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Barriers and Facilitators of Using Sensored Medication Adherence Devices in a Diverse Sample of Patients With Multiple Myeloma: Qualitative Study

Alemseged Ayele Asfaw[1], BPharm, MSc; Connie H Yan[1], BS, PharmD; Karen Sweiss[2], BS, PharmD; Scott Wirth[2], BS, PharmD; Victor H Ramirez[3], BS; Pritesh R Patel[4], MD; Lisa K Sharp[1], BSN, MA, PhD

[1]Pharmacy Systems, Outcomes & Policy, College of Pharmacy, University of Illinois at Chicago, Chicago, IL, United States

[2]Pharmacy Practice, College of Pharmacy, University of Illinois at Chicago, Chicago, IL, United States

[3]College of Medicine, University of Illinois at Chicago, Chicago, IL, United States

[4]Department of Medicine, Section of Hematology/Oncology, College of Medicine, University of Illinois at Chicago, Chicago, IL, United States

Corresponding Author:
Lisa K Sharp, BSN, MA, PhD
Pharmacy Systems, Outcomes & Policy
College of Pharmacy
University of Illinois at Chicago
MC871
833 South Wood Street
Chicago, IL, 60612
United States
Phone: 1 312 355 3569
Fax: 1 312 996 2954
Email: sharpl@uic.edu

Abstract

Background: Many recently approved medications to manage multiple myeloma (MM) are oral, require supportive medications to prevent adverse effects, and are taken under complex schedules. Medication adherence is a concern; however, little attention has been directed toward understanding adherence in MM or associated barriers and facilitators. Advanced sensored medication devices (SMDs) offer opportunities to intervene; however, acceptability among patients with MM, particularly African American patients, is untested.

Objective: This study aimed to explore patients' (1) perceptions of their health before MM including experiences with chronic medications, (2) perceptions of adherence barriers and facilitators, and (3) attitudes toward using SMDs.

Methods: An in-person, semistructured, qualitative interview was conducted with a convenience sample of patients being treated for MM. Patients were recruited from within an urban, minority-serving, academic medical center that had an established cancer center. A standardized interview guide included questions targeting medication use, attitudes, adherence, barriers, and facilitators. Demographics included the use of cell phone technology. Patients were shown 2 different pill bottles with sensor technology—Medication Event Monitoring System and the SMRxT bottle. After receiving information on the transmission ability of the bottles, patients were asked to discuss their reactions and concerns with the idea of using such a device. Medical records were reviewed to capture information on medication and diagnoses. The interviews were audio-recorded and transcribed. Interviews were independently coded by 2 members of the team with a third member providing guidance.

Results: A total of 20 patients with a mean age of 56 years (median=59 years; range=29-71 years) participated in this study and 80% (16/20) were African American. In addition, 18 (90%, 18/20) owned a smartphone and 85% (17/20) were comfortable using the internet, text messaging, and cell phone apps. The average number of medications reported per patient was 13 medications (median=10; range=3-24). Moreover, 14 (70%, 14/20) patients reported missed doses for a range of reasons such as fatigue, feeling ill, a busy schedule, forgetting, or side effects. Interest in using an SMD ranged from great interest to complete lack of interest. Examples of concerns related to the SMDs included privacy issues, potential added cost, and the size of the bottle (ie, too large). Despite the concerns, 60% (12/20) of the patients expressed interest in trying a bottle in the future.

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Conclusions: Results identified numerous patient-reported barriers and facilitators to missed doses of oral anticancer therapy. Many appear to be potentially mutable if uncovered and addressed. SMDs may allow for capture of these data. Although patients expressed concerns with SMDs, most remained willing to use one. A feasibility trial with SMDs is planned.

Introduction

Background

Cancer treatment is being transformed by the rapid expansion of novel oral therapies [1,2]. While greater than 50 oral anticancer (OAC) medications are currently approved and in use, many more are in development [1,3]. The transition to oral routes of administration offers potential benefits to patients and providers, but new challenges are also introduced. This new paradigm places significant responsibility on patients to manage their medications autonomously outside of the clinical setting. Moreover, 2 literature reviews found adherence rates to OAC medications across all cancer types ranged from 40% to 100% including 20% to 44% of patients who took more medication than directed [4,5]. These results are of concern because taking OAC medication in amounts other than the directed dosage can significantly reduce the efficacy of OAC therapies while contributing to adverse events and economic waste [6].

Multiple myeloma (MM) is a specific example of cancer where novel oral therapies have resulted in vast improvements in survival over the past decade [7,8]. We could find no empirical data exclusively addressing medication adherence in patients undergoing treatment for MM; however, concern is warranted. Risk factors for poor adherence to OAC medications include the number of medications prescribed, being older in age, associated side effects, costs associated with treatment, and identifying as an ethnic minority among others [5]. These factors are relevant for many patients with MM. The treatment regimen for MM is among the more complex of cancer treatments relying on multiple oral medications that need to be taken on irregular schedules. Patients are typically treated with 1 of the several OAC medications such as thalidomide [9], lenalidomide [10], pomalidomide [11], ixazomib [12], and panobinostat [13] combined with oral steroids. In addition, supportive care focuses on prevention of infectious complications, pulmonary emboli, and bone morbidity, which involves additional medications contributing to the overall medication burden [14]. The cost of OAC therapies for MM can exceed US $20,000 per month, and insurance coverage varies tremendously [15,16]. Most MM cases are diagnosed in the elderly aged 65 years and above [17] who present with pre-existing age-related chronic health problems that require daily medications to manage. Finally, for unknown reasons, African Americans are at a higher risk of being diagnosed with MM than other racial and ethnic groups.

A fundamental limitation in the field of medication adherence is measurement of real-time medication-taking behavior. To date, few interventions have been conducted to improve adherence to OAC medications, and results suggest that additional research is needed to further refine intervention development [18]. Ethnic minorities and individuals from lower socioeconomic backgrounds may be particularly vulnerable to adherence challenges [19]. With this in mind, the study team was interested in exploring the potential of using technology to capture patients' medication-taking behaviors as 1 component of a future intervention. Numerous real-time or sensored medication devices (SMDs) are currently available with additional devices under development [20]. The specific operations of each SMD vary widely. Simple SMDs include specialized caps or lids that fit onto traditional medication bottles and provide an alarm feature (ie sound or light) that can be scheduled at specified times based on medication regimen. Some have the added feature of recording the date and time of cap removal. More sophisticated SMDs provide the auditory and visual alarm in addition to transmitting *real-time* information to patients via text messages as well as texts or telephone calls to caregivers or providers. These are often supported by internet-based apps that track the date and time of device openings in visual graphics.

From an intervention development perspective, the more advanced SMDs are appealing because they transmit real-time information on missed device openings. Specially, when alerted that a patient missed a dose, researchers may be able to communicate with the patient to understand the contextual factors associated with each missed dose as it occurs. In turn, this information may allow for tailored medication support interventions that are more accurately matched to each patient's unique barriers. However, a fundamental question must be answered before intervention development is initiated—are SMDs that track patients' behavior and transmit real-time data acceptable to patients? Inclusion of African Americans was critical, considering that their rates of MM are higher [21].

Objective

This study was undertaken with the long-term goal of developing a patient-centered intervention to support adherence to OAC medications. Patients with MM were targeted because no data on adherence to MM regimens were identified despite numerous factors placing them at high risk for poor adherence. This initial phase of research aimed to understand patients' (1) perceptions of their health before MM including experiences with chronic medications, (2) perceptions of adherence barriers and facilitators, and (3) attitudes toward using SMDs. Although not a primary aim, information was collected on cell phone ownership, use of cell phone functions, and the internet to understand the degree to which the sample was comfortable with basic technology that might be integrated into an intervention.

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Methods

Participants and Recruitment

A convenience sample of patients was recruited from within an urban, minority-serving, academic medical center with an established cancer center. Patients were recruited as they presented for a regularly scheduled appointment with their established oncology team. Eligibility criteria were as follows: (1) aged 18 years or older, (2) current diagnosis of MM, (3) receiving orally administered oncology treatment for MM currently or in the past 3 months, and (4) English speaker. Before the days on which the MM clinic visit was scheduled, the research assistant spoke with the oncologist and 2 oncology pharmacists to identify scheduled patients who were qualified. When the patient presented to the clinic, a provider assessed interest in the research. Willing patients met the interviewers in a private conference room to sign the informed consent form and conduct the interview. Interviews were audio-recorded.

Development of the Interview Guide

A semistructured interview guide was drafted by a health psychologist with formal training in qualitative research (LKS) and experience working with diverse populations on adherence. An oncology physician and 2 pharmacists reviewed the interview draft of 12 open-ended questions for accuracy, clarity, and content from a medical perspective. To address the patients' perspective, the revised 9-item interview guide was assessed in 1 MM patient who responded to the questions and provided feedback. A final interview guide consisted of 9 open-ended questions (shown in Multimedia Appendix 1). Full ethics review and approval was obtained from the institutional review board.

Data Collection

All interviews were conducted by 2 trained team members, (LKS, VR) that began by assessing the type of cell phone ownership and use of short message service texts, internet, or internet apps. Although this was not a stated aim, experience with these technologies could influence responses to the interview and had implications for intervention design. As shown in Multimedia Appendix 1, additional questions addressed (1) the patient's health before being diagnosed with MM including pre-existing chronic comorbidities and experience with daily medications, (2) current health and medications, (3) priority of medications, (4) organization of medications, (5) perceived barriers and facilitators to adherence, and (6) perspectives on 2 specific SMDs. Before asking about perspectives on SMDs, all patients were allowed to hold and manipulate 2 different pill bottles with sensor technology. They did not have the opportunity to actually use the bottles themselves. The 2 devices used in this study were MEMS (Medication Event Monitoring System) bottle and the SMRxT bottle. These were selected because they were accessible to our team. The interviewers provided information on the transmission

ability of the bottles. Of note, the MEMS bottle recorded information that was downloaded later, whereas the SMRxT bottle transmitted information in real time. Demographic information and number of prescribed medications were abstracted from the electronic medical records to lessen patient burden. Patients were provided US $20 reimbursement for their time.

Data Analysis

Audio-recorded interviews were transcribed as they were completed. The lead investigator determined that thematic saturation had been attained after 20 interviews conducted over 2 months yielded no new information. In addition, the demographic characteristics of respondents were evaluated to ensure that premature saturation was not met due to homogeneous sample selection.

Coding followed a specific type of thematic analysis known as the framework method [22]. This deductive approach is often used in health-related research designed to answer specific questions with qualitative inquiry. Like all thematic analysis, the framework method involves developing an analytic framework of codes that is applied by independent coding of transcripts. To achieve this coding framework, 3 members of the research team (AAA, CHY, and LKS) with training in qualitative research independently read the transcripts and met twice to establish the application of the initial codes. Subsequently, the 3 members independently coded 2 randomly selected transcripts and met again to compare codes. Following discussion and minor modifications to the coding framework, the 3 members independently coded the remaining transcripts, managing the data in Microsoft Excel. The 3 members met to compare results and reached consensus on coding for all 20 transcripts.

Results

Sociodemographic Characteristics

A total of 20 patients were approached for participation and all agreed, resulting in a 100% response rate. The length of the interview varied from 20 to 40 min. As shown in Table 1, the median age of patients was 59 years (range 29-71 years) and 80% (16/20) were African American. The median time since being diagnosed with MM was 25.5 months, with a range from 2 months to 192 months. Consistent with the demographics of the larger patient population seen in this setting, the majority of participants were covered by government-issued insurance (Medicaid or Medicare). Although 7 patients had private insurance, 3 of these individuals expressed concern regarding the future of their coverage. Moreover, 2 patients were concerned that the insurance might "run out," and 1 male who had to stop working because of the MM stated that his insurance was only covering him for a few more months.

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Table 1. Sociodemographic characteristics of study participants.

Characteristics	Statistics
Sex, n (%)	
Female	9 (45)
Male	11 (55)
Age in years	
Median	59
Range	29-71
Race/ethnicity, n (%)	
African American	16 (80)
White	3 (15)
Hispanic/Latino	1 (5)
Marital status, n (%)	
Married	10 (50)
Single	8 (40)
Widow	1 (5)
Divorced	1 (5)
Type of insurance, n (%)	
Private	7 (35)
Medicaid	6 (30)
Medicare B	6 (30)
Uninsured	1 (5)

Cell Phone Ownership and Use of Internet

Out of the 18 (90%, 18/20) participants who reported owning an internet-enabled cell phone, 17 used it to navigate the internet, interact with apps, and text message. One male aged 60 years who owned a smartphone stated that he did not like to type so he did not use text messaging or cell phone apps. However, he did use his phone to access the internet, which required typing, and he also took pictures with his phone. The 2 female participants with basic phones that were not internet-enabled were aged 63 and 67 years, respectively. One owned a government-subsidized phone and did not know how to use the internet, phone apps, or text messaging. The second woman stated that she used her flip phone for emergencies only and rarely switched it on. She did not know how to use text messaging. Instead of a cell phone or texting, she preferred to use email on her computer, which she did frequently. She did not know how to use the internet on her phone. Importantly, this participant also had multiple sclerosis that affected her ability to use her hands at times. As a result, the keyboard on a computer was easier for her to use than a cell phone.

Experiences With Pre-Existing Disease and Current Number of Medications

A total of 10 individuals described feeling healthy and free of any chronic health problems requiring daily medications before their diagnosis of MM. Prior health issues consisted of minor injuries, colds, or broken bones. Not surprisingly, they recalled feeling overwhelmed or confused when they initiated their treatments for MM; however, that dissipated over time as they became more accustomed to the routine.

The remaining 10 patients reported having a range of pre-existing chronic diseases at the time they were diagnosed with MM: hypertension (n=3), high cholesterol, diabetes, multiple sclerosis, anemia, a mental health problem, chronic obstructive pulmonary disease, and goiter. All these patients required chronic daily medication except for a single 40-year-old African American female whose goiter required monitoring but no daily medications. At the time of the interview, medical records revealed that all 20 patients had multiple chronic diseases requiring daily medications. The median number of chronic medications was 10, with a range of 3 to 24 per person including those for MM.

Perspectives on Prioritizing Medications for Multiple Myeloma and Chronic Disease

Three distinct subthemes emerged within a larger medication priority theme: (1) the cancer medicine was the most important, (2) the cancer medicine and warfarin were the most important, or (3) all medicines were equally important. Furthermore, 2 patients expressed the feeling that their *cancer medication* was the most important among all their medications, referring specifically to the names of their respective OAC medication. Both conveyed the sense that their life depended on their adherence to the OAC medication. Interestingly, neither viewed the supportive medications used to manage their cancer- (ie, osteoporosis and anemia) and treatment-related effects as being

a *cancer medication*. A total of 2 patients identified their OAC medication along with their *blood thinner* (ie, warfarin) as being the most important, despite being on additional medications for comorbid diseases. They both understood that the *blood thinner* prevented them from having blood clots, which was a serious side effect from some of the OAC medications. The remaining 16 patients expressed a sense that all of their medications, for both cancer and chronic conditions, were needed to improve their health.

However, there were nuanced variations in why individuals felt their chronic disease medications were important. A total of 4 patients explained that their past medical experiences such as a myocardial infarct, worsening symptoms of multiple sclerosis, or symptoms of mental illness led them to conclude that the medications for chronic diseases were equally important. For example, a 60-year-old married African American male with MM for 60 months stated:

> *I had a heart attack, so that has solidified and strengthened my belief that my hypertension medication is just as important as my cancer medication. If I don't take it, I'm in danger of getting a heart attack again.*

For others, the belief that specific adverse outcomes might occur if they were to stop their medications for chronic diseases was sufficient to motivate medication adherence. Most provided more general explanations for their beliefs, suggesting that all the medications worked together in some manner to maintain their health.

Barriers to Oral Anticancer Medication Adherence and Missed Doses

Barriers to medication adherence were defined as factors that contributed to missed doses of MM medications. MM medications included OAC medications as well as the adjunct or supportive medications prescribed to minimize the adverse effects of the OAC medications. Despite expressing their feelings about the importance of medications, 14 (70%, 14/20) patients stated that they sometimes did miss doses of their OAC medications. Most of the patients described situations where the missed doses were unintentional. In addition, 10 major thematic areas related to barriers to medication adherence were identified in the interviews: side effects, distractions, insurance or pharmacy delays, number of medications, travel or being away from home, pill size, fatigue, stigma, homelessness, and spirituality.

Side Effects

A total of 6 (30%, 6/20) patients noted medication side effects as a barrier to taking their OAC medications as prescribed. Examples of side effects included stomach discomfort, diarrhea, vomiting, fatigue, stiff legs, ankle swelling, foot tingling, or constipation. Although 2 patients boldly explained that they intentionally skipped doses of their cancer medications to avoid side effects, others described approaches to decrease side effects such as taking the medications that they felt caused the side effects at night while they slept or making sure to eat food before taking the medication. Most of the patients expressed that although the side effects were bothersome, they were usually

willing to tolerate them recognizing the benefit of the OAC medicine.

Distractions

A total of 6/20 (30%) patients described distractions of various types that contributed to missed or delayed OAC medication doses. Distractions were a broad theme that encompassed events such as celebrating birthdays or holidays, rushing or moving quickly in response to something, being busy, and becoming involved in an activity such as a hobby or watching television. A married African American male with MM for 60 months reported:

> *I don't really forget to take my medicine completely [on weekends], I just don't take it at the same time as during the week days.*

The interviews implied that the patients' normal routine was altered in some way or they lost track of time due to the situation.

Insurance or Pharmacy Barriers

A total of 6 (30%, 6/20) patients reported experiencing health care system barriers that made it difficult to obtain their OAC medications at some point in their treatment. Specifically, 5 attributed delays in accessing their medication to their insurance companies. One patient reported missing at least 1 dose of his OAC due to the delay and another had a delay in treatment initiation. In addition to insurance barriers, 1 patient described that he had difficulty getting OAC medication refills on time due to what he perceived to be miscommunications between the oncologist and the pharmacy. In his words, "I have to figure out where my medications are." He described having to obtain an "emergency supply from a different pharmacy" to prevent missed doses.

Number of Medications

The number of medications patients were asked to take was mentioned negatively or as a burden by 6 (30%, 6/20) patients. Comments ranged from feelings of frustration or worry to being overwhelming or just feeling the number was excessive. Although some of the patients were experiencing the burden at the time of the interview, a few commented that their feelings of being overwhelmed by the medications was heightened earlier in their MM treatment but had subsided with a decrease in the number of medications prescribed at the time of the interview. A 41-year-old African American female with MM for 31 months who was on 24 medications stated:

> *I just worry that I am taking so many pills. Sometimes it's psychological when I feel that my throat closes up - refuses to swallow them. They won't go down. It's like my body is rejecting them but I have to force it thru.*

Pill burden was often given as a reason for forgetting to take medication.

Travel or Being Away From Home

A total of 3 (15%, 3/20) patients mentioned that when they were away from home or had a night out, they just took their evening medications whenever they returned home. As a result, they

took their evening medications, including the OAC medication, at irregular intervals or skipped doses.

Pill Size

A total of 3 (15%, 3/20) patients mentioned the size of the calcium pill as being a barrier that often resulted in missed doses. In the context of MM, calcium is often prescribed as an adjunct to treatment aimed at supporting bone health [23].

Fatigue

Fatigue was a common side effect of the medications; however, 2 (10%, 2/20) patients mentioned fatigue in relation to adherence. They commented that their nighttime medication was the hardest to adhere to because of feeling tired at the end of the day. At times, they fell asleep without taking their medication, which resulted in either taking the medication off schedule when they awakened during the night or missing the dose entirely.

Stigma

A total of 2 (10%, 2/20) patients made comments that reflected a stigma associated with the need for medications; however, they were subtly different. The youngest participant, a 29-year-old married African American male with MM for 7 months, reported that he missed his medications when he was "getting high with his homies." Although substance abuse could be considered the key barrier, a careful analysis of his transcript suggested otherwise. As this young man spontaneously explained, he kept all his medications in their bottles next to his bed, and he had considered just taking the bag with him when he partied with his friends. However, he had not told his friends that he had cancer, as he feared the stigma and rejection if they knew he was ill. The second example came from a 68-year-old married African American male who commented that all his medications "make my house look like a drug house," explaining that his son had a drug problem. Although he reported rarely missing his medications, he strongly disapproved of medications in general and struggled with his own need for them.

Homelessness and Spirituality

A 60-year-old single African American woman with MM for 53 months was the only patient who did not describe any location for keeping her medications, which was attributed to the fact that she was homeless and resided in shelters at times. Despite the lack of any consistent location for her medications, she stated that she tried to take them in the morning if she ate breakfast. She did mention using a pillbox in the past, but she was not using one at the time of the interview ostensibly because she could not keep up with it. She was very open about not being adherent to her medications throughout the interview, which was a great concern to her oncologist who was aware of the situation. However, she expressed that she was "a strong believer in God"; therefore, she did not worry when she missed her medications.

