key points for verification of the content (member check).

Results

Part 1: Patient Clusters

In total, 3989 colorectal cancer cases (1371 participants in the 2009 colorectal wave and 2618 participants in the 2010 colorectal wave) and 696 prostate cancer cases were included in the cluster analysis (Table 1). Participants varied in age between 29 and 85 years. A description of all characteristics is provided in Multimedia Appendix 5 [19,21,22,25,49].

Table 1. Basic characteristics of participants with colorectal cancer (n=3989) and participants with prostate cancer (n=696).

Variable	Colorectal cancer	Prostate cancer
Gender, n (%)		
Male	2220 (55.6)	696 (100)
Female	1769 (44.4)	0 (0)
Age (years), mean (SD)		
At the time of diagnosis	64.7 (9.8)	67.4 (7.3)
At the time of questionnaire	69 (9.6)	70.8 (7.2)
Marital status, n (%)		
Married	3011 (75.5)	586 (84.2)
Divorced	204 (5.1)	27 (3.9)
Widowed	640 (16)	65 (9.3)
Never married	134 (3.4)	18 (2.6)
Educational level, n (%)		
Lower education	777 (19.5)	117 (16.8)
Secondary education	1247 (31.3)	162 (23.3)
Secondary vocational education	1179 (29.6)	249 (35.8)
University	786 (9.7)	168 (24.1)
Employment status, n (%)		
Yes	604 (15.1)	89 (12.8)
No	3385 (84.9)	607 (87.2)
Socioeconomic status, n (%)		
Low	833 (20.9)	118 (17.0)
Medium	1631 (40.9)	270 (38.8)
High	1454 (36.4)	292 (41.9)
Living in a nursing home	71 (1.8)	16 (2.3)
BMI, mean (SD)	26.7 (4.2)	26.5 (3.3)
Assigned numbering cluster, n (%)		
Cluster 1	1788 (44.8)	197 (28.3)
Cluster 2	1144 (28.7)	85 (12.2)
Cluster 3	1057 (26.5)	144 (20.7)
Cluster 4	N/A[a]	159 (22.8)
Cluster 5	N/A	111 (16)

[a] N/A: not applicable.

Identification of Patient Clusters

We calculated the highest SC value within the prostate cancer sample for 5 patient clusters and the highest SC value within the colorectal cancer sample for 3 patient clusters (Figure 2).

The main distinguishing characteristics of the patient clusters are described in Table 2.

Figure 2. Silhouette coefficients per diagnosis group and number of clusters.

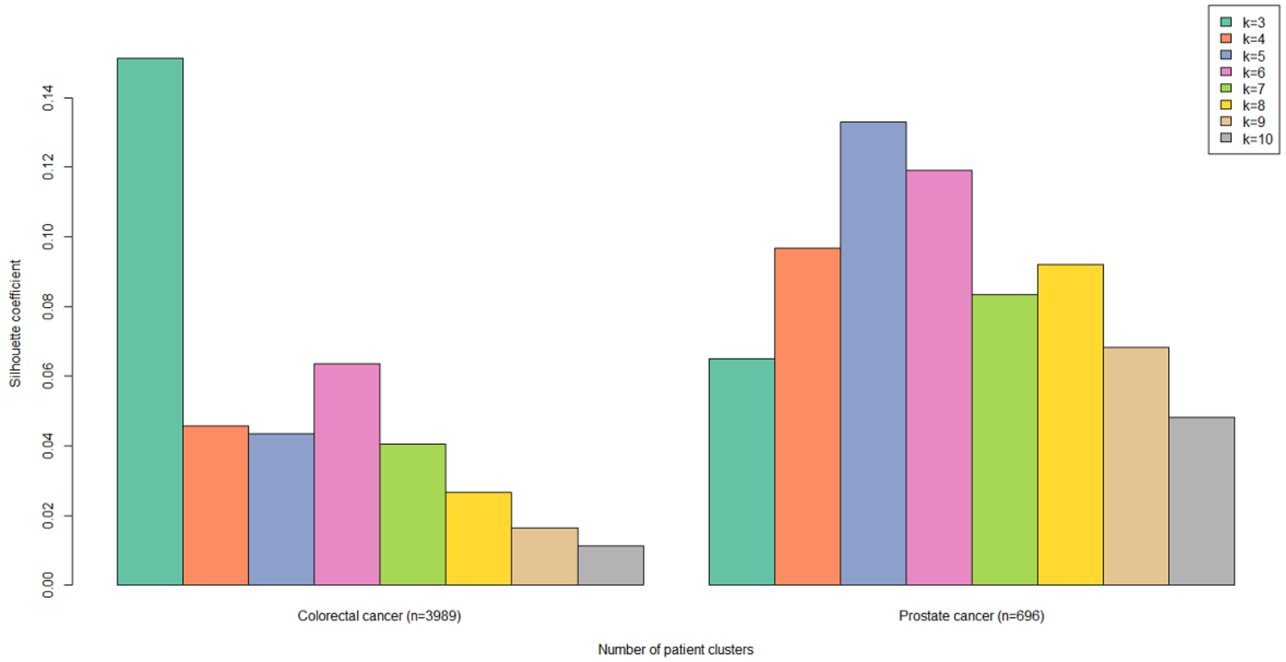


Table 2. Main characteristics of the patient clusters for colorectal cancer (n=3989) and prostate cancer (n=696).

Patient cluster	Colorectal cancer	Prostate cancer
Patient cluster 1	• Have a higher socioeconomic status • Have a lower BMI • More patients were diagnosed some time ago • Drink alcohol more often, mainly wine • More patients who exercise or do sports • Lower stage of disease • Do not frequently have an appointment with the specialist and have no need for one • Have the fewest comorbidities • Sense a small effect on their lives because of their illness • More likely to think that their illness will not last long, have a sense of control, and are confident that the treatment will work • Have a high understanding of their disease • Recognize fewer symptoms and worry less about their illness • Experience a small emotional effect • Score high on the functioning scales, including the highest on emotional functioning and quality of life.	• Younger • Relatively higher education but not the highest education • More often have a paid job • More smokers • Tend to drink alcohol more often • Do not feel well informed, are less satisfied with the information they receive, and find that information less helpful • Use the internet more often to find information about their disease.
Patient cluster 2	• Lower socioeconomic status • Have a higher BMI • More often elderly patients who are widows or widowers • More often have lower education • More patients who have been diagnosed with their disease a shorter time ago • More often deceased • Tend to represent fewer alcohol users and smokers • Least active in terms of exercise • Have most often a higher stage of the disease • Visit the general practitioner and cancer specialist more often • Discussed coming back more often • Have a higher number of comorbidities • Problems with personality and fatigue on a physical and mental level and more characterized by anxiety and depression • More likely to report a high degree of impact on their lives; think the illness will last longer • Indicate a lower level of control • Experience many symptoms • Have a high degree of concern about their illness • Feel an extreme effect on an emotional level • Have reasonable confidence in the success of their treatment • Score lower on the functioning scales • Score high on fatigue, breath shortness, insomnia, pain, loss of appetite, nausea, and vomiting	• Younger • More often have higher education • Higher socioeconomic status • Lower stage of disease • Tend to drink alcohol more often, even more than cluster 1 • More liver problems • Understand their illness better and have more confidence in their treatment • Higher scores on physical, emotional, and social scales and lower scores on fatigue and pain • Feel better informed and have less need for more information about their disease • Use the internet more often to find information about their disease.
Patient cluster 3	• Younger • More often divorced • Higher representation of middle socioeconomic status and people who live in an institution • More often patients who have a job • Drink alcohol more often • More patients who exercise or do sports • Have a higher stage of disease compared to cluster 1 • More often have an appointment with the specialist regarding cancer and have also discussed returning to the specialist more often compared to cluster 1 • Have fewer comorbidities, but depression is more common • Relatively fewer problems with personality, fatigue, and depression compared to cluster 2 • Relatively more fears and more negative affectation compared to cluster 1 • Have a more neutral perception of their disease • Not very distinctive on quality of life	• Lower education • Lower socioeconomic status • Do household tasks more often • More often stopped drinking alcohol • More comorbidities • Have a more negative self-image, feel a greater impact on their lives and emotions, and are more concerned • Lower score on the physical, emotional, and social scales and higher score on fatigue and pain • Do not feel well informed, are less satisfied with the information they receive, and find that information less helpful

Patient cluster	Colorectal cancer	Prostate cancer
Patient cluster 4	- N/A[a]	- Higher education but not the highest - More often have an advanced stage of disease - More often deceased - More often disabled due to their disease - More often stopped drinking alcohol - More comorbidities - Have a more negative self-image, illness has a greater impact on their lives and emotions, and are more concerned - Lower score on the physical, emotional, and social scales and higher score on fatigue and pain.
Patient cluster 5	- N/A	- Lower education - Lower socio-economic status - More often stay in a nursing home - More often without a partner - More often stopped drinking alcohol - Understand their illness better and have more confidence in their treatment - Use the internet less often to find information about their disease.

[a] N/A: not applicable.

Visualization and Description of Patient Clusters

We described participant characteristics of 5 clusters of patients with prostate cancer and the 3 colorectal cancer clusters in Table 2 based on the MFA analysis. Not all the same concepts were measured in the different data sets available (ie, colorectal data and prostate data), as displayed in Table 1. As a result, certain concepts could not be reflected in the clusters.

Part 2: Usability Study

Expert Panel Participants

A total of 23 people participated in this part of the study (Table 3). Of the 8 patient experts approached, 6 (75%) filled in the brief online questionnaire, with 3 (50%) for prostate cancer and 3 (50%) for colorectal cancer. Moreover, 5 (83.3%) took part in the group interviews. Reasons for not participating included not wanting to participate digitally (1/6, 16.7%) and an emergency medical appointment (1/6, 16.7%). One (16.7%) person did not state a reason. Of the 20 professional experts approached, 17 (85%) participated. Reasons for nonparticipation were maternity leave (1/20, 5%), no time (1/20, 5%), and unknown (no response, 1/20, 5%).

Table 3. Characteristics of expert panel participants (N=23).

Characteristic	Patient experts (n=6)	Professional experts (n=17)
Female gender, n (%)	1 (16.7)	13 (76.5)
Age, median (min-max)	60 (48-79)	48 (33-64)
Prostate cancer diagnosis, n (%)	3 (50)	N/A[a]
Colorectal cancer diagnosis, n (%)	3 (50)	N/A
Time since diagnosis, median (min-max)	2.8 (1-8)	N/A
Cancer detected during control visit, n (%)	2 (33.3)	N/A
Nurse specialist hospital, n (%)	N/A	2 (11.8)
Nurse specialist general practice, n (%)	N/A	2 (11.8)
General practitioner, n (%)	N/A	2 (11.8)
Internist oncologist, n (%)	N/A	2 (11.8)
Psychologist, n (%)	N/A	2 (11.8)
Oncology physiotherapist, n (%)	N/A	2 (11.8)
Oncology surgeon, n (%)	N/A	1 (5.9)
Rehabilitation physician, n (%)	N/A	1 (5.9)
Complementary health therapist/lifestyle coach, n (%)	N/A	1 (5.9)
Acupuncturist, herbalist, n (%)	N/A	1 (5.9)
Staff advisor oncology, n (%)	N/A	1 (5.9)
Years of work experience (oncology), median (min-max)	N/A	15 (0.5-40)
Cancer aftercare provider, n (%)	N/A	14 (82.4)

[a] N/A: not applicable.

Expert Panel Interviews

In total, 7 group interviews took place. We conducted 1 group interview with patients with prostate cancer (3/5, 60%) and 1 with patients with colorectal cancer (2/5, 40%). Five professional expert panel group interviews took place in varying compositions regarding the profession and with a group size of 3 to 5 participants. One individual interview was conducted.

Clinical Usability of the Patient Clusters

Most of the participants recognized the clustering as distinctive "profiles," and all variables described were assessed as important factors regarding tailored referral to aftercare. They indicated that the variables follow a certain hierarchy that should be accounted for when considering referral to appropriate aftercare. The expert panel stated that describing the clusters in tabular form with many variables outlined in the text was too difficult to oversee. Moreover, participants were concerned that patients would be placed into fixed categories by using this tabular format. Furthermore, a conversation with patients would be necessary to clarify their support needs. The clusters could also serve as a valuable starting point and guidance for this conversation because they provide meaningful content and structure.

> *Care providers often don't look beyond their specialism. A broad view is missing. Other fields should also be considered in the conversation about aftercare.* [Patient with prostate cancer]

Therefore, participants suggested the development of a conversation tool that could provide insight into the content and structure of these clusters. To guide professionals through the hierarchy of variables, a decision tree could be integrated into this tool. In addition, participants suggested that access to information about available aftercare initiatives should be made available. This would also ensure a good overview and seemed to be a precondition for finding suitable aftercare.

> *As a patient, you don't know what the disease entails and what you can expect, so you don't know what aftercare you need. You need to be well informed; only then do you know what you need.* [Patient with colorectal cancer]

> *You are very much searching and constantly retelling your whole story. It would be nice to have a choice of presorted relevant options of aftercare. The disease already costs you a lot of energy. Searching also takes a lot of energy!* [Patient with colorectal cancer]

The tool content should be comprehensive, clearly structured, and easy to use. The patient, not the professional or the application, should always make the final decision on aftercare. The professional experts also wished to link existing data from the electronic patient files to the decision tool.

> *Using a decision aid based on the patient clusters would be a good tool for care providers to gain a better understanding and to get an overview when it*

> *comes to referral to the right aftercare.* [Patient with prostate cancer]
>
> *This kind of tool could take the administrative burden off the nurses' shoulders.* [Oncology specialist]

Discussion

Principal Findings

This study aimed to (1) identify, visualize, and describe patient clusters within colorectal and prostate cancer populations and (2) explore the potential usability of the patient clusters in clinical practice to improve referral to cancer aftercare.

We identified, described, and presented 5 patient clusters among a prostate cancer population and 3 patient clusters among a colorectal cancer population to an expert panel for evaluation.

Most notably, by performing the cross-sectional data analysis, we included all available variables in the data sets without any human preselection, and the number of patient clusters was solely determined by the SC. Our approach to cluster the data of individuals based on their characteristics is consistent with clinical practice, wherein an oncology professional encounters a patient with individual characteristics. In our results, easily detectable characteristics such as age, employment status, and socioeconomic status clustered with less easily recognizable characteristics, such as illness perception. This interrelationship between different characteristics can support health care providers in the conversation with patients for referral to appropriate follow-up care.

Contrary to our method, de Rooij et al [50] explored the relation of symptoms among a selection of PROFILES registry variables in their network analysis, such as the European Organization for Research Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) symptom scales and emotional and cognitive functioning scales). Noticeably, however, our results for colorectal cancer data are in line with the findings of de Rooij et al [50] regarding the corresponding variables (eg, fatigue, pain, dyspnea, sleeping problems, appetite loss, and nausea and vomiting), which might strengthen our findings.

Professional and patient experts considered the insight that different subgroups can be distinguished within 1 diagnosis group and can be valuable for referring patients to the appropriate aftercare. Participants largely recognized the classification into the clusters. However, the expert panel deemed the way of presenting the clusters in textual tabular form to be unpractical for routine care. To have a meaningful conversation about referral to appropriate aftercare, professionals and patients would like to have guidance to help them discuss relevant topics, which then can lead to the most suitable choices for cancer aftercare. Therefore, a complete overview of current aftercare initiatives is also needed. The experts suggested developing a digital decision and referral aid based on the patient clusters to detect a patient's support needs and risks and link them to the available aftercare options.

Overall, this study succeeded in identifying patient clusters that are also seen in routine care and recognized by health care professionals. Our results show that this holistic, explorative machine-learning approach can provide a foundation to identify clinically meaningful patient clusters. Consequently, our results can serve as a first step to improve referrals to cancer aftercare in daily practice, which is in line with the goals of the Taskforce Cancer Survivorship [8,10].

Limitations

Like all research, this study has its limitations. Participant data were not highly distinguishable for all variables because not all answer options were distinguishable (ie, the distinguishing variables had a lot of overlap and were therefore not good indicators for distinguishing between clusters). This problem could technically be solved by using a larger number of patient clusters. However, this would be less appropriate for clinical use because a larger number of clusters makes it difficult for professionals to get an overview of the clusters.

The data from the PROFILES registry were generated about 10 years ago, while we retrieved the data from the qualitative study in 2020. However, we do not expect a negative impact from this time difference, as we assume that patients with cancer are not significantly different now than they were 10 years ago.

Finally, we interviewed mainly professional and patient experts, but patient experts' opinions were relatively underrepresented. Consequently, we may not have achieved data saturation.

Future Directions

Since the identification and use of patient clusters among colorectal and prostate cancer populations are still in their infancy, future research should further focus on identifying distinguishing key variables to optimize the number and content of patient clusters. Building upon a data-driven approach, an additional expert-driven approach could provide a qualitative improvement in the selection of variables. Both patient and professional experts should be equally involved in this process. Researchers should explore in what form a digital referral aid could be of added value in clinical practice. Our results might provide valuable insights as a basis for the development of smart referral technology.

Furthermore, identifying longitudinal patient patterns, based on data gathered over time, might be the next step to generate insights into the course of a patient's situation and deviations from "expected recovery." The process of identifying patient patterns could be automated by creating a data tunnel linked to electronic patient records and by automatically generating trend analyses that could provide insights into the development of an individual's disease and recovery over time.

Conclusions

This study demonstrates that a fully data-driven approach can be used to identify distinguishable and recognizable patient clusters in large data sets within colorectal and prostate cancer populations. Using patient clusters based on their characteristics can be supportive for health professionals in the aftercare conversation. Patient clusters integrated into a smart digital conversation and referral tool might be an opportunity to improve the referral to cancer aftercare.

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Data Availability

Data from the PROFILES (Patient-Reported Outcomes Following Initial Treatment and Long-term Evaluation of Survivorship) registry are freely available for noncommercial scientific research, subject to the study question, privacy and confidentiality restrictions, and registration [15].

Authors' Contributions

MJMB, IMK, and SB designed the study. MJMB conducted the quantitative substudy. IMK and SB conducted the qualitative substudy. MJMB wrote the script for the data cleaning, the K-means algorithm, and the multiple factor analysis. IMK and MJMB performed the analyses and denoted the clusters in conversation with MZ. IMK and MJMB drafted the manuscript, and SB and MZ reviewed all versions of the manuscript. All authors read and contributed to editing the manuscript for final submission.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Variables included in the cluster analysis available from the PROFILES (Patient-Reported Outcomes Following Initial Treatment and Long-term Evaluation of Survivorship) registry.
[DOCX File , 19 KB - cancer_v8i4e42908_app1.docx]

Multimedia Appendix 2
Handling missing data including imputation and handling outliers and used software packages.
[DOCX File , 22 KB - cancer_v8i4e42908_app2.docx]

Multimedia Appendix 3
The interpretation of the multiple factor analysis.
[DOCX File , 19 KB - cancer_v8i4e42908_app3.docx]

Multimedia Appendix 4
Topic list for the expert panel interview.
[DOCX File , 20 KB - cancer_v8i4e42908_app4.docx]

Multimedia Appendix 5
Remaining characteristics of participants with colorectal cancer (n=3989) and participants with prostate cancer (n=696).
[DOCX File , 36 KB - cancer_v8i4e42908_app5.docx]

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Abbreviations

EORTC QLQ-C30: European Organization for Research Treatment of Cancer Quality of Life Questionnaire
GP: general practitioner
KNN: K-nearest neighbor
MFA: multiple factor analysis
PROFILES: Patient-Reported Outcomes Following Initial Treatment and Long-term Evaluation of Survivorship
SC: silhouette coefficient

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Original Paper

A Web-Based Prostate Cancer–Specific Holistic Needs Assessment (CHAT-P): Multimethod Study From Concept to Clinical Practice

Veronica Nanton[1], BA, PGDip, MSc, PhD; Rebecca Appleton[2], BA, PhD; Nisar Ahmed[3], BSc, MMedSci, PhD; Joelle Loew[4], BA, MSc, PhD; Julia Roscoe[1], MSc; Radha Muthuswamy[5], BSc, MA, HSM, CIPP/E, CIPM, CDPSE; Prashant Patel[6], MBBS, MS, PhD; Jeremy Dale[1], BA, MBBS, MA, PhD; Sam H Ahmedzai[3], BMedSci, MBChB

[1]Warwick Medical School, University of Warwick, Coventry, United Kingdom
[2]Mental Health Policy Research Unit, Division of Psychiatry, University College London, London, United Kingdom
[3]Medical School, University of Sheffield, Sheffield, United Kingdom
[4]Lucerne School of Business, Lucerne, Switzerland
[5]Prostate Cancer UK, London, United Kingdom
[6]Institute of Cancer and Genomic Sciences, University of Birmingham, Birmingham, United Kingdom

Corresponding Author:
Veronica Nanton, BA, PGDip, MSc, PhD
Warwick Medical School
University of Warwick
Gibbet Hill Road
Coventry
United Kingdom
Phone: 44 2476 574025
Email: v.nanton@warwick.ac.uk

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Abstract

Background: Men with prostate cancer experience immediate and long-term consequences of the disease and its treatment. They require both long-term monitoring for recurrence or progression and follow-up to identify and help manage psychosocial and physical impacts. Holistic Needs Assessment aims to ensure patient-centered continuing cancer care. However, paper-based generic tools have had limited uptake within cancer services, and there is little evidence of their impact. With the expansion of remote methods of care delivery and to enhance the value of generic tools, we developed a web-based Composite Holistic Needs Assessment Adaptive Tool-Prostate (CHAT-P) specifically for prostate cancer.

Objective: This paper described the context, conceptual underpinning, and approach to design that informed the development of CHAT-P, starting from the initial concept to readiness for deployment. Through this narrative, we sought to contribute to the expanding body of knowledge regarding the coproduction process of innovative digital systems with potential for enhanced cancer care delivery.

Methods: The development of CHAT-P was guided by the principles of coproduction. Men with prostate cancer and health care professionals contributed to each stage of the process. Testing was conducted iteratively over a 5-year period. An initial rapid review of patient-reported outcome measures identified candidate items for inclusion. These items were categorized and allocated to overarching domains. After the first round of user testing, further items were added, improvements were made to the adaptive branching system, and response categories were refined. A functioning version of CHAT-P was tested with 16 patients recruited from 3 outpatient clinics, with interviewers adopting the think-aloud technique. Interview transcripts were analyzed using a framework approach. Interviews and informal discussions with health care professionals informed the development of a linked care plan and clinician-facing platform, which were incorporated into a separate feasibility study of digitally enhanced integrated cancer care.

Results: The findings from the interview study demonstrated the usability, acceptability, and potential value of CHAT-P. Men recognized the benefits of a personalized approach and the importance of a holistic understanding of their needs. Preparation for the consultation by the completion of CHAT-P was also recognized as empowering. The possible limitations identified were related to the importance of care teams responding to the issues selected in the assessment. The subsequent feasibility study highlighted the need for attention to men's psychological concerns and demonstrated the ability of CHAT-P to capture red flag symptoms requiring urgent investigation.

Conclusions: CHAT-P offers an innovative means by which men can communicate their concerns to their health care teams before a physical or remote consultation. There is now a need for a full evaluation of the implementation process and outcomes where CHAT-P is introduced into the clinical pathway. There is also scope for adapting the CHAT-P model to other cancers.

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KEYWORDS

Holistic Needs Assessment; prostate cancer; survivorship; cancer follow-up; coproduction; web-based communication; care planning

Introduction

Background

The increased incidence of many common cancers, combined with rising survival rates, is challenging the ability of health services to meet the range of patient needs both during and after treatment. Various models of care delivery have been implemented to meet these escalating demands. Cancer services are currently focused on the potential of digital technology to facilitate innovations, particularly in terms of enabling remote patient follow-up and monitoring [1]. The COVID-19 pandemic has highlighted the value of such systems and provided a stimulus for their further rapid development and implementation.

Composite Holistic Needs Assessment Adaptive Tool-Prostate (CHAT-P) is a digital technology designed to contribute to innovation in care delivery. As a web-based, adaptive, cancer-specific needs assessment, it enables men with prostate cancer to easily identify and communicate their concerns to members of their health care teams. The output of CHAT-P can be shared across settings to facilitate care coordination. In addition, triggered by the concerns identified, it provides links to sources of advice and information. The structured output of CHAT-P allows patients' priorities to drive the consultation, whether it is remote or face to face, and the tailored resources are designed to support self-management.

Aims

This paper describes the context and rationale for the design of CHAT-P, its conceptual underpinning, and the process of development, from the initial concept to readiness for deployment, across 3 stages of development. Through this narrative, we sought to contribute to the expanding body of knowledge regarding the design process of innovative digital systems with potential for enhanced cancer care delivery.

The Context: Prostate Cancer, Treatment Side Effects, and Follow-up

Prostate cancer is the most common cancer among men in the United Kingdom, affecting 1 in 8 over their lifetime (Prostate Cancer UK [PCUK]; [2]). With the 10-year survival rate at 78% [3], there are approximately 400,000 men in the United Kingdom living with or after the disease [4].

Treatments vary considerably for men within this patient population depending on factors such as disease stage, presence of comorbidities, and patient choice. Treatments may involve surgery, radiotherapy (using various delivery modes), androgen deprivation therapy (ADT), and chemotherapy for advanced disease [5]. Men identified to be at low risk with low-grade cancer may be offered active surveillance involving monitoring prostate-specific antigen (PSA) levels and regular contact with specialist clinicians. Men considered too frail for radical treatment and whose cancer does not present immediate problems may be assigned to *watchful waiting* before commencing ADT when symptoms occur.

Although survival rates are high, a diagnosis of prostate cancer has both immediate and long-term impacts on men's lives. Each treatment type is associated with changes across various aspects of quality of life [6]. For example, in many cases, radical prostatectomy leads to urinary and sexual dysfunction that may persist long term [7], while men who have undergone radiotherapy are particularly at risk of developing bowel problems, which may also be long lasting [7]. The consequences of ADT include loss of libido, weight gain, gynecomastia, and cognitive effects such as memory impairment [8]. Finally, men on active surveillance and watchful waiting may experience increased levels of distress due to the uncertainty of an untreated cancer [9].

In addition to these direct effects, men experience indirect impacts of the illness and its treatment, such as effects on relationships [10], occupations, and finances [11,12]. Hence, the prevalence of depression and anxiety across treatment types and over time is relatively high in comparison with the general population, with peaks identified at certain critical points in the care pathway [13].

Men diagnosed with prostate cancer require lifetime monitoring. Men assessed as being at low risk following curative treatment will often also need ongoing care and support as well as monitoring to detect progression or recurrence. The use of digital systems for PSA tracking is increasing within UK cancer services, and the digital reporting of standardized patient-reported outcome measures for audit purposes is being trialed in prostate and other forms of cancer [14,15]. The recent National Prostate Cancer Audit (2021) recommendations R4 and R5 highlight the need to respond to men's information needs regarding treatment and side effects and the importance of identifying and referring those who require specialist help for physical or psychological effects after treatment [16].

Conceptual Underpinning: Holistic Needs Assessment

The concept of Holistic Needs Assessment (HNA) dates back several decades [17-21]. The concept of holism itself is underpinned by humanistic philosophy assuming a unity between the physical, psychological, social, and spiritual aspects [22]. In nursing, the recognition of the importance of a holistic approach to care has been traced back to its origins in the work of Florence Nightingale [23]. Person-centered care, now a central tenet of the National Health Service (NHS), builds upon the holistic understanding of the individual, acknowledging the primacy of the patient's own values and the importance of their active participation in decision-making [24]. Although lacking an explicit theoretical underpinning, HNA is closely aligned with the patient-centered approach, recognizing the needs of the whole person.