Cost of Medications

Although all patients were able to financially access OAC medications at the time of the interview, financial concerns for the future were common and impacted life choices for some.

For example, 2 patients reported concern that their private employer-based insurance was reaching the limit soon and they were not able to return to work. Neither were clear on how they would afford health care or medications once their insurance coverage ended. Conversely, a 40-year-old single African American female was interested in working but feared losing Medicaid coverage if she returned to work. This was complicated by the fact that historically she had not found positions that offered employer-based health insurance. One 65-year-old single African American male reported that he was currently receiving his OAC medication with assistance from a patient access network. However, in his words, he "did not know how long this lasts" and felt that when it ended, he would have to decide if he wanted to "become broke or die." Most patients reported having manageable co-payments for their medications ranging from US $2 to US $15; although not everyone reported the exact cost. Several patients with insurance reported having no co-pay. The setting offered numerous medication financial assistance programs (ie, foundations and access networks) for patients who did not have insurance coverage.

Facilitators to Medication Adherence

Facilitators to medication adherence were defined as factors that aided patients in adhering to MM medication. As with barriers, MM medications included OAC medications and the adjunct or supportive medications. A total of 5 major thematic areas were identified in the interviews: location of medicines, organization of medicines, medication reminders, social support, and spirituality.

Location of Medications

The most common theme, identified in all but 1 patient's interview, was related to having a special location to keep medications. In describing their unique locations for storing medications, it was clear that most had a reason for the location selection. Several patients focused on selecting locations where they thought they would be when they needed to take the medications. For example, locating bottles on the top of a nightstand in the bedroom was strategic because "they [the bottles] are the first thing I see when I wake up and go to bed." Other locations included the top of the bedroom dresser, on the kitchen counter, or kitchen table. The kitchen was popular for those who took medications around mealtimes. Only a 41-year-old widowed African American female with MM for 31 months who was on 24 different medications described multiple locations for storing her medications. She stored her medications together based on the health problem they targeted. For example, all her cancer medications were in a drawer and all her blood pressure medications were in a cabinet. Although less common, a few patients preferred to keep their medications out of sight in a desk hutch, drawer, and medicine cabinet. They stated that they did not like to see the bottles because it reminded them of cancer or they just did not like seeing the bottles.

Medication Organization and Pillboxes

In addition to having a specific location, 4 (20%, 4/20) patients had a system for organizing the medications that they found facilitated their adherence. For example, a 60-year-old married

African American male with MM for 60 months kept his morning medications in his desk hutch on the right side, nighttime medications on the left, and cancer medications in the center. Placing the bottles in specific locations within the same drawer helped him remember when to take which medicines. A similar approach was used by a married Latino female with MM for 2 months who put all of her morning medications on 1 side of the bed and evening medications on the other side without special consideration of the MM medications.

The most sophisticated system was reported by a 67-year-old married white male with MM for 20 months. He kept a written diary with his medications in the original bottles next to his bed on a bed stand. He wrote down the time each dose of medications was taken. If he did not have time to use the diary, he took the medication and flipped the bottle upside down. When he returned home, he filled in the diary with an approximate time and flipped the bottle upright. Finally, a 40-year-old single African American with MM for 10 months stored all of her bottles in a special pouch that she found particularly attractive. The *cuteness* of the pouch was a source of pleasure contrasted with her feelings toward the contents of the pouch. She found it easy to locate the pouch in her bedroom and placed it in her purse when she went out.

A total of 6 (30%, 6/20) patients mentioned using pillboxes to hold their medications and 5 of those perceived this as a facilitator to taking their medications. However, this was not unanimous as a 50-year-old married African American male with MM for 50 months found the pillbox contributed to him confusing his morning and evening pills. He no longer used one, opting to keep the medicines in their original bottles.

Reminders

A total of 11 (55%, 11/20) patients described using specific visual and auditory reminders to take medications. Moreover, 7 patients commented that the location of their medicines served as a visual reminder to take the medicines, and the remaining 4 patients discussed auditory cell phone reminders. Of those, 2 used their cell phone alarm for evening medications and 2 used their cell phone calendar alert to remind them when to take their intermittent cancer medication.

Social Support

Social support from family was seen as an important facilitator of medication adherence for 10 (50%, 10/20) patients. A total of 3 different types of support were noted in the coding: medication reminders, emotional support to cope, and attendance at clinic visits to accurately capture information. Most commonly, patients described that a spouse provided a verbal reminder to take medications, which was described as wanted or helpful. One of the younger patients, a 33-year-old engaged African American female with MM for 61 months described relying heavily on her family for emotional support to cope along with tangible support to take her medication. Her son, in particular, often woke her up at night to remind her to take her evening medications. The 67-year-old married white male who used a written diary to track his medications described his wife and sister as being helpful at visits with the physician because

they took written notes and reviewed them with him at home after each visit to make sure he understood exactly what medications to take and when to take them. Finally, it was noted that a 67-year-old married white female with MM for 17 months described that she and her husband "took care of each other" because he was also ill and in poor health. He reminded her to take her medications on occasions and also provided her with emotional support in her fight against MM.

Spirituality

A total of 3 patients discussed the importance of spirituality and God in their coping with medication adherence. For example, a 47-year-old married Latino female with MM for 2 months identified her spirituality as an important facilitator for adherence to her cancer medications. Despite having pre-existing diabetes, she described that the cancer medications were *overwhelming*. She believed in *divine healing* and "prayed for the cancer medications to heal her without causing side effects." From her view, this worked as she had not experienced any side effects. As a result, she has been able "to cope with taking the cancer medications."

Perspectives on Sensored Medication Devices

Patients initial reactions to being presented with the SMDs were split with half reacting positively. Interestingly, several of the same SMD features were viewed positively by some and negatively by others. For example, participants were informed of the reminder features of SMDs such as text messaging and audio or visual alerts. A total of 2 patients were excited about the reminder alerts and 1 acknowledged that the alerts would be beneficial as she was already using her cell phone for this function; however, 3 (15%, 3/20) patients felt the alerts would be annoying, as expressed in other similar ways that can be summarized as "I don't want that bottle talking to me/beeping at me." Similarly, 4 (20%, 4/20) patients perceived they would benefit by having the provider notified of any missed doses. They liked the idea of having their providers gain access to the SMD data to "help monitor" them. Conversely, 3 (15%, 3/20) African American patients reacted strongly to the idea of their provider having access to the SMD information, seeing this as an invasion of privacy or "going too far." Furthermore, they felt that it suggested the provider did not trust what the patient told them. As expressed by 1 patient, "I know that I am taking my medications and that is enough."

The 60-year-old African American female who resided in a shelter and was open about her poor medication adherence felt that the SMDs would help her look forward to taking her medications. She found the technology novel and exciting. Moreover, 3 people mentioned that they liked the fact that they could "see what was going on," referring to the Web-based platform that plotted the day and time that the bottle was open.

In addition, 3 patients were very satisfied with their current approach to medication management and simply did not like the idea that using an SMD required them to change their system. Moreover, 5 patients were not interested in using an SMD because they traveled or were out of the house often. They did not want to carry the bottle with all the pills when they only needed a few doses. They were concerned that if they removed

all of the pills that they needed during their travels and left the bottle at home, this would be recorded inaccurately. Although seeing no personal benefit to using an SMD, these patients recognized the potential benefit to individuals who were older, had dementia, lived alone, or were otherwise struggling to remember to take their medications.

Several additional concerns were expressed even by those who were enthusiastic about the SMDs. Not surprisingly, privacy issues were identified by several patients. Some felt using the devices would be invasive even if used for a *good reason*, and a 67-year-old white married male who described himself as being comfortable with technology expressed that the SMDs made "a simple task too complicated." He highlighted that some older people, not himself, would find the SMDs "too high tech." Another pointed out that "many older people don't have their cell phones with them all the time," making the text reminders ineffective. Others focused on the bottle closure, suggesting that the lids would be difficult for people with arthritis to open or that they lids were not *childproof*. Furthermore, 2 patients were concerned that the cost of medications might go up if patients were asked to use SMDs. Finally, the 68-year-old African American married male stated that he was willing to use an SMD but was very clear that it was not foolproof. He expounded upon how someone could take out medication and never actually ingest it. As a result, he felt the technology was fatally flawed.

Although virtually everyone had a concern or doubt about the SMDs, when asked if they would be interested in trying a bottle in the future, 12 (60%, 12/20) patients expressed a willingness to test one out.

Discussion

Main Findings

The results of this qualitative study provide valuable insights into the medication-related attitudes of patients with MM and comorbid chronic conditions. With a median of 10 different medications per day, adherence to OAC medications was at times a challenge for 70% (14/20) of the patients. The inclusion of 80% (16/20) of patients who identified as African American further distinguishes the study. Attitudes toward SMDs identified concerns that could limit the willingness of some to engage with the technology.

Barriers and Facilitators

Patients' reported that barriers and facilitators of adherence provide rich data to inform intervention development. Of the 10 barriers to adherence identified, 7 are well known in the context of cancer: side effects, distractions, insurance or pharmacy delays, number of medications, pill size, fatigue, and spirituality [4,5]. In particular, 3 barriers have received less attention in the context of cancer. These included travel or being away from home, stigma, and homelessness. Cancer medications have historically been administered in the hospital setting. Treatment with OAC medications places new demands on the patient to manage their medications. Managing medications when patients are away from home is complicated by requirements for the safe handling of teratogenic OAC

medications that are used to treat MM, such as thalidomide. As these precautions preclude removing medications from their original packaging, patients cannot simply take the doses they need. As reflected in our study, patients may choose to take their medications when they return home, which can contribute to missed doses and timing irregularities for subsequent doses.

Research on the stigma associated with cancer has focused largely on experiences of distress or impaired quality of life as opposed to medication adherence [24]. Moreover, 2 male African Americans mentioned concerns related to stigma, which impacted their adherence. Both described life experiences involving exposure to illicit drugs that affected their medication adherence—experiences not typically represented in cancer research.

Homelessness as a barrier to adherence is not novel. However, it is rare to have the voice of a homeless person undergoing cancer treatment represented in research. As revealed in her interview, adherence was challenged by the lack of routine and permanent location for her medications to be stored. However, she expressed feeling comfortable with technology, owned a smartphone, and embraced the potential of trying an SMD.

Patients' adherence was facilitated by having a special location for medications, identifying an organizational structure, setting up visual or auditory reminders, receiving social support, and spirituality. Of those, medication organization, social support, and spirituality have received less attention in the context of medication adherence. There was a strong sense of ownership as patients discussed their management system, which was often informed by trial and error. Most notably, pillboxes worked for some but were abandoned by others who were confused (ie, mixed up morning and night medications) or burdened by them (ie, need to fill the boxes every week). Although identifying a consistent location and organizational system for medications may seem an obvious facilitator to adherence, we struggled to find published scientific articles at this granular level. Perhaps, this is so basic to clinical practice or pervasive among patients, it is not worthy of mention. However, patients' attachment to their current system for storing and organizing their medications diminished interest in adopting SMDs for some in our sample and was recently noted as a barrier to adopting health-related technology [25].

The positive effect of social support on medication adherence has been reported in several studies across chronic disease states but significantly less so in cancer [26-28]. Despite this fact, half of the sample mentioned some aspect of social support as helpful in adhering to their medications. Spouses and children provided instrumental support with verbal reminders for or actually awaking patients to take their medications. Emotional support reinforced the willingness to take medications when patients were experiencing fatigue or feeling overwhelmed. Finally, information and instrumental support at provider appointments were important for capturing accurate information on treatment or medication. It is important to remember that simply living with family does not equate to having access to social support. A total of 2 patients resided with a spouse or family but perceived no outside support or assistance for their medication adherence. Finally, spirituality was mentioned by 3 patients as

playing an important role in their adherence to OAC, which appears to have been a focus in only 1 prior publication among cancer patients [29].

Moreover, 60% (12/20) of the patients expressed a willingness to try an SMD, despite concerns. Most of the concerns related to either lack of privacy or were specific to elderly populations, such as bottles that were easy to open or comfort with technology. Privacy concerns are a common and expected barrier to the uptake of health-related technology [25]. Interestingly, patients differed in their response to the idea of their providers' having access to their adherence data. This seemed to cross a line of trust for some African American patients in particular. A few patients identified initiation of their MM treatment as a time when they struggled with adherence because they felt confused and overwhelmed with all the medications. This suggests that the need for adherence support may vary over time and even some highly motivated patients might struggle with unintentional nonadherence, particularly at initiation of treatment.

Study Limitations

Generalizability of the research findings is limited due to several factors. First, given the exploratory nature of the study, we recruited a small convenience sample of MM patients from 1 minority-serving academic institution in the Midwest United States. All the patients were established with their oncology providers, although they varied significantly in how long they had been diagnosed, which may have an impact on their experiences. Financial barriers to expensive anticancer medications were not an issue for any patient because the institution pursued avenues available to low-income individuals to access medications. As a result, financial barriers to adherence were limited to insurance co-payments, and this is uncommon

in most settings [30]. Although 70% (14/20) of the patients admitted to missing doses of their cancer medications, the exact level of adherence was not captured or relevant to this study. It is also important to note that maximum adherence is required to gain optimal treatment effect with OAC medications. Regardless, the results are consistent with the larger cancer literature on adherence to OAC medications [4,5]. Finally, patients were not allowed to use an SMD before sharing their attitudes toward the tools. Considering that attitudes are often poor predictors of actual behaviors, no clear conclusions can be drawn about the potential for uptake of SMDs in this population. Nonetheless, SMDs are unlikely to be acceptable to all patients. Despite these limitations, to our knowledge, this is the first study to explore OAC medication adherence within patients from lower socioeconomic backgrounds and ethnic minorities who are often the most likely to struggle with adherence.

Conclusions

Overall, the results of this small exploratory study in patients with MM are consistent with a growing body of research, suggesting that missed doses of OAC medication are common in cancer patients [31]. Advancing science in OAC medication adherence will require development and testing of theoretical models and not lists of barriers or facilitators as provided in this pilot. Novel interventions targeting adherence to OAC agents are beginning to emerge, and technology will likely have a role. These efforts need to include consideration of adherence to all prescribed medications and not exclusively OAC medications. SMDs can play a role in this research; however, patient concerns must be addressed. The knowledge gained from this exploratory study offers encouragement that an individual from lower socioeconomic backgrounds and ethnic minorities will be interested in being included in these efforts.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Interview guide.

[PDF File (Adobe PDF File), 13KB - cancer_v4i2e12_app1.pdf]

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Abbreviations

MM: multiple myeloma
OAC: oral anticancer
SMD: sensored medication device

Original Paper

Web-Based Patient-Reported Outcomes Using the International Consortium for Health Outcome Measurement Dataset in a Major German University Hospital: Observational Study

Maria M Karsten[1*], MD; Dorothee Speiser[1*], MD; Claudia Hartmann[2], Dipl Kffr; Nele Zeuschner[1], BA; Kai Lippold[3], MSc; Verena Kiver[1], BA; Peter Gocke[4], MD; Valerie Kirchberger[5], MD; Jens-Uwe Blohmer[1], MD

[1]Klinik für Gynäkologie mit Brustzentrum, Charité Universitätsmedizin Berlin, Berlin, Germany

[2]Ärztliches Direktorat, Charité Universitätsmedizin Berlin, Berlin, Germany

[3]Geschäftsstelle Vorstand, Charité Universitätsmedizin Berlin, Berlin, Germany

[4]Stabsstelle Digitale Transformation, Charité Universitätsmedizin Berlin, Berlin, Germany

[5]Value-Based Healthcare, Geschäftsbereich Strategische Unternehmensentwicklung, Charité Universitätsmedizin Berlin, Berlin, Germany

[*]these authors contributed equally

Corresponding Author:
Maria M Karsten, MD
Klinik für Gynäkologie mit Brustzentrum
Charité Universitätsmedizin Berlin
Charitéplatz 1
Berlin, 10117
Germany
Phone: 49 30450664279
Email: maria-margarete.karsten@charite.de

Abstract

Background: Collecting patient-reported outcome (PRO) data systematically enables objective evaluation of treatment and its related outcomes. Using disease-specific questionnaires developed by the International Consortium for Health Outcome Measurement (ICHOM) allows for comparison between physicians, hospitals, and even different countries.

Objective: This pilot project aimed to establish a digital system to measure PROs for new patients with breast cancer who attended the Charité Breast Center This approach should serve as a blueprint to further expand the PRO measurement to other disease entities and departments.

Methods: In November 2016, we implemented a Web-based system to collect PRO data at Charité Breast Center using the ICHOM dataset. All new patients at the Breast Center were enrolled and answered a predefined set of questions using a tablet computer. Once they started their treatment at Charité, automated emails were sent to the patients at predefined treatment points. Those emails contained a Web-based link through which they could access and answer questionnaires.

Results: By now, 541 patients have been enrolled and 2470 questionnaires initiated. Overall, 9.4% (51/541) of the patients were under the age of 40 years, 49.7% (269/541) between 40 and 60 years, 39.6% (214/541) between 60 and 80 years, and 1.3% (7/541) over the age of 80 years. The average return rate of questionnaires was 67.0%. When asked about the preference regarding paper versus Web-based questionnaires, 6.0% (8/134) of the patients between 50 and 60 years, 6.0% (9/150) between 60 and 70 years, and 12.7% (9/71) over the age of 70 years preferred paper versions.

Conclusions: Measuring PRO in patients with breast cancer in an automated electronic version is possible across all age ranges while simultaneously achieving a high return rate.

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Introduction

In Germany, every year, 70,000 women receive the diagnosis of breast cancer. Almost 30% are under the age of 55 years. Due to improved screening and treatment modalities, there has been a significant improvement in overall survival in the last decade [1-3]. Breast cancer-specific mortality in Europe reduced from 17.90 women in 2002 to 15.20 per 100,000 women in 2012 [4]. However, survival gains are often associated with the loss of physical functioning; increased morbidity; and new challenges regarding the emotional, social, and financial aspects of life [5-8]. Therefore, this increase in life expectancy of patients with cancer must lead to increased scrutiny regarding the long-term side effects of new and existing cancer treatments [9,10]. An important aspect in evaluating effects of any therapies is patients' voice and perception. This applies even more to patients with cancer. The best way to address this aspect is to use patient-reported outcome (PRO) measures. The US Food and Drug Agency describes PRO as "any report coming directly from patients about a health condition and its treatment" [11]. Nowadays, using electronic media, like smartphones and tablet computers, measuring PRO data is much easier and less time- and cost-consuming than it was in the past. The use of PRO data allows for the real-time evaluation of therapy concepts and monitoring of new treatments. At the same time, it is an easy way for a long-term follow-up. Increasingly complex therapies in medicine simultaneously require an increase in documentation—time missing in direct patient communication [12,13]. However, this time is essentially needed to adequately assess a patient's situation and symptoms. PRO has been shown in multiple studies to help clinicians to adequately assess patient symptoms, save time for patient communication, and therefore improve patient care and even survival [14,15]. The aim of this study was to establish a PRO system in a major German university hospital.

Methods

After obtaining ethics approval from the Charité Ethics Commission (EA 4/127/16), we implemented a Web-based system to collect PRO data at the Charité Breast Center. Data capturing started in November 2016. The PRO data collection was based on an international standard set for breast cancer outcome measures, which was developed by the International Consortium for Health Outcome Measurement (ICHOM). All new patients, who attended the breast clinic, were included in the PRO measurement. Afterward, those who had a diagnosis of breast cancer and received their treatment at Charité Breast Center were stratified into follow-up. After patients registered at the clinic, they were asked by the receptionist if they would be willing to participate and received a personal log-in after they signed consent. The waiting time until their appointment was used to answer the ICHOM questions as well as questions regarding their medical history on a tablet computer. The decision to use a tablet computer in the clinic setting was one of the comforts because it allowed the patients to continue sitting where they felt the most comfortable in the waiting area. The

follow-up emails patients received were designed in a way that they could also be answered on a mobile device.

After the successful completion of the questionnaire, answers and calculated PRO scores were immediately available to treating physicians for the upcoming consultation. During that, treating physicians had the option to add missing clinical data. If they decide not to record the clinical data necessary, it was later added by support staff. Once patients entered specific care pathways, like chemotherapy or surgery, an automated process was started through which they received follow-up emails containing the access code to their individual PRO measurement questionnaires. The follow-up emails were sent 6 weeks after their first treatment, then every 3 months thereafter for 2 years. After the first 2 years are finished, they will receive a follow-up questionnaire every 6 months for another 3 years and after this only on a yearly basis.

From a technical standpoint, the system for PRO collection was installed on campus as an on-premise installation. It was therefore only available within the Charité network. The core system was supported by an additional patient portal, which acted as an outward facing tool, to interact with patients. The patient portal was hosted in a different environment to allow for access to the Web. It enables patients to complete questionnaires from home using a secure connection.

Results

Monthly Increase in the Number of Patients Who Participate in the Patient-Reported Outcome Measurement Since the Program Implementation

Figure 1 shows monthly increase in the number of patients who were entered into the PRO evaluation at the Breast Center and agreed to participate after its implementation in November 2016. After an initial increase in January 2017 with 40 patients, there was a decline in participation, with the lowest rate in March 2017, with only 4 patients included. From July 2017, there was a marked increase in patient numbers—a trend that continued from there on.

Increase in Patients Numbers for Patient-Reported Outcome Measurement Compared With the Total Number of New Patients

Table 1 compares the number of new patients who entered into the PRO system with the total number of new patients seen at the Charité Breast Center. With the exemption of January 2017, where 34.4% (40/116) of the new patients were added to the PRO system, the percentage of all new patients stayed below 20% until July 2017, with the lowest percentage (4/166, 2.4%) in March 2017. After July 2017, there was a marked increase in adding new patients, almost continuously increasing and reaching its highest percentage in December 2017, with 73.5% (86/117) of all new patients included in the PRO system.

Table 2 shows patients' characteristics regarding educational levels.

Figure 1. Monthly increase in patient numbers for patient-reported outcome measurement since implementation.
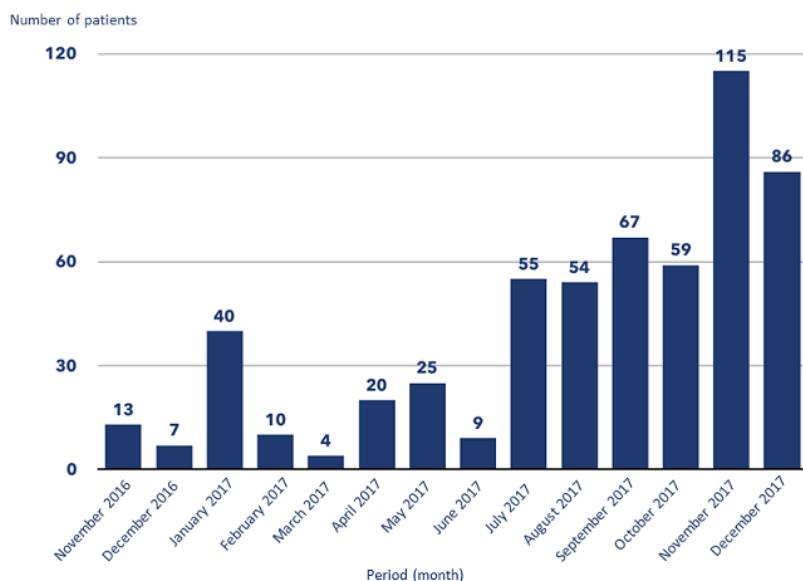
Table 1. Increase in patient numbers for patient-reported outcome measurement over time.

Period	New patients seen, n	Patients who participated in patient-reported outcome measurement, n (%)
November 2016	105	13 (12.3)
December 2016	90	7 (7.8)
January 2017	116	40 (34.4)
February 2017	124	10 (8.1)
March 2017	166	4 (2.4)
April 2017	104	20 (19.2)
May 2017	139	25 (17.9)
June 2017	112	9 (7.6)
July 2017	116	55 (47.4)
August 2017	108	54 (50.0)
September 2017	163	67 (41.1)
October 2017	93	59 (63.4)
November 2017	169	115 (68.0)
December 2017	117	86 (73.5)

Table 2. Level of academic training in all patients included in patient-reported outcome measurement (N=541).

Education level	Value, n (%)
Minimum German schooling requirement	201 (37.1)
Mid-level education	153 (28.2)
Higher level education	187 (34.5)

Decline in Patient Numbers to Participate in the Long-Term Follow-Up

Figure 2 shows the percentage of breast cancer patients who agreed to participate in the electronic follow-up PRO measurement compared with those who did not want to participate. In the age group of 20-30 years, 66.67% (2/3) agreed to follow up; in the age group of 30-40 years, 75% (6/8) agreed to follow up. The highest number was seen in the age group of 40-50 years, with 90.91% (37/40) followed up; 75.76% (25/33) agreed to follow up in the age group 60-70 years. Participation levels were the same, with 75% in the age groups of 70-80 (12/16) and >80 (3/4) years.

Return Rates of Questionnaires From Patients Participating in the Follow-Up Patient-Reported Outcome Measurement

Figure 3 shows the return rates of the online questionnaires completed by those patients who participated in the follow-up PRO measurement. After an initial drop to 28.6% (12/42) in

February 2017, there was a continuous increase in the return rate from 54.2% (13/24) in March of 2017 to 82.9% (68/82) in September 2017, with then another slow decline in October 2017 to 75.3 (70/93). November and December 2017 showed steady return rates above 81.3% (122/150) and 82.6% (114/138), respectively.

Preference for Using a Digital Way to Measure Patient-Reported Outcome Compared With a Paper-Based Version Across Age Groups

Figure 4 shows the percentage of patients who preferred a paper-based version of the questionnaire instead of a digital one. Notably, 100% (51/51) of the patients in the age groups of 20-40 years preferred a digital version, while 2.9% (7/244) of the patients in the age group of 40-50 years preferred a paper-based version. This increases to 5.9% (13/122) in the age group of 50-70 years and then further increases to 13.0% (3/23) in those aged 70-80 years. Above 80 years of age, there was a 100% (2/2) preference for paper-based questionnaires compared with digital questionnaires.

Figure 2. Patients who agreed to follow up versus who declined to follow up patient reported outcome measurement.
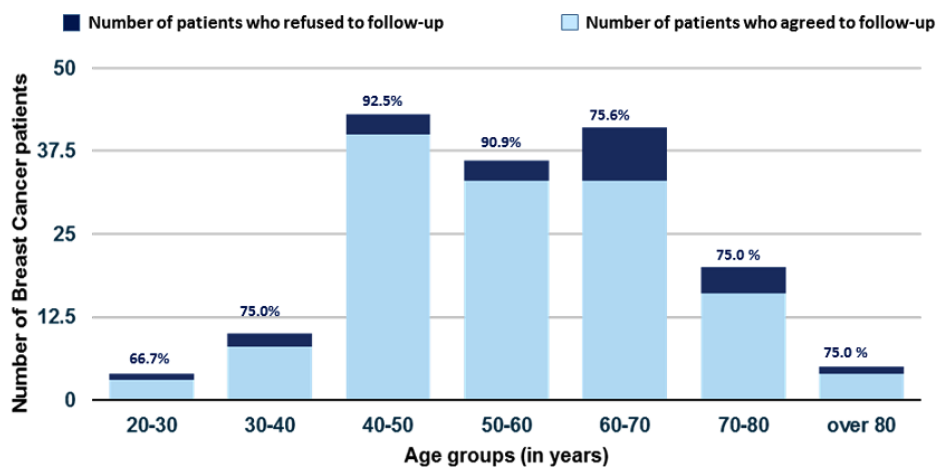

Figure 3. Return rates of the digital questionnaires completed by patients who participated in the long-term patient-reported outcome measurement.
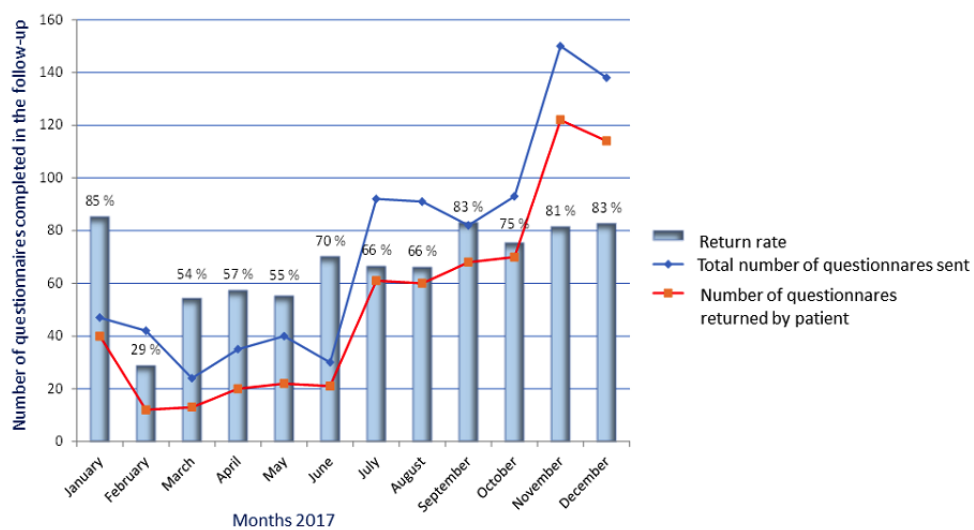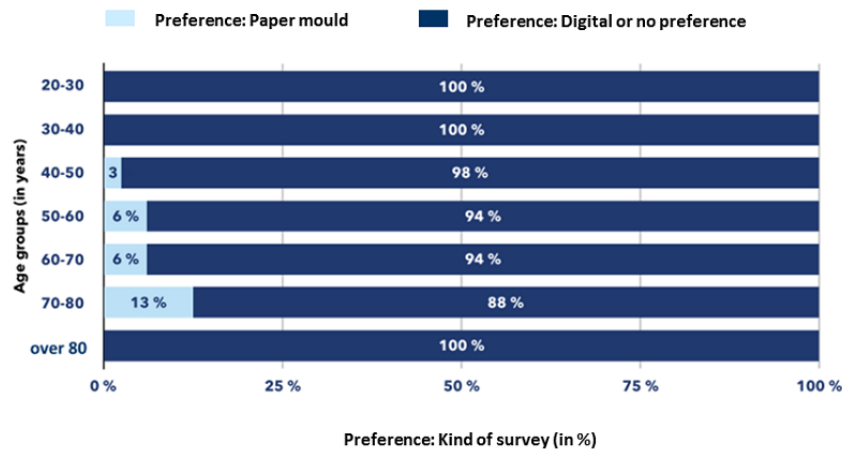
Figure 4. Preference for paper versus digital questionnaire according to age groups.

Discussion

Principal Findings

This study documents the successful implementation of measuring PROs using the ICHOM dataset for breast cancer in a German university hospital for the first time. During the implementation period, we made numerous observations. First, it takes at least 6 months to implement and establish a working system, get all key stakeholders to adopt it, while simultaneously solve those technical problems that arise during the implementation phase. Second, most patients, across all age groups, are willing to participate in the initial measurement as well as in the long-term follow-up. Third, contrary assumption, most patients, even those aged >60 years, prefer a digital survey over a paper-based way to answer the PRO questionnaires.

Our observation regarding the required timeframe to establish a successful electronic PRO system is matched by previous publications [16-18]. A crucial point in establishing a successful digital program is to explain and educate all health care providers who will be involved in the collection of PROs about the purpose and benefit of PRO. While there is increasing interest and knowledge about PRO measurement, there are concerns regarding workflow, increase in workload due to the additional measurements, as well as data overload and creation of additional needs [19-21]. These findings are mirrored in our low patient accrual data in the first 6 months after the implementation. It took this time to train, educate, and convince all involved staff members from front desk staff to treating physicians. Once this barrier was broken, there was a steady increase in patients with breast cancer who agreed to participate in the follow-up PRO measurement. Only a small percentage of patients declined to participate in the PRO follow-up. The highest percentage of patients who agreed to follow up was in the age group of 40-50 years, at an astonishing 90.91% (37/40).

The lowest rate was found in the age group of 20-30 years, with only 66.67% (2/3) agreeing to follow up. This is in part because of the low numbers of patients we have in this age group. Previous work has shown that especially technology literacy plays a role in the extent to which patients are participating in electronic-based PRO measurement [22]. We did not gather information regarding technology literacy but asked a question regarding the level of education patients had because there have been data showing a correlation between the level of education and the willingness to participate in Web-based data collection as well as the effects regarding PRO-based interventions [15,23]. As shown in Table 2, there was a fairly even distribution of educational levels in our patient population. Also, the access and ability to use a computer, smartphone, or smartwatch is a prerequisite, and therefore, patients who had neither of these and thereby often did not have an email address were not able to participate in the study. This could be a potential bias, especially regarding the return rates.

In addition to the finding that it is possible to establish a successful PRO measurement program at a German breast center integrated into the routine clinical workflow, this work showed for the first time that the majority of patients with breast cancer treated in a German university hospital preferred a digital survey. Patients did not want to fill out questionnaires in a paper and pencil-based version—despite contrary believes. In addition to this interesting finding, we were able to show that we can simultaneously achieve a high adherence rate even in the long-term follow-up. Similar observations have been made previously in the United States, for example, at Memorial Sloan Kettering Cancer Center [24], the University of North Carolina [25], or Group Health Cooperative in Seattle [26].

Limitations

Since this is a retrospective analysis of an implementation trial, it is not without limitations. In the beginning, reasons for decline in the number of patients participating was not systematically collected. Since this systematic approach was started only at a later point, we currently do not have enough data on this matter but are collecting them now. Also, we did not have enough resources to be able to contact those patients who decided not to continue in the follow-up. This point and the first point are important aspects, and we are currently addressing both and plan to publish the results in a following publication.

Comparison With Prior Work

While there is an increasing interest in the potential of PRO measurements in almost all disease entities [27-30], there is still a lack of standards regarding what to measure and how to measure it. The ICHOM initiative has therefore created a working group for a wide range of diseases with the goal to establish standard sets to compare outcomes between different providers, hospitals, and even countries [31]. This is the first published work to show that the implementation of one of their standard sets—in our case for breast cancer—is feasible and lays the foundation for further improvements in the complex care of patients with breast cancer.

Conclusions

The goal of this pilot trial was to create a template on how to establish a successful Web-based PRO measurement system at a German university hospital, setting the stage for what to expect and showing that it is possible to measure PRO in a digital manner in patients with breast cancer of all age groups.

Conflicts of Interest

None declared.

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Abbreviations

ICHOM: International Consortium for Health Outcome Measurement
PRO: patient-reported outcomes

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Original Paper

Online Decision Support Tool for Personalized Cancer Symptom Checking in the Community (REACT): Acceptability, Feasibility, and Usability Study

Marzena Ewa Nieroda[1], PhD; Artitaya Lophatananon[2], PhD; Brian McMillan[3], BSSc, MBChB, PhD MRCGP; Li-Chia Chen[4], PhD; John Hughes[5], BSc (Hons); Rona Daniels[6], MBChB, MSc, FFPH; James Clark[7], MPharm; Simon Rogers[8], MBChB (Hons); Kenneth Ross Muir[2], PhD

[1]Division of Management Sciences and Marketing, Alliance Manchester Business School, The University of Manchester, Manchester, United Kingdom

[2]Division of Population Health, Health Services Research and Primary Care, School of Health Sciences, Faculty of Biology, Medicine and Health, University of Manchester, Manchester, United Kingdom

[3]Centre for Primary Care, Division of Population Health, Health Services Research and Primary Care, School of Health Sciences, Faculty of Biology, Medicine and Health, University of Manchester, Manchester, United Kingdom

[4]Centre for Pharmacoepidemiology and Drug Safety, Division of Pharmacy and Optometry, School of Health Sciences, Faculty of Biology, Medicine and Health, University of Manchester, Manchester, United Kingdom

[5]IT Services, University of Manchester, Manchester, United Kingdom

[6]REACT project, University of Manchester, Manchester, United Kingdom

[7]Greater Manchester Cancer Vanguard Innovation, Manchester, United Kingdom

[8]Bodey Medical Centre, Manchester, United Kingdom

Corresponding Author:
Marzena Ewa Nieroda, PhD
Division of Management Sciences and Marketing
Alliance Manchester Business School
The University of Manchester
Booth Street West
Manchester, M13 9PL
United Kingdom
Phone: 44 161 275 6739
Email: marzena.nieroda@manchester.ac.uk

Abstract

Background: Improving cancer survival in the UK, despite recent significant gains, remains a huge challenge. This can be attributed to, at least in part, patient and diagnostic delays, when patients are unaware they are suffering from a cancerous symptom and therefore do not visit a general practitioner promptly and/or when general practitioners fail to investigate the symptom or refer promptly. To raise awareness of symptoms that may potentially be indicative of underlying cancer among members of the public a symptom-based risk assessment model (developed for medical practitioner use and currently only used by some UK general practitioners) was utilized to develop a risk assessment tool to be offered to the public in community settings. Such a tool could help individuals recognize a symptom, which may potentially indicate cancer, faster and reduce the time taken to visit to their general practitioner. In this paper we report results about the design and development of the REACT (Risk Estimation for Additional Cancer Testing) website, a tool to be used in a community setting allowing users to complete an online questionnaire and obtain personalized cancer symptom-based risk estimation.

Objective: The objectives of this study are to evaluate (1) the acceptability of REACT among the public and health care practitioners, (2) the usability of the REACT website, (3) the presentation of personalized cancer risk on the website, and (4) potential approaches to adopt REACT into community health care services in the UK.

Methods: Our research consisted of multiple stages involving members of the public (n=39) and health care practitioners (n=20) in the UK. Data were collected between June 2017 and January 2018. User views were collected by (1) the "think-aloud" approach when participants using the website were asked to talk about their perceptions and feelings in relation to the website, and (2) self-reporting of website experiences through open-ended questionnaires. Data collection and data analysis continued simultaneously, allowing for website iterations between different points of data collection.

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Results: The results demonstrate the need for such a tool. Participants suggest the best way to offer REACT is through a guided approach, with a health care practitioner (eg, pharmacist or National Health Service Health Check nurse) present during the process of risk evaluation. User feedback, which was generally consistent across members of public and health care practitioners, has been used to inform the development of the website. The most important aspects were: simplicity, ability to evaluate multiple cancers, content emphasizing an inviting community "feel," use (when possible) of layperson language in the symptom screening questionnaire, and a robust and positive approach to cancer communication relying on visual risk representation both with affected individuals and the entire population at risk.

Conclusions: This study illustrates the benefits of involving public and stakeholders in developing and implementing a simple cancer symptom check tool within community. It also offers insights and design suggestions for user-friendly interfaces of similar health care Web-based services, especially those involving personalized risk estimation.

Introduction

Cancer is the leading contributor to mortality worldwide; in the United Kingdom (UK) alone there are more than 300,000 new cancers (excluding skin cancers) diagnosed annually, and it is estimated that roughly one-third of the population will develop a cancer in their lifetime [1]. Favorable outcomes are more likely when cancer is detected and treated earlier [2], as noted in the World Health Organization report, "Every year, millions of cancer patients could be saved from premature death and suffering if they had timely access to early detection and treatment*"* [3]. Early detection of cancer could translate into significant savings for health care services, benefiting thousands of patients [4].

Regardless of the relevance of early cancer diagnosis for survival rates, for many years the UK has appeared "near the bottom of international league tables for cancer survival in economically developed countries*"* [5]. Hamilton et al [5] attribute this issue to patient and diagnostic delays, which means that patients might be unaware their symptoms could be cancerous and delay reporting it to their general practitioner (GP) or GPs might delay referral to secondary care services. In the UK, the task of early cancer detection typically rests with GPs, who are gatekeepers to all secondary care services [6]. However, "every year, a full-time GP will have one patient diagnosed with each of the four common cancers (breast, lung, colon, and prostate)" [7], thus potential lack of experience with different types of cancers and its symptoms might lead to a delayed referral to secondary care services [7]. Although individuals aged 40 years and over are eligible for the National Health Services (NHS) Health Check, which is "designed to spot early signs of stroke, kidney disease, heart disease, type 2 diabetes, or dementia" [8], cancer is not covered by the program.

To help GPs to minimize the diagnostic delay and expedite referral for diagnostic testing, models have been developed quantifying the severity of different cancerous symptoms in undiagnosed patients [5]. The two models in use with sufficient evidence from systematic reviews showing how those models can improve physician performance are Risk Assessment Tools (RATs) and QCancer [5]. RATs consider only symptoms reported to GPs by patients before a cancer diagnosis from both GP surgeries and electronic medical records in the UK, studying a sample of over 7000 cases involving over 6 million patients [7,9]. QCancer considers both symptoms and risk factors such as age, sex, and cigarette smoking, and is based on medical records of 754 UK general practices [5,9,10]. Both models provide GPs with a positive predictive value (PPV) which reflects the "chance of a patient having the disease of interest when they have reported the symptom" [7]. PPVs can be calculated for a single symptom or a combination of symptoms, can vary from 0.1% to >17%, and the 2015 guidelines of the National Institute for Health and Care Excellence (NICE) recommend further investigation for patients exceeding the threshold risk of 3% [1,5,7].