In the United Kingdom, the assessment of holistic needs was first recognized in cancer care by the National Institute for Care and Excellence guideline of 2004 on supportive care for adults with cancer [25]. The value of HNA was again emphasized by the National Cancer Survivorship Initiative, as survival rates for several common cancers were improving and many patients were living for years with both the direct and indirect effects of the illness and its treatment. HNA typically involves a structured questionnaire that includes a range of domains, from physical symptoms and psychological issues to information needs and broader social, financial, and spiritual concerns. Its aim is to facilitate communication between the patient and the health care professional and to enable a course of action to be mutually determined and documented in a care plan [26]. One of the first HNA tools to be designed for use among cancer survivors and palliative care populations was the Sheffield Profile for Assessment and Referral for Care, which was developed by 2 of the coauthors of this study (NA and SHA) [27]. Originally paper based, a shift toward an electronic format for HNA has taken place in recent years.

The National Cancer Survivorship Initiative [28] recommended the use of HNA for patients with cancer to monitor unmet needs at key stages in the care pathway: following diagnosis, at the end of treatment, when positive or negative events occur, and at the transition to end-of-life care. However, the adoption of these principles has been slow and patchy throughout cancer services [29].

Resistance to HNA and its lack of impact may, in part, be explained by the generic format of the HNA instruments currently in use. This limits the extent to which HNA reflects concerns related to particular cancers. Moreover, the simple structure and limitations of using paper forms allow only the identification of high-level issues. A significant weakness of generic HNA in cancer is that it does not necessarily identify high-risk problems that may require urgent follow-up, many of which are specific to each cancer type. Thus, although generic HNA enables the selection of broad areas of concern, its value remains dependent on further identification of specific issues (which differ between cancer types) during the consultation before in-depth exploration.

Approach to Design: Digital Technology in Prostate Cancer Care

The potential of digital technology to transform care and outcomes for men with prostate cancer was the focus of a global program of work initiated by the international nongovernmental organization the Movember Foundation in 2014 under the umbrella title of TrueNth [30]. In the United Kingdom, a range of projects were planned, coordinated, and overseen by the nongovernmental organization PCUK in a series of workshops involving men with prostate cancer, clinicians, and academics, which were delivered between 2014 and 2018. Discussions between patient representatives and researchers with experience in needs assessment and prostate cancer led to the concept of a prostate cancer–specific HNA that would be adaptive to the circumstances and needs of the individual patient. These discussions demonstrated that patients were frustrated by the limitations of follow-up consultations, which were perceived as being too narrowly focused and failing to address various needs such as concerns over the risk of their sons developing the cancer or the impact of their treatment on their relationships. This was attributed to time pressure and prioritization of monitoring for disease progression or recurrence.

Within the UK TrueNth program, the original purpose of the web-based prostate cancer–specific HNA was to provide men at low risk, whose care could be managed outside specialist services, with a PSA tracker system (estimated at up to 50% of those diagnosed) [31], which would identify their concerns to support workers. However, to make use of the full potential of adaptive digital technology to offer a broad as well as an in-depth assessment, the decision was made to create a system that would be suitable for all men with prostate cancer from diagnosis onward, regardless of the treatment pathway.

Approach to Design: Coproduction

In health care, the concept of coproduction refers to collaborative approaches to intervention development where health care professionals and patients work together, drawing on both their expertise to create "new opportunities for innovation and involvement" [32]. Coproduction has been described as representing a shift in power toward the patient and a recognition of patients as experts in their own experiences [33].

Patient representatives and clinicians were involved in all stages of this project, from the initial identification of the issues the intervention sought to address and thereafter, playing an advisory role throughout development and testing. Several rounds of user testing took place during the 2-year development period before testing in a clinical setting. Each stage of development was further guided by a project steering group comprising patient representatives recruited through PCUK, urologists and an oncologist, researchers, and information technology specialists.

Web-Based Platform: CHAT-P

CHAT-P is a web-based adaptive system designed to be used by men remotely before (or potentially in some instances instead of) a face-to-face or remote consultation in secondary or primary care. It is divided into 11 different sections, each representing a particular domain (Figure 1), with men being able to choose sections of relevance to themselves and their preferred order of completion. The questions included in these sections are adaptive, meaning that the response to top-level screening questions could open further detailed questions if problems were identified or skipped if not. Once CHAT-P is complete and has been submitted, a summary of results is made available to a linked member of the patient's health care team. This can be used as the basis for a care plan to address any identified issues or concerns. In addition, CHAT-P includes links to sources of reliable information and advice. A key feature of CHAT-P is that answers to specific questions identified by clinicians as needing urgent, rapid assessment (hereafter referred to as "red flags," eg, blood in urine, unexplained lower back pain, and the feeling that life is not worth living) could trigger an immediate message to the nominated health care professional.

Figure 1. The 11 domains of Composite Holistic Needs Assessment Adaptive Tool-Prostate.

Physical Symptoms	Not Started
Emotional and Psychological Issues	Not Started
Religious or Spiritual Issues	Not Started
Information, Communication and Relationships	Not Started
Independence and Activity	Not Started
Access and Services	Not Started
Rehabilitation and Recreation	Not Started
Illness, Treatment and Care Issues	Not Started
Occupational Issues	Not Started
Finance Issues	Not Started
Legal Issues	Not Started

Please select options from the menu of topics on the left to view or complete questions about the topic. Further instructions will appear on the following pages.

When you have completed all of the sections of relevance to you at present, please click the **Submit Assessment** button to submit your responses. You will then have the option to generate a summary of your responses.

The sections can be answered in any order and you do not have to answer every section.

Once a section has been submitted it will no longer be available for selection.

Methods

Overview

We used an iterative process involving scoping, development, and user testing, followed by refinement and testing with patients in a qualitative study. Further refinement took place following the qualitative study in conjunction with the completion of a clinician-facing site and care planning facility.

CHAT-P development took place in 3 stages, which are described as follows: stage 1, the process whereby we conducted initial scoping and development; stage 2, the qualitative study used to test CHAT-P in a patient population; and stage 3, the development of the individualized care plan and clinician-facing site.

Stage 1: Scoping of the Project, Generation of Item Bank and Domains, and User Testing (2013-2015)

The initial phase involved discussions between members of the project team, which included patient and public involvement representatives and members of the UK branch of the TrueNth Network, to clearly define the scope and scale of the project and identify its key requirements from the initial general concept.

The essential elements are summarized in Textbox 1.

Textbox 1. Key requirements of the web-based prostate cancer–specific Holistic Needs Assessment.

Requirements

- Suitable for all men from diagnosis onward
- Menu driven with a branching system adaptive to individual concerns
- Links to sources of information and advice related to specific concerns
- Inclusion of “red flag” items

During the initial set-up and scoping phase, a survey on the use of HNA and associated problems and benefits in prostate cancer services in the United Kingdom and cancer information management systems was undertaken to inform the design and to preempt potential downstream barriers. In addition, a rapid review of patient-reported outcome measures and quality of life instruments relevant to prostate cancer, either specific or generic but used in the context of prostate cancer, was carried out to inform the design and content of the system (PCUK, unpublished reports, 2013, 2014).

A total of 61 assessment tools were identified during the review. The questions from these tools were inserted into a master item bank created in a Microsoft Excel spreadsheet with additional items identified by the expert group.

VN and NA reviewed all 2790 questions included in the item bank to derive high-level domains or categories for the structure of CHAT-P. An iterative process of developing domains and checking for the inclusivity of items led to the final classification of 11 broad domains. Each item was then assigned to a domain. Certain items were assigned to more than one category; for example, items concerning appetite were assigned to both physical and psychological concerns. The response categories from the 61 instruments were entered into a linked database. Question format and response categories were then developed for each item aimed at identifying the level of concern and were standardized into categorical verbal scores, for example, “none at all,” “a little bit,” “quite a bit,” and “very much,” reflecting the earlier Sheffield Profile for Assessment and Referral for Care tool [17]. In other domains, response categories from all the instruments were considered, and a choice was made or a new response category was assigned before acceptability testing with users. Certain domains, such as finance, legal, and information needs, did not require levels (how much and how often). The details of this process are provided in Multimedia Appendices 1 and 2.

To make full use of the potential of the digital system, the structure of CHAT-P was planned as both hierarchical and branched; the selection of top-level domains opened up menus leading to further questions depending on the items selected. This design was mapped out by NA and VN on paper and reviewed by the research team before the development of the prototype for user testing. Building of the web-based platform from the prototype to the final version of CHAT-P was undertaken by a commercial medical IT company, Infoflex-CIMS (now CIVICA, UK).

Next, 2 sessions of face-to-face testing of the CHAT-P prototype were held in different parts of the United Kingdom to capture the diversity of experience. In total, 10 men with prostate cancer, who were members of the PCUK, attended events at each location. Each participant was provided with a laptop and instructions on how to log in and navigate CHAT-P. The men were asked to complete a short questionnaire on their views on the value and purpose of HNA and specific questions regarding the domains incorporated, question and response format, font, and color scheme. This provided the starting point for a discussion in which men offered their views on the potential for care delivery and specific elements of the design that were priorities for the men in terms of usability and practicality of the system.

Following adjustments to wording based on the men’s suggestions and some improvements to the branching structure, a further round of user testing took place remotely with a total of 10 men from the original 2 workshops.

Finally, in this stage of development, links to sources of information and advice from quality-assured sources (eg, PCUK and Macmillan Cancer Support) were incorporated into CHAT-P to assist men in managing their concerns. These sources include web pages, video clips, or other documents. The appearance of the links is triggered by the selection of certain items that represent a current concern. This context-sensitive feature prevents men from being overloaded with irrelevant information.

Stage 2: Testing With Patients (2016)

Overview

The first fully functioning version of CHAT-P was ready for testing with patients by early 2016. Here, we describe the conduct and findings of a nested qualitative study: “Holistic Assessment and Care Planning In Prostate Cancer.” This study explored the experience of using CHAT-P with men currently receiving treatment, monitoring, or follow-up for prostate cancer. The care planning facility was not a focus of this investigation, as its design was not completed at this time.

Aim and Objectives

The overarching aim of this stage was to understand patients' perceptions of the potential of CHAT-P to enhance care.

We sought to explore (1) how men with a range of clinical characteristics and different levels of experience with IT responded to CHAT-P; (2) their views on its design, usability, and utility to themselves and others; (3) and their views on its limitations and barriers to its adoption.

Methodology

Design

The chosen design was a cross-sectional qualitative interview study.

Ethical Considerations and Governance

The interviews were designed with a focus on minimizing distress to participants, as we did not want to directly ask about sensitive topics. We followed the principles of co-design, where members of our steering group with lived experience were involved throughout. The study was approved by Yorkshire and the Humber Bradford Leeds Research Ethics Committee on February 2, 2015, and a substantial amendment was approved on June 6, 2016 (Research Ethics Committee reference: 15/YH0021).

The study was conducted in urology clinics in 2 NHS Foundation Trusts in central England. The sponsor of this study was the University of Warwick.

Eligibility

Men with a diagnosis of prostate cancer at any stage of disease or stage in the care pathway (other than those actively receiving specialist palliative care), the ability to give informed consent, and the ability to read English were eligible to participate.

Recruitment

Purposive sampling was used to recruit participants from different clinical settings. Eligible patients were selected from urology clinic lists at site 1 by clinical nurse specialists and a urology consultant surgeon. Study information packs containing letters of invitation and reply slips were sent to the patients. At site 2, a member of the research team (RA) visited a urology clinic and was invited by a clinic staff member to approach eligible patients to whom she explained the study and handed information packs. The study information packs were also sent by post to eligible patients on an active surveillance pathway. Interested participants returned reply slips to the research team, and interviews were scheduled.

Face-to-face interviews were conducted by trained researchers (RA and JL) either in the clinic or in the patients' homes, audio recorded, and transcribed. The data were collected between October and December 2016.

Study Procedure

Written consent was obtained from the participants by the researcher before the interviews. Participants were introduced to CHAT-P, which was demonstrated to them, and the key features were explained. Men were then invited to select domains to try out for themselves.

Semistructured interviews took place while participants were trying CHAT-P using the "think-aloud" technique [34]. They sought to capture men's views on the experience of using CHAT-P and their views on its potential for cancer care.

Analysis

The 2 data sets were combined for data analysis, which was performed using a framework approach [35]. This method produces structured data summaries, which facilitates coding and thematic development.

A total of 4 overarching categories were identified a priori to reflect the aims of this study, namely the user interface and design, suitability of content, personal value, and implementation and use in the clinical care pathway.

Following familiarization with the first 4 transcripts by 3 members of the project team, 1 team member assigned the data to the 4 categories and undertook initial coding. In addition, 2 other members of the research team scrutinized the coding and participated in an iterative process of developing further codes and subcategories until a complete analytical framework was derived. The remaining data were coded into the framework, which was then shared with the members of the wider project team. Themes, subthemes, and concepts were developed and refined through discussion and reflection to produce the final analysis.

Results

Overview

A total of 16 participants took part in the interviews, with 5 patients recruited from site 1 and 11 from the list of patients on active surveillance at site 2. The participant characteristics are presented in Table 1.

The findings relating to the 4 a priori categories (user interface and design, suitability of content, personal value, and implementation and use in the clinical care pathway) are described in subsequent sections, exploring men's views on the use of CHAT-P in the prostate cancer care pathway and their feedback on the design and content. The findings within each theme are grouped into categories and illustrated using relevant participant quotations.

Table 1. Participant characteristics.

Study ID	Age band (years)	Treatment	Time since the start of treatment	Comorbidities	Self-reported computer literacy
D001	65-70	Not known	13 years	None mentioned	Yes—high
D002	65-70	Not known	—[a]	Hearing problems	Yes—medium
D003	65-70	Radiotherapy and hormone injections	13 years	None mentioned	Yes—high
D004	65-70	Not known	10 years	None mentioned	Yes—high
D005	80-85	Hormone treatment and radiotherapy	8 years	Chronic obstructive pulmonary disease, restricted mobility, and collapsed lung	Yes—high
B001	70-79	Active surveillance	—	None mentioned	Yes—medium
B002	70-79	Active surveillance	—	Arthritis	Yes—low
B003	50-59	Active surveillance	—	None mentioned	Yes—high
B004	50-59	Active surveillance	—	None mentioned	Yes—high
B005	70-79	Radical prostatectomy	2 years	Depression	Yes—high
B006	70-79	Active surveillance	—	Diabetes	Yes—high
B007	70-79	Radical prostatectomy	6 months	None mentioned	Yes—medium
B008	60-65	Active surveillance	—	Head and neck cancer (all clear)	Yes—low
B009	65-69	Radical prostatectomy	1 month	None mentioned	Yes—medium
B010	70-79	Active surveillance	—	None mentioned	Yes—medium
B011	70-79	Active surveillance	—	Hearing loss	No

[a] This information was not available for this participant.

User Interface and Design

Ease of Use

Most participants found CHAT-P straightforward to use. The instructions were useful, comprehensive, and in the right font size:

> *I think it's brilliant for those people that are reasonably computer literate, and even if they're not [sic] I think that's pretty easy to follow.* [D001]

However, 5 participants found that there was too much text on the introductory page with the instructions or that the font size was too small.

Graphics

The colors and images were received well by most participants, who commented that they liked the look of CHAT-P. One participant commented that the images should be enlarged. For example, the icons used to indicate a link to further information were overlooked by most participants before the researchers pointed them out.

Suitability of Content

The participants were generally very satisfied with the content, with many commenting on the difficulty of creating a system responsive to the needs of patients with such diverse experiences.

Scope

The range of the questions also met with approval from the participants:

> *Well as I said it's very comprehensive, it would be very difficult to try and think of anything that it hasn't covered.* [B005]

> *There's enough down there without being too much, but I think there's enough down there that you're covering everybody, or hopefully everybody.* [B008]

The participants also appreciated being able to select only the sections that were relevant to them once they understood the concept. All the participants saw some sections that were relevant to them or would have been at another stage of their care pathway:

> *I mean I know some of these things don't probably apply...well they don't apply to me because I mean I'm ten years down the line now, but generally most of these questions, at the time I would like to have the answer to anyway.* [D004]

> *I can see you're trying to cover everybody.* [B004]

Improved Access to Web-Based Information

The participants valued the way in which the HNA can help make information that is readily available on the internet more accessible and make it easier to find what they needed:

> *But the fact that you've got them all together here, would make it a lot easier and a lot quicker to find the information you need. And all the information that I've got off the internet seems to be here.* [B007]

Questions on Comorbidities

Some participants questioned the relevance of the subsections and items about symptoms that are not directly related to prostate cancer, prompting the researcher to clarify the purpose of CHAT-P as an HNA designed to flag various concerns and issues, including comorbidities. Others deemed the inclusion of comorbidities very important:

> *I've got diabetes which affects some of my answers to questions. I've got other issues which affected my answers. So unless you've got a complete picture, or a reasonable picture, of the illness, the state of health of the people, then I think you're probably missing out on a lot of answers.* [B006]

Sensitive Questions

The participants were asked whether some of the questions were too sensitive. All of them felt that the questions were appropriate, and a few mentioned that they had learned to talk about sensitive issues because of their condition and were comfortable in addressing such issues:

> *No, I've gone beyond being sensitive about personal things so it's fine.* [B009]

Personal Value

Identification and Articulation

The participants recognized the value of CHAT-P in helping them to think about concerns that they might not have considered otherwise:

> *As I see it at the moment it's very comprehensive and it almost seems to be taking you down routes that perhaps you wouldn't automatically have gone yourself, you know, things which may be due to other problems, nothing to do with the condition.* [B005]
>
> *...this is good in that it asks questions that I don't even think about.* [B006]

In addition, the HNA was seen as a help to both articulate a wide range of needs and gain a more structured understanding of their needs; that is, being able to classify concerns:

> *I think to do it once is interesting because it enables myself, for instance, to think about things more fully than I would normally do. Or to think about things in little boxes, rather than as a global thing, which is what everybody does.* [B006]

Preparation for the Consultation

The participants also identified the potential of CHAT-P in preparing for a consultation by gathering information, thus enabling more informed communication with the clinician:

> *I would have liked to have used it myself at home. I think the more you know before you talk to your consultant or your doctor, the more you can understand about it. And that's what I did. I mean, I went through YouTube and all sorts, to get as much information as I could so I knew what the consultant was talking about and what the options were. But as I say, if I'd have had this, it would have been a lot quicker and more clear.* [B007]

Preferences

For some, disclosure through a digital assessment was preferable to a face-to-face conversation. Others questioned whether they would want to disclose some mental health concerns to their clinician or whether they would feel embarrassed to admit the number of concerns they had.

Implementation and Use in the Clinical Care Pathway

Use Over Time

The participants identified a variety of clinical settings in which CHAT-P could be used, including a hospital and general practitioner (GP) environment at times before, during, or after treatment. They also identified points in time that were particularly relevant, including after the diagnosis, when information needs are high in terms of treatment options, and immediately after treatment when care comes to an abrupt end:

> *I think if somebody has been diagnosed with prostate cancer from day one, I think once the, the news has sunk in, perhaps a couple of weeks later if they're invited to go down to, I don't know, the local GP or the nurse or something and say, well we know it's early days but these are some of the issues that might arise, and do that exercise. And then perhaps repeat it, the same exercise sort of, I don't know, six months later or a year later, that sort of thing, perhaps when they've had the treatment that they need.* [D001]
>
> *It's the post op stage and knowing whether it's been successful, what are the implications of the operation, so it's round about that period where I think it's most useful because you have all sorts of questions...* [B005]

Time Saving

Many participants mentioned that CHAT-P could save the clinician's time by focusing a consultation on the patient's key concerns and by providing information to the patient that they might otherwise have to gather elsewhere:

> *Yeah, I could see it will save them time, and also make it easier, because...when you come out of the consultation you think, oh I wish I'd said so and so.* [B002]
>
> *The biggest benefit I see of something like that is you save your clinicians time, because if it's something that's relatively straightforward that you find out your answer, you're not going to be on the phone to them, seeing them unnecessarily. So it frees up more time, so it's more treatment, and the whole thing becomes a lot more cost-effective.* [B003]

Acceptability to Service Users

The participants appreciated the "red flag" capability of CHAT-P to pick up critical issues and prompt patients to contact a health professional as well as the summary of patient concerns that is generated in the clinician-facing site. However, it was pointed out that to be of value, men needed to know that the concerns they identified through CHAT-P would be picked up and addressed by the relevant clinician:

> *So it's having confidence I suppose, in the system, that if you're basically putting stuff in from a question point of view...that one it's being picked up, and secondly it's being dealt with by the appropriate kind of person.* [B003]

Many participants expressed enthusiasm toward CHAT-P, anticipating its imminent availability. Some participants expressed an intention to use the system themselves, as illustrated by a patient on active surveillance:

> *I would be very keen on seeing this up and running. I think I'd find that a very, very useful tool that would save me hours and hours and hours of wandering about looking for various bits; it brings it all together. Yeah, I quite like that.* [B005]

Summary of the Stage 2 Qualitative Study

The participants recognized the potential of CHAT-P to facilitate the communication they saw as central to their care. By enabling them to easily identify and articulate their concerns and access relevant information, the participants felt they would be better prepared and able to take an active role in the subsequent consultation. CHAT-P would enable clinicians to focus immediately on their specific concerns by providing a clear summary before or at the start of the consultation. However, the participants also reported that the value of CHAT-P would depend to a large degree on the clinician responding to the issues raised.

Feedback provided by the participants, which included the need for increased clarity in the user guidance, was collated and discussed with the study steering group. Further wording alterations and other small refinements, including changing the icons representing the internet links, were agreed upon and implemented.

Stage 3: Development of Care Plan (2016)

Although further improvements to functionality continued, the focus of the final phase of development was the design, content, and format of the output of CHAT-P. This mainly comprised the care plan, which needed to be incorporated into a clinician-facing site. This stage was essential before testing within the clinical pathway. Interviews and discussions with clinicians, including urologists, oncologists, CNSs, and GPs, identified key features, which are outlined in Textbox 2. A total of 6 urologists provided comments collated through the TrueNth United Kingdom Supported Self-Management project colead. Other specialties were represented in the CHAT-P study steering group.

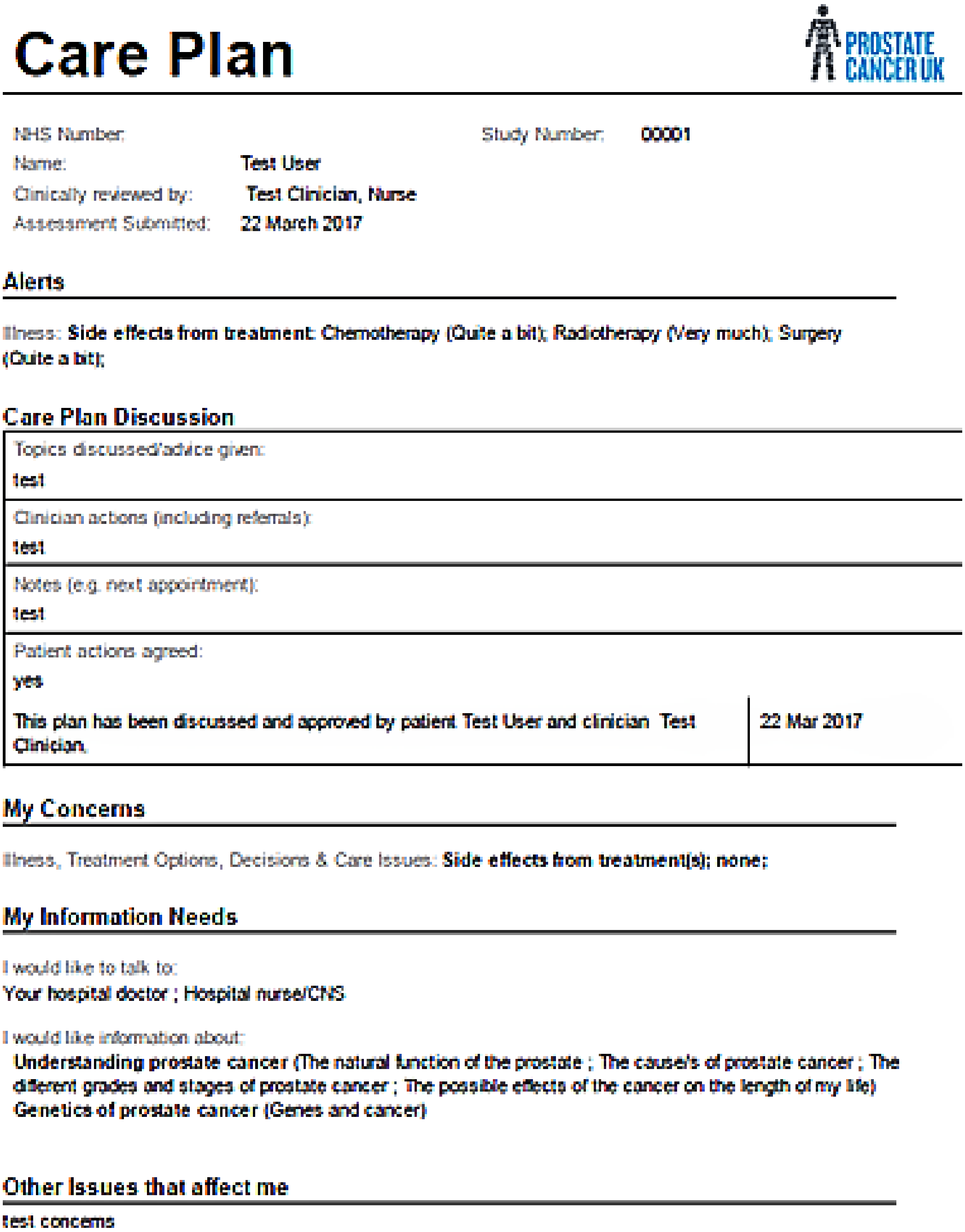
Textbox 2. Key features of the care plan.

Features

- Concerns summarized on one page
- Red flag symptoms included
- Concerns presented in the order of importance
- Space for recording clinician and patient actions
- Downloadable

The care plan was developed through a series of versions following clinician feedback, which primarily emphasized the importance of brevity and easy identification of "red flag" items. The latter was seen by clinicians as representing clinical and psychological concerns that should prompt an urgent referral from the system to the nominated attending health care professional. The IT team created a clinician-facing website through which clinicians could access care plans associated with their patients. An example of the care plan is shown in Figure 2. The TrueNth CHAT-P project concluded in June 2016 following testing with patients and the finalization of the clinician-facing site that hosted the care plan. Although the findings were encouraging, an assessment of the impact of CHAT-P on consultation and ensuing actions would determine its potential in terms of care delivery. Funding for the next stage of the CHAT-P program, testing the impact of CHAT-P in the clinical setting, was obtained from the National Institute for Health and Care Research, Research for Patient Benefit program (grant PB-PG-0214-33092). This is briefly described in the subsequent section as an additional phase of work after the 3-stage development and testing process described earlier.

Figure 2. The care plan.