Considering the effectiveness of RATs and QCancer in improving performance of GPs, as well as the fact that these risk assessment models are still not widely used in General Practice across the UK [5], our objective is to use the information provided by these models and offer it to the public with an aim of shortening the delay in reporting cancer symptoms by patients. It is important to note that RATs and QCancer are different from many existing risk assessment models directed at members of the public. The majority of the existing risk assessment models evaluate individual's future risk of developing different cancers based on the combination of genetic, environmental, and behavioral risk factors (eg, Your Disease Risk, Reflect) [11,12].

Our focus in this article is on the design and development of the REACT (*R*isk *E*stimation for *A*dditional *C*ancer *T*esting) website, a symptom-based cancer risk assessment tool offered through a Web-based interface in a community setting. REACT is not designed to be a screening or diagnostic tool; but a tool to assist people in deciding whether or not they need to consult their GP about potentially cancerous symptoms. The tool assesses the symptoms of 5 major cancers affecting people in the UK (ie, bowel cancer [also known as colon or colorectal cancer], breast, ovarian, lung, and prostate cancer) and is designed to raise awareness of symptoms that may be indicative of cancer amongst the public. Greater awareness of cancer symptoms could shorten the person's delay when it comes to recognition and reporting cancer symptoms to primary care, as evidenced by results of some symptom awareness campaigns [5,13-15]. Equally, if the symptom is not found to be related to an underlying cancer then it is important to rule such a

possibility out; furthermore, most of the symptoms are sufficiently serious to merit further investigation in their own right. Risk estimation in REACT is based on the RAT models [7]. The reason for using RATs is that, by utilizing a representative record of symptoms and avoiding the complexity associated with a mixture of symptoms and risk factors, it is less susceptible to ascertainment bias when the population studied is not representative of the entire population [5,6].

REACT can help the general public to identify symptoms that may be related to cancers and estimate the personal risk of cancer, as indicated by a PPV. Each clinical symptom listed in the original RAT models (eg, constipation or dyspnea, terms easily understood by GPs but necessarily not by a layperson) was translated into layperson language to be used in the REACT questionnaire. This was done by referring to commonly used descriptors on the NHS websites [16] and other medical sites from well-established organizations, such as cancer charities or government related sites. For example, the Breast Cancer Now organization, one of the UK breast cancer charities [17], was referenced to develop symptom-based questions related to breast cancer. As RATs utilize the most relevant symptoms per cancer (ranging from 5 to the maximum of 9 symptoms) as well as frequency of those symptoms (eg, a single vs reoccurring symptom) [7], we also needed to ensure that reoccurrence of each symptom was recognizable in the questionnaire. This was achieved by adding timeframe for a given symptom (eg, has the symptom occurred more than once in 12 months).

Regardless of the potential of REACT, offering such a tool to the public is associated with various challenges. First, there are individual cognitive and emotional factors that can affect public acceptance of such a tool, and an understanding of these is necessary for successful development and approval of internet-based health interventions [18,19]. As cancer is one of the most feared diseases [20-22] and a cancer diagnosis is often life changing [23], individuals may avoid considering this issue by downplaying their own cancer risk or ignoring symptoms. Therefore, any intervention offered to the public should aim to minimize potential anxiety, at the same time showing early cancer detection as a positive step to improve treatment potential. While the existing literature does not show that risk assessment communication increases anxiety [11], it is important to consider risk communication literature in developing risk assessment tools that are likely to minimize potential fear associated with the communicated risk [24,25]. Thus, it is important to understand how to increase perceived self and response efficacy (ie, belief one can perform the recommended actions such as discussing REACT results with his or her GP and belief that results of such a discussion could minimize the threat), factors shown to have mitigating effects on fear experienced during risk communication [24,25].

In addition, when designing such a tool, the optimal (leading to best understanding of the risk score) approach to communicate personal risk to individuals is essential. While there is plethora of recommendations on how to communicate risk (eg, presenting outcome estimates, using visual formats, using evaluative labels about estimates) [26,27], more research is needed on how to combine those different recommendations in actual symptom-based intervention about cancer.

Furthermore, the user needs in human-computer interaction involving a website need to be considered. For instance, website content, layout, look and feel, may all affect perceived usability [28-30]. There is also a need to consider different stakeholders that could utilize the website in the future (eg, community pharmacies, NHS Health Check teams) and use their views to understand the best implementation pathway for such an intervention.

Methods

Overview

Our research utilized focus groups and open-ended questionnaires distributed firstly at a showcase event dedicated to development of the REACT website, and secondly during a trial of REACT within community settings. Six focus group interviews preceded with a trial of the website involving the "think aloud" technique [29,31] were conducted with members of public and health care professionals (who could potentially use REACT in the future) in Greater Manchester, UK. Furthermore, the research team organized an event showcasing REACT to members of public. Participants of the event were invited to participate in research, use the REACT website, and provide their feedback in an open-ended questionnaire [32]. The same open-ended questionnaires were also used in a trial within community settings where members of the public could fill in the REACT questionnaire with assistance of a health care professional.

Data were collected between June 2017 and January 2018, with a timeline for each research step illustrated in Figure 1. Participant recruitment, data collection, and data analysis continued simultaneously, allowing for website iterations between different points of data collection and check for acceptability of the modifications in subsequent stages of data collection. The majority of changes to the website were implemented between July 7 and August 21 2017, and between August 23 and October 2, 2017. Following the focus group on October 3 2017, only minor changes were implemented to the website as the feedback gained in those studies predominantly featured themes and ideas previously mentioned by research participants, thus pointing to data saturation [33]. The issue of data saturation was also discussed and agreed upon by members of the steering group overseeing the research project, meeting on a monthly basis. Ethical approval was obtained from the University of Manchester Ethics Committee (Ref: 2017-2065-3599). All participants participated in the research voluntarily and provided written consent.

Design

Our research into REACT involved 6 focus groups with 15 members of public and 20 health practitioners, and 24 open-ended questionnaires with self-reported evaluation of the REACT website provided by members of public.

Figure 1. Timeline of research into the REACT (Risk Estimation for Additional Cancer Testing) website.
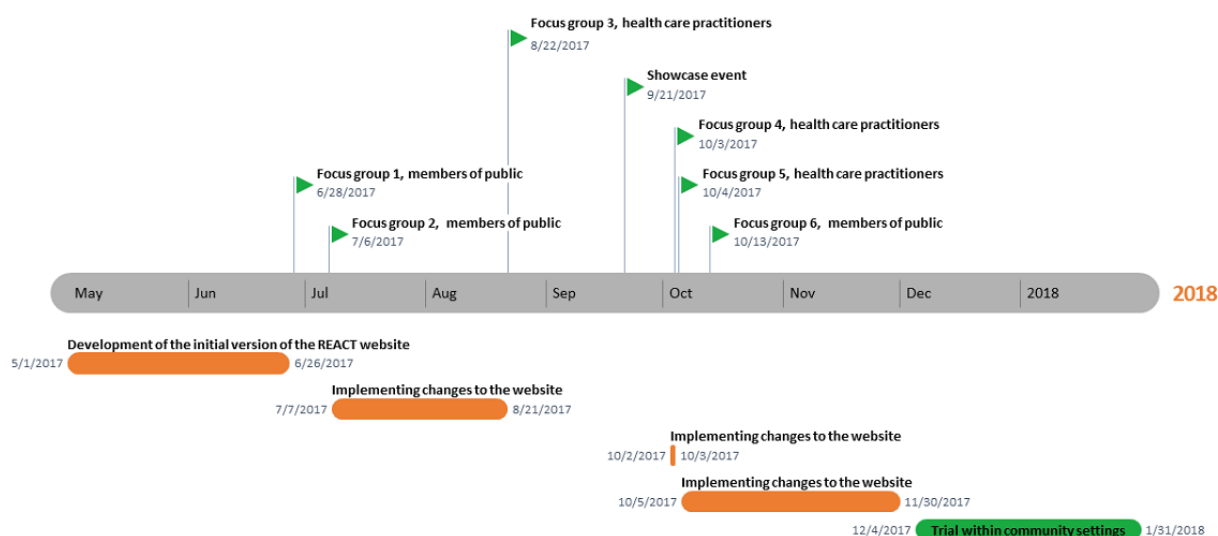
Three focus groups involved members of public and 3 involved health care practitioners. The "think aloud" technique was used to explore users' website experience. Qualitative research, especially involving "think aloud" procedures, is considered the most appropriate method to gain insights about user perceptions and for usability testing of websites [29,30,34]. The "think aloud" technique relies on research participants reporting their experiences, thoughts, and ideas while using the website. This approach addresses the issue of data loss which can be experienced when information is collected after website use. This technique typically leads to identification of between 80% to 90% of usability problems of an evaluated website [35-37]. Focus groups were preferred over one-to-one interviews as they allow for views and opinions to be developed and discussed, at the same time allowing for reporting of individual opinions [38].

Apart from focus groups, we also utilized open-ended questionnaires enabling self-reporting of user experiences without the presence of a researcher, often referred to as asynchronous remote usability evaluation [39]. Such techniques are deployed due to the benefits of collecting usability data from many participants in a relatively short amount of time [39]. Use of open-ended questionnaires is also a technique used in market research for the purpose of evaluating consumer and user views about a product or service [32]. Apart from being easy and convenient to implement, this technique is appreciated for its ability to elicit spontaneous views and less prone to response bias [40].

Participants and Recruitment

Focus groups one, two, and six were made up of members of the public. Focus groups three to five involved health care

professionals. Members of the public (men and women) aged 40 years and older, with or without a previous history of cancer, and with a range of backgrounds were invited to participate in the 3 focus groups. We targeted people who could potentially use REACT in the future. Individuals with a history of cancer were not excluded, as (1) having cancer does not mean someone will not develop another type of cancer in the future; and (2) those individuals could evaluate the symptoms they had experienced and raise issues in the event that the REACT algorithm was not accurate. Our sampling objective was to obtain diverse representation of views, not to compare views of different groups of people. Focus groups participants were recruited through Macmillan Cancer Support, via posters around the university and community centers within the Greater Manchester area (eg, gyms and libraries); and from the NHS Cancer Bowel Screening Program. Participants were reimbursed for their time with a £20 high street voucher except for two participants who did not accept it. Participant characteristics are summarized in Table 1.

In addition, health promotion or prevention professions that could in the future take an active part in implementing REACT into health services ecosystem in the UK were invited to participate in 3 focus groups. Participants were (1) employees of a community pharmacy (n=10), (2) NHS Health Check workers within Greater Manchester (n=5), and (3) members of the NHS Cancer Prevention and Early Intervention group in Greater Manchester (n=5). These focus groups were organized as part of presentation sessions about REACT to the Clinical Commissioning Groups, where GPs and other health professionals were present.

Table 1. Sample characteristics of members of public (focus groups and open-ended questionnaires combined).

Characteristic	Value, n (%)
Age (years)	
40-49	8 (20)
50-59	12 (31)
60-69	9 (23)
70 and over	4 (10)[a]
Gender	
Male	20 (51)
Female	18 (46)[b]
History of cancer	
Yes	6 (15)
No	33 (85)

[a]Six participants did not reveal their age.

[b]One participant did not reveal their gender.

Participants evaluating the REACT website through open-ended questionnaires were recruited through (1) an event organized by Greater Manchester Cancer Vanguard (GMCV), the founder of research into REACT, and (2) a trial of the REACT website within community settings. The showcase event was a presentation of research undertaken into REACT and was open to the public and GMCV associates (patient groups, health care representatives, and industry), and was advertised through various channels, such as the GMCV website, newsletters, social media channels, and email. The event was attended by 32 participants and 10 of them agreed to provide evaluation of REACT through an open-ended questionnaire.

As the feedback from all the data collection pointed to use of REACT in assisted manner, with a health care professional present, we also evaluated user experiences during a trial of REACT in community settings. A local community pharmacy agreed to recruit participants (pharmacy customers) and assist them with filling in the REACT questionnaire. Following the evaluation, participants were asked to provide their feedback through the use of the same open-ended questionnaires used after the GMCV showcase. A total of 14 questionnaires were collected during that research phase.

Data Collection

The focus groups were conducted by 3 moderators—female researchers with experience of conducting qualitative research (a market researcher, an epidemiology researcher, and an academic clinician)—as well as the software engineer responsible for the design of the REACT website and a note taker. Each focus group lasted between 60 and 90 minutes. Most of the focus groups were performed in a room at the University of Manchester, and 2 focus groups with health care practitioners were performed at the participants' workplace. Field notes were taken in each focus group [41].

The user experiences of REACT were collected during a trial of the website by using the "think aloud" technique [29]. During the "think aloud" procedures participants in each focus group were split into smaller groups of 2 to 3 participants, with each group accompanied by one of the focus group moderators. This separation was aimed at obtaining independent views, unbiased by the influence of the majority of the focus group participants.

After the trial of the REACT website, participants were asked (after merging into one group) a series of questions about different pages and sections of the website (eg, landing page or cancer questionnaire page). The questions about different pages were accompanied by a screenshot from that page.

Finally, participants were asked about their general impressions of viewing and using the website within the health care service (eg, on their own or with the help of health care practitioner). Depending on the area of expertise (ie, members of the public or health care practitioners) emphasis was placed on different questions. For instance, members of the public were questioned more about the user experience than the practitioners were; and the opposite was the case for the questions about potential implementation of programs such as REACT within health care services.

The link to open-ended questionnaire was emailed to the participants of the GMCV showcase who had previously agreed to participate in research. Those individuals were provided with a temporary link to the REACT website (available only to those participants for a week) and they were asked to use the website and to fill in the open-ended questionnaire. The questions asked in the questionnaire are provided in Multimedia Appendix 1. The same questionnaire was later used in the trial within community settings, when research participants filled in the questionnaire after completing the REACT assessment in their community pharmacy.

Data Analysis

The interviews were audio-recorded and transcribed verbatim by a professional agency. The data obtained from open-ended questionnaires were exported from the survey software into a Word document. Data were analyzed with a thematic analysis approach [33]. Four researchers (the same group that was

involved in data collection procedures) read all the documents and searched for patterns in the data, focusing on the patterns that related to research questions and objectives of the study.

The coding of usability evaluation data was guided by 2 different perspectives: (1) navigation strategy, pointing to used navigation tools, and (2) navigation problems (or facilitators), pointing to potential barriers (or facilitators) to completing the cancer risk evaluation activity [29,42].

The data about website design were coded into 2 main categories: (1) website design and (2) risk presentation. In the website design section, 3 factors were identified: content and related functionality, readability of the cancer questionnaire, and website look and feel. In the risk presentation section, we identified problems about different types of risk presentation: numeric, visual, and evaluative. The attitudinal and perceptual data about REACT and its future implementation into health care services were coded by highlighting existing cognitive or emotional states as well as barriers and facilitators to implementation.

The initial analysis was performed by 4 researchers (the same group that was involved in data collection procedures). The coders showed fairly high levels of consistency in coding the themes, with kappa statistics between 0.71 and 0.87 [43]. The final validation of the results was performed by members of the steering group overseeing the research project.

Results

Overview

Sample characteristics for the members of public group are provided in Table 1. Practitioners participating in this research held various positions, including pharmacists, pharmacy senior management, NHS Health Check workers and management, a multi-agency group, inclusive of a GP from the NHS in Greater Manchester, and cancer awareness facilitators. Of the 20 participating health care practitioners, 13 were female.

In general, the feedback in relation to the website and its implementation into health care services was consistent across members of the public (regardless of whether they had cancer history or not) and health care practitioners. Therefore, the views of these groups are summarized together. In cases where the rationale for certain preferences differed between the groups, the differing views were elaborated.

Finally, the view of the majority of participants was that REACT should be offered in community settings with assistance of a health care practitioner and individuals should not attempt to assess their risk on their own. While we discuss the details on pathways to delivery of REACT later, it is important to mention this issue before discussing the results in more depth, as some of the comments relate to assisted delivery of this service.

Perceptions and Attitudes in Relation to REACT

The initial reaction to REACT was very positive, with all participants appreciating the value and importance of such an intervention. While some members of public were aware of symptoms of specific cancers (eg, bowel cancer), in most cases, their awareness of different cancers and its symptoms was limited. Hence, they appreciated the capabilities of REACT. As one participant stated:

> *I think it's important to be informed and to get there as early as possible. To go and see the GP, and if there's a tool perhaps, you know, to help me do this, that may be of interest.* [Focus group 2]

One of the greatest challenges seen about the future of such a tool was related to creating a positive image of this intervention. This was important, considering the perception and stigma of cancer as a deadly disease. Participants reported that it was of utmost importance to emphasize the positive aspects of early detection tools, and their relevance to cancer management and improving survival rates. This was emphasized by the following quotes from participants:

> *I don't think it's an issue with leaflets [promoting early cancer detection]. I think it's an issue with cancer. And I'm wondering whether there is a way to raise awareness of cancer symptoms without stigmatizing it.* [Focus group 3]

> *Advertise it [REACT]. Social media is probably quite a good one because it's being increasingly used not just by young people, I mean, things like Facebook seems to be…I mean, a lot of the youngsters are a bit like, oh, I've gone off Facebook, I don't use that anymore. But my generation seem to be more and more into this…* [Focus group 1]

Some participants suggested using testimonials from cancer survivors or celebrity endorsement to promote early detection and the role REACT can play in it.

> *Also on here could be, you've got statements here [landing page] about people who did the assessment and did not have cancer. It would be really nice for somebody to say: "So I did the assessment and it really put my mind at rest."* [Focus group 3]

> *It helps to get a celebrity endorsement, I think, you know, a celebrity that's had cancer or something.* [Focus group 1]

Following those suggestions, the content of the REACT website emphasizes early detection success rates (Figure 2, content based on a graphic created by Cancer Research UK) and also contains individual testimonials at the carousel (changing display) available on the landing page.

Key Features of a User-Friendly Website Design

Participants identified some key features related to a user-friendly design of the website, which can be classified into 3 key categories: content and associated functionality, clarity and readability of the cancer questionnaire, and look and feel of the website.

Figure 2. Image on the REACT (Risk Estimation for Additional Cancer Testing) website promoting the importance of early detection of cancer.
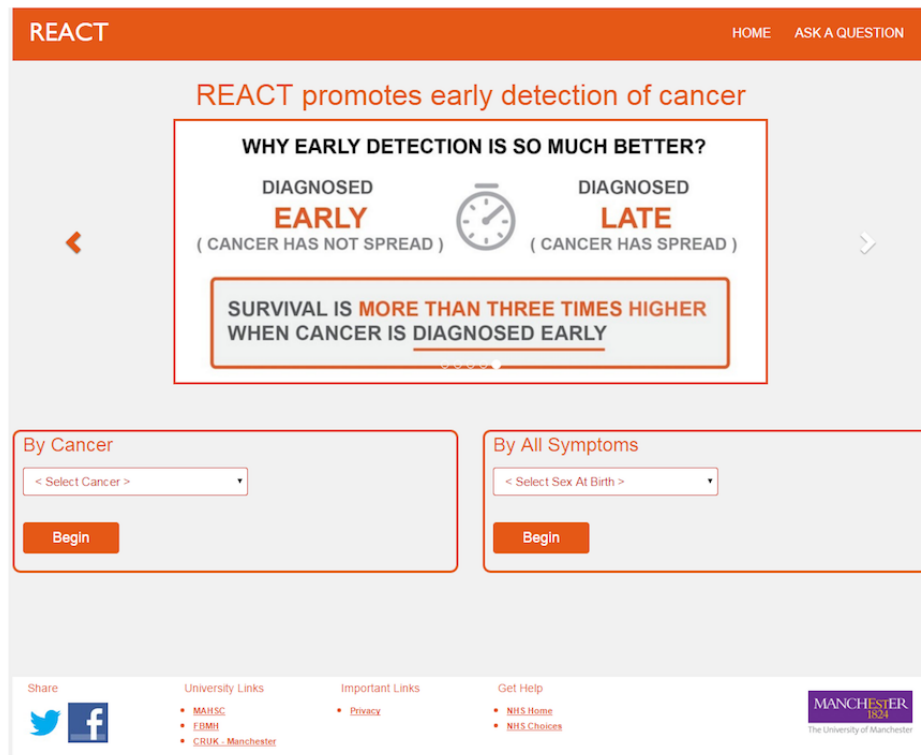
Content and Functionality

Content and related functionality of different sections of the website were crucial in affecting perceived usability and user-friendliness. Originally, the REACT website only allowed users to evaluate their symptoms in relation to a particular cancer (eg, breast cancer). However, the participants, especially health care practitioners, regarded it was important that the website allows for 2 methods of completion, either by cancer type or by symptom. For example, one focus group participant noted:

> I think… firstly we have to select which cancer you want to check, as this is something I do not think many of our customers will know. So, you need to help them here and list various symptoms for different cancers. [Focus group 3]

Consequently, the revised version of the website allows users to select a questionnaire either by cancer type or by symptoms (Figure 2). If someone selects the questionnaire by symptoms (vs a single cancer type), they will answer more questions as there are more symptoms related to different body parts to be evaluated.