Care Plan

PROSTATE CANCER UK

NHS Number: Study Number: 00001
Name: Test User
Clinically reviewed by: Test Clinician, Nurse
Assessment Submitted: 22 March 2017

Alerts

Illness: Side effects from treatment: Chemotherapy (Quite a bit); Radiotherapy (Very much); Surgery (Quite a bit);

Care Plan Discussion

Topics discussed/advice given: test	
Clinician actions (including referrals): test	
Notes (e.g. next appointment): test	
Patient actions agreed: yes	
This plan has been discussed and approved by patient Test User and clinician Test Clinician.	22 Mar 2017

My Concerns

Illness, Treatment Options, Decisions & Care Issues: Side effects from treatment(s); none;

My Information Needs

I would like to talk to:
Your hospital doctor ; Hospital nurse/CNS

I would like information about:
Understanding prostate cancer (The natural function of the prostate ; The cause/s of prostate cancer ; The different grades and stages of prostate cancer ; The possible effects of the cancer on the length of my life)
Genetics of prostate cancer (Genes and cancer)

Other Issues that affect me

test concerns

Brief Description of CHAT-P Used in a Prospective Feasibility Study (2016-2018)

We subsequently conducted a mixed methods feasibility study (Integrated Care in Prostate Cancer [36]) in a primary care setting with CHAT-P incorporated into the prostate cancer care pathway. In addition to testing the feasibility of a larger-scale study, this study provided a means of assessing the potential of the clinician-facing site and care planning function and the role of CHAT-P in enabling information sharing between patients and relevant clinical services. The information pathway is shown in Figure 3.

Figure 3. The potential of Composite Holistic Needs Assessment Adaptive Tool-Prostate in the prostate cancer care pathway.

CHAT-P is built on a platform developed by a major information service provider, Infoflex-CIMS (now CIVICA), which is embedded in hospital trusts across the United Kingdom. Nevertheless, reaching an agreement regarding hosting and access to CHAT-P was challenging, requiring rigorous and complex processes involving the information services provider, NHS trust, and university undertaking the research. Governance approvals and penetration testing to ensure data security and agreements regarding data sharing were required before the start of the intervention.

Quantitative findings relating to the feasibility of the primary care–based study, patient use of CHAT-P, and technology acceptance and qualitative findings relating to patient and health care professional experience are reported in full elsewhere [36,37]. Several design issues were highlighted by the participants and by the practice nurses for attention in the final version. These are summarized in Multimedia Appendix 1.

The study demonstrated the practicality and utility of the assessment and improved information flow among the patient, primary care, and secondary care. The participants identified concerns in every domain of the assessment; emotional and psychological issues were the most commonly identified concerns, followed by physical problems and issues around access to services. Practice nurses followed up on these concerns and made appropriate onward referrals. When red flag symptoms were identified, immediate action was taken through phone calls to the secondary care team. The care planning document was easily accessible and straightforward to use. Primary care–based recruitment to the study proved challenging owing to the relatively small number of eligible participants identified in each participating practice and the competing demands on practice nurse time.

Final Version

Following the feasibility study, the final version of CHAT-P is ready for implementation and evaluation at scale. The final version has incorporated the suggested changes, and major improvements have been made to the "Welcome" and "Introduction" screens. The welcome text has now been replaced by a short film featuring a patient, a GP, a CNS, and a consultant urologist (Multimedia Appendix 2). An overview of each element of CHAT-P is shown in cartoon format to prepare patients to access CHAT-P for the first time (Multimedia Appendix 3).

Discussion

Principal Findings

CHAT-P was developed in response to a need identified by men with prostate cancer and was coproduced with them, initially as part of the TrueNth program [30]. It aims to boost the agency and empowerment of men by enabling the identification and communication of their concerns as they change over time and by providing links to relevant information and advice. CHAT-P also seeks to help health care professionals provide optimum care by focusing consultations according to men's individual, preidentified needs and to facilitate the provision of remote care, limiting the need for outpatient attendance.

There has been a rapid expansion in the field of electronic patient-reported outcome measures for people with cancer in recent years, and evaluation has shown considerable benefits

[1]. HNA has also gone on the web; however, to date, these tools are generic, not adaptive, and, importantly, do not generate alerts in response to the selection of a red flag item [38]. As far as we have been able to ascertain, CHAT-P is the first web-based, adaptive tool that allows patients to select items from a series of menus and submenus without the need to respond to every item presented. CHAT-P is also unique in the wide-ranging nature of the 11 domains included and its ability to generate links in response to item selection.

Technical Challenges

Initial challenges lay in ensuring that the content was both adequately holistic, including sufficiently detailed items within each of the 11 domains, and adequately specific to the needs of men with prostate cancer at different stages clinically. Question wording and response format had to be easily understood and consistent without being overly repetitive. The lack of clarity of language has hitherto been identified as a barrier to the uptake of web-based symptom monitoring [39,40]. Thus, we felt that coproduction with men with prostate cancer was critical to ensuring that CHAT-P met this key requirement.

Among the design challenges was the need to create a system that was both secure and easily accessible to men through registration and log-in process. A second challenge lay in developing a novel hierarchical branching system to ensure that top-level broad concerns led to relevant lower-level menus of items. Coding relevant links to sources of information and advice to appear in response to the selection of specific items was also a critical part of the design process. An additional issue for the team was to develop a care plan function, which was easy to use and fitted in with the current care pathway, importantly including the “red flag” items to alert both patients and health care professionals to serious concerns.

Through the iterative processes in the 3-stage development, we addressed each of these challenges and made amendments to the CHAT-P system, which were acceptable to the men with prostate cancer and their clinicians who were working with us.

Strengths

Good communication and information tailored to patients’ concerns are the cornerstones of patient-centered care and underpin the concept of HNA. Both are central to the ability of people with cancer to manage the uncertainty of their situation, without which anxiety and depression frequently result [41]. CHAT-P has been coproduced by a team with a wide range of expertise, including men with prostate cancer, from the project planning stage. Their guidance has helped ensure that CHAT-P is accessible, comprehensive, and relevant to men’s needs. The iterative process of user testing and refinement has further contributed to its robust design. In the clinical setting, testing has demonstrated the wide-ranging concerns across domains that may be captured by an individualized adaptive assessment. In addition, testing has demonstrated the potential of the CHAT-P for information sharing between patients and clinical teams across settings.

In our study, men with prostate cancer were the key codrivers of the initial concept. The technology development and exploratory and feasibility studies have all involved a range of professional and lay stakeholders as team participants. Through the identification of common goals, close collaboration, and communication, differences in perspectives and requirements were acknowledged and discussed and compromises were reached that could combine end-user priorities, usability, and technical feasibility.

Limitations

CHAT-P is built on a flexible platform that can be adapted to local requirements. Although this represents a strength, it also necessitates some active involvement of NHS IT departments and a member of the clinical team (eg, a CNS), who will also be required to monitor and update the links provided by the system.

An age-related digital divide in the use of IT is recognized as a barrier to the uptake of digital health technology. Prostate cancer is a disease that affects men increasingly as they age, and the risk of digital exclusion due to age was of particular concern in the early stages of the project. Our patient representative steering group members and project team members were all men with experience and confidence in IT, who were hence more inclined to see the usefulness and potential of a digital HNA. However, they were closely involved with other men with a range of IT skills whose views were also represented. In our interview study, all but one participant owned a computer tablet, and their computer literacy varied among low, medium, and high. Since the study, recently published figures indicate that 93% of the households in the United Kingdom now have access to the internet [42]. Although our sample represents a relatively narrow sociodemographic, it is an indication of a rising trend and suggests increasing familiarity with the digital world in the general population. In addition, the COVID-19 pandemic has seen a huge increase in the implementation and use of web-based health care and remote communication [43,44].

While our user testing involved men recruited through support associations, our patient participants in the interview study and in the subsequent feasibility study were sampled through clinic and general practice lists and represented a wider range of socioeconomic backgrounds; however, it is important to acknowledge that there was little ethnic diversity in our patient sample [36].

CHAT-P in the Era of the COVID-19 Pandemic

Although the NHS has been championing the use of digital technology since 2012, remote consultation as a substitute for outpatient and general practice appointments has rapidly become established since the beginning of the COVID-19 pandemic. Overall, rates of remote consultations across general practice and hospital settings increased significantly due to the COVID-19 pandemic [45]. Remote consultation represents a considerable cost saving to the NHS, and where quality and safety criteria as advised by the General Medical Council are met, it is likely to become embedded as a part of the standard of care [46]. An initial driver for the development of CHAT-P was the notion that a cancer-specific HNA, combined with a PSA tracker, would enable remote monitoring for men with low-risk prostate cancer. Linked to telephone or video consultations, CHAT-P, which is able to identify and alert patients and clinicians to symptoms requiring urgent attention, may contribute significantly to the confidence of using remote care for men regardless of their disease profile and clinical pathway.

Implementation and Evaluation

HNAs for all patients with cancer have been recommended in the recent NHS long-term plan, in addition to a personalized care plan and information to help overall health and well-being [47]. Evidence indicates that HNA is well accepted by patients. However, previous research has shown that generic HNAs (often without any clear link to a care planning consultation) have little impact on outcomes in terms of onward referrals or advice regarding self-management. Unless the HNA is used during consultations and incorporated into care plans and appropriate referrals made, its impact on patients' quality of life can be negative because of expectations among patients being raised but remaining unmet, as a previous work by members of our team has demonstrated [17].

CHAT-P represents an advance in generic and especially paper-based HNA in terms of its potential to empower men to identify and communicate their changing needs over time and along the pathway of care and to provide reliable information and resources for men to actively manage their own health. However, its value must ultimately be judged in terms of its outcomes. A full evaluation of CHAT-P is needed of both process and outcomes to determine the extent and level of adoption in secondary care, as well as clinical, quality of life and health economic outcomes from the beginning of the clinical pathway. Recruited patients should be diverse in terms of both clinical and sociodemographic characteristics. Crucially, a theoretically driven implementation strategy is required. Evidence indicates that in the absence of such a strategy, digital innovations in health care are unlikely to succeed. The normalization process theory [48-51] has been used as the basis for the successful implementation of digital health innovations and may provide a useful framework for the development of implementation and adoption strategies in relation to CHAT-P and its evaluation. Awareness raising and training for staff on the use of the system and on how to introduce it to patients and encourage them to use it are critical elements of the implementation process. It is also important that staff do not perceive the intervention as a burden. A project to electronically capture and remediate the late effects of pelvic radiation reported significant variation in uptake by patients across sites, which was largely attributed to differences in staff engagement and perceptions of burden [15].

In addition, information governance and related approvals must be obtained, which may present a barrier to adoption. Conclusions from an intervention that includes an electronic HNA and remote monitoring within the context of a supported self-management pathway recommend the appointment of a clinical champion to drive and oversee this process [31].

Once established, we aim to investigate the potential for integrating the CHAT-P output directly to the National Prostate Cancer Audit site and the Somerset Cancer Registry to aid health policy makers in determining priorities for follow-up and care.

The Future of Cancer-Specific HNA

We are now developing a second cancer-specific HNA focused on the needs of people with bladder cancer (CHAT-B). Following the testing process, it is intended that both systems will be integrated within the clinical pathway from the point of diagnosis onward in several NHS trusts. Studies are needed to determine the extent of adoption and evaluate effectiveness in improving quality of life outcomes, enhancing patient enablement, and reducing the demand for NHS resources.

Conclusions

CHAT-P is the first web-based interactive platform for cancer-specific HNA. This platform provides an innovative means to allow men to communicate their concerns to their health care teams before an in-person or remote consultation. There is a need for a full evaluation of the implementation process and outcomes following the introduction of CHAT-P into the clinical pathway. The CHAT-P model also has the potential to be adapted to other cancers.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Final edits to Composite Holistic Needs Assessment Adaptive Tool-Prostate.

[DOCX File , 16 KB - cancer_v8i4e32153_app1.docx]

Multimedia Appendix 2
Composite Holistic Needs Assessment Adaptive Tool-Prostate film featuring clinicians, one of our patients, and representatives of public involvement.
[MP4 File (MP4 Video), 162944 KB - cancer_v8i4e32153_app2.mp4]

Multimedia Appendix 3
Composite Holistic Needs Assessment Adaptive Tool-Prostate instruction video.
[PPTX File , 35926 KB - cancer_v8i4e32153_app3.pptx]

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Abbreviations

ADT: androgen deprivation therapy
CHAT-P: Composite Holistic Needs Assessment Adaptive Tool-Prostate
CNS: clinical nurse specialist
GP: general practitioner
HNA: Holistic Needs Assessment
PCUK: Prostate Cancer UK
PSA: prostate-specific antigen

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Original Paper

Racial Disparities in Patient-Provider Communication During Telehealth Visits Versus Face-to-face Visits Among Asian and Native Hawaiian and Other Pacific Islander Patients With Cancer: Cross-sectional Analysis

Jared D Acoba[1], MD; Chelsea Yin[2], MD; Michael Meno[3], MD; Justin Abe[4], BA; Ian Pagano[1], PhD; Sharon Tamashiro[5], RN; Kristy Fujinaga[5], RN; Christa Braun-Inglis[1], DrNP; Jami Fukui[1], MD

[1]University of Hawaii Cancer Center, Honolulu, HI, United States
[2]Kaiser Permanente, Oakland, CA, United States
[3]University of Washington, Seattle, WA, United States
[4]University of Southern California, Los Angeles, CA, United States
[5]Queen's Medical Center, Honolulu, HI, United States

Corresponding Author:
Jared D Acoba, MD
University of Hawaii Cancer Center
701 Ilalo St
Honolulu, HI, 96813
United States
Phone: 1 8085318521
Email: jacoba@hawaii.edu

Abstract

Background: Telehealth visits increase patients’ access to care and are often rated as “just as good” as face-to-face visits by oncology patients. Telehealth visits have become increasingly more common in the care of patients with cancer since the advent of the COVID-19 pandemic. Asians and Pacific Islanders are two of the fastest growing racial groups in the United States, but there are few studies assessing patient satisfaction with telemedicine among these two racial groups.

Objective: Our objective was to compare satisfaction with communication during telehealth visits versus face-to-face visits among oncology patients, with a specific focus on Asian patients and Native Hawaiian and other Pacific Islander (NHOPI) patients.

Methods: We surveyed a racially diverse group of patients who were treated at community cancer centers in Hawaii and had recently experienced a face-to-face visit or telehealth visit. Questions for assessing satisfaction with patient-physician communication were adapted from a previously published study of cancer survivors. Variables that impact communication, including age, sex, household income, education level, and cancer type and stage, were captured. Multivariable logistic models for patient satisfaction were created, with adjustments for sociodemographic factors.

Results: Participants who attended a face-to-face visit reported higher levels of satisfaction in all communication measures than those reported by participants who underwent a telehealth encounter. The univariate analysis revealed lower levels of satisfaction during telehealth visits among Asian participants and NHOPI participants compared to those among White participants for all measures of communication (eg, when asked to what degree “[y]our physician listened carefully to you”). Asian patients and NHOPI patients were significantly less likely than White patients to strongly agree with the statement ($P<.004$ and $P<.007$, respectively). Racial differences in satisfaction with communication persisted in the multivariate analysis even after adjusting for sociodemographic factors. There were no significant racial differences in communication during face-to-face visits.

Conclusions: Asian patients and NHOPI patients were significantly less content with patient-physician communication during telehealth visits when compared to White patients. This difference among racial groups was not seen in face-to-face visits. The observation that telehealth increases racial disparities in health care satisfaction should prompt further exploration.

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KEYWORDS

cancer; telemedicine; telehealth; eHealth; racial disparities; race; racial; Asia; Asian; Hawaii; Hawaiian; Native Hawaiian; Pacific Islander; cross-sectional; satisfaction; cancer; oncology; racially diverse; patient-physician communication

Introduction

Telehealth is the use of real-time audio and video technologies for telecommunication between patients and health care providers. Telehealth visits increase patients' access to care by reducing travel time and expenses and by providing increased schedule flexibility. Telehealth also allows health care providers to reach patients and other specialists remotely, allows them to reach larger segments of the population, alleviates workforce shortages in remote areas, and improves care coordination [1-6]. Patient satisfaction with telehealth has been well documented, particularly among residents from rural communities [2,4,6-8], with as many as 95% of patients rating telehealth visits as "better than" or "just as good" as face-to-face visits [6,9,10]. Specifically, studies of oncology patients have reported high levels of satisfaction with telehealth [3-5,8,11-14].

With the advent of the COVID-19 pandemic, the American Society of Clinical Oncology released guidelines that advocate for the use of telemedicine for patients not requiring face-to-face services, such as physical examinations, treatments, and in-office diagnostics [15]. In response, oncology practices increased the number of telehealth visits to reduce the risk of SARS-CoV-2 transmission [3,13,14,16]. Teleoncology studies that were conducted during the COVID-19 pandemic demonstrated that telehealth visits met the needs of oncology patients, without a reduction in services [14,17].

As the use of telehealth increases, it is important to ensure that this care modality is beneficial to all patients with cancer. Numerous studies have shown the lower use of telehealth among racial minority patients [18-21]. Chunara et al [20] demonstrated that while Black individuals increased their use of telehealth during the early part of the COVID-19 pandemic, their use remained lower than that of their White counterparts. Hiratsuka et al [21] noted that Native Hawaiian and Alaska Native patients see the "lack of physical contact and hands-on interaction" as a disadvantage of telehealth visits.

There is a paucity of literature evaluating patient satisfaction and the quality of communication during telehealth encounters among Asian patients and Native Hawaiian and other Pacific Islander (NHOPI) patients. Asians and Pacific Islanders are two of the fastest growing racial groups in the United States [22,23], and cancer incidence and mortality rates are higher among patients belonging to these groups than those among White patients [24]. Assessing Asian patients' and NHOPI patients' interactions with health care providers in telemedicine encounters could prove valuable. Our objective was to compare satisfaction with communication during telehealth visits versus face-to-face visits among oncology patients, with a specific focus on Asian patients and NHOPI patients.

Methods

Participants and Eligibility Criteria

This study compared survey responses from a racially diverse group of patients with cancer who were treated at community cancer centers in Hawaii. Patients with cancer aged ≥18 years were eligible, and participants needed to be able to communicate in English without the assistance of a translator.

Face-to-face Survey

We assessed patient satisfaction with communication during face-to-face visits by surveying patients who underwent survivorship care visits from January 2014 through June 2018 at the Queen's Cancer Center (Honolulu, Hawaii). These cancer survivors had received definitive cancer therapy with curative intent and were invited to complete the survey during a period of follow-up care. We mailed eligible participants invitations to the survey and collected survey responses via the internet or over the phone from September 2018 through December 2018.

Telehealth Survey

To gauge satisfaction during telehealth visits, we surveyed patients who experienced a telehealth visit between March 2020 and August 2020 at outpatient cancer centers in Hawaii that were affiliated with the Queen's Cancer Center and Hawaii Pacific Health (Honolulu). Eligible participants included patients who were actively receiving treatment with either curative or palliative intent and patients in follow-up care. We approached participants of the telehealth survey sequentially within the survey time frame and invited them to participate in the survey either by phone or via the internet.

Data Collection and Measurement

All face-to-face and telehealth surveys were completed anonymously, and no personal health information or personally identifiable information was collected. The demographic data collected included sex, age, education level, household income, insurance type, race, the type of cancer, and the stage of cancer. Age was categorized as <50 years, 50 to 59 years, 60 to 79 years, and ≥80 years. Education levels were grouped into the following five categories: high school degree or less, some college but no formal degree, associate's or bachelor's degree, master's or doctorate degree, and other. Classifications for household income included "prefer not to say," <US $30,000 per year, US $30,000 to US $59,999 per year, US $60,000 to US $89,999 per year, and ≥US $90,000 per year. Patients self-identified a single race that best described them and were grouped as White, NHOPI, Asian, or other race patients. Cancers were clustered as gastrointestinal cancer (colon cancer, cholangiocarcinoma, hepatoma, gastric cancer, or esophageal cancer); hematopoietic cancer (acute myeloid leukemia, myelodysplastic syndrome, lymphoma, or myeloma); genitourinary cancer (prostate, bladder, or kidney cancer); gynecologic cancer (ovarian or uterine cancer); breast cancer;

lung, head, and neck cancer; or other. Cancer stages were grouped as “I do not remember,” stage 0 to 2, and stage 3 to 4.

Questions for assessing communication were adapted from a previous study of cancer survivors by Palmer et al [25]. These questions were part of the Assessment of Patient Experiences of Cancer Care (APECC) study [26], which included questions from existing surveys and items developed by the APECC investigators. Patients were asked to rate their degree of agreement with the following eight statements regarding communication with their physician: (1) “Your physician listened carefully to you,” (2) “Your physician explained things in a way you could understand,” (3) “Your physician showed respect for what you had to say,” (4) “Your physician encouraged you to ask all of the cancer-related questions you had,” (5) “Your physician made sure that you understood all of the information he or she gave you,” (6) “Your physician spent enough time with you,” (7) “Your physician gave you as much cancer-related information as you wanted,” and (8) “Your physician involved you in decisions about your medical care as much as you wanted.” Responses were assessed on a 5-point response scale ranging from “strongly disagree” to “strongly agree.”

Outcomes

The main outcomes of interest were (1) the degree to which patients agreed that their health care provider met the measures of communication described in the *Data Collection and Measurement* section and (2) whether the ratings for communication varied significantly by race.

Statistical Methods

To avoid issues of nonnormality and to ensure that the methods used to analyze all variables were consistent, continuous demographic variables were grouped into categories, and chi-square tests were used to assess differences across groups. A *P* value of <.05 was considered statistically significant. The degree of patient satisfaction was analyzed by comparing patients who strongly agreed with statements to those who submitted other answers. Multivariable logistic models for patient satisfaction were built to obtain odds ratios (ORs) and 95% CIs, adjusting for sociodemographic factors. SPSS version 27.0 (IBM Corporation) was used for all analyses.

Ethics Approval

This study was approved by the Queen’s Medical Center and Hawaii Pacific Health research and institutional review committees (approval numbers: RA-2020-20 and RA-2018-038).

Results

Patient Population

A total of 593 surveys were collected, with 362 participants in the face-to-face group (response rate: 362/1419, 25.5%) and 231 in the telehealth group (response rate: 231/464, 49.8%). Baseline demographics, including sex (*P*=.79), age (*P*=.10), education level (*P*=.15), household income (*P*=.82), and race (*P*=.41), did not differ significantly between the two groups (Table 1). Participants were highly educated, with the majority (479/587, 81.6%) having some college or more education. There were more cases of gynecologic cancers and head, neck, and lung cancer among the face-to-face group respondents and more cases of gastrointestinal and hematologic cancers among the telehealth group participants (*P*<.001). The majority (240/362, 66.3%) of the face-to-face group reported earlier cancer stages than those reported by the telehealth group.

Table 1. Baseline characteristics (N=593).

Characteristic	Face-to-face group (n=362), n (%)	Telehealth group (n=231), n (%)	*P* value
Sex			.79
Female	240 (66.3)	150 (64.9)	
Male	122 (33.7)	81 (35.1)	
Age (years)			.10
<50	23 (6.4)	27 (11.7)	
50-59	58 (16.1)	42 (18.3)	
60-69	137 (38.1)	77 (33.5)	
≥70	142 (39.4)	84 (36.5)	
Education			.15
High school degree or less	52 (14.6)	37 (16.1)	
Some college	82 (23)	40 (17.4)	
Associate’s or bachelor’s degree	139 (38.9)	105 (45.7)	
Master’s or doctorate degree	75 (21)	38 (16.5)	
Other	9 (2.5)	10 (4.3)	
Household income per year (US $)			.82
<30,000	48 (13.3)	37 (16)	
30,000-59,999	64 (17.7)	35 (15.2)	
60,000-89,999	69 (19.1)	44 (19)	
≥90,000	117 (32.3)	71 (30.7)	
Prefer not to say	64 (17.7)	44 (19)	
Race			.41
White	87 (24.4)	51 (22.6)	
Asian	213 (59.8)	127 (56.2)	
Native Hawaiian and other Pacific Islander	41 (11.5)	36 (15.9)	
Other	15 (4.2)	12 (5.3)	
Cancer type			<.001
Breast	132 (36.5)	101 (43.7)	
Lung, head, and neck	64 (17.7)	21 (9.1)	
Genitourinary	54 (14.9)	22 (9.5)	
Gastrointestinal	32 (8.8)	53 (22.9)	
Gynecologic	46 (12.7)	0 (0)	
Hematologic	11 (3)	25 (10.8)	
Other[a]	23 (6.4)	9 (3.9)	
Cancer stage			<.001
0-1	151 (41.7)	69 (29.9)	
2	89 (24.6)	37 (16)	
3-4	70 (19.3)	74 (32)	
Unsure	52 (14.4)	51 (22.1)	

[a] Includes melanoma, Merkel cell carcinoma, sarcoma, thyroid cancer, and unknown primary cancer.

Face-to-face Visits Versus Telehealth Visits

Participants who attended a face-to-face visit reported higher levels of satisfaction in all communication measures (all *P* values were <.05) than those reported by participants who experienced a telehealth encounter (Figure 1).

Logistic regression models were created to measure the association between patient demographics and satisfaction with patient-physician communication. The univariate analysis revealed significant racial differences in the telehealth group but not in the face-to-face group. For example, White patients were more likely to strongly agree with the statement “Your physician listened carefully to you” (Table 2) than Asian patients (OR 0.26, 95% CI 0.10-0.6) and NHOPI patients (OR 0.20, 95% CI 0.06-0.64).

Table 2 illustrates the degree to which patients agreed that their physicians listened carefully to them by characteristic. Degrees of satisfaction were divided into 2 groups—the strongly agree and other answers groups—to calculate an OR.

Similar racial disparities were detected for each of the eight communication statements (Table 3). Asian patients and NHOPI patients were significantly less likely to be satisfied with patient-physician communication during telehealth visits when compared to White patients. This difference was not seen in face-to-face visits.

Table 3 illustrates the results of a univariate analysis of the degree to which patients agreed that their health care provider met measures of satisfaction by race. Degrees of satisfaction were divided into 2 groups—the strongly agree and other answers groups—to calculate an OR. Participants who selected “White” as their primary ethnicity were used as the reference group.

Differences in racial perceptions of communication during telehealth visits persisted in a multivariate analysis even after adjusting for age, sex, household income, education level, and cancer type and stage (Table 4). In contrast, there were no significant racial differences in communication during face-to-face visits.

Table 4 illustrates the results of a multivariate analysis of the degree to which patients agreed that their health care provider met measures of satisfaction by race. Degrees of satisfaction were divided into 2 groups—the strongly agree and other answers groups—to calculate an OR. Sex, age, education, and household income were factored into the regression model. Participants who selected “White” as their primary ethnicity were used as the reference group.

Figure 1. Satisfaction among the telehealth and FTF groups. FTF: face-to-face.

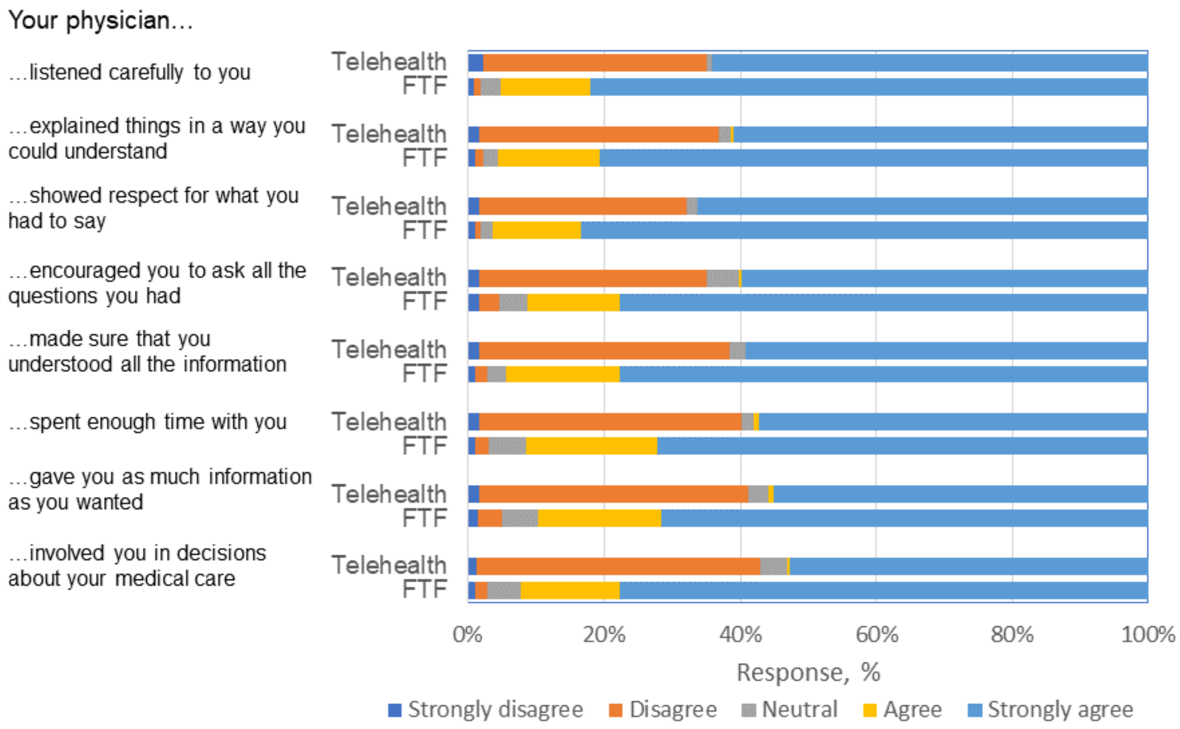

Table 2. Univariate analysis of results for the statement “Your physician listened carefully to you.”

Characteristic	Face-to-face group		Telehealth group	
	Odds ratio (95% CI)	*P* value	Odds ratio (95% CI)	*P* value
Sex				
Male (reference)	N/A[a]	N/A	N/A	N/A
Female	0.80 (0.27-2.34)	.68	2.58 (1.02-6.51)	.045[b]
Age (years)				
<50 (reference)	N/A	N/A	N/A	N/A
50-59	0.46 (0.10-2.05)	.31	0.40 (0.12-1.34)	.14
60-69	0.68 (0.16-2.91)	.60	0.46 (0.16-1.31)	.15
≥70	1.43 (0.32-6.36)	.64	0.72 (0.23-2.31)	.58
Education				
High school degree or less (reference)	N/A	N/A	N/A	N/A
Some college	1.83 (0.69-4.88)	.23	3.04 (1.06-8.78)	.04[b]
Associate’s or bachelor’s degree	1.41 (0.55-3.58)	.47	1.60 (0.62-4.10)	.33
Master’s or doctorate degree	1.64 (0.55-4.83)	.37	3.14 (0.92-10.79)	.07
Household income per year (US $)				
<30,000 (reference)	N/A	N/A	N/A	N/A
30,000-59,999	4.50 (1.30-15.65)	.02[b]	0.33 (0.11-1.02)	.053
60,000-89,999	0.95 (0.33-2.73)	.92	1.04 (0.35-3.12)	.95
≥90,000	1.79 (0.62-5.21)	.29	0.82 (0.30-2.25)	.70
Race				
White (reference)	N/A	N/A	N/A	N/A
Asian	1.19 (0.54-2.64)	.66	0.26 (0.10-0.64)	.004[b]
Native Hawaiian and other Pacific Islander	1.33 (0.43-4.16)	.63	0.20 (0.06-0.64)	.007[b]
Cancer type				
Breast (reference)	N/A	N/A	N/A	N/A
Lung, head and neck	1.92 (0.55-6.68)	.31	2.85 (0.73-11.20)	.13
Genitourinary and prostate	4.05 (0.88-18.61)	.07	2.27 (0.47-10.97)	.31
Gastrointestinal	1.77 (0.46-6.81)	.41	1.61 (0.57-4.56)	.37
Endometrial and ovarian	0.41 (0.17-0.97)	.04[b]	N/A	N/A
Blood	0.54 (0.12-2.39)	.42	1.52 (0.42-5.51)	.53
Cancer stage				
0-1 (reference)	N/A	N/A	N/A	N/A
2	0.89 (0.37-2.03)	.74	0.73 (0.28-1.86)	.51
3-4	0.37 (0.15-0.90)	.03[b]	0.75 (0.31-1.81)	.52
Unsure	0.39 (0.13-1.16)	.44	0.86 (0.30-2.44)	.78

[a] N/A: not applicable.

[b] Significant at the *P*<.05 level.

Table 3. Univariate analysis.

Statement and race	Face-to-face group		Telehealth group	
	Odds ratio (95% CI)	*P* value	Odds ratio (95% CI)	*P* value
"Your physician listened carefully to you"				
Asian	1.19 (0.54-2.64)	.66	0.26 (0.10-0.64)	.004[a]
NHOPI[b]	1.33 (0.43-4.16)	.63	0.20 (0.06-0.64)	.007[a]
"Your physician explained things in a way you could understand"				
Asian	0.87 (0.46-1.64)	.66	0.27 (0.12-0.61)	.003[a]
NHOPI	1.10 (0.41-2.91)	.86	0.21 (0.08-0.57)	.008[a]
"Your physician showed respect for what you had to say"				
Asian	1.02 (0.53-1.99)	.94	0.26 (0.11-0.63)	.003[a]
NHOPI	1.01 (0.38-2.71)	.98	0.18 (0.06-0.50)	.005[a]
"Your physician encouraged you to ask all of the cancer-related questions you had"				
Asian	0.97 (0.53-1.75)	.91	0.48 (0.23-0.98)	.04[a]
NHOPI	1.27 (0.51-3.19)	.61	0.24 (0.10-0.61)	.004[a]
"Your physician made sure that you understood all of the information he or she gave you"				
Asian	0.81 (0.44-1.49)	.49	0.46 (0.23-0.95)	.04[a]
NHOPI	1.09 (0.43-2.77)	.85	0.31 (0.12-0.76)	.02[a]
"Your physician spent enough time with you"				
Asian	0.76 (0.43-1.36)	.36	0.48 (0.24-0.97)	.04[a]
NHOPI	0.88 (0.38-2.06)	.77	0.27 (0.11-0.67)	.01[a]
"Your physician gave you as much cancer-related information as you wanted"				
Asian	0.64 (0.36-1.14)	.13	0.44 (0.22-0.88)	.03[a]
NHOPI	0.73 (0.32-1.69)	.47	0.30 (0.12-0.73)	.02[a]
"Your physician involved you in decisions about your medical care as much as you wanted"				
Asian	0.80 (0.43-1.51)	.50	0.45 (0.23-0.89)	.03[a]
NHOPI	0.63 (0.18-2.23)	.10	0.33 (0.13-0.79)	.02[a]

[a] Significant at the $P<.05$ level.

[b] NHOPI: Native Hawaiian and other Pacific Islander.

Table 4. Multivariate analysis.

Statement and race	Face-to-face group		Telehealth group	
	Odds ratio (95% CI)	*P* value	Odds ratio (95% CI)	*P* value
"Your physician listened carefully to you"				
Asian	1.25 (0.60-2.62)	.34	0.27 (0.11-0.65)	.004[a]
NHOPI[b]	1.39 (0.47-4.15)	.54	0.20 (0.06-0.64)	.007[a]
"Your physician explained things in a way you could understand"				
Asian	1.26 (0.60-2.62)	.44	0.26 (0.11-0.63)	.002[a]
NHOPI	1.62 (0.54-4.87)	.36	0.24 (0.08-0.76)	.01[a]
"Your physician showed respect for what you had to say"				
Asian	1.32 (0.60-2.88)	.36	0.25 (0.10-0.63)	.004[a]
NHOPI	1.28 (0.41-3.99)	.63	0.19 (0.06-0.64)	.005[a]
"Your physician encouraged you to ask all of the cancer-related questions you had"				
Asian	1.10 (0.56-2.19)	.69	0.46 (0.21-1.11)	.07
NHOPI	1.40 (0.50-3.93)	.49	0.23 (0.08-0.68)	.006[a]
"Your physician made sure that you understood all of the information he or she gave you"				
Asian	1.04 (0.52-2.07)	.43	0.49 (0.23-1.06)	.08
NHOPI	1.51 (0.53-4.33)	.88	0.35 (0.12-1.00)	.049[a]
"Your physician spent enough time with you"				
Asian	0.86 (0.45-1.63)	.75	0.47 (0.22-1.01)	.07
NHOPI	1.12 (0.43-2.89)	.83	0.29 (0.10-0.83)	.02[a]
"Your physician gave you as much cancer-related information as you wanted"				
Asian	0.71 (0.37-1.38)	.13	0.47 (0.22-0.99)	.049[a]
NHOPI	0.90 (0.35-2.35)	.47	0.38 (0.14-1.10)	.06
"Your physician involved you in decisions about your medical care as much as you wanted"				
Asian	0.96 (0.47-1.95)	.98	0.43 (0.20-0.92)	.04[a]
NHOPI	0.67 (0.25-1.78)	.43	0.40 (0.14-1.14)	.06

[a] Significant at the *P*<.05 level.

[b] NHOPI: Native Hawaiian and other Pacific Islander.

Discussion

Principal Findings

Overall, patients with cancer in our racially diverse cohort were content with patient-physician communication. However, the patients who experienced telehealth visits were less satisfied than their counterparts who underwent face-to-face visits. Importantly, Asian patients and NHOPI patients were significantly less content with patient-physician communication during telehealth visits when compared to White patients—a disparity that was not evident in face-to-face visits.

The difference in satisfaction demonstrated between the two types of patient visits differs from the results of prior studies that demonstrated equivalent satisfaction with communication between face-to-face encounters and telehealth encounters [27,28]. In these prior studies, telehealth was an accepted alternative and was pursued due to the long distances between the patients' homes and the clinics. In our telehealth group, lower ratings may have occurred because these patients viewed face-to-face visits as the standard of care and only converted to telehealth due to the COVID-19 pandemic. In addition, our face-to-face group consisted only of cancer survivors who had received definitive cancer therapy with curative intent, whereas our telehealth group included patients in follow-up care and those who were being actively treated with both curative intent and palliative intent. These differences may have adversely impacted perceptions of communication among the telehealth patients, as patients with a poor health status tend to report worse experiences [29].

Our study showed that Asian and Pacific Islander patients were significantly less satisfied with communication with their physicians during telehealth visits when compared to White patients. This racial disparity was not present in face-to-face visits and persisted even after adjusting for age, education level, and household income. Racial differences in perceptions of communication among patients with cancer have been previously reported. For instance, Asian cancer survivors have reported poorer follow-up communication and care quality [25] compared to those reported by White cancer survivors. Our study however is the first to demonstrate a racial disparity in communication exclusively for those who experienced telehealth visits. A study assessing telemedicine perspectives in Native Hawaiian and Alaska Native communities highlighted the need for a culturally appropriate telehealth approach. The focus groups stressed that a successful visit hinged on understanding the importance of the communication practices of racial minority patients, such as processing before speaking [21]. Methods of practicing culturally sensitive care during telehealth visits should be explored, given the increasing efforts to reduce barriers to telehealth for racial minority patients [30].

In contrast to other studies demonstrating racial disparities in communication [25], our study found no significant racial differences in the face-to-face setting. The higher level of satisfaction that we observed among racial minority patients may have been due to the difference in racial distribution between Hawaii and the continental United States. Hawaii is a majority-minority state, and racial minority patients and White patients with cancer receive care at the same clinical centers. The majority of cancer health care providers in Hawaii are also racial minority individuals, and racial concordance between patients and health care providers [31-33] has been shown to improve communication. It is conceivable that the oncology providers at Hawaii's community cancer centers may display greater cultural competence when compared to the average oncology provider [34].

To our knowledge, this is the first study to differentiate Asian perceptions and NHOPI perceptions of communication in telehealth encounters. When asked about the time and encouragement given by their health care providers to ask questions during telehealth visits, NHOPI patients gave lower scores than those given by White patients. NHOPI patients have stressed that taking time to talk and verifying their understanding were ways to show genuine concern and care [21]. These steps may not have been taken, as telehealth was abruptly introduced not only to the patients but also to the health care providers, who may not have been aware of these particular NHOPI perceptions. Further, when asked about the information that they were given in telehealth visits and their involvement during these visits, Asian patients gave lower scores than those given by White patients, which is consistent with studies showing lower perceived self-efficacy and control over care among Asian patients [25]. Health care providers caring for Asian individuals and NHOPI individuals should be attentive to these communication disparities in telehealth visits.

Limitations

This study has several strengths. The participants were treated at community cancer centers, which makes our findings generalizable to the majority of patients with cancer in the United States [35]. The majority of patients (455/593, 76.7%) comprising the study population were from racial minority groups who are typically underrepresented in cancer studies. Specifically, we incorporated a large number of NHOPI patients with cancer, for whom there are limited data on perceptions of communication and telemedicine. There are also limitations to our study. First, as stated above, the face-to-face group patients were all cancer survivors, per the definition provided by the Commission on Cancer [36], as they received definitive cancer therapy with a curative intent, while the telehealth patients included both cancer survivors and patients with cancer on active treatment. Second, the patients and health care providers viewed face-to-face visits as the norm and only converted to telehealth visits due to the COVID-19 pandemic. Although these differences may have affected the overall satisfaction levels of the two groups, they were not expected to account for the racial disparity seen exclusively in the telehealth group. Third, although we adapted our communication assessment from a previously published study [25], we did not use a validated communication assessment tool. However, we showed significant racial differences across a number of communication questions, and it is likely that a disparity would have been similarly demonstrated by a validated tool. Fourth, we did not capture information on English language proficiency. Although all eligible patients were able to communicate in English, it is conceivable that English being a second language was more prevalent among Asian patients and NHOPI patients than among White patients, and this could have impacted satisfaction with communication more greatly in telemedicine visits than in face-to-face visits [30].

Conclusion

We present a study of patient-provider communication among a racially diverse population of patients with cancer that provides insight into racial disparities in telehealth visits that are not seen in face-to-face encounters. With the increasing popularity of telehealth, it is likely that telehealth visits will continue beyond the COVID-19 pandemic. Further investigation is needed to understand the strengths and limitations of telehealth and provide optimal care. The observation that telehealth increases racial disparities in health care satisfaction should prompt further exploration. An improved understanding of this issue will aid health care providers in making decisions about the delivery of care for their patients.

Conflicts of Interest

None declared.

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Abbreviations

APECC: Assessment of Patient Experiences of Cancer Care
NHOPI: Native Hawaiian and other Pacific Islander
OR: odds ratio

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Original Paper

Meditation Mobile App Developed for Patients With and Survivors of Cancer: Feasibility Randomized Controlled Trial

Jennifer Huberty[1*], PhD; Nishat Bhuiyan[2*], PhD; Megan Puzia[3*], MSc; Lynda Joeman[4*], BSc; Linda Larkey[5*], PhD; Ruben Mesa[6*], MD

[1]Mays Cancer Center, University of Texas Health San Antonio MD Anderson, Phoenix, TX, United States
[2]College of Health Solutions, Arizona State University, Phoenix, AZ, United States
[3]Behavioral Research and Analytics, LLC, Salt Lake City, UT, United States
[4]Lynda Joeman Research Consultancy, Tonbridge, United Kingdom
[5]Edson College of Nursing and Health Innovation, Arizona State University, Phoenix, AZ, United States
[6]Mays Cancer Center, University of Texas Health San Antonio MD Anderson, San Antonio, TX, United States
[*]all authors contributed equally

Corresponding Author:
Jennifer Huberty, PhD
Mays Cancer Center
University of Texas Health San Antonio MD Anderson
7979 Wurzbach Rd.
Phoenix, TX, 78229
United States
Phone: 1 402 301 1304
Email: jenhubertyphd@gmail.com

Abstract

Background: To address the unmet need for a commercial cancer-specific meditation app, we leveraged a long-standing partnership with a consumer-based app (ie, *Calm*) to develop the first commercial meditation app prototype adapted specifically for the needs of patients with cancer. Input was obtained at both the individual user and clinic levels (ie, patients with and survivors of cancer and health care providers).

Objective: This study aimed to determine the feasibility of a cancer-specific meditation app prototype.

Methods: Patients with and survivors of cancer who were recruited and enrolled in the feasibility randomized controlled trial were asked to use the prototype app daily (≥70 minutes per week) for 4 weeks. Participants completed web-based weekly questionnaires and a final poststudy questionnaire and were asked to participate in an optional web-based poststudy interview. The questionnaires and interviews covered the following feasibility categories: acceptability, demand, practicality, and adaptation.

Results: A total of 36 patients with and survivors of cancer completed the baseline questionnaire, 18 completed the final questionnaire, and 6 completed the optional interviews. Weekly and poststudy questionnaires indicated high overall enjoyment, ease of use, and satisfaction with the app content, aesthetics, and graphics. The objective use data indicated that the average total app use rate was 73.39 (SD 7.12) minutes per week. Interviews (N=6) revealed positive and mixed responses to the app prototype and informative differences related to preferences for narrators, emotional content, and meditation teaching but an overall appreciation for the variety of options.

Conclusions: The most likely candidates for moving from cancer-specific meditation apps to dissemination are through partnering with the industry, in which name recognition and market distribution are already established (even showing a base of users from the targeted population with cancer). This study established the feasibility of a cancer-specific mobile meditation app prototype for patients with and survivors of cancer, using a commercially available app. The quantitative and qualitative data demonstrated the acceptability, demand, practicality, and adaptation of the prototype. Improvements suggested by the participants will be considered in the final app design before testing the efficacy of the app in a future study.

Trial Registration: Clinicaltrials.gov NCT05459168; https://clinicaltrials.gov/ct2/show/record/NCT05459168

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KEYWORDS

cancer; mobile health; mHealth; meditation; feasibility; mobile phone

Introduction

Background

The need for effective nonpharmacologic strategies, such as meditation, to manage the debilitating and costly chronic symptom burden faced by patients with and survivors of cancer has been well established [1-3]. Furthermore, there is a clear need to translate in-person delivered meditation programs into more accessible and maintainable formats for patients with and survivors of cancer owing to the costs, limited sustainability, and patient-reported barriers (eg, distance, scheduling, and symptom burden) associated with in-person programs [4]. One promising method for delivering meditation programs to patients with and survivors of cancer is the use of mobile health apps. Research has clearly demonstrated the short-term benefits of mobile apps and web-based meditation programs [5,6]. Reports indicate that as many as 97% of patients with and survivors of cancer have access to smartphones and are willing to use app-based meditation [5,6].

Evidence suggests that more general meditation apps do not sufficiently meet the unique physical, emotional, and social needs of patients with and survivors of cancer [7-9]. Populations with cancer may have specific fears (fear of cancer progression, recurrence, etc) and stressors that can arise during meditation, physical limitations to seated meditation, symptom-monitoring needs, and survivor-related social support needs specific to meditation that could be addressed within a cancer-specific meditation app [7-9]. Furthermore, there are significant limitations associated with existing commercial meditation apps, including not being specifically tailored toward populations with cancer and not including inputs from patients with and survivors of cancer before development. To date, there are no commercially available evidence-based apps for patients with cancer that are specifically devoted to meditation. A cancer-specific meditation app is necessary to ensure clinical acceptability, effectiveness, and safety for this population. The most likely candidates for moving from cancer-specific meditation apps to dissemination are through partnering with the industry, in which name recognition and market distribution are already established (even showing a base of users from the targeted population with cancer).

The primary author developed a partnership with a consumer-based app (ie, *Calm*) to conduct investigator-initiated research with broad reach and potential for sustainability in a variety of populations. We leveraged the long-standing partnership with *Calm* to develop the first commercial meditation app prototype adapted specifically for the needs of patients with cancer, titled *Calm for Cancer*. Details regarding the development of this app have been reported elsewhere [10]. Briefly, the development of the *Calm for Cancer* app was guided by the Integrate, Design, Assess, and Share framework [11] and input from an advisory committee of patients with and survivors of cancer. We worked with not-for-profit partners to ensure that there was representation of the advisory committee (end users at both the individual and clinic levels) who contributed to the prototype design and development. Specifically, the committee included patients with and survivors of cancer, health care providers, and subscribers of the parent app, *Calm*, who participated in surveys, daily journals, and focus groups. Insights from the advisory committee were integrated into the development process to build the *Calm for Cancer* prototype's content and features [10].

Objectives

The purpose of this paper was to report the findings of a 4-week feasibility randomized controlled trial (RCT) of the *Calm for Cancer* app among patients with and survivors of cancer. Using the feasibility model by Bowen et al [12] as a guiding framework, we aimed to determine the acceptability, demand, practicality, and adaptation of the *Calm for Cancer* app using questionnaires and objective use data. The secondary aim was to explore the associations between app use and satisfaction outcomes. Finally, we aimed to gain further insight into the overall experiences of the patients with and survivors of cancer with the meditation app prototype via qualitative in-depth interviews. The findings will help develop the next phase of the prototype to be tested for its efficacy.

Methods

Ethics Approval

All study materials and procedures were approved by the institutional review board of Arizona State University (protocol ID STUDY00011444).

Overview

Study recruitment took place between October 7, 2021, and December 10, 2021, with participants enrolled in the study on a rolling basis. Patients with and survivors of cancer were recruited nationwide, using internet-based strategies, including social media (ie, Facebook, Twitter, and Instagram), various cancer groups' and organizations' listservs and websites, closed social media groups, and by contacting patients with cancer who were ineligible for prior web-based studies and who had consented to being contacted about future research opportunities. The research team provided flyers to recruitment contacts, which included a description of the study and a link to the web-based eligibility screening survey. In an effort to recruit racially and ethnically diverse patients, recruitment materials included the statement, "We are looking for patients with and survivors of cancer who represent diverse racial and ethnic groups, gender, and cancer types and those who have never meditated." Partner cancer groups, organizations, and closed social media groups were asked to focus on diverse patients when sharing recruitment materials. Patients and survivors who were interested in participating completed the eligibility survey via REDCap (Research Electronic Data Capture; Vanderbilt University) [13]. Potential participants were eligible for the study if they (1) had a cancer diagnosis within the past 2 years, (2) were aged ≥18 years, (3) owned an iPhone or iPad with iOS 9.0 or later, (4) were willing to download a mobile app, (5) were able to read and understand English, and (6) were not currently engaged in a regular meditative movement practice (eg, yoga, tai chi, or qi gong with substantial meditation) for ≥60 minutes per week in the past 6 months. The eligibility survey took approximately 5 to 10 minutes to complete. Participants who did not meet the eligibility criteria were sent an email notification regarding their eligibility status and the reasons for ineligibility.

Eligible participants were emailed a link to an informed consent page via REDCap with details about the requirements of the study as well as potential risks and benefits. Those who agreed to participate were instructed to type their electronic signatures, which constituted their consent to participate in the study. After receiving the signed consent form, participants were sent an email containing (1) an overview of the study procedures, (2) a link to the baseline demographic questionnaire, (3) instructions for downloading and using the *Calm for Cancer* app prototype, and (4) instructions and an invitation link to join a private *Calm for Cancer* Facebook support group (detailed in further sections). In addition to the baseline demographic questionnaire, participants were asked to complete 4 weekly satisfaction questionnaires on the web via REDCap and a final overall study satisfaction questionnaire via REDCap. The weekly satisfaction questionnaires took approximately 5 minutes to complete, and the final overall study satisfaction questionnaire took approximately 15 to 20 minutes to complete. Finally, after completing the 4-week feasibility RCT, participants were given the option to participate in an in-depth interview to discuss their overall experience of using the *Calm for Cancer* app. The interviews were conducted by a member of the research team via Zoom teleconferencing software (Zoom Video Communications). The interview questions are presented in Multimedia Appendix 1. The participants had the option of not participating in the interview if they did not want their interviews to be recorded. Each interview took approximately 30 minutes to complete. Participants received US $5 for submitting each weekly satisfaction questionnaire, US $20 for completing the final poststudy satisfaction questionnaire, and US $20 for completing the virtual poststudy interview (up to US $60 for completing all study questionnaires and the interview).

The Calm for Cancer Prototype

The *Calm for Cancer* prototype was a stand-alone app available for download in the Apple store and only available to research participants. Participants were asked to use the *Calm for Cancer* prototype for 4 weeks at any time for at least 10 minutes per day but were encouraged to use it as much as they would like, mimicking how a new paying member would use the original *Calm* app. This dose was chosen because positive effects have been reported even after 10 minutes of daily meditation practice [14-16], which is consistent with our work in patients with hematologic conditions [5,6]. Participants were also encouraged to explore and use the different features of the app, such as the optional prompts to rate the session at the end of the meditation sessions, setting meditation reminders, and tracking their participation within the app.

The *Calm for Cancer* prototype contained a variety of guided meditations and breathing exercises that were developed based on our formative work with patients with and survivors of cancer and health care providers [8]. These include (1) introductory meditations: 7 days of basic meditation that introduced meditation practices to the user; (2) calming the chaos and uncertainty meditations: a series of 23 brief daily meditations that were guided by storytelling; (3) meditations with an oncologist: a series of meditations to help the user understand the science behind meditation and its benefits; (4) meditations for the authentic self: a series of guided meditations for self-love; (5) power of breath: a series of breath work practices to cultivate gratitude, self-kindness and so on; (6) reset your emotions: a series of brief 2- to 3-minute meditation sessions to help reset emotions in times of panic and anxiety (eg, in the doctor's office); (7) meditations with a survivor of cancer: a series of meditations led by a survivor of cancer; (8) content from the original *Calm* app: various guided meditations and master classes not specific but relevant to patients with and survivors of cancer to help with processing and acceptance, managing emotions, and working with anxiety and fear; (9) sleep stories from the original *Calm* app: narrated fictional tales to help promote sleep; and (10) calming music: an assortment of relaxing music that patients with and survivors of cancer can listen to during treatments or at their own leisure.

The app was built upon a variety of behavior-change strategies known to improve behavior, as well as insights from patients with and survivors of cancer and the advisory committee. First, meditations and other content in the *Calm for Cancer* prototype app were led by yoga instructors and meditation teachers specializing in cancer or who had personal experience with cancer (ie, themselves or immediate family), spiritual teachers, and oncologists. The teachers were male and female and represented a variety of racial minority groups. Tailored interventions have been shown to be more effective in improving outcomes than nontailored interventions. In addition, patients with and survivors of cancer may be more receptive to content when guided by someone with a similar experience and when a sense of relatedness is felt [17,18]. Second, the *Calm for Cancer* prototype included a feature that allowed participants to complete check-ins in which they could log their emotions, self-reflections, gratitude, and sleep. Patients and survivors wanted the ability to monitor how they feel and observe the changes over time. Providing feedback or SMS text messaging based on user performance may also help increase adherence, and users are more likely to use an app with a self-monitoring mechanism [19,20]. Third, because patients with and survivors of cancer want to connect with others to support belonging, and social media-based support groups for patients with and survivors of cancer have increased knowledge and decreased anxiety in app-based interventions, the *Calm for Cancer* prototype also allowed the user to share their meditation participation with others via social media.