The cancer symptom questionnaire (described in the following section), and the information it provided to individuals, was regarded as another content factor that affected the perceived functionality of REACT. Participants indicated that apart from obtaining their risk estimation after trying REACT, they also wanted something more tangible about that risk score that could serve as a decision aid in a potential meeting with a health professional. For example, one focus group participant asked:

> How do I know what affected my risk score? And how do I communicate this information to my GP? [Focus group 1)]

Health care practitioners also supported that idea, but for them the tangible output of the risk assessment was considered as an important factor that could simply improve customer journey for their clients or patients.

> I think for me the thing that will determine how we use it (REACT) here, is that customer experience, so that they come out of that discussion knowing what to do next, where to go but ultimately they're not walking out of that room suicidal about their result. So, we need to make sure that they go out with the right information feeling positive about taking that test. So that customer journey is really important. [Focus group 3]

Consequently, REACT provides individuals (and their GPs via email) with a summary of the symptoms that triggered the risk score and signposts them to various support resources (eg, the Cancer Research UK website as an example of an educational resource or encouragement to contact own GP as an example of a more actionable behavior pathway). This information can help individuals to recognize and understand cancer symptoms better and can be a tangible decision aid supporting decision making during a consultation with GP, thus rising perceived self-efficacy and minimizing anxiety associated with risk communication [24,25].

Furthermore, some participants inquired whether it was possible to obtain any further cancer-related information from the website, especially in case the symptoms they evaluated with REACT were not associated with a higher risk of having cancer. Some individuals felt fortunate that their symptoms were not due to cancer, but still wanted to find out whether there was anything they could do to minimize any future risk. Health care practitioners considered the information on how to reduce future

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risk of having cancer as a value-added factor that could contribute to that important consumer experience. For example, one focus group participant noted:

> *Is there anything those people can do to reduce their future risk of having cancer? If there is something like that, it just could be worth the extra time [guiding people through another questionnaire] if we can improve the customer journey...* [Focus group 3]

To address those requests, after displaying an individual's risk estimation on the results page (after filling in the cancer questionnaire), REACT provides a link to a website that deploys risk algorithms to calculate individual risk of having cancer in the future: REFLECT (*R*isk *E*stimation *F*or *L*ifestyle *E*nhancement *C*ombined *T*rial) [12]. If interested, users could learn about how their lifestyle choices (eg, smoking and physical activity) affect their future cancer risk and can see how potential lifestyle changes would affect their cancer risk. Provision of a link to REFLECT was seen as a way to increase perceived response efficacy and minimize anxiety related to risk communication [24,25].

In addition, some participants suggested that the website should include an explanation of how REACT was developed, emphasizing the scientific background, expertise, funders, and stakeholders that contributed to the website development. This is currently addressed by designing an "About us" and "News" section of the website.

Cancer Questionnaire

The cancer questionnaire, in particular its clarity, readability, and ability to point to relevant symptoms, was of utmost importance to participants. In general, participants were in favor of language that could be easily understood (eg. explain that diarrhea relates to symptoms such as loose or watery feces and/or stomach cramps). As research has shown that keeping some level of medical terminology enhances the credibility of a website [44], in cases where medical terminology was used, a layperson explanation was provided where possible. Our changes were well received by research participants:

> *One thing I like about the tool is that it's really easy-to-use, I think, no matter how confused or illiterate, I don't think anyone would struggle with the yes/no and the tapping what your answer is. Besides, one of us [health care practitioner] would be most likely there to explain any questions, right?* [Focus group 4]

One way to reliably assess readability of written material is to use tests for readability [45,46]. The wording in the questionnaire, as well as other parts of the website, was adjusted using the Flesch Reading Ease score to ensure readability scores were 60% and above (out of 100%, where a score between 60-70% translates to a UK or US grade 9-10 or 8-9 respectively, when students are 13-15 years old) [46,47]. Cancer questionnaires (for single cancers and for symptoms) have the highest readability scores, with readability ranging from 72%

to 88%, risk results have the lowest readability scores ranging from 60% to 70%. Thus, the REACT content shows satisfactory readability levels.

Another aspect related to the ability of the questionnaire to highlight actual changes in one's body that would point to potential cancerous symptoms. An example of this problem is the fact that some of the symptoms in the questionnaire might be "normal" for some people (eg, loose feces or bloating existing throughout one's life), and hence might produce an overestimated risk score. The following quotes from focus group participants illustrate this issue:

> *You know, when you explain that diarrhea can be associated with going more frequently to the toilet ... although there are more detailed symptoms below, my first impression it that I might answer 'yes' but this will be because of my diet... I drink a lot of water and have a fiber-rich diet.* [Focus group 6]

> *I might be bloated because I have IBS [Irritable Bowel Syndrome]) or because I am a female, and we older ladies can be like that...So would I select it as a symptom? I know bloating is an important one for ovarian cancer that is often missed.* [Focus group 1]

To address this issue, the following sentence was added at the start of the questionnaire: *"When you answer the questions, please try to think about symptoms that are not normal for you"*. This addition was designed to help individuals avoid pointing to symptoms that were unlikely due to cancer. While this could pose danger of omission of an important symptom, the fact that health care practitioners would be able to assist during the assessment would solve this potential problem.

Furthermore, building on the ability to distinguish relevant changes in one's body, an important aspect was to ensure that the questionnaire provides all possible options for potential answers (eg, "Yes," "No," or "Do not know" in relation to a symptom such as bloating). In case a symptom was newly appearing, it was also important to emphasize the difference in frequency of experiencing that symptom, as well as how recently they had that symptom (Figure 3).

Website Look and Feel

Firstly, it was important that REACT allowed users to easily access the cancer questionnaire. The initial versions of the website had a short introduction page explaining what REACT was and what it did. This was followed by a disclaimer, then the questionnaire. However, participants did not like the "waiting" and "clicking" associated with getting to the questionnaire, for example one focus group participant noted:

> *Yeah, just one disclaimer... But I mean by the time I've read through this I have lost interest. I mean I've read a lot on the first page, I've seen all of this but I've had enough, you know, I'm going to go and watch TV or, you know, go and make a cup of tea, or something.* [Focus group 2]

Figure 3. An example of cancer questions.

Consequently, the REACT landing page incorporates an introduction and prominent "start" button, followed by a succinctly phrased disclaimer (Figure 4). To provide different types of information at the landing page, without stopping participants from starting the questionnaire, we provided REACT related information, testimonials, and early detection information (Figure 2) on a carousel, a moving display that changes images every 20 seconds but also can be changed instantly by clicking on the arrows.

An important decision about the website design related to the selection of the main color used on the website. Because different colors have been associated with reflecting emotions and personality types and are often used by different organizations and brands to reflect organizational or brand values [48,49], we wanted to use a color that would be encouraging and invite participation. Originally, we used green, which is often related to health and nurturance [49]. However, this was criticized by some respondents as too "cheerful and relaxing" in the context of early detection of cancer. Consequently, we used orange, which is perceived as warm, optimistic, and sociable [49,50]. This color was well received by research participants who often mentioned (unprompted) the color of the website as one of the most likeable and noticeable website features.

Another important observation related to the fact that participants wanted the website to have a "human" image rather than one that is more medical or technical. One way to assure this was to use some images to reflect human values and lifestyles. This proved to be a challenging task. At first, we used cartoon images, which were quickly criticized by participants as inappropriate for the target audience. The following quotes from focus group participants illustrate the concerns with using animations on the website:

And then the second thing [animation] that came after is that this is for families when, you know, a lot of people, they're likely to be older; they're likely to be individuals living on their own. I don't see any connection with that image in cancer other than a kid's drawing of their family. So, I don't like it. [Focus group 2]

I would use animations when sending a WhatsApp message to my kids or something like that. On there, basically, you only do it for a bit of humor to add to things. Seeing it on there, I don't think it's doing any harm, but it's not helping me. [Focus group 1]

Therefore, the animations were replaced by real-life images (Figure 4), which were more favorably received. The images were of real people, not posed stock images (disliked as "too perfect"), and this was appreciated by participants, as it contributed to creating a realistic image of REACT as a community tool. Health care professionals emphasized the need to make the website appealing to different ethnic groups. This issue of social inclusion and exclusion was considered a very important and challenging outcome to achieve:

We often struggle to reach out to different ethnic groups. We for instance work with Bangladeshi females, who… my guess is, would not feel REACT is designed for their community - based on the images you have here. One way would be to make sure your images reflect that diversity… But to capture this you probably need to hire a photographer and work with them within communities. So that what you get is realistic. But there is no perfect solution. [Focus group 5]

Following this suggestion, more diverse images featuring people of different races, ages, and ethnic groups were added to the carousel on the landing page.

Figure 4. Look and feel of the REACT (Risk Estimation for Additional Cancer Testing) landing page.
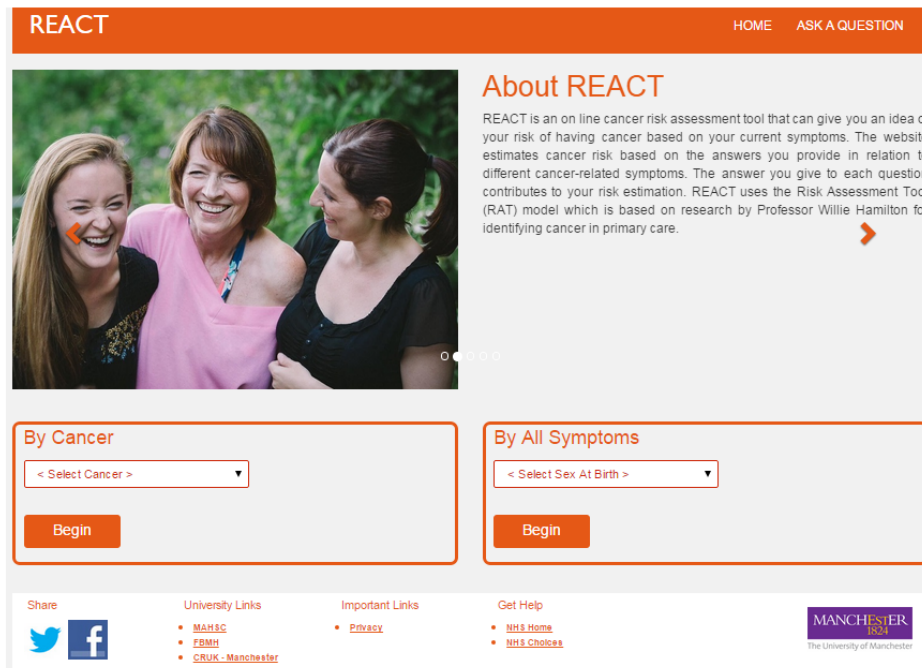
User-Friendly Risk presentation

Risk presentation proved the most difficult aspect in developing REACT, as people wanted to ensure the risk score was understandable and at the same time motivating (serious) enough to lead to action. In general, participants preferred a simple frequency format of risk presentation (eg, x in 100) over percentages (eg, x %). Furthermore, they felt more comfortable with having their risk information provided in both written (numeric) format and a visual format.

Interestingly, when the risk estimation was presented as a graph, participants preferred to have the graph representing one's disease risk in relation to affected individuals (as illustrated on the left side of Figure 5; in this case, the score would be 5 out of 11, where 11 refers to number of people with the same symptoms diagnosed with the disease). When graphs were used as reflective of the entire population at risk (following the same example discussed above with 5 people, this would be reflected as 5 out of 100 people with symptoms like yours, majority of whom were not diagnosed with the disease, as only 11 were), this made an impression of a very small risk. However, the visuals with the entire population were still desirable, and favorably received if presented as icon arrays (blocks or stick figures such as the "waffle chart" visual used in REACT, as illustrated on the right side in Figure 5).

Regarding the evaluative labels about personalized risk estimates, participants were satisfied with a distinction between low, medium, and high risk. Yellow was used to show low and medium risk, and red to illustrate high risk. Those decisions were again guided by feedback that having any of the symptoms would increase anxiety, and also can signal another disease. In earlier versions of the REACT website, green was used instead of yellow to point to low risk, but while this was liked by members of public, it was discouraged by health care practitioners. For members of public, green was seen as a "safety zone", assurance that the symptoms are not cancerous. However, health care practitioners saw the "green light" option as potentially leading to complacency in case of non-cancerous symptoms that could signal another illness:

> So, people may be using this for cancer, but they may not present with any symptoms of cancer at all, but they may present with symptoms of diabetes…and the "halo effect" of that [green light] can be dangerous. [Focus group 3]

To minimize unnecessary anxiety, the meaning of the score was explained with the following sentence:

> Remember, most people with this result will not have cancer. Even if you are one of the small number that turns out to have cancer you have done the right thing by completing the questionnaire and going to see your GP, as a cancer discovered early is much more likely to be easily treated, and is more likely to be curable. [message for medium risk]

As the data collection process allowed for website iterations between different data collection sessions, the process of website changes is illustrated in Table 2.

Figure 5. The selected graphics for individual risk presentation: a graph illustrating one's risk in relation to affected individuals at risk (left) and a "waffle chart" illustrating one's risk in relation of the entire population at risk (right).
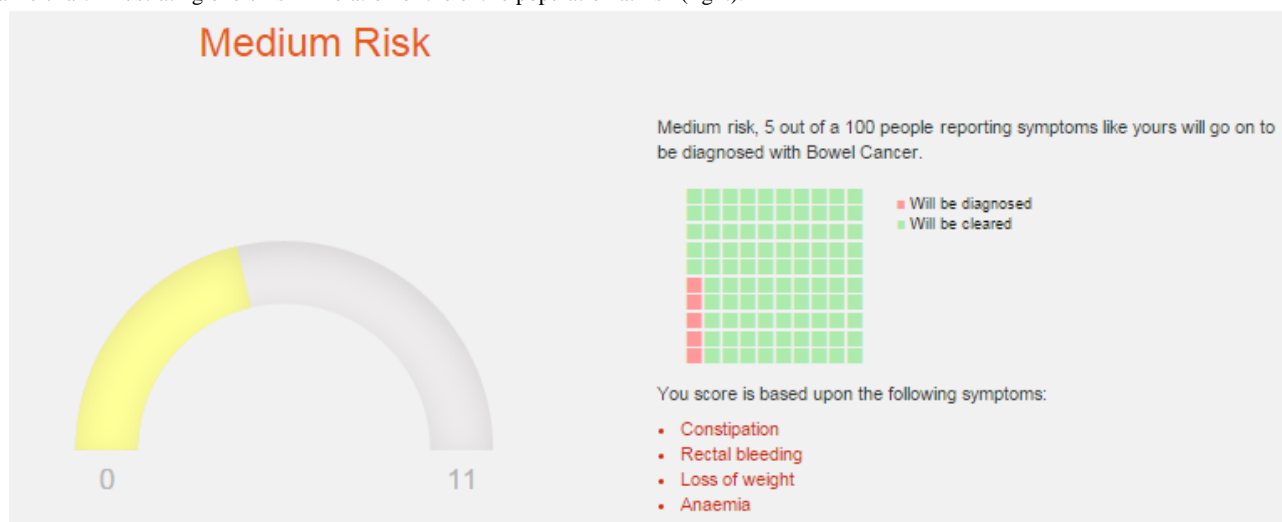

Table 2. Development stages for Risk Estimation for Additional Cancer Testing (REACT).

Time	Development and changes to the REACT website
May 1st to June 26th 2017	• Development of the initial version of the REACT website
July 7th to August 21st 2017	• Simplifying the website (eg, giving immediate access to the questionnaire, changing disclaimer to a single click pop up) • Change of website theme color from green to orange • Removal of any animations included on the website • Addition of realistic images with people • Adding carousel to the website (including user testimonies, REACT description) • Cancer questionnaire iterations • Cancer risk presentation iterations
August 23rd to October 2nd 2017	• Addition of multiple cancers • Enabling printout for users pointing to the cancerous symptoms • Addition of the REFLECT model • Cancer questionnaire iterations • Cancer risk presentation iterations (mainly added "waffle chart" visual for representation of 100 people representing population risk) • Positive framing in relation to early cancer detection (mainly in the carousel on the landing page of the website)
October 5th to November 30th 2017	• Cancer questionnaire iterations (emphasizing that the questions relate to "not normal to you" symptoms • Cancer risk presentation iterations (using both affected and population risk presentation)

Pathways to Practice

As indicated earlier, and illustrated throughout the reported results, research participants indicated the preferred methods of delivering and receiving advice from REACT. While some participants believed that the advice could be offered to public (via a public website), the majority believed the best way forward was through a guided approach supported by health care practitioners. This type of delivery was strongly recommended by health care practitioners. As cancer is an emotive topic, it was believed that while some individuals could cope with the results they obtained, others could experience stress and anxiety about their results. Considering the fact that some individuals might need help with interpreting and answering the REACT questions (eg, what is normal to me and how do I report it in the questionnaire) and results (eg, I have

a low risk of cancer but I am still concerned about the symptom(s) I had reported), as well as using technology, it was believed that they might need professional help in order to complete and understand their cancer assessment correctly. Considering this feedback, it was not recommended that REACT or similar websites are available in the public domain.

Participants believed that REACT can be offered at a variety of locations, where the needed support can be offered. Apart from community pharmacies and NHS Health Check services, respondents who filled in the open-ended questionnaire indicated that REACT would be a desirable addition in voluntary organizations (87% agreed), leisure centers (79%), council offices (75%), and workplaces (75%), to a lesser degree in benefit offices (46% agreed this was a good idea).

Discussion

Overview

In this study we provide novel insights into how members of public and health care practitioners perceive a Web-based intervention providing personalized symptom-based cancer risk estimation. We report the process of developing such a website and evaluate opportunities for introducing such an intervention within health care services in the UK. Our results show that there is a need for such a tool and that it would be well received. The best way to offer it to the public appears to be through a guided approach, where a trained individual supports members of the public in the process of risk assessment and evaluation.

Website design, content, functionality, look and feel as well as risk evaluation and presentation are all important factors affecting perceptions of usability of such a website. Users want a positive image of early cancer detection, a simple website with the ability to evaluate and detect multiple cancers, and value added in the form of explanation of their risk score and further lifestyle-based information about potential reduction of their future risk of having cancer.

While medical content and sources of information on such a website are important, individuals want those tools to have a "human face" and community feel that can be conveyed by the use of real-life images of people from various backgrounds and links to social media, community groups and portals. In terms of risk presentation, a direct approach to cancer communication is preferred. All risk presentation types (ie, numeric, visual, and evaluative) are appreciated, with two types of visual risk representation desired: with affected individuals only and the entire population at risk.

Comparison with Prior Work

Perceptions and Attitudes in Relation to Community-Based Cancer Risk Estimator

Our study is the first to date to demonstrate the potential of offering a symptom-based risk estimation tool in relation to a current cancer diagnosis (and potentially other diseases) to the wider public in the UK. Taking such a tool, typically used only in Primary Care settings [5,7,10], and offering it to public in a guided way might be a way to address the issue of patient and diagnostic delays which are often seen as barriers to early detection of cancer [5]. In addition, this research shows that individuals show willingness to understand their symptoms better and appreciate the ability to subsequently verify if those symptoms could be cancerous. It appears that such a community-based approach can be a starting point to shared decision making in the field of health care [51,52].

User-Friendly Website Design

Our findings confirm the growing need for Web-based tools like REACT that could facilitate shared decision making, and in the case of cancer, lead to early detection [51,52]. Users desire such tools to help overcome the stigma of cancer by being encouraging and by emphasizing positive, gain-framed outcomes [53]. Furthermore, the results indicate the need to emphasize the scientific evidence for REACT and show the need to build

associations of expert knowledge and trustworthiness in relation to this new intervention, noted previously as important in health-related websites [28,44].

Apart from the image of the website, a functional yet at the same time simplistic design is crucial, as noted earlier in literature [29,51]. In the case of REACT, functional aspects include the ability to cover multiple cancers and clear readability of the cancer questionnaire and associated results [51]. Creating an engaging, realistic, and socially inclusive look and feel of the website is crucial in successfully promoting such interventions to a wider public [28,54].

User-Friendly Risk Presentation

In general, the research findings in relation to risk presentation show that a range of numeric, visual, and evaluation risk estimates can provide most value to different users with different numeric skills [26]. Interestingly, the participants have shown some preferences in relation to each type of presentation. The preference for simple frequency (eg, x in 100) over percentages (eg, x %) might point to the fact that risk presented as a simple frequency is perceived as higher [55,56]. Such preferences are consistent with the preference for a direct approach to risk communication indicated by research participants.