Facebook Group

Because our formative work suggested that patients with and survivors of cancer wanted a place to discuss their meditation participation (but not within the app or with their physician), the research team developed a private *Calm for Cancer* support group on Facebook. The Facebook group served as an informal platform where participants could connect with other study participants to share their experiences with meditation related to their cancer. The Facebook group had a moderator (ie, a member of the research team) and rules about what could and could not be posted (eg, no derogatory comments or profanity). Participants were asked to log on to the page at least once per week *but were not required to adhere to any other criteria for engagement (eg, number of posts) other than the weekly log-in*. Every week, the moderator posted a discussion prompt to encourage participation; the complete list of Facebook discussion prompts is available in Multimedia Appendix 2.

Measures

Demographics

Participants self-reported the following demographic characteristics at baseline: sex, ethnicity, race, annual income, education, employment status, marital status, and cancer diagnosis.

Feasibility

Feasibility questionnaires and interviews were based on the feasibility model by Bowen et al [11]. Bowen et al [11] posit that for an intervention to be worthy of testing its efficacy, relevant questions must be addressed within feasibility. The key areas of focus for feasibility according to Bowen et al [11] were used here and included the following: (1) acceptability (ie, satisfaction, perceived appropriateness, and perceived positive and negative effects), (2) demand (ie, use of the app, interest, or intention to use), (3) practicality (ie, how it makes them feel and ease of use), and (4) adaptation (ie, suggestions for modifications to improve the app to better meet the unique needs of patients with and survivors of cancer). Bowen et al [11] suggest that methodologies used to address each area can vary and be creatively combined to fit the setting, community, or population under study. Feasibility outcomes were assessed via 4 weekly questionnaires, a final poststudy questionnaire, and in-depth poststudy interviews. The questionnaires and interviews were developed by a team of research investigators (ie, oncologists and researchers in cancer, mobile apps, and meditation).

Use (Demand)

In addition to the questionnaires and interviews, the demand for the app was further assessed through objective participation (ie, use data). Participation (ie, use data) were automatically tracked within the *Calm for Cancer* prototype over 4 weeks and provided to the research team by *Calm*. The objective participation (ie, use) data included the total number of meditation sessions completed within the app, total number of minutes using the app, and specific components used (ie, master class, series, music, sleep story, freeform, and sequential).

Interviews

The purpose of the qualitative in-depth interviews was to gain further insight into the participants' overall experience using the *Calm for Cancer* app prototype. Interview questions included, "Tell us about your experience using the meditation app prototype," "Were there things that were missing from your experience with the app that you would have benefited from?" and "Do you think other patients with and survivors of cancer will have any difficulty accessing or using the meditation app? Describe why or why not." The complete semistructured interview guide is available in Multimedia Appendix 1.

Statistical Analysis

Descriptive statistics and frequencies were computed to describe sample baseline characteristics and to summarize weekly self-reported feasibility outcomes, poststudy self-reported feasibility outcomes, and objective use data. As an additional exploratory analysis, linear regression models were used to examine whether app use (ie, total minutes of app use per week and total completed meditation sessions per week) predicted participants' self-reported overall enjoyment and satisfaction with content, ease of use, aesthetics, and graphics. All statistical analyses were performed using SPSS (version 28.0; IBM Corp), with significance inferred at $P<.05$.

Qualitative Analysis

The interview transcripts were imported into NVivo 12 qualitative analysis software (QSR International) for coding and analysis. Top-level themes were identified deductively based on the main information requirements of the study and topics covered in the interview guide. Within these, lower-level themes and findings were inductively identified from the interview transcripts.

Results

Overview

A total of 120 patients with cancer completed the eligibility screening survey, and 50 (41.7%) met the eligibility criteria and consented to participate in the study. Of these 50 participants, 36 (72%) completed the baseline questionnaire, of these 36 participants, 18 (50% of baseline questionnaire completers) participants completed the final poststudy questionnaire. Reasons for dropout included 17 participants lost to follow-up (ie, participants who did not complete additional surveys and who were unable to be contacted further) and 1 participant who declined further participation. A total of 6 participants completed the optional poststudy interviews. As shown in Table 1, most participants were female, non-Hispanic, White, and had a relatively high socioeconomic status (ie, had completed a Bachelor's degree or higher, were employed, and had an annual household income of ≥US $100,000). The most common type of cancer was blood cancer (10/36, 28%), followed by breast cancer (9/36, 25%). Approximately half of the participants (18/36, 50%) received their first cancer diagnosis between 1 and 3 years ago.

As shown in Table 2, weekly questionnaire responses indicated enjoyment, ease of use, and satisfaction with the meditation app prototype.

As shown in Table 3, poststudy questionnaire responses also indicated enjoyment, perceived ease of use, satisfaction with the meditation app content, and satisfaction with the meditation app aesthetics and graphics after the study. Similar to the weekly survey responses, most participants (10/11, 91%) enjoyed or very much enjoyed using the meditation app prototype; found the meditation app prototype easy or very easy to use; and were satisfied or very satisfied with the meditation content, aesthetics, and graphics. Most users found that the length of meditation sessions was just right (9/11, 82%) and found that the app was helpful for improving or managing symptoms or difficulties related to cancer (10/11, 91%). All participants (11/11, 100%) who responded indicated that they would recommend the *Calm for Cancer* meditation app prototype to other patients with and survivors of cancer and that they were likely or extremely likely to continue using the app. Participation in the *Calm for Cancer* Facebook group was low among app users; a total of 14 participants accepted the invitation and joined the group, and only 4 participants responded to weekly discussion posts. In the poststudy period, most participants (7/9, 78%) rated their overall satisfaction with the Facebook group as neutral.

On average, enrolled participants (who completed surveys at least at week 1) used the app (ie, total app use, including meditations and sleep content) for 73.39 (SD 7.12) minutes per week and completed 4.92 (SD 1.05) sessions per week. More specifically, participants completed an average of 4.62 (SD 1.29) meditation sessions, 0.19 (SD 0.25) music sessions, and 0.11 (SD 0.12) sleep stories per week, which corresponds to 60.33 (SD 5.75) minutes of meditation, 8.41 (SD 11.23) minutes of music, and 4.63 (SD 5.36) minutes of sleep stories. Table 4 shows the breakdown of weekly use of specific types of meditation. Across all weeks, series meditations were the most used content type.

Finally, as shown in Tables 5 and 6, linear regression models demonstrated that the average weekly app use (measured both as average minutes per week and average sessions per week) was not significantly associated with poststudy reports of enjoyment using the app, ease of app use, satisfaction with app content, or satisfaction with the app’s aesthetics and graphics.

Table 1. Participant demographic characteristics (N=36).

	Participants, n (%)
Sex	
Female	30 (83)
Male	6 (17)
Race	
White	29 (81)
Black or African American	1 (3)
Asian or Asian American	3 (8)
Alaska Native or Pacific Islander	1 (3)
Mixed race	2 (6)
Ethnicity	
Hispanic or Latino	5 (13)
Non-Hispanic or Latino	31 (87)
Education	
High-school diploma	3 (8)
Some college	4 (11)
Associate or 2-year degree	3 (8)
Bachelor’s degree	13 (36)
Graduate school or above	13 (36)
Employment	
Employed	23 (64)
Unemployed or unable to work	9 (25)
Retired	2 (6)
Homemaker	2 (6)
Annual income (US $)	
<20,000	2 (6)
20,001 to 40,000	1 (3)
40,001 to 60,000	5 (14)
60,001 to 80,000	7 (19)
80,001 to 100,000	2 (6)
>100,000	19 (53)
Marital status	
Single	11 (31)
Partnered or in a relationship	3 (8)
Married	19 (53)
Divorced	3 (8)
Type of cancer	
Blood	10 (28)
Breast	9 (25)
Gynecologic	6 (17)
Thyroid	4 (11)
Kidney	2 (6)
Bone	2 (56)

	Participants, n (%)
Ampullary	1 (3)
Appendiceal	1 (3)
Rectal	1 (3)
First cancer diagnosis	
<3 months ago	4 (11)
3 to <6 months ago	2 (6)
6 months to <1 year ago	7 (19)
1 to 3 years ago	18 (50)
>3 years ago	5 (14)

Table 2. Average weekly questionnaire responses.

	Study week, n (%)			
	Week 1 (N=22)	Week 2 (N=13)	Week 3 (N=12)	Week 4 (N=11)
Overall enjoyment with using the meditation app prototype				
Very much enjoyed	7 (33)	8 (62)	7 (58)	6 (55)
Enjoyed	7 (33)	3 (23)	3 (25)	3 (27)
Neutral	4 (19)	1 (8)	2 (17)	1 (9)
Did not enjoy	1 (5)	1 (8)	0 (0)	0 (0)
Did not enjoy at all	2 (10)	0 (0)	0 (0)	0 (0)
Did not respond	0 (0)	0 (0)	0 (0)	1 (9)
Overall ease of use of the meditation app prototype				
Very easy to use	9 (43)	9 (64)	5 (42)	6 (55)
Easy to use	6 (29)	1 (7)	5 (42)	2 (18)
Neutral	3 (14)	2 (14)	1 (8)	2 (18)
Difficult to use	1 (5)	2 (14)	0 (0)	1 (9)
Very difficult to use	2 (10)	0 (0)	0 (0)	0 (0)
How satisfied were you this week with the meditation content?				
Very satisfied	10 (45)	7 (50)	3 (25)	5 (45)
Satisfied	9 (41)	6 (43)	8 (67)	6 (55)
Neutral	2 (9)	1 (7)	1 (8)	0 (0)
Dissatisfied	1 (5)	0 (0)	0 (0)	0 (0)
Very dissatisfied	0 (0)	0 (0)	0 (0)	0 (0)
How satisfied were you this week with the sleep content?				
Very satisfied	3 (38)	3 (50)	1 (14)	2 (40)
Satisfied	3 (38)	1 (17)	5 (71)	2 (40)
Neutral	2 (25)	1 (17)	1 (14)	1 (20)
Dissatisfied	0 (0)	1 (17)	0 (0)	0 (0)
Very dissatisfied	0 (0)	0 (0)	0 (0)	0 (0)
How satisfied were you this week with the music content?				
Very satisfied	3 (30)	3 (33)	1 (20)	1 (17)
Satisfied	6 (60)	5 (56)	3 (60)	4 (67)
Neutral	1 (10)	1 (11)	0 (0)	1 (17)
Dissatisfied	0 (0)	0 (0)	1 (20)	0 (0)
Very dissatisfied	0 (0)	0 (0)	0 (0)	0 (0)
How satisfied were you this week with the breathing exercises content?				
Very satisfied	4 (27)	4 (40)	1 (25)	2 (40)
Satisfied	8 (53)	5 (50)	3 (75)	3 (60)
Neutral	3 (20)	1 (10)	0 (0)	0 (0)
Dissatisfied	0 (0)	0 (0)	0 (0)	0 (0)
Very dissatisfied	0 (0)	0 (0)	0 (0)	0 (0)

Table 3. Poststudy questionnaire responses (N=11).

	Participants, n (%)
Overall enjoyment with using the meditation app prototype	
Very much enjoyed	6 (55)
Enjoyed	4 (36)
Neutral	1 (9)
Did not enjoy	0 (0)
Did not enjoy at all	0 (0)
Overall ease of use of the meditation app prototype	
Very easy to use	7 (64)
Easy to use	3 (27)
Neutral	0 (0)
Difficult to use	1 (9)
Very difficult to use	0 (0)
Overall satisfaction with meditation app content	
Very satisfied	6 (55)
Satisfied	4 (36)
Neutral	1 (9)
Dissatisfied	0 (0)
Very dissatisfied	0 (0)
Overall satisfaction with meditation app aesthetics and graphics	
Very satisfied	7 (64)
Satisfied	2 (18)
Neutral	0 (0)
Dissatisfied	1 (9)
Very dissatisfied	1 (9)
Overall, how helpful was using the meditation app prototype in improving or managing symptoms or difficulties related to your cancer?	
Very helpful	4 (36)
Somewhat helpful	6 (55)
Not too helpful	1 (9)
Really not helpful	0 (0)
I thought that the length of the meditation sessions was...	
Just right	9 (82)
Too long	0 (0)
Too short	2 (18)
Did you use the reminder feature when using the meditation app prototype?	
Yes	7 (64)
No	4 (36)
How useful were the reminders to you?	
Very useful	4 (36)
Somewhat useful	3 (27)
Really not very useful	0 (0)
Not applicable	4 (36)
Did you use the tracking-streaks feature offered in the meditation app prototype?	

	Participants, n (%)
Yes	7 (64)
No	4 (36)
How useful did you find the tracking streaks feature in promoting regular meditation or use of the app?	
Very useful	4 (36)
Somewhat useful	3 (27)
Really not very useful	0 (0)
Not applicable	4 (36)
Did you use the share status feature offered in the meditation app prototype?	
Yes	10 (91)
No	1 (9)
If yes, how often did you share your status with friends or on social media?	
Very often	0 (0)
Often	0 (0)
Occasionally	1 (9)
Never	0 (0)
Not applicable	10 (91)
Would you recommend using the meditation app prototype for other patients with and survivors of cancer?	
Yes	13 (100)
No	0 (0)
How likely are you to continue using the meditation app prototype in the future?	
Extremely likely	7 (64)
Likely	4 (36)
Unlikely	0 (0)
Extremely unlikely	0 (0)
Please rate your satisfaction with the *Calm for Cancer* Facebook group	
Very satisfied	0 (0)
Satisfied	2 (22)
Neutral	7 (77)
Dissatisfied	0 (0)
Very dissatisfied	0 (0)

Table 4. App use by study week and meditation type.

	Study week			
	Week 1	Week 2	Week 3	Week 4
Completed sessions, mean (SD)				
Master class	0.11 (0.58)	0.30 (1.34)	0.00 (0.00)	0.00 (0.00)
Series	6.15 (5.48)	4.05 (3.73)	3.12 (4.06)	3.46 (4.16)
Freeform	0.04 (0.19)	0.00 (0.00)	0.12 (0.49)	0.15 (0.55)
Sequential	0.04 (0.19)	0.45 (1.61)	0.12 (0.49)	0.38 (1.39)
Total minutes used, mean (SD)				
Master class	2.28 (11.87)	4.68 (20.94)	0.00 (0.00)	0.00 (0.00)
Series	63.09 (67.44)	48.34 (58.77)	49.79 (88.90)	51.45 (78.37)
Freeform	0.33 (1.70)	0.00 (0.00)	1.47 (6.06)	3.19 (11.51)
Sequential	0.48 (2.50)	6.35 (22.99)	1.53 (6.31)	8.35 (30.09)

Table 5. Linear regression models exploring associations between minutes of app use and participants' overall enjoyment, ease of use, satisfaction with content, and satisfaction with aesthetics and graphics.

Feasibility outcome	b (SE; 95% CI)	*t* test (*df*)	*P* value
Enjoyment with using the app	−0.001 (0.001; −0.003 to 0.001)	−0.87 (12)	.40
Ease of use of the app	−0.002 (0.001; −0.005 to 0.001)	−1.75 (12)	.11
Satisfaction with app content	−0.001 (0.001; −0.003 to 0.001)	−0.90 (12)	.38
Satisfaction with aesthetics	−0.002 (0.002; −0.006 to 0.001)	−1.34 (12)	.20

Table 6. Linear regression models exploring associations between total completed app sessions and participants' overall enjoyment, ease of use, satisfaction with content, and satisfaction with aesthetics and graphics.

Feasibility outcome	b (SE; 95% CI)	*t* test (*df*)	*P* value
Enjoyment with using the app	−0.016 (0.026; −0.073 to 0.040)	−0.63 (12)	.54
Ease of use of the app	−0.043 (0.030; −0.109 to 0.022)	−1.45 (12)	.17
Satisfaction with app content	−0.020 (0.026; −0.076 to 0.035)	−0.79 (12)	.44
Satisfaction with aesthetics	−0.039 (0.042; −0.131 to 0.052)	−0.93 (12)	.37

Qualitative Themes From Interviews

Because the qualitative research was based on a small subsample of participants, many of the responses were quite specific to individuals, and the findings are therefore reported in some detail within themes, along with the number of participants providing different types of responses. Verbatim quotes were also used to illustrate key points and capture the experiences of the participants in their own words.

Overall Experience of Using the App

Of the 6 interview participants, 4 (67%) reported very positive experiences of using the app:

> *I actually loved it. I loved everything about it. It was way more than I thought what meditation would be about. Like I said, it opened my eyes to the new world of meditation. I just thought it was fabulous.*

A total of 33% (2/6) of participants indicated that their experiences had been more mixed, with some aspects that they had not enjoyed. One of the participants with mixed experiences explained that they preferred to use faith-based practices to cope with the experience of having cancer. Because the non–faith-based app did not resonate so much with this participant, meditating for the study felt "more like homework," although they did report some benefits, "I think in some ways it helped, it was relaxing as a whole, but it's not my usual go-to.*"* The other participant who reported mixed experiences explained that these were due to the features of the app that they had disliked, such as some of the narrators' voices or difficulties in navigating the app. Regardless of their overall level of satisfaction with the app, all 100% (6/6) of participants were able to identify features that they disliked as well as those that they liked, as reported in the following sections.

What Participants Liked About the Calm for Cancer App

Specific Narrators

When asked what they had particularly liked about the *Calm for Cancer* app, 67% (4/6) of interviewees mentioned the specific narrators (ie, Tamara Levitt and Teri Richardson) that they had especially enjoyed listening to because of their voices, content, or relatability.

In all, 50% (3/6) of interviewees stressed the importance of relatability when selecting narrators for an app designed for patients with cancer:

> *I think that that goes a long way...to the patients because they like to know, "Oh, wow, somebody understands, has been through the same thing," maybe not in the same way, but it just makes someone feel a little bit better about—whether it's using the app or telling someone their story. There's a relationship there.*

Types of Content

Of the 5 participants who mentioned that they had particularly liked certain types of meditations, 3 (60%) said that they liked the guided meditations, with one stressing the value of having guided meditations available that were tailored to their mood:

> *I did appreciate that there were guided meditations depending upon the emotions you were feeling or going through.*

Other types of content that were particularly liked by the participants were those that taught them either how to meditate or about other practices that helped them cope with the experience of having cancer, such as gratitude:

> *It went through steps on gratitude and how it, being grateful meant in the long run would help you throughout your cancer...That was my number one that I loved.*

Individual participants also mentioned the meditation series and storytelling as features of the app that they liked.

Functions and Features

In all, 67% (4/6) of interviewees mentioned one or more specific features of the app they liked, with 6 different features mentioned among them, and 33% (2/6) of participants mentioned that they liked the visual appearance of the app, which was clear and simple to navigate. Other liked features mentioned by individual participants were mood check-in, automatic reminder notifications, the option to rate the meditations, the use tracker, and automatic bookmarking that suggested the next meditation in a series:

> *I do like that it wasn't very overwhelming. It was just straight forward and accessible.*
>
> *I thought it was very user friendly, that I was able to navigate around in it pretty easily.*

Sound, Music, and Voices

In all, 67% (4/6) of interviewees mentioned that they liked the app's background music, sound effects, or narrators' voices, finding them soothing and relaxing:

> *I found the voice to be...just perfect. It wasn't irritating. It was very calm. He was very calm.*

Variety of Meditation Options

Finally, 33% (2/6) of participants highlighted that they liked having such a wide range of options to choose from when meditating, both in terms of the length of meditation (1 participant) and the variety of topics (2 participants):

> *I liked that there were many options. I was clicking around...If I didn't feel like I was getting into something, then I could click into something else and then focus.*

Table 7 shows the number of participants who gave particular types of responses when asked what they liked about the Calm for Cancer app.

Table 7. Features liked by the participants.

Theme and subtheme	Participants, n (%)
Favorite narrators (N=6)	
Favorite narrators	4 (67)
Relatability	3 (50)
Types of content (N=5)	
Guided meditations	3 (60)
Educational or topic-based	1 (20)
Series	1 (20)
Story-based	1 (20)
Specific functions and features (N=4)	
Visual appearance	2 (50)
Rating of meditations	1 (25)
Automatic bookmarking	1 (25)
Mood check-in	1 (25)
Reminder notifications	1 (25)
Use tracker	1 (25)
Sounds, music, or voices (N=4)	
Music	2 (50)
Narrator voices	2 (50)
Background sleep sounds	1 (25)
Variety of meditation options (N=2)	
Range of topics	2 (100)
Different lengths	1 (50)

What Participants Disliked About the Calm for Cancer App

The study participants were also asked if there was anything that they had disliked about the *Calm for Cancer* app or what their least favorite features were. In all, 83% (5/6) of participants mentioned specific features or content in response to this question, although the remaining participant (1/6, 17%) could not recall anything they disliked about the app.

Narrator Voices or Styles

Of the 5 participants who disliked some aspects of the app, 4 (80%) mentioned that they disliked the voices or narrative styles of some of the narrators and found these irritating or nonconducive to a relaxed meditative state. A participant mentioned that although they had enjoyed the bedtime story meditations, they were challenging and difficult to follow:

> *...I think it would be better to have that more soothing voice, that less talking, less interaction and just try to focus on what is it that I'm trying to focus.*
>
> *The voices to me were not relaxing...they just didn't work for me.*

Other Features or Content

A total of 4 other aspects of the app were mentioned by individual participants when asked what they had disliked or what their least favorite features were. A participant referred to mood check-in, which they initially liked but had become irritated, as the purpose of this was unclear:

> *I got tired of doing the check-ins because I had the same little smiley face every time. I didn’t really understand...I didn’t really connect that, so that was probably my least favorite.*

For another participant, having so many categories and meditations to choose from had been a little overwhelming and their least favorite aspect of the app. This participant also mentioned that they had disliked a meditation series in particular:

> *Too many categories, too many choices. That was a little bit hard to go through and try to pick and choose which ones best.*

Finally, a participant referred to the tracker function, which sometimes increased their anxiety:

> *I don’t like to see myself fail, so if I saw I missed a day or something...It would actually cause more anxiety for me.*

Table 8 shows the number of participants who mentioned particular factors when asked what they liked the least about the Calm for Cancer app.

Table 8. Features disliked by the participants.

Theme and subtheme	Participants, n (%)
Specific narrator voices or styles (N=4)	4 (100)
Other features or content (N=3)	
Mood check-in	1 (33)
Use tracker	1 (33)
Too many choices	1 (33)
Specific meditation series	1 (33)

Ease of Access and Use

The interviews explored the participants' views on ease of use of the app and how easy they felt it would be for other patients with or survivors of cancer to access and use it. All 100% (6/6) of participants reported that they found the app easy to access and use. A participant mentioned that they liked the simplicity of the app, which could be used at any time or place without any special arrangements:

> *I don't mind going into a quiet space and participating, but to actually have a place in a house where I set up and have this own mediation corner is more difficult. I don't think you need to do that necessarily to participate in the app.*

Only 33% (2/6) mentioned that they had experienced any difficulties in navigating content on the app, although these individuals also stressed that, in general, they had found the app easy to use. All 100% (6/6) of participants also indicated that they felt that other patients with or survivors of cancer would have no difficulty in accessing or using the app, although a participant stressed that older people with little experience in using apps might have a little more difficulty:

> *Depending on the age, younger ones no problem whatsoever. You start getting into people that are maybe Baby Boomer age...it's probably a little bit more for them to learn. Anybody who's familiar with apps, it's pretty easy.*

Mental or Physical Benefits

In all, 83% (5/6) of participants mentioned that using the app helped them deal with the stress or anxiety of their condition:

> *Before my diagnosis, I had anxiety. That was something that was helpful for me to have this schedule at night to listen to these meditations and get out of my own thoughts for a minute and just really focus.*
>
> *I felt myself not only calm during the app, during a meditation, but I felt myself more calm throughout the day.*

A total of 33% (2/6) of participants had experienced better sleep when using the app to meditate:

> *I was waking up feeling better because I was going to sleep better, instead of reading and being on my phone for an hour and then just rolling over and trying to go to sleep. I think having this schedule and listening to this before bed helped with the overall night of sleep, for sure.*

When asked specifically whether the app had helped them to sleep better, 50% (3/6) of participants reported that they had not tried using it for this purpose, with 67% (2/3) of these explaining that coexisting health conditions or their cancer treatments have a negative impact on sleep, which they did not think meditation could overcome. In addition, 33% (2/6) of participants expressed the view that their religious beliefs or existing lifestyle practices helped them cope with the experience of having cancer and that using the app did not provide any clear additional benefits. None of the participants reported any ways in which using the app helped them deal with physical pain, although several stressed that their cancer did not cause any pain.

Ideal Length of Meditations

When asked for their views on the ideal length of meditation for patients with cancer, the responses ranged from 5 to 15 minutes. Most participants (4/6, 67%) expressed the view that approximately 10 to 15 minutes is the best length.

In addition, 33% (2/6) of participants indicated that they felt shorter durations for meditation (ie, 5-8 minutes) would be more appealing to users or easier to fit into a busy schedule, used either once or more than once daily.

Suggested Improvements

When asked for suggested improvements to the *Calm for Cancer* app, 83% (5/6) of participants provided 22 separate suggestions, which were categorized as relating to navigation (2 participants), content (4 participants) or style (2 participants). Suggestions for navigation included the ability to save or bookmark favorite meditations, improved search function or visibility, different categories of meditations for different users, and the length of meditations shown. Suggestions for the content included religion, metastatic disease, and depression. Suggested improvements for style included the choice of surroundings or backgrounds for meditations and longer meditations (approximately 15 minutes):

> *I think it might be helpful to break out the category for the different populations. For example, cancer patient versus caretakers, but also...my condition is*

> *not as severe as others. I think that if there was a different category for different people that have different daily experiences, I think would be helpful.*
>
> *I didn't see in the app where it covered depression...that would be something I would think to zero in on, and it would help people with cancer possibly deal with it more 'cause there's a lot of depression with...just the medications you're on.*

Intentions to Continue Meditation

When asked whether they intended to continue their meditation practice in future, 67% (4/6) of participants indicated that they definitely did, with 33% (2/6) explaining that they had already purchased the main *Calm* app or another app for use in their practice. However, several of those who expressed an intention to continue meditating admitted that they had not been very successful in adhering to a regular meditation schedule since the conclusion of the study:

> *I downloaded the overall Calm app. I haven't been as successful as I'd like in using it.*

A participant expressed uncertainty about whether they would continue with the app, whereas another indicated that they did not intend to continue mediating.