Considering different types of visual presentation of data and different preferences [26], an option of showing two different visuals appears as the best option. Consequently, while we follow recommendations of Garcia-Ratamero and Galesic [57] in ensuring that a visual with the entire population at risk is shown to REACT visitors, we also follow recommendations for visual risk presentation for greater risk aversion, observed with a graphical display showing only the number of people affected [58,59]. Using two different graphs and assistance of a trained professional present during taking the REACT questionnaire can help to clarify potential confusion in relation to those different risk displays. Showing individual evaluative labels for their risk score (ie, low, medium, or high risk) has been recommended to help users understand their personal risk in the context of the disease [26].

Finally, while REACT does not manipulate fear appeal to affect behavior change, it's undeniable that communicating cancer risk estimates is associated with certain amount of fear for REACT users [24]. Thus, our findings (although relating to constantly present rather than manipulated fear appeal) can advance the risk communication literature [24,25] by pointing to ways to increase self and response efficacy when communicating symptom-based cancer risk. Providing people with clear printed information about specific symptoms is seen as an important aspect that increases their confidence that they can successfully describe their symptoms to their GPs, thus raising their self-efficacy. Response efficacy in this case mainly relates to breaking with the stigma of cancer as *only* a deadly disease. To help people feel that talking to their GP about their symptoms can help them improve their health outcomes, it is important to make them aware that cancer diagnosed early is more likely to be treated successfully. In this case, early detection should be seen as a way to reduce the risk of late cancer detection when cancer has spread and is more difficult to treat [60].

Pathways to Practice

The opportunities for using tools such as REACT are considerable and all the more important in the current financial climate when resources are scarce [61]. The tool has been shown to be user friendly, helpful and empowering. It has the potential to be used in the health care setting, alongside other health related activities such as the NHS Health Check and NHS screening programs as well as part of other consultations such as a chronic disease review. There is scope for the tool to be used in the voluntary sector with trained volunteers helping people, such as the elderly, people with a disability, those accessing community venues or Black and Minority Ethnic groups to know more about their health and potential cancer symptoms.

The biggest opportunity, albeit also with some risk, is for open access to the tool perhaps linked to an existing NHS website such as NHS Choices, where a positive result leads to an automatic referral and triage by a health professional and potential direct referral to diagnostic services. The risks with this include multiple referrals of the "worried well" and increasing the strain on limited resources. The opportunities include earlier diagnosis and faster access to treatment for an audience who might feel more comfortable entering symptoms into an online questionnaire, rather than speaking to their GP.

Limitations

The results of this study into a wider context need to be interpreted with consideration of the limitations. First, this research is limited to the context of the UK health care system and the 5 evaluated cancers. Consequently, future research can evaluate different cancer types and as the number of questions in the REACT questionnaire increases, further work using cognitive techniques [62] will be needed to further refine question wording and response options. Furthermore, due to differences in health care systems across the world, implementation pathways for interventions like REACT might be different for different countries.

Second, participants representing members of public were a small and self-selected group of individuals. This means that our sample could be limited to individuals who show a strong interest in their health or even in (avoiding) cancer, especially considering the fact that some were previously diagnosed with the disease. While we tried to address this limitation and reach a diverse group of participants by recruitment at various locations and using different means, we cannot exclude the possibility that self-selection impacted our results. This issue will be further explored in the next stage of this research project involving an evaluation of REACT. This future evaluation will consider the ability of REACT to detect symptomatic patients as well as its impact on GP workload, secondary care referral rates, and impact on health economics.

Conflicts of Interest

None declared.

Multimedia Appendix 1

REACT open-ended evaluation questionnaire.

[PDF File (Adobe PDF File), 21KB - cancer_v4i2e10073_app1.pdf]

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Abbreviations

GP: general practitioner
GMCV: Greater Manchester Cancer Vanguard
NICE: National Institute for Health and Care Excellence
NHS: National Health Service
PPV: positive predictive value
RAT: Risk Assessment Tool
REACT: Risk Estimation for Additional Cancer Testing
REFLECT: Risk Estimation For Lifestyle Enhancement Combined Trial

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<u>Original Paper</u>

Association Between Adherence to Cancer Screening and Knowledge of Screening Guidelines: Feasibility Study Linking Self-Reported Survey Data With Medical Records

Aisha K Lofters[1,2,3,4,5], MD, PhD, CCFP; Deanna Telner[3,6], MD, MEd, CCFP, FCFP; Sumeet Kalia[3,7], MSc; Morgan Slater[3], PhD

[1]Centre for Urban Health Solutions, Li Ka Shing Knowledge Institute, St. Michael's Hospital, Toronto, ON, Canada

[2]Department of Family and Community Medicine, St. Michael's Hospital, Toronto, ON, Canada

[3]Department of Family & Community Medicine, University of Toronto, Toronto, ON, Canada

[4]Institute for Clinical Evaluative Sciences, Toronto, ON, Canada

[5]Dalla Lana School of Public Health, Toronto, ON, Canada

[6]South East Toronto Family Health Team, Toronto, ON, Canada

[7]University of Toronto Practice-Based Research Network, Toronto, ON, Canada

Corresponding Author:
Aisha K Lofters, MD, PhD, CCFP
Centre for Urban Health Solutions
Li Ka Shing Knowledge Institute
St. Michael's Hospital
30 Bond Street
Toronto, ON,
Canada
Phone: 1 416 864 6060
Email: aisha.lofters@utoronto.ca

Abstract

Background: It is possible that patients who are more aware of cancer screening guidelines may be more likely to adhere to them.

Objective: The aim of this study was to determine whether screening knowledge was associated with the documented screening participation. We also assessed the feasibility and acceptability of linking electronic survey data with clinical data in the primary care setting.

Methods: We conducted an electronic survey at 2 sites in Toronto, Canada. At one site, eligible patients were approached in the waiting room to complete the survey; at the second site, eligible patients were sent an email inviting them to participate. All participants were asked to consent to the linkage of their survey results with their electronic medical record.

Results: Overall, 1683 participants responded to the survey—247 responded in the waiting room (response rate, 247/366, 67.5%), whereas 1436 responded through email (response rate, 1436/5779, 24.8%). More than 80% (199/247 and 1245/1436) of participants consented to linking their survey data to their medical record. Knowledge of cancer screening guidelines was generally low. Although the majority of participants were able to identify the recommended tests for breast and cervical screening, very few participants correctly identified the recommended age and frequency of screening, with a maximum of 22% (21/95) of screen-eligible women correctly answering all 3 questions for breast cancer screening. However, this low level of knowledge among patients was not significantly associated with screening uptake, particularly after adjustment for sociodemographic characteristics.

Conclusions: Although knowledge of screening guidelines was low among patients in our study, this was not associated with screening participation. Participants were willing to link self-reported data with their medical record data, which has substantial implications for future research.

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Introduction

According to the Canadian Cancer Society, 23 Canadians are diagnosed with cancer each hour, resulting in 202,400 new cases of cancer diagnosed in 2016 alone [1]. Screening for cancer is an important tool in our efforts to prevent cancer mortality. A number of initiatives to increase screening uptake have been undertaken in the past few decades, including the introduction of centralized, organized screening programs for cervical (through the Pap test), breast (mammogram), and colorectal cancer (fecal occult blood testing, FOBT) in Ontario, Canada's most populous province [2-4]. The provincial agency responsible for cancer services, Cancer Care Ontario, currently recommends that FOBT should be used for colorectal cancer screening, although those who have had a colonoscopy in the preceding 10 years are considered up-to-date [5].

Despite the known benefits of screening and the existence of organized screening programs in Ontario, the screening uptake in the province is still suboptimal. With the screening uptake currently estimated at 65% for breast cancer, 63% for cervical cancer, and 60% for colorectal cancer [6], more investigation is needed into how to improve screening rates. Various factors may impact the likelihood of screening. Health literacy has been shown to be associated with being within recommended cancer screening guidelines [7,8], and studies have shown an association between knowledge about cancer screening and screening uptake [9-13]. It is possible that patients who are more educated about screening guidelines may be more likely to adhere to them. For example, Hansen et al found that women who received cervical cancer screening were more likely to be aware of the recommended screening interval [14]. However, previous studies suggested that knowledge of screening guidelines is low in primary care [15-17]. Considering that primary care physicians play a central role in screening—performing Pap tests, distributing FOBT kits, and referring patients for mammography, as well as educating patients about screening and screening guidelines—it is important to understand if patients' knowledge of cancer screening guidelines is associated with screening uptake. As self-report of cancer screening can often be inaccurate [18-21], we wanted to directly link self-reported survey responses to patients' electronic medical record (EMR). However, attempting to link self-reported data to electronic clinical data is relatively new in the Canadian primary care setting. We were unsure as to how feasible this process was as well as how acceptable this would be to patients. As such, the specific objectives of this feasibility study were to assess the feasibility and acceptability of linking electronic survey data with clinical data in the primary care setting and determine whether cancer screening knowledge is associated with the documented screening participation among eligible participants.

Methods

Study Design

An electronic survey was developed to assess patients' knowledge of cancer screening guidelines (see details below) at 2 primary care organizations in Toronto, Canada's most populous city. At Site A, all patients presenting for appointments were approached to complete the survey on a tablet in the waiting room; at Site B, all eligible patients were sent an email inviting them to participate in the survey. Patients were also asked to consent to the linkage of their survey results with their EMR.

Study Setting

This study was based at 2 distinct primary care organizations in the city of Toronto. Site A is a multidisciplinary multisite primary care practice that provides care to >35,000 patients in downtown Toronto. The practice serves many patients who are low income, homeless or underhoused, and living with addictions. Site B is a multidisciplinary primary care practice that provides care to approximately 19,000 patients in the eastern portion of Toronto. The practice serves a multicultural patient population that is mostly low-to-middle income. The practice has been collecting email addresses for patients over the age of 18 years since 2011, and at the time of the study, had email addresses for approximately 50% of their patient population. When patients provide their email, they are given an information letter and asked to sign a consent form, acknowledging the risks of email communication and conditions for appropriate use.

We used 2 sites to increase the generalizability of our findings through a larger and more diverse sample. In addition, these 2 sites allowed us to evaluate 2 different methods of patient recruitment (tablet vs email), especially as the use of email contact for research purposes is still relatively new; however, comparing results between sites was not a study objective.

Eligibility Criteria

Patients of the primary care practices were eligible to participate in this study if they were eligible for cancer screening based on their age and sex (women aged 21-74 years and men aged 50-74 years). An additional criterion for Site B was that they had to have a documented email address in their medical record. The eligibility criteria based on age and gender match provincial screening guidelines; women are eligible for cervical cancer screening if they are aged 21-69 years and for breast cancer screening if they are aged 50-69 years. Men and women are eligible for colorectal cancer screening if they are aged 50-74 years [2,22,23].

This survey was offered to all eligible patients presenting for appointments at Site A over a 5-month period (March-August 2016) and was emailed to all eligible patients with email addresses on file at Site B on September 19, 2016. The email survey was open until October 20, 2016.

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Survey

The survey was adapted from a previous survey used in the preliminary work conducted at Site A [15]. It included questions regarding knowledge of the 3 evidence-supported guidelines of cancer screening in Ontario [15], and sociodemographic questions including immigration status, ethnicity, and financial strain [24]. Specifically, knowledge of guidelines was assessed by asking about the age of the screening eligibility, screening modality, and frequency of screening for each of cervical, breast, and colorectal cancer (see Textboxes 1-3). At the end of the survey, participants were asked if they consented to have their survey responses linked to their medical chart to assess their screening history. Once participants completed the survey, they were given information outlining the current screening guidelines in Ontario.

All survey data were collected utilizing the Ocean Studies platform, a cloud-based software program [25], which is integrated with the EMR. The platform allows self-reported patient data to be collected through the use of a secure and unique identifier through a "pseudonymization" process, which allows each patient to be identified without having to store any information that could identify the patient outside of the EMR. At Site A, eligible patients were identified from the EMR and approached to complete the survey on a tablet at the time of checking in to the front desk. At Site B, eligible patients were sent an email through the Ocean Studies platform, which contained a link to the survey. It was not possible for patients to reply to the email.

Chart Review

For the subset of patients consented, we extracted data on their cancer screening history, including the date of the most recent cancer screening, from their electronic chart using the automated search feature in the EMR.

Data Analysis

Responses to each of the screening knowledge questions were categorized as being correct or incorrect, and a count of the number of correct questions for each cancer screening type among those eligible for that type of screening was calculated as a measure of the screening guideline knowledge. Descriptive analyses were performed to describe the demographics and characteristics of the study participants, including their knowledge of current screening guidelines.

Textbox 1. Questions on screening eligibility age, screening modality, and frequency of screening for breast cancer. The bolded text represents the correct response

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The following questions are about current breast cancer screening guidelines:

1. The screening test for breast cancer is:

   - Ultrasound
   - Magnetic resonance imaging (MRI)
   - **Mammogram**
   - Breast exam by doctor/nurse
   - Unsure/don't know

2. Between what ages should women of average risk be screened for breast cancer:

   - 20-74 years
   - 30-74 years
   - 40-74 years
   - **50-74 years**
   - Unsure/don't know

3. How often should women have a screening test for breast cancer?

   - Every 6 months
   - Every 1 year
   - **Every 2 years**
   - Every 3 years
   - Unsure/don't know

Textbox 2. Questions on screening eligibility age, screening modality, and frequency of screening for cervical cancer. The bolded text represents the correct response.

The following questions are about current cervical cancer screening guidelines:

1. The screening test for cervical cancer is:
   - Fecal occult blood test
   - **Pap test**
   - Pelvic ultrasound
   - Pelvic exam
   - Unsure/don't know

2. Which of the following women should be screened for cervical cancer?
   - Those who are at least 18 years old and who have ever been sexually active
   - **Those who are at least 21 years old and who have ever been sexually active**
   - Those who are at least 21 years old, whether or not they have been sexually active
   - Those who are at least 25 years old, whether or not they have been sexually active
   - Unsure/don't know

3. How often should women have a screening test for cervical cancer?
   - Every 6 months
   - Every 1 year
   - Every 2 years
   - **Every 3 years**
   - Don't know

To assess the association between screening knowledge and documented screening behavior, we conducted a subgroup analysis of participants who consented to the linkage to their EMR. The dates of participants' last screening test(s) were used to categorize participants as being up-to-date on screening (ie, a Pap test in the previous 3 years, a mammogram in the previous 2 years, or an FOBT in the previous 2 years) [26]. We assessed the association between screening uptake and screening knowledge (the count of correct answers) for patients who were eligible for each type of screening using the Cochrane-Armitage trend test [27]. Multivariate regression analyses (logistic or log-binomial, as appropriate) were used to assess associations between screening uptake and knowledge, adjusting for age, income, immigration status, and ethnicity. We decided *a priori* to adjust for these variables as they have been shown in the literature to be significantly associated with cancer screening uptake [28-33]. Logistic regression is not the most suitable statistical analysis when the outcome is common (as it was for breast cancer screening), as it can contribute to the underestimation or overestimation of the true effect [34,35]. Hence, a log-binomial regression model was fitted for breast cancer screening.

All statistical analyses were conducted using SAS version 9.4 (SAS Institute Inc, Cary, NC, USA) and $P<.05$ was considered statistically significant. Research policies at the practice sites where the research was conducted require that any individual cells in a table with a numerical value of ≤5 cannot be reported, to reduce the risk of identifying participants. As such, all cell sizes <5 were suppressed.

Ethics

This study was approved by the Research Ethics Board at St. Michael's Hospital and Michael Garron Hospital, which is associated with the South East Toronto Family Health Team.

Textbox 3. Questions on screening eligibility age, screening modality, and frequency of screening for colorectal cancer. The bolded text represents the correct response.

The following questions are about current colorectal cancer screening guidelines:

1. The recommended screening test for adults of average risk of colorectal cancer is:

   - **Fecal occult blood test**
   - Rectal exam
   - Abdominal ultrasound
   - Colonoscopy
   - Unsure/don't know

2. When should adults of average risk start being screened for colorectal cancer?

   - 40 years of age
   - 45 years of age
   - **50 years of age**
   - 55 years of age
   - Unsure/don't know

3. How often should adults be screened for colorectal cancer?

   - Every 1 year
   - **Every 2 years**
   - Every 3 years
   - Every 10 years
   - Don't know

Results

In total, 506 eligible patients were seen in waiting rooms at Site A during the recruitment period and 6400 eligible patients with email addresses identified at Site B (Figure 1). The response rate significantly differed between the 2 sites—67.5% (247/366) of those approached in the waiting room versus only 24.85% (1436/5779) of those approached by email participated. However, the absolute number of study participants was much lower through recruitment in clinic (247 participants at Site A) than through the use of email (1436 participants at Site B). More than 80% (199/247, 80.6%, at Site A and 1245/1436, 86.70%, at Site B) of participants at both sites were willing to link their survey responses to their medical chart.

Table 1 describes the demographic characteristics of study participants overall and at the 2 study sites. Female participants were predominant at both sites, in line with 2 of the 3 evidence-based cancer screening actions being targeted at females only, and roughly 20% (328/1683) of participants at both sites reported having not enough income at the end of the month. More than 20% (374/1683) of participants were foreign-born at both sites, but participants at Site A were twice as likely to identify as visible minorities (58/247, 23.5%, vs 172/1436, 11.98%).

Knowledge of cancer screening guidelines was generally low. Respondents were likely to be able to report the recommended tests for breast (1453/1683, 86.33%) and cervical (1447/1683,

85.98%) cancer screening (Figure 2). However, very few participants correctly identified the age and criteria at which cervical cancer screening should begin (116/1683, 6.89%). Only 35.06% (590/1683) participants were able to correctly identify FOBT as the recommended test for colorectal cancer screening, with 49.32% (830/1683) naming colonoscopy as the appropriate screening test for colorectal cancer. The proportion of patients correctly responding to questions was consistently lower at Site A than at Site B; for example, 76.1% (188/247) patients at Site A identified mammogram as the recommended test for breast cancer screening versus 88.09% (1265/1436) of patients at Site B.

When we considered an overall measure of screening knowledge (the count of correct responses), more participants answered zero questions correctly than answered all questions correctly aside from those women eligible for breast cancer screening (Figure 3). Figure 3 shows percentages of study participants among 464 participants eligible for breast cancer screening, 1344 for cervical cancer screening, and 770 for colorectal cancer screening. Participants were most likely to get zero questions correct for colorectal cancer screening. While screen-eligible women were most knowledgeable about breast cancer screening, only 22% (21/95) answered all 3 questions correctly for breast cancer screening. However, the majority of participants knew, at least, one fact about each screening type they were eligible for. Knowledge levels appeared to be different between the 2 sites, with a higher proportion of respondents at site A being unable to answer any questions correctly for all 3 cancer types.

While over 80% (199/247, 80.6%, at Site A and 1245/1436, 86.70%, at Site B) of participants agreed to the linkage of their survey responses to their clinical data, technical issues at Site A did not allow for the actual linkage to occur (EMR identification numbers were not retained because of software malfunction). As such, the analysis of the association between screening knowledge and uptake is limited to 1245 participants at Site B who consented to the chart linkage. Among these patients, the screening uptake among screen-eligible participants ranged as follows: 20.7% (119/576) for colorectal, 66.21% (672/1015) for cervical, and 89.9% (319/355) for breast cancer screening. The level of knowledge of screening guidelines appeared to have no association with breast cancer or colorectal

cancer screening (Figure 4). However, increasing knowledge was associated with an increase in the cervical screening uptake (P=.04).

When adjusting for age, income, immigration status, and ethnicity, the number of questions answered correctly was not significantly associated with the screening uptake for any cancer screening type (Table 2). In addition, age, income, immigration status, and ethnicity were not statistically significant in the models, except for age for cervical cancer screening, where women aged 30-39 years were more likely to be up-to-date than women aged 60-69 years (adjusted odds ratio 3.24, 95% CI 1.95-5.39).

Figure 1. Study recruitment.