Wider Market for the App

All but one of the participants indicated that they would download the *Calm for Cancer* app if it became publicly available. In all, 50% (3/6) of participants expressed the view that the app would be of considerable interest to other patients with or survivors of cancer and should be made more widely available:

> *I just feel like somebody always knows somebody that's going through cancer or can recommend it. Yeah, I think it would catch on. I think people would pick it up.*

Discussion

Principal Findings

We assessed the feasibility of a cancer-specific meditation mobile app prototype, *Calm for Cancer*, among patients with and survivors of cancer, using questionnaires, objective use data, and in-depth interviews. Both quantitative and qualitative data demonstrated the overall feasibility of the *Calm for Cancer* app in patients with and survivors of cancer. Weekly and poststudy questionnaire data showed that users reported high overall enjoyment, ease of use, and satisfaction with the app content, aesthetics, and graphics. The emergent top-level themes arising from the poststudy interviews included the overall experience of using the app, what participants liked about the app, what participants disliked about the app, ease of access or use, mental or physical benefits, ideal length of meditations, suggested improvements, intentions to continue meditation, and wider market for the app. The objective use data further showed that, on average, participants used the app for 73 (SD 7.1) minutes per week, demonstrating compliance with use prescriptions (ie, 70 minutes per week). Overall, this feasibility RCT provides insight into considerations for the final app design and serves as an important step before testing the efficacy of the *Calm for Cancer* meditation app.

Overall, both weekly and poststudy questionnaire responses indicated high feasibility across the following categories: (1) acceptability (ie, satisfaction, perceived appropriateness, and perceived positive and negative effects), (2) demand (ie, use of the app, interest, or intention to use), and (3) practicality (ie, how it makes them feel and ease of use). In addition to the self-reported survey data, objective participation data also supported the demand, as participants were compliant with the prescription app use of 70 minutes per week. Previously, no commercially available meditation apps have been specifically developed for the needs of patients with cancer and designed with input from end users at both the individual and clinic levels (ie, patients with and survivors of cancer and health care providers), making the *Calm for Cancer* prototype the first of its kind. In 2019, a feasibility RCT of the parent *Calm* app was conducted among patients with hematologic cancer, who were asked to use the *Calm* app for 10 minutes per day for 4 weeks [6]. The study found that the use of the *Calm* app was feasible among patients with hematologic cancer; specifically, 83% of participants reported enjoyment, 84% reported being satisfied with the content, and 97% reported that they would recommend it to others, and the average objective app use was 71 (SD 74) minutes per week [6]. However, despite general satisfaction, poststudy qualitative interviews revealed strong recommendations for adapting the app more specifically for cancer [5]. Compared with our 2019 feasibility RCT assessing the feasibility of the general *Calm* app that did not include cancer-specific content or modifications to meet the needs of patients with cancer, participants using the *Calm for Cancer* app reported greater satisfaction with the prototype app after 4 weeks (eg, higher enjoyment, higher satisfaction with content, and greater likelihood of recommending the app to others). In addition, although the objective app use data indicate similar average weekly engagement between this study and the 2019 study [6] (mean 73 minutes per week for the *Calm for Cancer* app vs 71 minutes per week for the general *Calm* app) across the sample and over time, there was much more consistent use of the *Calm for Cancer* app than we previously observed with the general *Calm* app (ie, SD 7 minutes per week for the *Calm for Cancer* app vs SD 74 minutes per week for the general *Calm* app). Furthermore, the previous feasibility RCT of the *Calm* app was limited to hematologic cancer, whereas this study was conducted among a range of diverse cancer types [5]. Overall, our results suggest that the *Calm for Cancer* app is more feasible and may be more suitable than the parent *Calm* app for meeting the needs of patients with and survivors of cancer. This was despite attrition, missing data, and a self-selected study sample.

Our exploratory analyses did not support the hypothesis that greater app use would predict greater satisfaction with the app (ie, enjoyment, ease of use, satisfaction with content, and aesthetics). However, as reported earlier, in addition to the high rates of satisfaction with the app prototype, there was consistently high compliance with use prescriptions across participants and over time (mean 73, SD 7 minutes per week of the prescribed 70 minutes per week). Although these high levels of engagement provide strong support for the feasibility of the app as an intervention for patients with and survivors of cancer, they limit the statistical power of detecting differences in satisfaction based on app use. Despite the lack of power to detect statistically significant differences, these findings show that high levels of app engagement are associated with high satisfaction among end users and clear feasibility of the app as an intervention for patients with and survivors of cancer. Aligned with a substantial body of behavioral research, this study supports the importance of creating effective strategies that help initiate and maintain engagement with behavioral health interventions. For example, previous studies have shown that greater user engagement with a mobile app can lead to greater feasibility outcomes (eg, greater intention to continue using the app, greater likelihood of recommending the app to others, and higher positive ratings of the app) [21]. Given the small sample size in our feasibility RCT, studies that are powered by larger sample sizes are necessary to further explore and establish the potential associations between use and other feasibility outcomes in meditation app interventions among patients with and survivors of cancer.

The qualitative findings from the in-depth interviews with a subsample of participants provided further insight into the overall feasibility of the *Calm for Cancer* app prototype as well as specific feedback related to adaptation (ie, suggestions for modifications to improve the app to better meet the unique needs of patients with and survivors of cancer). Qualitative analyses based on participant interviews (N=6) revealed that most participants had a very positive experience of using the app (n=4, 67%), although some participants expressed mixed responses because they preferred a faith-based approach and disliked the narrators' voices (n=2, 33%). In addition, the interviews revealed that all participants perceived the app as easy to use (6/6, 100%), most participants found that the app provided mental health benefits (5/6, 83%), and half of the participants thought that the app would be marketable to other patients with and survivors of cancer (3/6, 50%). Specific features of the *Calm for Cancer* app that participants liked included narrators or narrator voices, relatability, guided meditations, educational and topic-based content (especially those related to the emotional and cancer-related challenges they experienced), series, story-based, visual appearance, rating of meditations, automatic bookmarking, mood check-in, reminder notifications, use tracker, music, background sleep sounds, range of topics, and different meditation lengths.

When asked about any dislike, some participants (2/6, 33%) expressed that they disliked the voices or narrative styles of some of the narrators; thus, including more narrators can be explored in the final design of the *Calm* voices or narrative styles for cancer apps so that users have more options for voices and narrative styles. A participant found the bedtime story meditations challenging and difficult to follow, a participant found the purpose of the mood check-in feature unclear, a participant found that the choice of many categories and meditations was overwhelming, and a participant disliked the tracker function; however, most other participants expressed that they liked these features.

Specific recommendations for app adaptations for the planned efficacy trial included adding the ability to save or bookmark favorite meditations, improving the search function or increasing the visibility of the search function, adding different categories of meditations for different users, including content-related metastatic disease and depression, adding options for different surroundings or backgrounds, and adding longer meditations.

The *Calm for Cancer* app prototype capitalized on a partnership with a popular consumer-based app (ie, *Calm*) to contribute to the future success of the cancer-specific meditation app. More specifically, the research team had a long-standing relationship with the *Calm* app, which provided in-kind app subscriptions for the feasibility and pilot RCTs conducted by the research team. This is one of the first prototypes to be developed by leveraging a consumer-based product and is important for several reasons: (1) the *Calm* app has an extremely large reach, name recognition, and a committed user base that will help the *Calm for Cancer* app to be successful in the market [21]. Second, when marketed to cancer care clinics, professionals, and patients with and survivors of cancer, *Calm* offers subscriptions at highly reduced rates. Overall, this partnership allowed the research team to uniquely draw on the strengths of both academic research and the commercial sector by combining rigorous science with industry standards. Leveraging industry partnerships is also efficient and cost-effective in the long term [21], because many researchers do not have access to resources to maintain an app after development or the costs to publish the app to multiple platforms (eg, Apple). Future directions for this line of research include finalizing the *Calm for Cancer* app design and conducting a randomized clinical trial to determine its efficacy and sustainability in reducing symptom burden in patients with and survivors of cancer. After establishing efficacy and sustainability, the app could be marketed to both consumers and clinics working with cancer care providers via our already existing cancer center partnerships.

Limitations

Despite study strengths, there are some limitations to this research that should be noted. This feasibility study was conducted among a sample that primarily consisted of White women with relatively high socioeconomic status, thereby limiting the generalizability of the study results. Future feasibility RCTs of the *Calm for Cancer* app are warranted in samples such as racial and ethnic minorities, men, and individuals with lower socioeconomic status to assess the feasibility and efficacy of this app specifically among diverse patients with and survivors of cancer. Another limitation of this study was the relatively high attrition rate, given that approximately half of the participants (18/36, 50%) who were enrolled and completed the baseline questionnaire remained in the study through the final poststudy questionnaires. Future research should explore the use of effective retention strategies for participants engaging in mobile health research trials. Finally, a control group was not included, and the sample size was not powered. However, the study design and sample size were appropriate for a feasibility RCT.

Conclusions

This study established the feasibility of *Calm for Cancer*, a cancer-specific mobile meditation app prototype that was developed with input from patients with cancer, survivors of cancer, and health care providers. Questionnaires and objective use data were used to demonstrate feasibility across the following categories: acceptability, demand, practicality, and adaptation. In addition, qualitative interviews were conducted to gain further insight into the experiences of patients with and survivors of cancer with the meditation app prototype. The options suggested by the participants for additional or revised content, narrators, and length, as well as suggested feature improvements, will be considered in the final app design before testing the *Calm for Cancer* meditation app for its efficacy in a future study.

Conflicts of Interest

JH discloses that she receives an annual salary from Calm and holds stock in the company. However, her salary and equity are not dependent upon the results of her research. RM reports research support by Incyte, Sierra, CTI BioPharma, Bristol Myers Squibb, Abbvie, Genetech, Blueprint, and Morphosys. In addition, RM acts as a consultant for Novartis, Sierra Oncology, Genetech, Sierra, Blueprint, Geron, Telios, CTI BioPharma, Incyte, Bristol Myers Squibb, Abbvie, GSK.

Multimedia Appendix 1
Poststudy interview questions.
[DOCX File , 14 KB - cancer_v8i4e39228_app1.docx]

Multimedia Appendix 2
Facebook discussion prompts.
[DOCX File , 16 KB - cancer_v8i4e39228_app2.docx]

Multimedia Appendix 3
CONSORT-eHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 9628 KB - cancer_v8i4e39228_app3.pdf]

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Abbreviations

RCT: randomized controlled trial
REDCap: Research Electronic Data Capture

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Original Paper

COVID-19 Diagnosis and Risk of Death Among Adults With Cancer in Indiana: Retrospective Cohort Study

Nimish Valvi[1*], MPH, MBBS, DrPH; Hetvee Patel[2], MS; Giorgos Bakoyannis[2], PhD; David A Haggstrom[3,4,5], MD, MAS; Sanjay Mohanty[4], MD; Brian E Dixon[1,2,3*], MPA, PhD

[1]Center for Biomedical Informatics, Regenstrief Institute, Indianapolis, IN, United States

[2]Richard M. Fairbanks School of Public Health, Indiana University, Indianapolis, IN, United States

[3]Center for Health Information and Communication, Health Services Research & Development Service, Richard L. Roudebush VA Medical Center, Veterans Health Administration, Indianapolis, IN, United States

[4]Department of Surgery, Indiana University School of Medicine, Indianapolis, IN, United States

[5]Center for Health Services Research, Regenstrief Institute, Indianapolis, IN, United States

[*]these authors contributed equally

Corresponding Author:
Brian E Dixon, MPA, PhD
Richard M. Fairbanks School of Public Health
Indiana University
1050 Wishard Boulevard, Floors 5 and 6
Indianapolis, IN, 46202-2872
United States
Phone: 1 3172783072
Email: bedixon@regenstrief.org

Abstract

Background: Prior studies, generally conducted at single centers with small sample sizes, found that individuals with cancer experience more severe outcomes due to COVID-19, caused by SARS-CoV-2 infection. Although early examinations revealed greater risk of severe outcomes for patients with cancer, the magnitude of the increased risk remains unclear. Furthermore, prior studies were not typically performed using population-level data, especially those in the United States. Given robust prevention measures (eg, vaccines) are available for populations, examining the increased risk of patients with cancer due to SARS-CoV-2 infection using robust population-level analyses of electronic medical records is warranted.

Objective: The aim of this paper is to evaluate the association between SARS-CoV-2 infection and all-cause mortality among recently diagnosed adults with cancer.

Methods: We conducted a retrospective cohort study of newly diagnosed adults with cancer between January 1, 2019, and December 31, 2020, using electronic health records linked to a statewide SARS-CoV-2 testing database. The primary outcome was all-cause mortality. We used the Kaplan-Meier estimator to estimate survival during the COVID-19 period (January 15, 2020, to December 31, 2020). We further modeled SARS-CoV-2 infection as a time-dependent exposure (immortal time bias) in a multivariable Cox proportional hazards model adjusting for clinical and demographic variables to estimate the hazard ratios (HRs) among newly diagnosed adults with cancer. Sensitivity analyses were conducted using the above methods among individuals with cancer-staging information.

Results: During the study period, 41,924 adults were identified with newly diagnosed cancer, of which 2894 (6.9%) tested positive for SARS-CoV-2. The population consisted of White (n=32,867, 78.4%), Black (n=2671, 6.4%), Hispanic (n=832, 2.0%), and other (n=5554, 13.2%) racial backgrounds, with both male (n=21,354, 50.9%) and female (n=20,570, 49.1%) individuals. In the COVID-19 period analysis, after adjusting for age, sex, race or ethnicity, comorbidities, cancer type, and region, the risk of death increased by 91% (adjusted HR 1.91; 95% CI 1.76-2.09) compared to the pre–COVID-19 period (January 1, 2019, to January 14, 2020) after adjusting for other covariates. In the adjusted time-dependent analysis, SARS-CoV-2 infection was associated with an increase in all-cause mortality (adjusted HR 6.91; 95% CI 6.06-7.89). Mortality increased 2.5 times among adults aged 65 years and older (adjusted HR 2.74; 95% CI 2.26-3.31) compared to adults 18-44 years old, among male (adjusted HR 1.23; 95% CI 1.14-1.32) compared to female individuals, and those with ≥2 chronic conditions (adjusted HR 2.12; 95% CI 1.94-2.31) compared to those with no comorbidities. Risk of mortality was 9% higher in the rural population (adjusted HR 1.09; 95% CI 1.01-1.18) compared to adult urban residents.

Conclusions: The findings highlight increased risk of death is associated with SARS-CoV-2 infection among patients with a recent diagnosis of cancer. Elevated risk underscores the importance of adhering to social distancing, mask adherence, vaccination, and regular testing among the adult cancer population.

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KEYWORDS

COVID-19; SARS-CoV-2; coronavirus; cancer; survival; mortality; death; oncology; cancer experience; outcome; electronic health record; EHR; patient with cancer; cancer population; Kaplan-Meier; Cox proportional hazards model; hazard ratio; risk

Introduction

As of July 2022, there have been over 1 million deaths from COVID-19 in the United States [1]. Certain patient subgroups, such as older adults, as well as individuals with chronic conditions such as hypertension, diabetes, and chronic lung diseases, have been shown to be at increased risk of morbidity and mortality due to COVID-19 [2]. Given immunosuppression due to both disease and treatment among patients with cancer, there exists increasing risks among patients with cancer who have COVID-19, require hospitalization and intensive care, and are at risk of death [3-5].

As a precaution because of increasing transmission, cancer care providers made sweeping changes to the management of patients with cancer at the start of the pandemic, with changes to radiation therapy sessions, immunotherapy, and administration of oral medications instead of intravenous chemotherapy [6-9]. These changes were introduced based on early evidence, primarily drawn from outside the United States. Early studies from China [10-12] reported a 2- to 4-fold increase in mortality due to COVID-19 among patients with cancer compared to those without cancer, while a few smaller studies reported a case-fatality rate of 29% [13] and poorer outcomes [3] among patients with cancer who have COVID-19. Some studies from Europe and the United States have investigated mortality among cancer subpopulations and demonstrated a 34% [14] increase among individuals with solid tumors compared to hematologic tumors. A retrospective cohort study from the United States found a 2.5-fold increase in hospitalizations among patients with hematologic tumors compared to solid tumors and a 67% increase in hospitalization among adults 65 years and older compared to those 65 years and younger [15].

Prior studies in the United States were generally conducted at single institutions, most with small sample sizes that focused on case-fatality rates [4,16]. Some of the larger studies conducted in the United Kingdom evaluated case fatality rates [17] and cross-sectionally compared all-cause mortality among individuals with active cancer treatment [18,19]. However, these studies did not report negative outcomes because of anticancer therapies, suggesting mortality is driven by demographic factors and comorbidities [18,19]. Furthermore, prior studies [4,12,15,20] generally examined in populations with COVID-19 severe disease following infection with the SARS-CoV-2 virus. These studies were important to our understanding of the novel COVID-19 as they were conducted within the first 6 months of the pandemic. Now that more than 2 years have passed since the start of the pandemic, it is important to conduct larger retrospective analyses to better understand risks of COVID-19 on mortality among individuals with cancer. As additional protections against COVID-19 become widespread, such as effective vaccines for individuals with immunosuppressive conditions [21-26], patients with cancer should be aware of their risks to make informed choices about prevention and treatment.

The objective of this study is to estimate risk of SARS-CoV-2 infection and death in a large, statewide cohort of adults recently diagnosed with cancer. This study is unique in its use of a population approach to estimating risk, as opposed to earlier studies from a single institution or network of hospitals in a city or region. The study is further unique in its use of infection-based risk rather than examining patients who present for care to a clinic or hospital. Comprehensive cancer diagnosis captured from electronic medical records linked to governmental, hospital-based, and private SARS-CoV-2 testing centers enabled robust data capture for examining population-level risk.

Methods

Overview

We conducted a retrospective cohort study of all individuals aged 18 years and older with a recent diagnosis of cancer. Data were extracted from Regenstrief Institute’s Indiana Network for Patient Care (INPC). The INPC [27], developed almost 30 years ago, is among the largest regional health information exchange (HIE) networks and contains over 17 million patient-level medical records. Medical records served as the source for identifying cancer diagnoses using the International Classification of Diseases, 10th Revision codes in the population. Moreover, due to its role in supporting population-level surveillance during the COVID-19 pandemic [28,29], the INPC medical records are linked to governmental, hospital, and private SARS-CoV-2 testing data from across the state. The integrated data set provided comprehensive information on cancer diagnosis along with SARS-CoV-2 infection during the entire study period. This includes information on positive SARS-CoV-2 individuals with cancer who did not present for medical care (eg, asymptomatic individuals and individuals with mild symptoms). The INPC further contains information from death certificates (eg, date of death) provided by the Indiana Department of Health. This enabled determination of death status among individuals who were not treated for COVID-19 in a hospital setting.

All individuals 18 years and older, with an incident of cancer diagnosis between January 1, 2019, and December 31, 2020, were included for this study. Individuals with a prior history of cancer (eg, diagnosis before January 1, 2019) were excluded.

Because INPC diagnoses date back to 2011 for most institutions, the data source possessed sufficient documentation of prior cancer diagnosis and treatment. In keeping with practice guidelines, individuals were deemed to have COVID-19 if a reverse transcription polymerase chain reaction assay test from a throat or nose swab was positive for the SARS-CoV-2 virus. Participants with a clinical or radiological diagnosis of COVID-19 without the reverse transcription polymerase chain reaction test were not included in this study. This report is based on the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines for cohort studies [30].

Covariates

Covariates for the study included demographic and clinical variables obtained from the INPC. The demographic variables were age groups in years (18-44, 45-64, and ≥65), sex, race or ethnicity (White, Black, Hispanic, and other), and region of residence (rural or urban). The region of residence was defined based on the Rural-Urban Commuting Area codes [31]. The clinical variables were number of chronic diseases, cancer types, and staging. The number of chronic disease variable was categorized as ("0," "1," and "≥2"), and cancer types were classified according to International Classification of Diseases, 10th Revision codes (Table S5 in Multimedia Appendix 1). The "Other" category included cancers of the bone and articular tissue, endocrine glands, central nervous system, mesothelioma and soft tissue, male reproductive organs (excluding prostate), and female reproductive organs. The "Other digestive" cancer group included esophagus, stomach, small intestine, liver and intrahepatic bile ducts, gall bladder, and pancreas. Individuals with nonmelanoma skin cancers were excluded from the study [17,18]. The list of chronic diseases, obtained from prior studies [10,17,18], included hypertension, diabetes, coronary heart disease, chronic kidney disease, cerebrovascular disease, hepatitis, and chronic obstructive pulmonary disease.

Staging information was captured using natural language processing from free text within the clinical notes stored in the INPC. We used nDepth, a natural language processing tool developed at the Regenstrief Institute to extract tumor-node-metastasis concepts from oncology notes provided by the comprehensive cancer centers in Indiana to the INPC. The work was developed from previous research and validated in earlies studies [32-35]. The cancer-staging variable was classified as I, II, III, and IV based on the tumor-node-metastasis classification [36].

Exposure

We included time from cancer diagnosis to SARS-CoV-2 infection as a time-dependent variable as the first exposure variable. We further divided time as a binary variable defined as COVID-19 period, where the pre–COVID-19 (January 1, 2019, to January 14, 2020) period was coded as 0 and the COVID-19 period (January 15, 2020, to December 31, 2020) was coded as 1.

Outcome

The primary endpoint was all-cause mortality, which was evaluated between January 1, 2019, and December 31, 2020. All individuals who were alive on December 31, 2020, were considered as right-censored observations in this analysis.

Ethical Considerations

Study approval was obtained from the Indiana University Institutional Review Board (Exempt Protocol #2009667926). Informed consent was waived due to retrospective use of preexisting, deidentified data from medical records.

Statistical Analysis

Descriptive statistics of baseline demographic and clinical characteristics are presented in Table 1. The distributions for cumulative proportion of survival over time for age group, sex, race or ethnicity, comorbidities, and COVID-19 diagnosis were estimated using Kaplan-Meier method (Figures 1-5).

The study period started from January 1, 2019, and follow-up ended at death or at the end of the study period on December 31, 2020. In this approach, we compared mortality during the COVID-19 period (January 15, 2020, to December 31, 2020) with that of the pre–COVID-19 period (January 1, 2019, to January 14, 2020). We allowed for pre–COVID-19 period follow-up of survivors to be censored on January 14, 2020, accounting for comparable average time to each event in each period. First, we estimated the survival function using the nonparametric Kaplan-Meier estimator for both the COVID-19 and the pre–COVID-19 period. Next, we estimated the effect of the COVID-19 period variable on all-cause mortality using a Cox proportional hazards model that adjusted for other demographic and clinical variables.

We assessed SARS-CoV-2 infection as a time-dependent exposure. We allocated time spent before a positive SARS-CoV-2 laboratory test to the group that did not have COVID-19 and time spent after the first positive SARS-CoV-2 laboratory test to the group that were confirmed to have COVID-19. This time-dependent approach reduces the immortal-time bias [37]. We estimated mortality hazard ratios (HRs) using time-dependent Cox proportional hazards models [38] adjusting for relevant covariates and assessing proportionality [39] assumptions with cumulative martingale residuals and the Supremum test.

Table 1. Characteristics of study cohort diagnosed with cancer during the pre–COVID-19 (January 1, 2019, to January 14, 2020) and COVID-19 (January 15, 2020, to December 31, 2020) periods—Indiana, 2019-2020 (N=41,924).

Characteristics	Pre–COVID-19 period		COVID-19 period		Total
	Dead		Dead		
	No (n=18,895), n (%)	Yes (n=2074), n (%)	No (n=19,631), n (%)	Yes (n=1324), n (%)	
Age range (years)					
18-44	1638 (8.7)	86 (4.2)	1635 (8.3)	30 (2.3)	3389 (8.1)
45-64	7005 (37.0)	631 (30.4)	7100 (36.2)	366 (27.6)	15,102 (36.0)
≥65	10,252 (88.3)	1357 (65.4)	10,896 (55.5)	928 (70.1)	23,433 (55.9)
Race or ethnicity					
White	15,051 (79.6)	1694 (81.7)	15,015 (76.5)	1107 (83.6)	32,867 (78.4)
Black	1239 (6.6)	166 (8.0)	1173 (6.0)	93 (7.0)	2671 (6.4)
Hispanic	416 (2.2)	28 (1.3)	371 (1.9)	17 (1.3)	832 (2.0)
Other	2189 (11.6)	186 (9.0)	3072 (15.6)	107 (8.1)	5554 (13.2)
Sex					
Female	9345 (49.5)	889 (42.9)	9725 (49.5)	611 (46.1)	20,570 (49.1)
Male	9550 (50.5)	1185 (57.1)	9906 (50.5)	713 (53.9)	21,354 (50.9)
Comorbidities					
0	13,863 (73.4)	1095 (52.8)	14,567 (74.2)	699 (52.8)	30,224 (72.1)
1	3221 (17.0)	495 (23.9)	3313 (16.9)	324 (24.5)	7353 (17.5)
≥2	1811 (9.6)	484 (23.3)	1751 (8.9)	301 (22.7)	4347 (10.4)
Cancer					
Breast	2743 (14.5)	101 (4.9)	2919 (14.9)	34 (2.6)	5797 (13.8)
Colorectal	1391 (7.4)	131 (6.3)	1438 (7.3)	83 (6.3)	3043 (7.3)
Leukemia	665 (3.5)	95 (4.6)	714 (3.6)	65 (4.9)	1539 (3.7)
Lip, oral cavity, and pharynx	415 (2.2)	48 (2.3)	466 (2.4)	25 (1.9)	954 (2.3)
Lung, trachea, and bronchus	1629 (8.6)	431 (20.8)	1662 (8.5)	322 (24.3)	4044 (9.6)
Lymphoma	821 (4.3)	100 (4.8)	859 (4.4)	51 (3.8)	1831 (4.4)
Myeloma	411 (2.2)	46 (2.2)	328 (1.7)	26 (2.0)	811 (1.9)
Other hematological	97 (0.5)	7 (0.3)	89 (0.5)	2 (0.1)	195 (0.5)
Other digestive	1033 (5.5)	367 (17.7)	1139 (5.8)	225 (17.0)	2764 (6.6)
Prostate	2592 (13.7)	103 (5.0)	2729 (13.9)	44 (3.3)	5468 (13.0)
Skin (melanoma)	2734 (14.5)	98 (4.7)	2511 (12.8)	43 (3.2)	5386 (12.8)
Urinary tract	1270 (6.7)	125 (6.0)	1399 (7.1)	78 (5.9)	2872 (6.8)
Other[a]	3094 (16.4)	422 (20.3)	3378 (17.2)	326 (24.6)	7220 (17.2)
COVID-19 positive					
No	17,545 (92.9)	1942 (93.6)	18,346 (93.4)	1197 (90.4)	39,030 (93.1)
Yes	1350 (7.1)	132 (6.4)	1285 (6.5)	127 (9.6)	2894 (6.9)
Region					
Urban	14,436 (76.4)	1536 (74.1)	14,222 (72.5)	952 (71.9)	31,146 (74.3)
Rural	4459 (23.6)	538 (25.9)	5409 (27.5)	372 (28.1)	10,778 (25.7)

[a] Includes cancer types such as malignant neoplasia of the bone and articular tissue, endocrine glands, central nervous system, mesothelioma and soft

tissue, male reproductive organs (excluding prostate), and female reproductive organs.

Figure 1. Kaplan-Meier survival estimates of overall cancer population by age group (years), Indiana, 2019-2020.

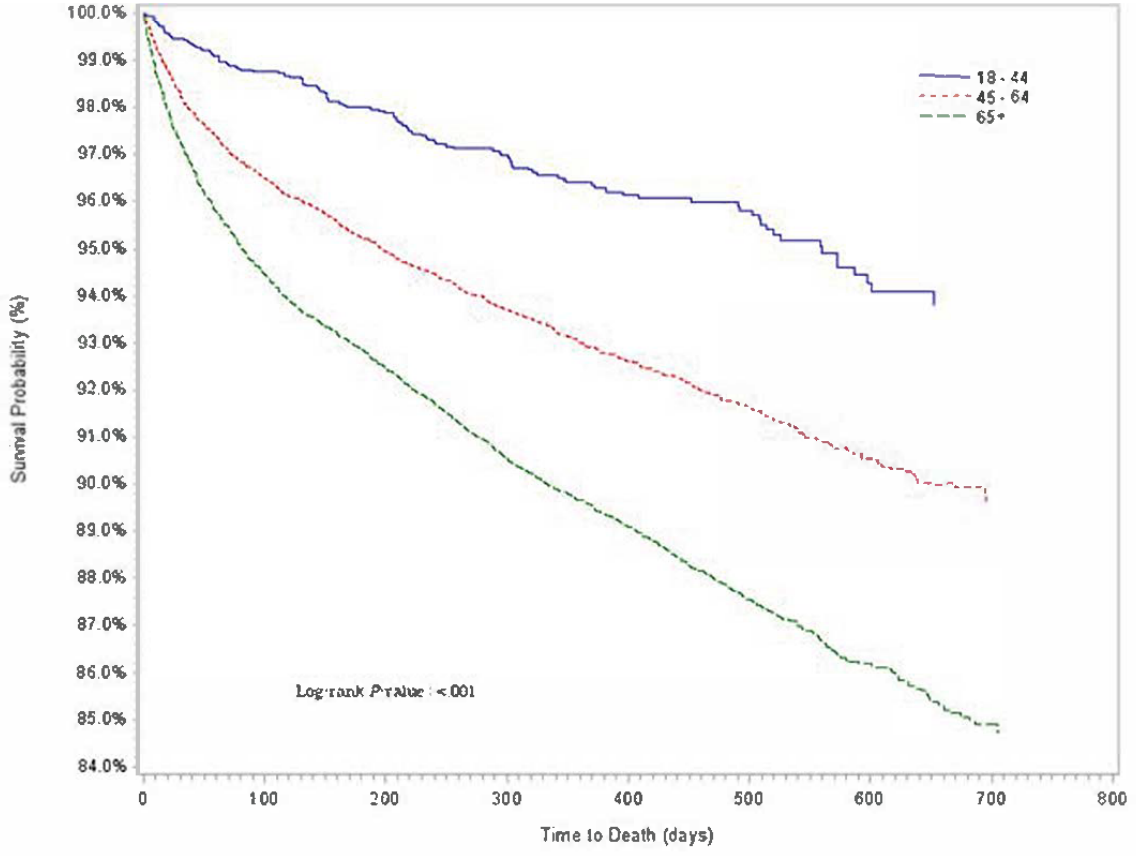


Figure 2. Kaplan-Meier survival estimates of overall cancer population by sex, Indiana, 2019-2020.

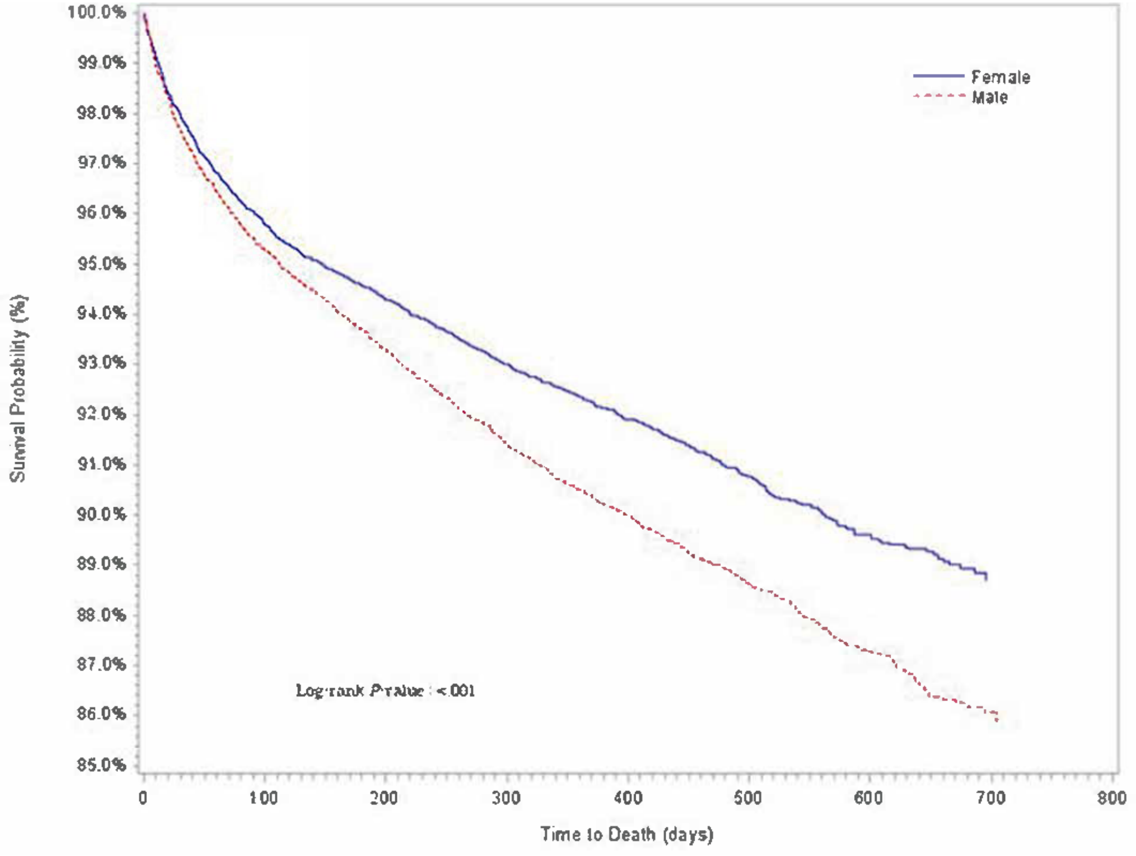


Figure 3. Kaplan-Meier survival estimates of overall cancer population by race and ethnicity, Indiana, 2019-2020.

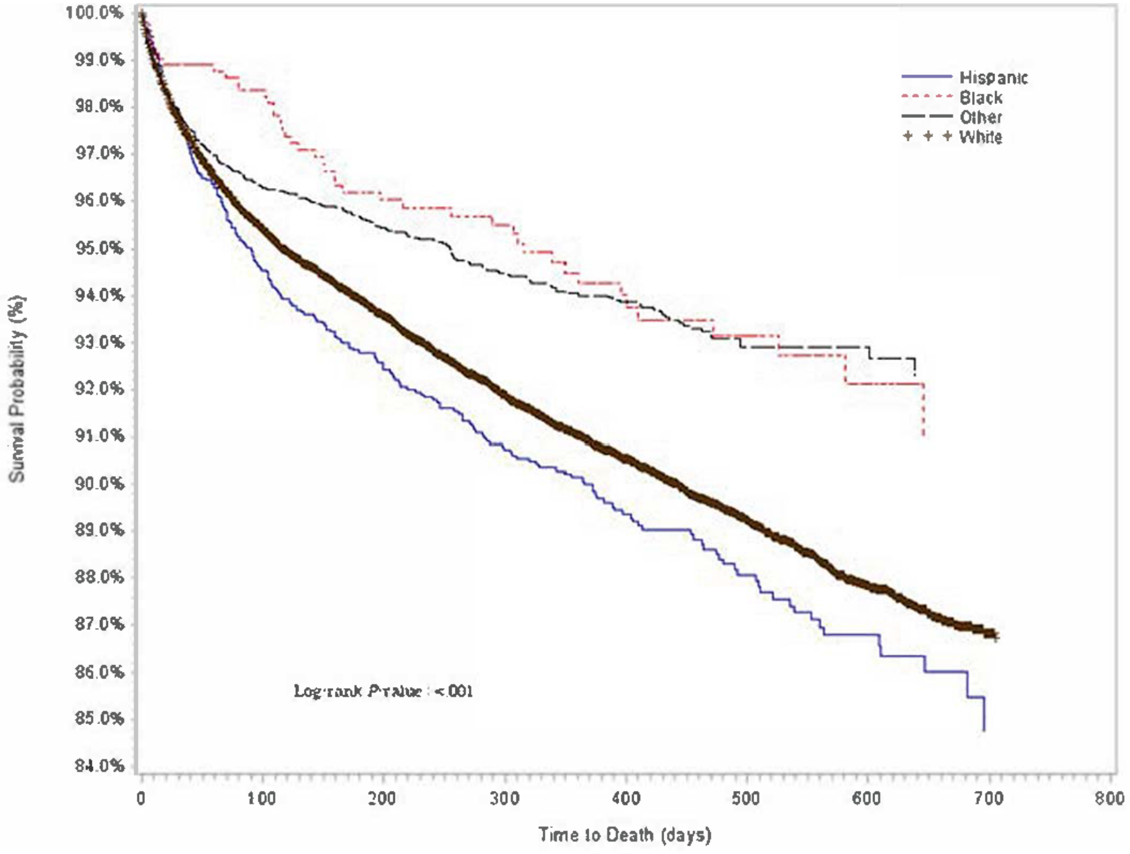


Figure 4. Kaplan-Meier survival estimates of overall cancer population by number of comorbidities, Indiana, 2019-2020.

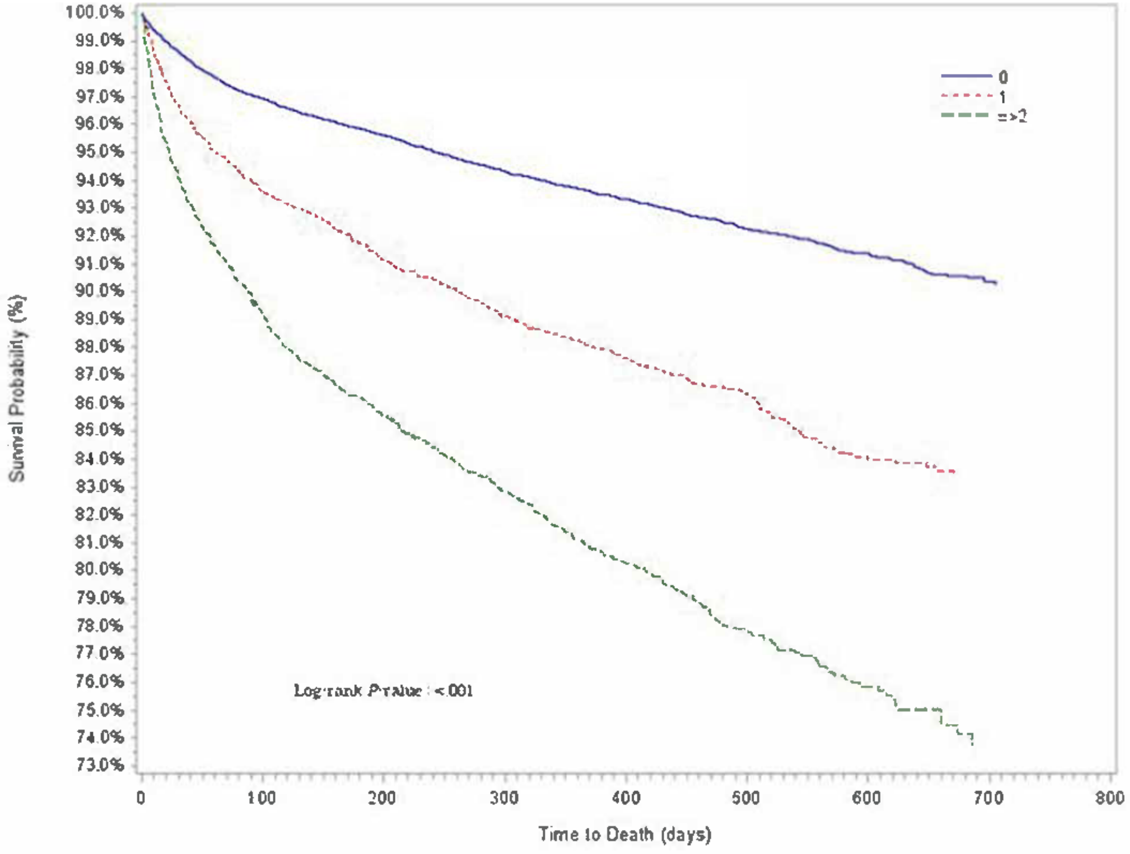
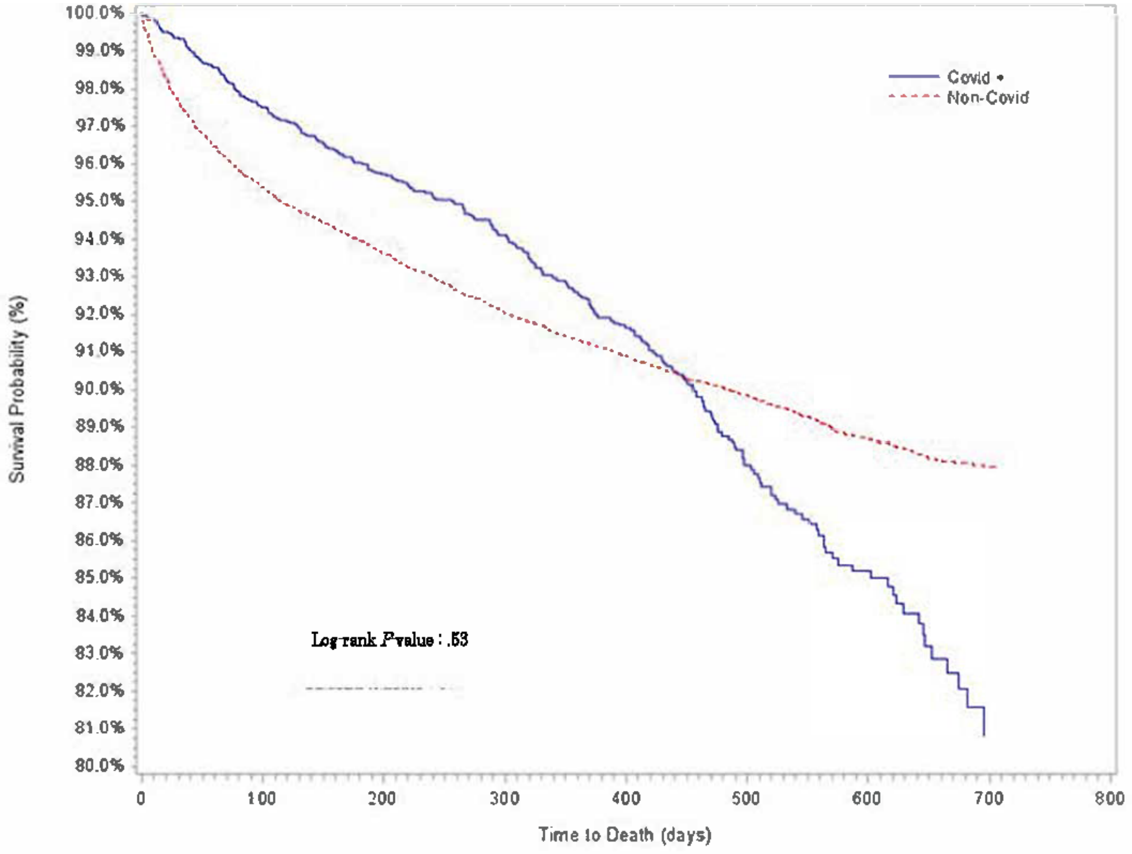


Figure 5. Kaplan-Meier survival estimates of overall cancer population by SARS-CoV-2 diagnosis, Indiana, 2019-2020.



Sensitivity Analysis

We further performed a sensitivity analysis with the 2 methods (time-dependent and COVID-19 period analysis) by additionally adjusting for cancer staging. The missingness of the staging variable was considered “missing not at random”; therefore, we performed the analysis on individuals who had the information on the cancer-staging variable. Baseline characteristics are found in Table S1 in Multimedia Appendix 1, COVID-19 period analysis is presented in Table S2 in Multimedia Appendix 1, and the time-dependent analysis from cancer to COVID-19 diagnosis is presented in Table S3 in Multimedia Appendix 1.

An additional time-dependent analysis was performed on individuals restricted to incident cancer cases from January 15, 2020, to December 31, 2020, to further reduce a possible immortal-time bias (Table S4 in Multimedia Appendix 1). All comparisons were 2-sided, and *P*<.05 was considered statistically significant. Analyses were conducted with SAS version 9.4 (SAS Institute).

Results

Cohort Characteristics

The study population consisted of 41,924 individuals with an incident diagnosis of cancer between January 1, 2019, and December 31, 2020 (Table 1). Of these, 2894 (6.2%) were laboratory-confirmed SARS-CoV-2 cases. Most cancer patients were white (n=32,867, 78.4%) and male (n=21,354, 50.9%). Approximately 1 in 5 (n=3221, 17.0%) patients with cancer possessed a single comorbid condition, and 1 in 10 (n=1811, 9.6%) had ≥2 comorbid conditions at the time of cancer diagnosis. Most patients were diagnosed with breast (n=5797, 13.8%), prostate (n=5468, 13.0%), and melanoma (n=5386, 12.8%) cancers during the study period.

All-Cause Mortality

During the study period, 3398 (8.1%) individuals died. In the COVID-19 period, there were 1324 (38.9%) deaths. Of the individuals who died in the COVID-19 period, 127 (9.6%) tested positive for SARS-CoV-2 (Table 1).

COVID-19 Period Analysis

The COVID-19 period analysis (Table 2) was adjusted for age group, sex, race or ethnicity, number of comorbidities, cancer type, and region of residence. Mortality was 91% higher during the COVID-19 period (adjusted HR 1.91; 95% CI 1.76-2.09; *P*<.001) compared to the pre–COVID-19 period. The risk of mortality was 3-fold higher among adults 65 years and older (adjusted HR 3.35; 95% CI 2.58-4.35; *P*<.001) compared to adults in the age group of 18-44 years. Risk of mortality among adults in rural residence (adjusted HR 0.99; 95% CI 0.91-1.09; *P*=.87) was 1% lower compared to urban residence, but it was not statistically significant.

Table 2. Unadjusted and adjusted Cox-regression analyses using landmarks during the pre–COVID-19 and COVID-19 periods as well as all-cause mortality—Indiana, 2019-2020 (N=41,924).

Variable	Unadjusted			Adjusted		
	Estimate (SE)	Hazard ratio (95% CI)	*P* value	Estimate (SE)	Hazard ratio (95% CI)	*P* value
Covid-19 period[a]						
No	N/A[b]	Reference	<.001	N/A	Reference	<.001
Yes	0.63 (0.04)	1.88 (1.73-2.05)		0.65 (0.04)	1.91 (1.76-2.09)	
Age group (years)						
18-44	N/A	Reference	<.001	N/A	Reference	<.001
45-64	0.91 (0.13)	2.48 (1.91-3.22)		0.86 (0.13)	2.36 (1.81-3.08)	
≥65	1.33 (0.13)	3.80 (2.94-4.91)		1.20 (0.13)	3.35 (2.58-4.35)	
Sex						
Female	N/A	Reference	<.001	N/A	Reference	<.001
Male	0.16 (0.04)	1.17 (1.08-1.27)		0.18 (0.04)	1.20 (1.10-1.30)	
Race or ethnicity						
White	N/A	Reference	<.001	N/A	Reference	<.001
Black	0.13 (0.08)	1.14 (0.98-1.34)		0.14 (0.08)	1.15 (0.98-1.34)	
Hispanic	–0.74 (0.21)	0.48 (0.32-0.72)		–0.60 (0.21)	0.55 (0.36-0.83)	
Other	–0.27 (0.07)	0.76 (0.66-0.87)		–0.20 (0.07)	0.82 (0.71-0.94)	
Comorbidities						
0	N/A	Reference	<.001	N/A	Reference	<.001
1	0.66 (0.05)	1.94 (1.76-2.15)		0.39 (0.05)	1.48 (1.33-1.63)	
≥2	1.20 (0.05)	3.31 (2.99-3.67)		0.82 (0.05)	2.27 (2.04-2.52)	
Cancer						
Other	N/A	Reference	<.001	N/A	Reference	<.001
Breast	–1.82 (0.12)	0.16 (0.13-0.21)		–1.72 (0.13)	0.17 (0.14-0.23)	
Colorectal	–0.51 (0.09)	0.60 (0.50-0.72)		–0.61 (0.09)	0.54 (0.45-0.66)	
Leukemia	0.08 (0.09)	1.08 (0.89-1.32)		–0.03 (0.10)	0.96 (0.79-1.17)	
Lip, oral cavity, and pharynx	–0.52 (0.16)	0.59 (0.44-0.81)		–0.60 (0.16)	0.55 (0.40-0.75)	
Lung and bronchus	0.59 (0.06)	1.82 (1.61-2.04)		0.33 (0.06)	1.39 (1.23-1.57)	
Lymphoma	–0.28 (0.11)	0.76 (0.61-0.93)		–0.29 (0.11)	0.74 (0.60-0.92)	
Myeloma	–0.34 (0.15)	0.71 (0.52-0.96)		–0.53 (0.15)	0.58 (0.43-0.80)	
Other digestive	0.72 (0.06)	2.07 (1.82-2.35)		0.53 (0.06)	1.69 (1.48-1.93)	
Other hematological	–1.63 (0.33)	0.41 (0.21-0.80)		–1.75 (0.58)	0.17 (0.06-0.54)	
Prostate	–1.70 (0.12)	0.25 (0.21-0.30)		–1.94 (0.12)	0.14 (0.11-0.18)	
Melanoma	–1.83 (0.13)	0.24 (0.20-0.28)		–1.93 (0.13)	0.14 (0.11-0.19)	
Urinary tract	–0.52 (0.09)	0.67 (0.57-0.78)		–0.79 (0.09)	0.45 (0.37-0.55)	
Region						
Urban	N/A	Reference	<.001	N/A	Reference	<.001
Rural	0.07 (0.04)	1.07 (0.98-1.17)		0.007 (0.05)	0.99 (0.91-1.09)	

[a] COVID-19 period calculated as a binary variable; no=January 1, 2019, to January 14, 2020; yes=January 15, 2020, to December 31, 2020.

[b] N/A: not applicable.

Time-Dependent Analysis

After adjusting for age, race, sex, number of comorbidities, and cancer subtypes, SARS-CoV-2 infection was associated with a 7-fold increase in the hazard of death (adjusted HR 6.91; 95% CI 6.06-7.89; *P*<.001; Table 3). The hazard of death was 23% higher for male individuals (adjusted HR 1.23; 95% CI 1.14-1.32; *P*<.001), compared to female individuals. All-cause mortality was higher by 45% in the lung cancer group (adjusted HR 1.45; 95% CI 1.31-1.61; *P*<.001) and 80% in other digestive cancers group (adjusted HR 1.80; 95% CI 1.61-2.00; *P*<.001), compared to other cancer types.

Table 3. Unadjusted and adjusted time-dependent (cancer diagnosis to COVID-19 diagnosis) Cox-regression analysis and all-cause mortality—Indiana, 2019-2020.

Variable	Unadjusted			Adjusted		
	Estimate (SE)	Hazard ratio (95% CI)	*P* value	Estimate (SE)	Hazard ratio (95% CI)	*P* value
Covid-19 diagnosis						
No	N/A[a]	Reference	<.001	N/A	Reference	<.001
Yes	1.87 (0.07)	6.53 (5.72-7.44)		1.93 (0.07)	6.91 (6.06-7.89)	
Age group (years)						
8-44	N/A	Reference	<.001	N/A	Reference	
45-64	0.69 (0.09)	2.00 (1.65-2.42)		0.65 (0.09)	1.91 (1.57-2.32)	
≥65	1.20 (0.09)	3.10 (2.54-3.70)		1.01 (0.09)	2.74 (2.26-3.31)	
Sex						
Female	N/A	Reference	<.001	N/A	Reference	<.001
Male	0.19 (0.03)	1.21 (1.13-1.30)		0.21 (0.04)	1.23 (1.14-1.32)	
Race or ethnicity						
White	N/A	Reference	<.001	N/A	Reference	<.001
Black	0.11 (0.06)	1.12 (0.98-1.27)		0.10 (0.06)	1.11 (0.97-1.26)	
Hispanic	–0.50 (0.15)	0.60 (0.45-0.81)		–0.47 (0.15)	0.62 (0.46-0.84)	
Other	–0.34 (0.06)	0.71 (0.63-0.80)		–0.23 (0.06)	0.79 (0.70-0.90)	
Comorbidities						
0	N/A	Reference	<.001	N/A	Reference	<.001
1	0.65 (0.04)	1.91 (1.75-2.07)		0.37 (0.04)	1.44 (1.33-1.57)	
≥2	1.15 (0.04)	3.16 (2.90-3.43)		0.75 (0.04)	2.12 (1.94-2.31)	
Cancer						
Other	N/A	Reference	<.001	N/A	Reference	<.001
Breast	–1.51 (0.09)	0.22 (0.18-0.26)		–1.43 (0.09)	0.24 (0.20-0.29)	
Colorectal	–0.41 (0.07)	0.67 (0.57-0.78)		–0.51 (0.07)	0.60 (0.51-0.70)	
Leukemia	0.03 (0.08)	1.03 (0.87-1.22)		–0.10 (0.09)	0.90 (0.76-1.07)	
Lip, oral cavity, and pharynx	–0.31 (0.12)	0.73 (0.58-0.93)		–0.39 (0.12)	0.67 (0.53-0.86)	
Lung and bronchus	0.63 (0.05)	1.87 (1.69-2.07)		0.38 (0.05)	1.45 (1.31-1.61)	
Lymphoma	–0.25 (0.09)	0.79 (0.66-0.94)		–0.31 (0.09)	0.73 (0.61-0.87)	
Myeloma	–0.24 (0.12)	0.78 (0.61-0.99)		–0.44 (0.12)	0.64 (0.50-0.82)	
Other digestive	0.78 (0.05)	2.18 (1.96-2.43)		0.58 (0.05)	1.80 (1.61-2.00)	
Other hematological	–0.90 (0.33)	0.41 (0.21-0.78)		–1.06 (0.33)	0.35 (0.18-0.67)	
Prostate	–1.38 (0.09)	0.25 (0.21-0.30)		–1.64 (0.09)	0.19 (0.16-0.23)	
Melanoma	–1.43 (0.09)	0.24 (0.20-0.28)		–1.56 (0.09)	0.21 (0.17-0.25)	
Urinary tract	–0.39 (0.08)	0.67 (0.58-0.79)		–0.68 (0.08)	0.50 (0.43-0.59)	
Region						
Urban	N/A	Reference	<.001	N/A	Reference	<.001
Rural	0.13 (0.04)	1.14 (1.06-1.23)		0.08 (0.04)	1.09 (1.01-1.18)	

[a] N/A: not applicable.

Sensitivity Analysis

Finally, we assessed the impact of cancer-staging variable (n=9567) in a sensitivity analysis (Table S1 in Multimedia Appendix 1). Risk of death increased over 2.5-fold after SARS-CoV-2 infection (adjusted HR 2.55; 95% CI 2.17-2.99; *P*<.001) after adjusting for other covariates and the staging variable (Table S2 in Multimedia Appendix 1) in the COVID-19 period. In the time-dependent analysis, the hazard of death increased by 4.5-fold (adjusted HR 4.63; 95% CI 3.58-5.99) in the COVID-19 period compared to the pre–COVID-19 period, after adjusting for the other covariates and the staging variable (Table S3 in Multimedia Appendix 1).