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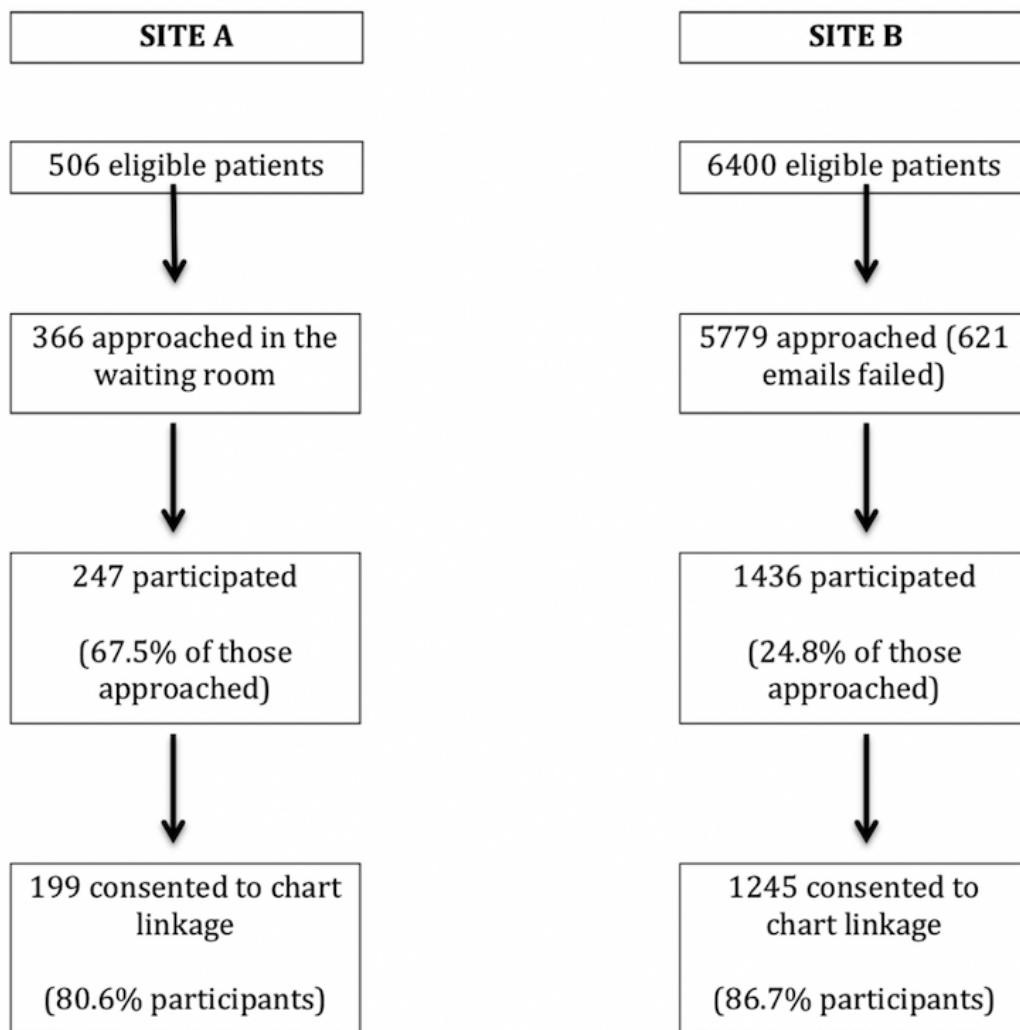
Table 1. Demographic characteristics of study participants, overall and broken down by the site.

Characteristics	Overall[a] (n=1683)	Site A (n=247)	Site B (n=1436)
Gender, n (%)			
Male	251 (14.91)	47 (19.03)	204 (14.21)
Female	1393 (82.77)	183 (74.09)	1210 (84.26)
Age in years, n (%)			
21-29	142 (8.37)	27 (10.93)	115 (8.01)
30-39	409 (24.30)	51 (20.64)	358 (24.93)
40-49	336 (19.96)	37 (14.98)	299 (20.82)
50-59	388 (23.05)	63 (25.51)	325 (22.63)
60-69	302 (17.94)	40 (16.19)	262 (18.25)
>70	81 (4.81)	14 (5.67)	67 (4.67)
Immigration status, n (%)			
Foreign born	374 (22.22)	64 (25.91)	310 (21.59)
Canadian born	1279 (75.99)	164 (66.40)	1115 (77.65)
Race, n (%)			
Caucasian	1359 (80.74)	157 (63.56)	1202 (83.70)
Other	230 (13.67)	58 (23.48)	172 (11.98)
Income at the end of the month, n (%)			
More than enough	530 (31.49)	68 (27.53)	462 (32.17)
Just enough	579 (34.40)	69 (27.94)	510 (35.52)
Not enough	328 (19.49)	51 (20.65)	277 (19.29)

[a]Not all questions were answered by all participants, and proportions will not add up to 100%.

Figure 2. Proportion of participants who correctly identified the test modality, age and frequency of breast, cervical and colorectal cancer screening guidelines.

Figure 3. Percentage of study participants by the number of questions answered correctly stratified by screening type.

Figure 4. Percentage of study participants at Site B who were up-to-date on cancer screening by modality and the number of questions correctly answered relative to each modality.

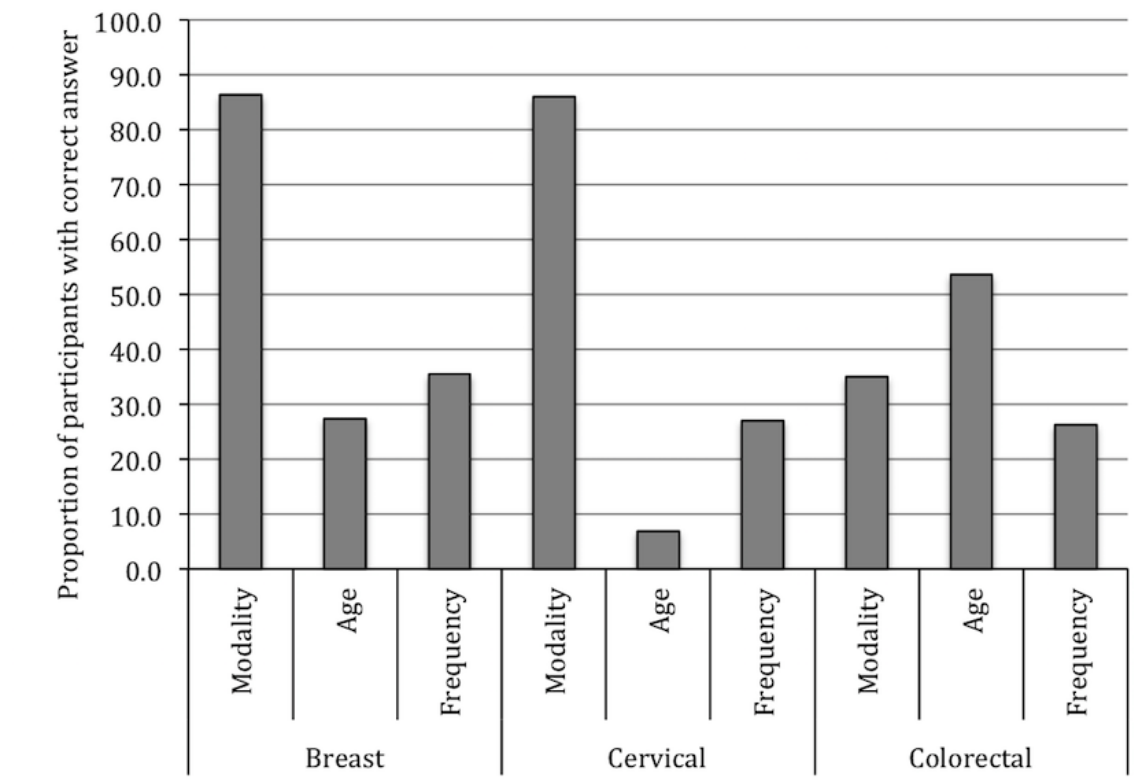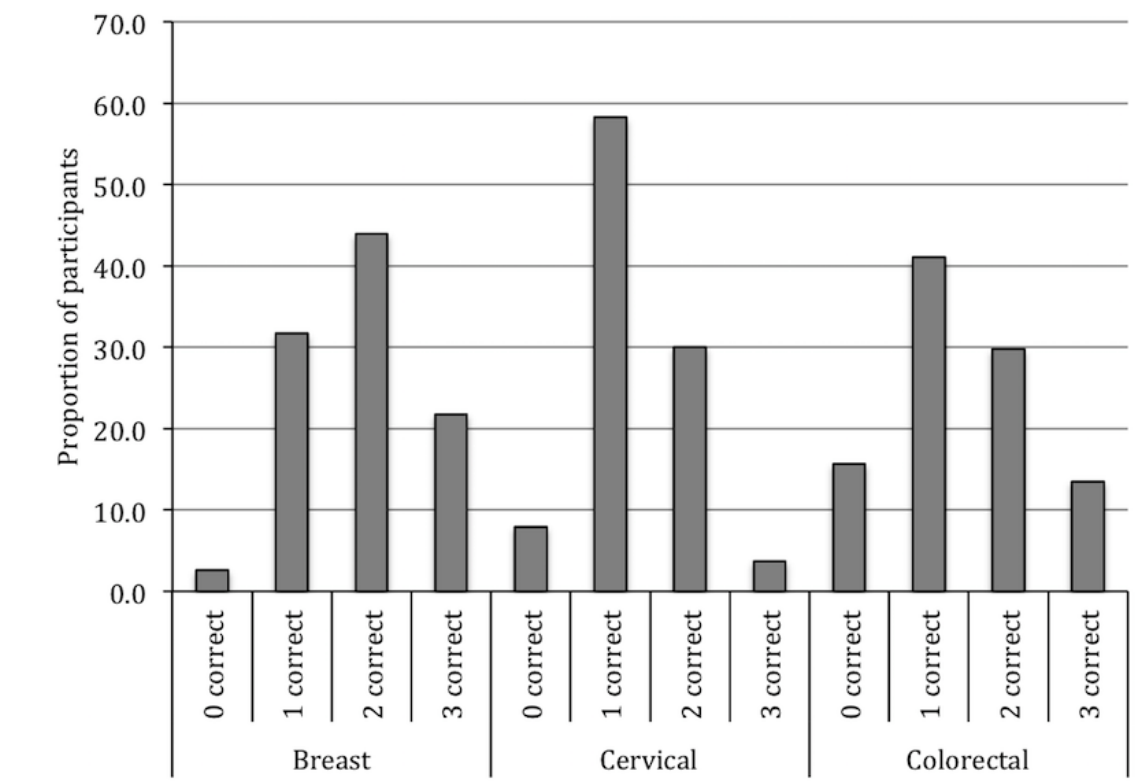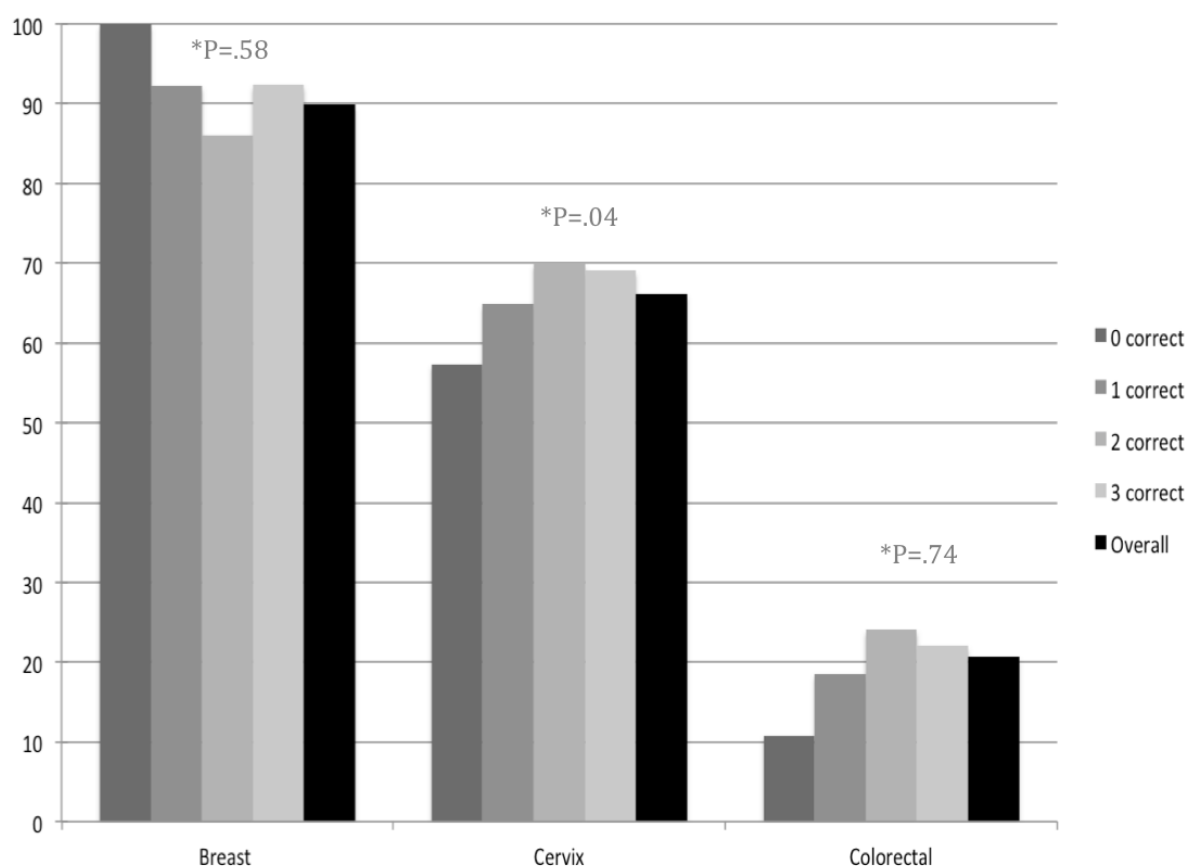**Table 2.** Results of multivariate regression analyses for the 3 types of cancer screening among study participants at Site B who agreed to the chart linkage. Other variables in the model included age, income, immigration status, and ethnicity.

Correct responses	Breast adjusted relative risks (95% CI)	Cervical adjusted odds ratios (95% CIs)	Colorectal adjusted odds ratios (95% CIs)
0	N/A[a]	0.82 (0.29-2.28)	0.87 (0.31-2.40)
1	0.99 (0.90-1.10)	0.82 (0.37-1.84)	1.46 (0.68-3.14)
2	0.93 (0.84-1.02)	0.87 (0.38-1.99)	1.62 (0.74-3.55)
3	1.0	1.0	1.0

[a]N/A: not applicable; of women who consented to the chart linkage and who had complete data for all covariates, only 8 women had zero questions correct.

Discussion

This study found that knowledge of cancer screening guidelines, specifically appropriate screening ages, modalities, and time intervals, was low among primary care patients. Very few patients correctly identified the recommended test, age and frequency of screening for breast, cervical, or colorectal cancer, with a maximum of 22% (21/95) of screen-eligible women correctly answering all 3 questions for breast cancer screening. Knowledge was particularly low for colorectal cancer screening, where more patients selected colonoscopy as the appropriate screening test compared with FOBT. However, this low level of knowledge among patients was not significantly associated with screening uptake, particularly after adjustment for sociodemographic characteristics.

Although educating patients about the benefits of screening has been shown to improve screening uptake [10,36-39], our findings suggest educating patients on the specific details of screening guidelines may not be a meaningful way of increasing adherence. Patient education interventions that have been shown to be effective for increasing screening have conveyed information on the epidemiology of relevant cancer, indications for screening including guidelines, details of the screening test, risks and benefits of screening, and ways to overcome potential barriers to screening [10,38,39]. Knowledge of these factors may directly motivate eligible adults to pursue screening [39] and thus is likely more important in improving adherence than knowing the appropriate age, test, and time interval. This is particularly relevant in the primary care setting where the provider can alert screen-eligible patients to when they are next

due and order the appropriate test. Furthermore, provider recommendation for screening has been shown to improve screening [40].More than 80% (199/247, 80.6%, at Site A and 1245/1436, 86.70%, at Site B) of patients were willing to share their EMR data with the research team and link their survey responses to their personal health information. As EMRs become pervasive, these numbers hold promise for future research studies in the primary care setting making use of these data. The use of anonymized EMR data on its own without the need for patient consent is common [41,42], but this study is an example of how identifiable records can be combined with self-reported data to produce useful findings.

We used 2 different methods to reach patients in this study—recruiting patients in the waiting room and by email. Although our response rate was much higher when offering the survey to patients in the waiting room than by email (247/366, 67.5%, vs 1436/5779, 24.85%), which was expected [43,44], we were able to reach many more patients with the email survey and thus have much higher absolute numbers. An email survey allows participants to complete it at their own pace, as opposed to in the waiting room, where surveys may be abandoned if patients are called in to be seen by their provider. Sending the survey by email also required much less staff time. Several research staff recruited patients at Site A over the course of several months, whereas all emails at Site B were sent to all eligible patients in a single batch. These results suggest that using email is a feasible way of recruiting patients for clinical studies and more time-efficient and cost-efficient than recruitment in the waiting room. Moreover, email surveys have the added advantage of allowing for recruitment of patients who come into the office infrequently and would be unlikely to be captured in waiting room surveys. As EMRs become more advanced, it is quite possible that in the future, practice-based researchers will be able to identify patients with particular medical diagnoses through EMR searches and email them regarding participating in relevant studies.

In health care, electronic communication is still relatively new, and most research has focused on the acceptability of utilizing email for clinical purposes as opposed to research [45,46]. The use of email to communicate with patients for research purposes still presents challenges. It is not possible to guarantee the privacy and security of email messages and know whether the email will be received by the one it is intended. Although our survey contained no personal health information, it did identify each participant as a patient of the primary care site. Not surprisingly, the Canadian Medical Practice Association has highlighted email communication with patients as holding potential legal risks, and the privacy commissioner of the province of Ontario has indicated that email communication with patients is not recommended, but if to be used, requires appropriate safeguards and security procedures to be in place [47]. Other practical issues include ensuring that email addresses are kept up-to-date, assessing if patients with email addresses are representative of the practice as a whole, determining an appropriate age of consent for email communication, updating email addresses as this age of consent is reached for pediatric patients and monitoring the total number of emails being sent out to patients by the practice, whether for research or other purposes, to avoid email fatigue.

This study has several limitations. First, we were unable to link surveys at one site to patient charts because of technical issues with the software. Despite significant advances in technology in recent years, unfortunately software glitches and malfunctions are still common. Second, the survey was available in only English, so patients who were not able to read English well were unlikely to participate. Third, we did not consider colonoscopy as a correct answer to the recommended screening test or as a measure of being up-to-date on colorectal cancer screening because it is not recommended by the provincial cancer agency for patients at average risk. However, almost half of the patients thought this was the recommended test and patients with colonoscopy in the past 10 years do not require FOBT screening. Anecdotally, many primary care providers at the participating site use colonoscopy for screening, which likely explains the very low FOBT screening rate (119/576, 20.7%) that we observed.

Although knowledge regarding the age of initiation, recommended screening test, and time interval for breast, cervical, and colorectal cancer screening was low among primary care patients in this study, this was not associated with a lack of screening participation. It is possible that physicians' recommendation and meeting a minimum threshold of screening knowledge may be sufficient to facilitate screening uptake. For example, if a 40-year-old woman knows that she should have a Pap test at least once every 3 years, it may not matter if she believes screening should start at the age of 18 years instead of 21 years. We also found that patients were willing to link self-reported data with their medical record data, which has significant implications for the possibilities for future research. Future research that builds directly on the findings from this study should use the EMR to identify patients in primary care practices who meet screening criteria and are due for screening, send them email reminders with accompanying evidence-based educational information on screening, and assess the effect on screening uptake.

Conflicts of Interest

None declared.

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Abbreviations

EMR: electronic medical record
FOBT: fecal occult blood testing

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Original Paper

Exploring the Most Visible German Websites on Melanoma Immunotherapy: A Web-Based Analysis

Julia Brütting[1*], BEd, MPH[‡]; Theresa Steeb[2*], BEd, MPH; Lydia Reinhardt[1], Dipl Soz; Carola Berking[2], MD; Friedegund Meier[1], MD

[1]Department of Dermatology, Dresden University Hospital and Medical Faculty Carl Gustav Carus, Technical University of Dresden, Dresden, Germany

[2]Department of Dermatology and Allergy, University Hospital, LMU Munich, Munich, Germany

[‡]Written on behalf of Skin Cancer Council Germany

[*]these authors contributed equally

Corresponding Author:
Julia Brütting, BEd, MPH
Department of Dermatology
Dresden University Hospital and Medical Faculty Carl Gustav Carus
Technical University of Dresden
Fetscherstraße 74
Dresden, 01307
Germany
Phone: 49 176 207 896 27
Fax: 49 351 458 4338
Email: julia.bruetting@uniklinikum-dresden.de

Abstract

Background: Patients diagnosed with melanoma frequently search the internet for treatment information, including novel and complex immunotherapy. However, health literacy is limited among half of the German population, and no assessment of websites on melanoma treatment has been performed so far.

Objective: The aim of this study was to identify and assess the most visible websites in German language on melanoma immunotherapy.

Methods: In accordance with the common Web-based information-seeking behavior of patients with cancer, the first 20 hits on Google, Yahoo, and Bing were searched for combinations of German synonyms for "melanoma" and "immunotherapy" in July 2017. Websites that met our predefined eligibility criteria were considered for assessment. Three reviewers independently assessed their quality by using the established DISCERN tool and by checking the presence of quality certification. Usability and reliability were evaluated by the LIDA tool and understandability by the Patient Education Materials Assessment Tool (PEMAT). The Flesch Reading Ease Score (FRES) was calculated to estimate the readability. The ALEXA and SISTRIX tools were used to investigate the websites' popularity and visibility. The interrater agreement was determined by calculating Cronbach alpha. Subgroup differences were identified by t test, U test, or one-way analysis of variance.