Discussion

Principal Findings

In this large population-based study of individuals with recently diagnosed cancer, we found that SARS-CoV-2 infection negatively impacted survival with a 7-fold increase in death. Survival was largely impacted among adults with increasing age, those with 2 or more comorbid conditions, and among males. Individuals with lung cancer and other digestive cancers had the highest risk of death after SARS-CoV-2 infection. This analysis provides additional empirical evidence on the magnitude of risk to patients with cancer whose immune systems are often weakened either by the disease or treatment. This evidence may help providers and public health authorities take steps to improve outcomes among people with cancer, including messaging for vaccination campaigns as well as the need for continued vigilance against infection given continued waves of infection in the United States, Europe, and other nations.

Comparison With Prior Work

One of the notable findings from this study has been that SARS-CoV-2 infection shows a markedly increased risk of death in comparison to previous studies [10,11,14,15,17,40,41]. Previous case-control studies from China reported findings of 2-fold [10] and 3-fold [11] increases in all-cause mortality, which are much lower compared to our finding of a 7-fold increase in the time-dependent analysis. Multicenter cohort studies from Europe [14,18,40,41] and the United States [4,15,42] have reported similar findings on subgroups such as age, sex, and race. In retrospect, our statewide findings support the important policy decisions that were undertaken at the height of the pandemic of limiting exposure of SARS-CoV-2 for the general population and for individuals with cancer and other immunocompromised populations. However, some of these measures diverted resources to control the spread of the virus and reduced cancer screening access with a short drop in cancer diagnosis [43]. In comparison to the general population, our prevalence of SARS-CoV-2 (n=2894, 6.2%) in this study was substantially lower compared to the general population (17.9%) [44] in Indiana. Thus, showing that the cancer population likely took preventive measures to avoid exposure to the SARS-CoV-2 virus.

Our finding of increased mortality in individuals with lung cancer and other digestive cancers can partly explain the increased mortality among males. This increased mortality for lung cancers could be related to the underlying disease (eg, bronchial carcinoma) or due to coronaviruses that cause severe lung injury [45] observed during the SARS-CoV-1 outbreak in 2003 [46]. It may also be related to underlying health behaviors, including smoking [47], which is also associated with lung cancer. We found significantly lower mortality among hematological malignancies compared to the other solid tumors such as lung, digestive, and breast cancer. This contrasts with a multicenter study [14] in Europe and the United States, which found 40% increased odds in mortality for hematological cancers (such as lymphoma, leukemia, and myeloma) compared to solid tumors. This rather contradictory result may be explained by the fact that the prior study [14] grouped the cancers into three broader categories such as hematological, solid, and multiple cancers, which differ from our cancer variable that includes individual cancer types. Our population-based analysis enabled sufficient power for more granular analysis of individual cancer types compared with prior work.

In comparison to similar studies [4,14-16,18] of cancer cohorts, we accounted for time, which better explains the increased hazard due to SARS-CoV-2 infection. Thus, the increased hazard from our study highlights the need to further continue the care planning and conversations with family on treatment options, vaccinations, and SARS CoV-2 testing during treatment [14,15]. Recent findings demonstrate that individuals with compromised immune systems, including patients with cancer, do not have a strong protection from COVID-19 after full vaccination (eg, 2 doses of mRNA vaccine) [24-26]. Therefore, both the US Centers for Disease Control and Prevention and the US Food and Drug Administration recommend patients who have cancer and are receiving mRNA COVID-19 vaccines should receive 3 doses and a booster, practice nonpharmaceutical interventions, and, if infected, be monitored closely and considered early for proven therapies that can prevent severe outcomes [25,48].

The strengths of the study include that we were able to account for time to diagnosis of SARS-CoV-2 infection, which was a limitation for prior studies due to the nature of a global crisis. Second, we were able to account for individuals with cancer and without COVID-19, which places our findings in better context compared with previous studies that reported findings only among individuals with cancer and a COVID-19 diagnosis. Third, we were able to leverage data from a large statewide HIE representative of the underlying population, which supports generalization of findings to cancer populations compared to single institutions or multicenter studies in more narrow geographic regions. For example, one-third of Indiana's population lives in rural areas, and the HIE accesses electronic health records from community hospitals in addition to 3 large regional cancer care providers in the state. Therefore, our findings strengthen the justification of treatment planning and care guidelines required for the management of patients with cancer, which were highlighted in prior studies.

Limitations

There are some limitations in our study. First, our analysis is dependent on the testing and reporting of SARS-CoV-2 from different facilities. This could underreport total COVID-19 cases in patients with cancer; however, this bias would be only toward those individuals who never received testing, given the HIE is linked to statewide testing databases. Early in the pandemic, however, testing was limited to symptomatic individuals. This could have led to testing among those with only severe COVID-19, thereby overestimating severity. Second, we were unable to account for COVID-19 severity and treatment confounders in our study; however, from previous studies, we know that treating the underlying cancer and with regular testing were prudent choices in either initiating or continuing with cancer treatment. In addition, cancer diagnoses [49-53] were ascertained via diagnostic codes, which introduces known measurement errors in terms of positive and negative predictive value. Lastly, the impact of the pandemic led to a substantial reduction in new cancer diagnosis and health services across the US [43,54] and globally [55-57], which might have overestimated the HR for our study.

Conclusion

In summary, this large study among individuals with cancer and SARS-CoV-2 emphasizes the need for continuing testing and monitoring patients for the delivery of oncology services. Given the risk of severe disease and mortality is substantially larger for patients who have cancer, the study further underscores the need for patients with cancer to receive complete vaccination, including recommended booster doses authorized by the Food and Drug Administration as well as Centers for Disease Control and Prevention.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Supplemental tables.
[DOCX File , 41 KB - cancer_v8i4e35310_app1.docx]

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Abbreviations

HIE: health information exchange
HR: hazard ratio
INPC: Indiana Network for Patient Care
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology

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Original Paper

How TikTok Is Being Used to Help Individuals Cope With Breast Cancer: Cross-sectional Content Analysis

Corey H Basch[1], MPH, EdD; Grace C Hillyer[2], MPH, EdD; Bhavya Yalamanchili[1]; Aldean Morris[1], EdD, MPH

[1]Department of Public Health, William Paterson University, Wayne, NJ, United States

[2]Department of Epidemiology, Mailman School of Public Health, Columbia University, New York, NY, United States

Corresponding Author:
Corey H Basch, MPH, EdD
Department of Public Health
William Paterson University
300 Pompton Rd
Wayne, NJ, 07470
United States
Phone: 1 973 720 2603
Email: baschc@wpunj.edu

Abstract

Background: Acknowledging the popularity of TikTok, how quickly medical information can spread, and how users seek support on social media, there is a clear lack of research on breast cancer conversations on TikTok. There is a paucity of information on how these videos can advocate for those impacted by breast cancer as a means to provide support and information as well as raise awareness.

Objective: The purpose of this cross-sectional content analysis was to describe the content of videos from the hashtag #breastcancer on TikTok. Content related to breast cancer support and coping, cancer education, and heightening the awareness of breast cancer early detection, prevention, and treatment was evaluated.

Methods: This study included 100 of the most viewed TikTok videos related to breast cancer through June 30, 2022. Videos were excluded if they were not in the English language or relevant to the topic being studied. Content was deductively coded into categories related to video characteristics and content topics using a screener based on expert breast cancer information sheets. Univariable analyses were conducted to evaluate differences in video characteristics and content when stratified as advocating or not advocating for breast cancer (yes or no) support, education, and awareness.

Results: The cumulative number of views of the videos included in this study was 369,504,590. The majority (n=81, 81%) of videos were created by patients and loved ones of individuals with breast cancer, and the most commonly discussed topic was breast cancer support (n=88, 88%), followed by coping with the myriad issues surrounding breast cancer (n=79, 79%). Overall, <50% of the videos addressed important issues such as body image (n=48, 48%), surgery (n=46, 46%), medication and therapy (n=41, 41%), or the stigma associated with a breast cancer diagnosis (n=44, 44%); however, in videos that were advocacy oriented, body image (40/62, 64% vs 8/38, 21%; *P*<.001), stigma associated with breast cancer (33/62, 53% vs 11/38, 29%; *P*=.02), and breast cancer surgery (36/62, 58% vs 10/38, 26%; *P*=.002) were discussed significantly more often than in videos that did not specifically advocate for breast cancer.

Conclusions: The use of videos to display health journeys can facilitate engagement by patients, family members, and loved ones interested in information about challenging conditions. Collectively, these findings highlight the level of peer-to-peer involvement on TikTok and may provide insights for designing breast cancer educational campaigns.

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KEYWORDS

TikTok; breast cancer; social media; short video apps; social support; content analysis; video; patient support; medical information; health information; peer support; online conversation; online health information

Introduction

Globally, the World Health Organization reports that breast cancer is the most common newly diagnosed cancer [1], only just recently edging out lung cancer. There were 2.3 million cases of breast cancer diagnosed globally during 2020 and 685,000 breast cancer deaths [2]. The incidence of breast cancer is increasing in most countries [3], and it is the most prevalent in high-income countries [4]. The incidence of breast cancer, particularly in women aged ≥20 years from 2004 to 2018 [5], is believed to be due to controllable risk factors, which also increased during that time [5].

The American Cancer Society reports that breast cancer is the second most common cancer among women in the United States [6] and projects that there will be approximately 287,850 new cases of invasive breast cancer in women, with about 43,250 breast cancer deaths in the United States in 2022 [6]. Given the expansive impact of breast cancer, it is imperative that the general public become as informed as possible about breast cancer detection and treatment. Social media has become an incredibly popular mechanism for attaining such information.

In fact, according to a Pew Research Center survey of adults, 7 in 10 (72%) Americans use social media [7], and a similar percentage have sought out health information on the web [8]. People with chronic diseases such as cancer are most likely to seek out others with similar diagnoses through social media [8]. For example, Facebook, YouTube, Twitter, and Quora share an enormous, combined audience of 5 billion viewers, and studies on these platforms suggest that there is an active level of discourse related to breast cancer on them [9].

Further, there is more traffic on social media, specifically Twitter and Instagram, regarding women's reproductive cancers than there is traffic about male reproductive cancers in relation to targeted campaigns [10]. Vraga et al [10] theorize that this finding is because breast cancer awareness campaigns have branded their cause well, with a pink ribbon and other pink symbols, and have also engaged powerful partners such as the National Football League to increase awareness.

Other social media platforms are also active on the subject of cancer [11-16]. An increase of over 300% in tweets associated with breast cancer was observed during Breast Cancer Awareness Month from 2012 to 2018 [17]. There is also a relationship between Twitter participation and improvements in patients' self-reported knowledge about breast cancer [18]. Twitter generated more traffic when it came to both male and female reproductive cancer campaigns than Instagram, leading researchers to consider Instagram as an underused resource for the communication of information to the public about these cancers [10]. The most shared material on social networking sites is personal or social in nature; two-thirds of posts portray true experiences or otherwise provide support [19]. It is also used as a form of self-distraction from the stressors caused by a new, recurring, or terminal illness [20], which is helpful to both providers and patients.

Cancer advocacy works to improve the lives of people with cancer. Of the several key elements of cancer advocacy [21], social media platforms are the best positioned to guide individuals (eg, listening and sharing personal stories and providing support), educate about cancer, and raise awareness of important issues. Web-based peer-to-peer support can reduce social isolation and address unmet support needs by connecting individuals, especially younger individuals, to share their experiences and validate their treatment and life concerns [22].

TikTok is one of the most popular applications in 2022, attracting an audience of 1.5 billion active users [23]. The TikTok audience is generally younger, which could explain why TikTok has been underused in breast cancer awareness campaigns in the past. Further, breast cancer awareness campaigns are usually targeted at an older audience. However, a substantial proportion of young people are diagnosed with breast cancer, and it is beneficial to create awareness and discussion from an earlier age for early detection and treatment purposes. More than half (67%) of teens aged 13-17 years use TikTok, with 73% of girls aged 13-17 years using TikTok [24]. Acknowledging the popularity of TikTok, how quickly medical information can spread, and how users seek support on social media, there is a clear lack of research on breast cancer conversations on TikTok. Therefore, the purpose of this cross-sectional content analysis was to describe the content of videos from the hashtag #breastcancer on TikTok and to assess the breast cancer advocacy potential of these videos.

Methods

Data Collection

This study included the 100 most viewed TikTok videos related to breast cancer as a means of evaluating the content and messages seen by individuals at the time of data collection (through June 30, 2022). At the start of the study, the hashtag #breastcancer was the most popular, with 1.1 billion views; thus, our sample of 100 videos with 369,504,590 views represents approximately one-third of breast cancer–related Tik Tok videos viewed. Videos were excluded if they were not in the English language or relevant to the topic being studied. In total, 6 of the top 100 videos were not in English and 2 were not relevant to the study (8 in total). Thus, the next 8 most liked, relevant videos in English were included.

Data were collected by watching and analyzing the videos for mentions or suggestions of predetermined content categories. The content categories were created based on breast cancer and the breast cancer gene (fact sheets from the Mayo Clinic [25], a well-known and respected source of expert-vetted medical information). For each video, the link, date of posting, views, likes, comments, and shares were collected. The type of creator and content were also analyzed.

The content categories included the use of dance, music, or humor; mention or suggestion of cancer; new diagnosis; relapse or recurrent cancer; breast cancer gene testing; advocacy (ie, content that advocated for breast cancer support, provided breast cancer information to educate viewers, and raised awareness of breast cancer issues such as early detection, prevention, and treatment); body image; hair loss; anxiety; stigma; support; coping; surgery; medication and therapy; radiation treatment;

combination treatment; nonmedical treatment; adverse effects; opinion, feelings, and experiences regarding providers of health care; cost of health care; and loss of a loved one due to breast cancer.

Statistical Analysis

Frequency distributions were conducted for the categorical and dichotomous variables and mean with SD and range for continuous variables. The number of views, likes, comments, and shares were summed. We compared differences between TikTok videos that were related to or supported breast cancer advocacy, whether self-advocacy or advocacy on behalf of a loved one, and performed univariable analyses using chi-square test for categorical and dichotomous variables and ANOVA for continuous variables. A random sample of 10% of the videos was coded by a second coder. Discrepancies between the 2 coders were resolved through discussion. The interrater reliability was computed and found to be very high (κ=0.98). All analyses were performed using SPSS statistical software (version 28; IBM Corp) [26]. *P* values <.05 were considered statistically significant.

Ethical Considerations

This study was exempt from review by William Paterson University's Institutional Review Board due to the lack of human subject involvement.

Results

Of the 100 TikTok videos related to breast cancer reviewed, 60% (n=60) were created since 2021 (Table 1). The cumulative number of views of the videos included in this study was 369,504,590. On average, the videos had approximately 3.7 million (SD 3,581,698) views each and collectively were shared more than half a million times. Patients and loved ones of individuals with breast cancer created the greatest number of videos (n=81, 81%). Videos that were related to breast cancer advocacy (n=62, 62%) differed from those that did not (n=38, 38%) by both characteristics and content. Videos advocating for breast cancer received substantially more shares (mean 7396, SD 11,903 vs mean 1290, SD 1951; *P*=.002; Table 1).

The majority (n=83, 83%) of the videos featured an individual who currently has or has had breast cancer, although only 14% (n=14) revealed a new breast cancer diagnosis (Table 2). The most commonly discussed topic was having breast cancer support (n=88, 88%), followed by coping with the myriad issues surrounding breast cancer (n=79, 79%). Between one-third and about one-half of videos talked about important issues such as body image (n=48, 48%), hair loss following treatment (n=38, 38%), surgery (n=46, 46%), medication and therapy (n=41, 41%), adverse effects of treatment (n=33, 33%), or the stigma associated with a breast cancer diagnosis (n=44, 44%). Very few videos addressed radiotherapy (n=1, 1%), combination therapy (n=9, 9%), or nonmedical treatment (n=4, 4%). Advocating videos more often discussed body image (40/62, 64% vs 8/38, 21%; *P*<.001), stigma associated with breast cancer (33/62, 53% vs 11/38, 29%; *P*=.02), and breast cancer surgery (36/62, 58% vs 10/38, 26%; *P*=.002) compared to videos that did not specifically advocate for breast cancer. Among videos with no mentions of breast cancer advocacy, content focused more frequently on near-term breast cancer issues that included hair loss (20/38, 53% vs 18/62, 29%; *P*=.02), anxiety (18/38, 47% vs 9/62, 14%; *P*<.001), coping (35/38, 92% vs 44/62, 71%; *P*=.01), medication and therapy (23/38, 60% vs 18/62, 29%; *P*=.002), and adverse effects of treatment (18/38, 47% vs 15/62, 24%; *P*=.02).

Table 1. Differences in the characteristics of TikTok videos (N=100) related to breast cancer among those related to breast cancer advocacy (n=62) and those that did not (n=38).

	Total (N=100)	Advocacy		*P* value
		Yes (n=62)	No (n=38)	
Video characteristics				
Year (total: N=100; advocacy, yes: n=62; advocacy, no: n=38), n (%)				.33
2019	1 (1)	0 (0)	1 (2.6)	
2020	14 (14)	9 (14.5)	5 (13.2)	
2021	60 (60)	35 (56.5)	25 (65.8)	
January to July 2022	25 (25)	18 (29)	7 (18.4)	
Number of views (n=369,504,590)				
n (%)	369,504,590 (100)	262,825,700 (71.1)	106,678,890 (28.8)	.05
Mean (SD)	3,695,046 (3,581,698)	4,239,124 (3,879,713)	2,807,339 (2,864,258)	
Range	290,600-18,900,000	290,600-18,900,000	446,000-11,600,000	
Number of comments (n=676,604)				
n (%)	676,604 (100)	492,062 (72.7)	184,542 (27.3)	
Mean (SD)	6766 (11,314)	7936 (13,703)	4856 (5183)	.19
Range	70-92,500	70-92,500	133-22,000	
Number of shares (n=507,638)				
n (%)	507,638 (100)	458,603 (90.3)	49,035 (9.7)	
Mean (SD)	5076 (9879)	7396 (11,903)	1290 (1951)	.002
Range	45-66,400	45-66,400	84-11,700	
Format (total: N=100; advocacy, yes: n=62; advocacy, no: n=38), n (%)				
Uses dance				.71
Yes	8 (8)	6 (9.7)	2 (5.3)	
No	92 (92)	56 (90.3)	36 (94.7)	
Uses music				.13
Yes	70 (70)	40 (64.5)	30 (78.9)	
No	30 (30)	22 (35.5)	8 (21.1)	
Uses humor				.13
Yes	27 (27)	20 (32.3)	7 (18.4)	
No	73 (73)	42 (67.7)	31 (81.6)	
Video creator				.12
Patient	68 (68)	42 (67.7)	26 (68.4)	
Loved one	12 (12)	5 (8.1)	7 (18.4)	
Health professional	3 (3)	3 (4.8)	0 (0)	
Company	7 (7)	6 (9.7)	1 (2.6)	
Consumer	9 (9)	6 (9.7)	3 (7.9)	
Patient/loved one	1 (1)	0 (0)	1 (2.6)	

Table 2. Differences in the content of TikTok videos (N=100) related to breast cancer among those related to breast cancer advocacy (n=62) and those that did not (n=38).

Content	Total (N=100), n (%)	Advocacy		*P* value
		Yes (n=62), n (%)	No (n=38), n (%)	
Have or had breast cancer				.01
Yes	83 (83)	47 (76)	36 (95)	
No	17 (17)	15 (24)	2 (5)	
New breast cancer diagnosis				<.001
Yes	14 (14)	3 (5)	11 (29)	
No	86 (86)	59 (95)	27 (71)	
***BRCA*[a] genetic mutation**				.37
Yes	5 (5)	2 (3)	3 (8)	
No	95 (95)	60 (97)	35 (92)	
Body image				<.001
Yes	48 (48)	40 (64)	8 (21)	
No	52 (52)	22 (36)	30 (79)	
Hair loss following treatment				.02
Yes	38 (38)	18 (29)	20 (53)	
No	62 (62)	44 (71)	18 (47)	
Anxiety				<.001
Yes	27 (27)	9 (14)	18 (47)	
No	73 (73)	53 (86)	20 (53)	
Stigma associated with breast cancer				.02
Yes	44 (44)	33 (53)	11 (29)	
No	56 (56)	29 (47)	27 (71)	
Support				.56
Having support	88 (88)	56 (90)	32 (84)	
Lack of support	5 (5)	3 (5)	2 (5)	
Unknown	7 (7)	3 (5)	4 (11)	
Coping				.01
Yes	79 (79)	44 (71)	35 (92)	
No	21 (21)	18 (29)	3 (8)	
Surgery				.002
Yes	46 (46)	36 (58)	10 (26)	
No	54 (54)	26 (42)	28 (74)	
Medication and therapy				.002
Yes	41 (41)	18 (29)	23 (60)	
No	59 (59)	44 (71)	15 (40)	
Radiation therapy				>.99
Yes	1 (1)	1 (2)	0 (0)	
No	99 (99)	61 (98)	38 (100)	
Combination therapy				>.99
Yes	9 (9)	6 (10)	3 (8)	
No	91 (91)	56 (90)	35 (92)	

Content	Total (N=100), n (%)	Advocacy		*P* value
		Yes (n=62), n (%)	No (n=38), n (%)	
Nonmedical treatment				.63
Yes	4 (4)	2 (3)	2 (5)	
No	96 (96)	60 (97)	36 (95)	
Adverse effects of treatment				.02
Yes	33 (33)	15 (24)	18 (47)	
No	67 (67)	47 (76)	20 (53)	

[a] *BRCA*: breast cancer gene.

Discussion

To our knowledge, this is the first study describing the content of the most viewed TikTok videos on the larger topic of breast cancer. Our review of the literature revealed one prior publication focusing on fat grafting in breast cancer [27]. Prior research evaluated breast cancer coverage on various social media platforms [16,28]. The findings of this study indicate that the 100 TikTok videos related to breast cancer reviewed were filled with messages created to support and advocate for individuals with breast cancer. Social support has long been noted as being beneficial [29], especially in health situations [30] and more specifically in the case of patients with cancer, survivors, and their loved ones [31-33]. In the digital era, social support can easily take place through technological mediums, whether through preplanned interventions or spontaneously through individual use [22,34-38]. Our findings corroborate with this existing research in that the overwhelming majority of videos in our sample mentioned support, coping, and advocacy [39,40].

Although there is research that indicates the possibility of misinformation spreading on TikTok, as it has on many social media platforms [41,42], emerging research also supports the concept that TikTok can provide a high level of support for those experiencing difficulty [43,44]. This possibility of far-reaching effects of support are enhanced by the widespread reach of TikTok. The nature of expression over social media can lead to greater support as geographic boundaries are eliminated.

Issues affecting the individual both physically and psychologically were frequently noted in the videos we reviewed. The psychological factors that accompany breast cancer include substantial life changes, dealing with a life-threatening illness, and painful treatments. Physical changes and issues related to a new body image also amplify psychological distress [45,46]. Breast cancer surgeries such as biopsies, lumpectomies, mastectomies (total, double, modified radical, radical, nipple-sparing, or skin-sparing), aesthetic flat closures, and breast reconstruction are all options that impact physical appearance [47] and leave many women stigmatized, which can affect quality of life [48]. Video creators discussed the stigma of surgery options that they faced and their experience with chemotherapy. They mentioned not feeling feminine or losing their femininity and hair loss—all part of self-identity and body image. For instance, although hair loss is common with chemotherapy, it can lead to psychological disturbance and stress [49,50].

The limitations of this study include the fact that the design was cross-sectional and that we only reviewed English-language videos. Additionally, only one popular hashtag was used, which can lead to a limited perspective. The relatively small sample of only 100 videos may not represent the full range of videos. Content analysis does not allow an in-depth reflection of how information in these videos is processed and used by viewers. Hence, this is an area for future research. Of note, TikTok is only one social media platform, with content delivered in a specific way. Therefore, findings cannot be generalized across other social media platforms. Further, although patients and loved ones claim to be creating many of the videos included in this study, there is no way to verify this information. However, this study offers perspective into the use of TikTok to discuss breast cancer and the level of support found on this medium.

Social media platforms such as TikTok provide a space for health information to be disseminated to a wide variety of populations with varying health literacy skills [51]. Video creators on this platform used advocacy and support to cope with breast cancer in some respect.

The findings of this study indicate that most of the interest in TikTok videos was around patient journeys, coping mechanisms, and support systems. As cancer interventions have better outcomes in patients with early diagnosis, it is important to reach vulnerable populations at a young age. TikTok, which is predominantly used by young women, represents an ideal platform for outreach by professional societies and advocacy groups focusing on breast cancer. Their campaigns may benefit from incorporating the findings of this study.

Conflicts of Interest

CHB serves as an Editorial Board Member for JMIR; she did not have a role in the review or editorial process for this article. All other authors declare no conflicts of interest.

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Corrigenda and Addenda

Correction: A Web-Based Prostate Cancer–Specific Holistic Needs Assessment (CHAT-P): Multimethod Study From Concept to Clinical Practice

Veronica Nanton[1], BA, PGDip, MSc, PhD; Rebecca Appleton[2], BA, PhD; Nisar Ahmed[3], BSc, MMedSci, PhD; Joelle Loew[4], BA, MSc, PhD; Julia Roscoe[1], MSc; Radha Muthuswamy[5], BSc, MA, HSM, CIPP/E, CIPM, CDPSE; Prashant Patel[6], MBBS, MS, PhD; Jeremy Dale[1], BA, MBBS, MA, PhD; Sam H Ahmedzai[3], BMedSci, MBChB

[1]Warwick Medical School, University of Warwick, Coventry, United Kingdom
[2]Mental Health Policy Research Unit, Division of Psychiatry, University College London, London, United Kingdom
[3]Medical School, University of Sheffield, Sheffield, United Kingdom
[4]Lucerne School of Business, Lucerne, Switzerland
[5]Prostate Cancer UK, London, United Kingdom
[6]Institute of Cancer and Genomic Sciences, University of Birmingham, Birmingham, United Kingdom

Corresponding Author:
Veronica Nanton, BA, PGDip, MSc, PhD
Warwick Medical School
University of Warwick
Gibbet Hill Road
Coventry
United Kingdom
Phone: 44 2476 574025
Email: v.nanton@warwick.ac.uk

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In “A Web-Based Prostate Cancer–Specific Holistic Needs Assessment (CHAT-P): Multimethod Study From Concept to Clinical Practice” ([JMIR Cancer 2022;8(4): e32153]) the authors noted one error in the order of the authors.

The author list appeared as:

> *Rebecca Appleton, Veronica Nanton, Nisar Ahmed, Joelle Loew, Julia Roscoe, Radha Muthuswamy, Prashant Patel, Jeremy Dale, Sam H Ahmedzai*

Whereas it should have been:

> *Veronica Nanton, Rebecca Appleton, Nisar Ahmed, Joelle Loew, Julia Roscoe, Radha Muthuswamy, Prashant Patel, Jeremy Dale, Sam H Ahmedzai*

The correction will appear in the online version of the paper on the JMIR Publications website on 1st November 2022, together with the publication of this correction notice. Because this was made after submission to PubMed, PubMed Central, and other full-text repositories, the corrected article has also been resubmitted to those repositories.

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Toronto, ON, M5A 3Y5
Phone: (+1) 416-583-2040
Email: support@jmir.org