Results: Of 480 hits, 45 single websites from 30 domains were assessed. Only 2 website domains displayed a German quality certification. The average assessment scores, mean (SD), were as follows: DISCERN, 48 (7.6); LIDA (usability), 40 (2.0); LIDA (reliability), 10 (1.6); PEMAT, 69% (16%); and FRES, 17 (14), indicating mediocre quality, good usability, and understandability but low reliability and an even very low readability of the included individual websites. SISTRIX scores ranged from 0 to 6872 and ALEXA scores ranged from 17 to 192,675, indicating heterogeneity of the visibility and popularity of German website domains providing information on melanoma immunotherapy.

Conclusions: Optimization of the most accessible German websites on melanoma immunotherapy is desirable. Especially, simplification of the readability of information and further adaption to reliability criteria are required to support the education of patients with melanoma and laypersons, and to enhance transparency.

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Introduction

Melanoma incidence has been increasing worldwide [1,2]. In Germany, it accounts for about 4% of all cancer types and is the fifth most common malignancy [3]. Approvals of new effective therapies in the last decade have substantially expanded the treatment spectrum, especially for patients with melanoma and metastatic disease. One of these treatment options is immunotherapy, the application of which has resulted in pioneering response rates and markedly increased survival chances of patients with melanoma [4-6].

Given the novelty, complexity, and potential toxicity of immunotherapy, the need for educating patients with melanoma has been increasing. Physicians serve as the primary information source in this context. However, recent research suggests that the information-seeking behavior of patients with melanoma [7-9] and the resources they use have been changing alongside with the application of modern media and structural changes in health care provision. Besides medical consultations and written information [10], as cancer patients' persisting primary and most important sources of health information, a growing preference of the internet to acquire disease-specific information has been observed [8-11]. The search engines Google, Bing, and Yahoo are the most searched in this respect by the public and patients [12-15]. However, although the internet becomes increasingly popular, many patients with cancer are skeptical of Web-based information [16,17]. Not all websites on cancer issues are prepared by health professionals or medical and health care authorities, and the reliability and accuracy of the information available remain questionable [18]. Web-based information for patients with melanoma was previously found to be difficult to read [16], did not provide complete basic and transparent information, or contained misinformation [19].

It has become a common practice to review the most visible Web-based cancer information on therapy using scientifically validated tools [20-24] to explore what shortcomings exist and what should be considered when using the information. Web-based treatment information is used by patients to support their treatment decision making [25]. Therefore, genuine information should be presented in a complete and simple manner. The aim of this study was to explore first, what websites with information on melanoma immunotherapy in German language are currently visible and accessible at most when applying common Web-based search engines, and then to assess them in terms of their quality, reliability, usability, understandability, readability, visibility, and popularity. The results of this study will be beneficial for dermatologists to recommend and for patients with melanoma to identify appropriate websites with information on immunotherapy. Moreover, the results will indicate potential issues that providers should address to improve their websites.

Methods

Search Strategy

In accordance with common Web-based search patterns of the general population, including patients with cancer [12-15], 2 independent researchers (JB and TS) searched the first 20 hits on the most frequently used Web-based search engines Google, Bing, and Yahoo for a combination of German synonyms for "melanoma" and "immunotherapy." *A priori*, Google trends analysis was used to identify relevant search combinations that people frequently used when searching Google for this topic. The search terms were adapted according to the Google trends analysis and were combined as "Melanom + Immuntherapie," "Malignes Melanom + Immuntherapie," "Hautkrebs + Immuntherapie," and "Schwarzer Hautkrebs + Immuntherapie." The search was performed between July 10 and July 14, 2017, using the Web-based browsers *Internet Explorer version 11* or *Mozilla Firefox version 57*.

Inclusion and Exclusion Criteria

To be eligible for assessment, websites had to meet the following inclusion criteria: (1) contain information on immunotherapy referring to melanoma; (2) contain at least 5 sentences of information; (3) be accessible for free and for all users (including patients and laypersons); and (4) information is provided in German language. Websites were excluded if they were solely patient exchange platforms, advertising websites, conference or congress websites (eg, of medical conferences), websites dealing with nonmelanoma skin cancer (NMSC), websites about melanoma and NMSC in animals, websites solely providing videos or images, and websites of restricted access (eg, asking for log-in).

All hits of the search engine queries were screened for duplicates, and the predefined eligibility criteria were applied. Whenever discrepancies on the relevance of a website arose, a third researcher (FM or CB) was consulted as arbiter for resolution.

Grouping of Websites

Owing to the variability in the creators of websites and for comparison, the websites were grouped by application of 2 different approaches, similar to Azer et al [20]. First, the websites were grouped according to their providers as follows: (1) commercial and pharmaceutical companies; (2) noncommercial or charity providers; (3) medical or scientific providers; (4) general public press; (5) commercial health information services; (6) clinics or health professionals; and (7) Wikipedia.org. The categorization was conducted independently by 2 researchers (JB and TS); disagreements were discussed and remedied in a subsequent meeting. Second, the groups (1)-(3) and (6) were summarized as oncology expert domains, and the groups (4), (5), and (7) were summarized as domains provided by the general public press. "General public press" domains describe domains that do not primarily address a particular subgroup of users, such as patients or medical experts, but the general public; these are usually provided by media such as news magazines, tabloids, and radio or television channels.

Data Management and Website Assessment

The available baseline information (URL, title, name of the website provider, and year of publication) of each included website was documented. For inaccessible information, the tool Whois Lookup was used to complete the data collection.

Assessment was performed on the individual website level and the domain level, depending on the assessment tool.

Three reviewers (JB, TS, and LR) independently assessed the websites' quality of information, usability, reliability, and understandability by applying different validated tools. Prior to the final assessment of the websites, the 3 reviewers piloted the use of the assessment tools by independently evaluating individual websites on NMSC to discuss potential difficulties or points of disagreement and resolve questions. The degree of agreement between all 3 reviewers for the final assessment was quantified by an interrater agreement analysis.

Furthermore, the readability of individual websites, as well as the visibility and popularity of the domains, was determined by using established calculating Web-based tools. The baseline information was extracted to an internally piloted data extraction sheet using Microsoft Excel 2010. The German melanoma guideline [26] was used as reference standard to check the scientific accuracy of a websites' content.

Quality of Information Assessment

The DISCERN tool (discern.de) is commonly used to assess the quality of information on cancer [20,24,27] and was developed for use by laypersons [28]. It consists of 16 items to review (1) a publication's transparency (items 1-8); (2) content (items 9-15); and (3) to give an intuitive assessment summary (item 16). Items are scored on a 5-point scale ranging from 1 ("criterion is not met at all") to 5 ("criterion is fully met"). An overall score of 80 and a summary mean score of 5, respectively, corresponds to the high quality of a publication (Table 1).

In addition, the presence of a health information quality certification, such as HONcode from the Health On the Net Foundation, Public Health Foundation (German: Stiftung Gesundheit) certificate, or the certificate from afgis (German:

Aktionsforum Gesundheitsinformationssystem e.V.), was documented for each domain as well. Quality certifications on health topics are used to indicate that a domain meets particular quality criteria (eg, for transparency, reliability, and funding) and are usually awarded by charitable associations.

Assessment of Usability and Reliability

LIDA is a validation tool for health care websites. It contains 41 items [29] for the assessment of the *accessibility*, *usability*, and *reliability* of domains on health topics. Each item can be rated with a score of 0 ("never"), 1 ("sometimes"), 2 ("mostly"), or 3 ("always"). We only assessed the domains' *usability* (items 7-24 assessing the clarity of information, consistency of the domain design, the presence of effective browsing and search functions, and the presence of media) and *reliability* (items 25-41, assessing the domain update frequency, conflicts of interest, the methodology of the content production, and the accuracy of content). As we excluded websites with restricted access and also because of the unavailability of the basic corresponding LIDA category during our assessment, we decided to leave the category *accessibility* out. The overall LIDA score was calculated as a sum of the 2 mentioned categories, resulting in a maximum score of 81.

Assessment of Understandability and Actionability

The Patient Education Materials Assessment Tool (PEMAT) [30,31] was used to assess the individual websites' *understandability*. The *understandability* part comprises 17 items that cover content, word choice and style, numbers, structure, layout and design, and the use of visual aids. Another part covers *actionability* by 7 items. Each item can be scored as 0 ("disagree"), 1 ("agree"), or N/A ("not applicable"). Then, percentages of fulfilled items are calculated. The higher the value, the more understandability elements are applied on a website.

Table 1. Overview of assessment tools.

Category assessed	Tool used	Level of analysis	Score range	Interpretation of results
Quality	DISCERN	Individual websites	1-80	Higher values indicate higher quality
	Check for the Presence of Quality certificates	Domains	Presence or absence	
Validity	LIDA	Domains	0-81	Higher values indicate higher validity
Usability			0-54	Higher values indicate better usability
Reliability			0-27	Higher values indicate higher reliability
Understandability	PEMAT[a]	Individual websites	0%-100%	Higher percentage indicate higher understandability
Readability	FRES[b]	Individual websites	<0 to >60	Higher values indicate better readability <20 very low, 21-40 low, 41-60 average, >60 easy
Visibility	SISXTRIX	Domains	0-max	Higher values indicate higher visibility
Popularity	ALEXA	Domains	1-max	Lower values indicate better popularity rank

[a]PMAT: Patient Education Materials Assessment Tool.

[b]FRES: Flesch Reading Ease Score.

Readability Analysis

Since the websites under investigation are accessible for laypersons and patients with melanoma, we evaluated whether they provide information in an appropriate readability level and whether they cover the general public and patients' readability needs. Consistent with Azer et al [20], we analyzed a sample of 200-500 words or 4-5 sentences if the information was presented in up to 10 sentences. We then calculated the Flesch Reading Ease score (FRES) by using a Web-based tool adaptation for German texts [32] to determine the *readability* of individual websites. If the text was >10 sentences, we randomly extracted 4-5 connected sentences and 200-500 words, respectively. The score was calculated by using a formula that takes into account the word and sentence length, as well as characters and syllables per word, resulting in an absolute score that expresses the readability of a text ranging from <20 (very difficult), 21-30 (difficult), 31-40 (fairly difficult), 41-60 (standard), 61-70 (fairly easy), 71-80 (easy), and >80 (very easy). Owing to the FRES formula, it is possible that negative values may be results of the calculation, if, for example, sentence or words are very long:

$$FRES = 206{,}835 - 84.6 \times \text{average length of words (number of syllables)} - 1015 \times \text{average length of sentences (number of words)}.$$

Popularity and Visibility Analysis

In order to have a reference to a domain's *popularity* and *visibility*, the ALEXA traffic tool [33] and the SISTRX tool [34] were used, respectively. We determined the domains' ALEXA traffic rank in Germany, which is calculated through a combination of average daily visitors and pageviews on this domain over the past 3 months, that is, the domain with the highest combination is rated as number one. In addition, we estimated the daily pageviews per visitor and the time users spent on the domain. The SISTRIX visibility index is a measure of a domain's discoverability within the search results in Google. The higher the value, the more visitors browse the domain.

Statistical Analysis

Statistical analyses were conducted by using SPSS (IBM SPSS Statistics version 24, IBM Corporation, Armonk, NY, USA). Descriptive analyses included mean (SD) or median and interquartile ranges (IQR). Subgroup differences were explored by means of the *t* test or *U* test and by one-factor analysis of variance or the Kruskal–Wallis test. Statistical significance was set at $P \leq .05$. The interrater agreement of the 3 reviewers was determined using the intraclass correlation coefficient, as well as by determining the interitem correlations *r* between the individual reviewers.

Results

Identification of Eligible Websites

Our initial search in Google, Yahoo, and Bing identified 480 individual websites.

Using a multistep process, we screened the 480 websites for duplicates and checked them for accordance with our eligibility criteria. Multimedia Appendix 1 presents the detailed identification process of eligible websites. Finally, 45 individual websites provided by 30 domains met our eligibility criteria and were considered for the assessment.

Grouping of Websites

Of 45 individual websites considered, 6 could be assigned to pharmaceutical companies, 4 to a noncommercial provider, 13 to medical science providers, 11 to the general public press, 7 to commercial health information services, 2 to Wikipedia, 1 to a hospital, and 1 to a health professional. Multimedia Appendix 2 lists all analyzed websites.

Baseline Information of the Websites

The individual websites were published between 2007 and 2017 with 44% (20/45) published in 2017 and 56% (25/45) in the years before. The oldest websites were provided by Pharmazeutische Zeitung (2007) and the University Hospital of Ulm (2008; Multimedia Appendix 2; #11 and #26). Two-thirds (n=30) provided information on immunotherapy of melanoma and one-third (n=15) reported on immunotherapy in cancer, including melanoma.

Quality of Information

Presence of Quality Certification

The domain krebsgesellschaft.de had a HONcode and an afgis quality certificate, and the domain apotheken-umschau.de displayed an afgis certificate, as well as a certificate of the Public Health Foundation [Stiftung Gesundheit] (Multimedia Appendix 2; #2 and #5). The other domains had no certificate.

DISCERN Results

Out of a total of 80 points, the 45 individual websites scored between 35 and 63 points. The mean DISCERN scores ranged from 2.1 to 3.7 points, indicating a medium–low to medium–high quality. Most score deductions were because of lacking information on nontreatment (item 12), on the potential impact of treatment on the patients' quality of life (item 13) and the lack of information on scientifically uncertain aspects of treatment (item 8; Multimedia Appendix 3). The lowest DISCERN score was obtained from the website medecon.ruhr (35 points), and the highest score from wikipedia.org and uniklinik-ulm.de (63 points each; Multimedia Appendix 2; #22 and #8).

Usability and Reliability—LIDA Results

The 30 domains scored between 39 and 67 points (maximum of 81 points possible). The assessment by LIDA and the separate analysis of the usability and reliability sections indicated that the usability criteria (74%; mean (SD): 40 (2.0) out of 54 points) were more frequently fulfilled than the reliability criteria (38%; 10 (1.6) out of 27 points; Multimedia Appendix 4; Figure 1). In particular, the currency and conflicts of interest criteria were least met (Multimedia Appendix 5). Medecon.ruhr and scinexx.de were the domains that received the lowest overall LIDA scores (39 points each), aerzteblatt.de and krebsgesellschaft.de were rated highest (67 and 66 points; Multimedia Appendix 2; #22, #18, #1, and #2).

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Figure 1. Quality, usability, reliability, understandability, and readability of 45 websites providing information on melanoma immunotherapy. Box, lower line: quartile Q1 (25% quantile), middle line: median, upper line: Q3 (75% quantile); aerials, highest values. PEMAT: Patient Education Materials Assessment Tool; FRES: Flesch Reading Ease Score.
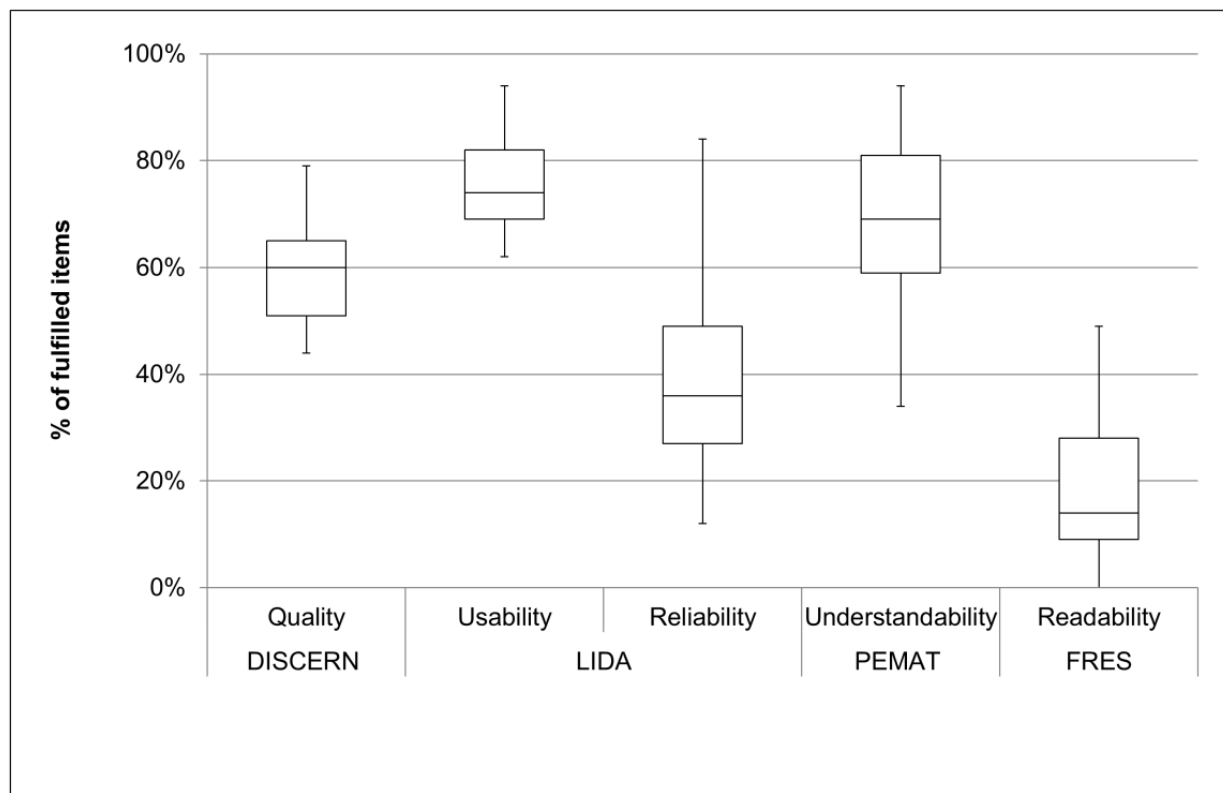
Understandability and Actionability—PEMAT Results

On average, 69% of the understandability elements were applied by the 45 websites. The lowest PEMAT score was received from journalonko.de (34%) and the highest from uniklinik-ulm.de (94%; Multimedia Appendix 2; #9 and #26). The reviewers could assess an item of actionability in only 16% (7/45) of websites, indicating that actionability was nonexistent in nearly all identified websites.

Readability—Flesch Reading Ease Scores

The median FRES was 14 (IQR: 8.5-28.0), indicating that the information of at least 50% (23/45) of the 45 websites was very difficult to read for laypersons. Receiving a FRES of 49, the most readable text was provided by swr.de, whereas the lowest FRES was calculated for the text provided by a link from krebsgesellschaft.de with a score of –15 (Multimedia Appendix 2; #6 and #2).

Interrater Agreement

We determined intraclass correlation coefficients of .831 to .964, indicating a high overall interrater agreement concerning the assessment by DISCERN, LIDA, and PEMAT (Multimedia Appendix 6) [35]. The interitem correlations r varied between .401 and .974, indicating moderate to a high individual

agreement among the 3 reviewers when assessing the individual items.

Popularity and Visibility

The majority of users visited the domains almost twice a day [median, 1.7 (IQR: 1.6-2.2)] and browsed a website between 22 and 350 seconds and 142 seconds on average. The domain t-online was the most frequently and longest visited of the domains considered and was ranked the most popular according to the ALEXA tool. The least popular website considered was journalonko.de (Multimedia Appendix 2; #9). Wikipedia.de showed the highest SISTRIX visibility value (Multimedia Appendix 2; #8). Multimedia Appendix 4 summarizes the results of the assessments using DISCERN, PEMAT, and LIDA by 3 independent reviewers and the determined FRES, ALEXA (Germany), and SISTRIX values.

Subgroup Analyses

Differences Between Domains of Different Providers

In addition to significant differences in popularity, visibility (*P*=.02), and daily visit values (*P*=.02), differences between the websites of different providers were particularly evident from the readability (*P*<.001) and understandability scores (*P*<.001), indicating that the links of the noncommercial provider had the lowest readability and general public press the highest

readability (Multimedia Appendix 7). However, pharmaceutical companies, hospital or health professional, and Wikipedia were most keen in applying understandability elements. DISCERN (between 49 (SD 7) and 62 (SD 1) points; *P*=.07) and LIDA (between 46 (SD 4) and 66 points; *P*=.12) scores were not significantly different.

Differences Between General Public Domains and Oncology Expert Domains

Websites addressing the general public had significantly higher popularity (ALEXA; *P*<.001) and visibility (SISTRIX) ranks (*P*=.001) and were visited longer on average (*P*=.04) but not necessarily more often (*P*=.23) than websites predominantly addressing or provided by oncology experts. The most visible and popular oncology expert domains were pharmazeutische-zeitung.de, aerzteblatt.de, and krebsgesellschaft.de. Furthermore, the public domains had better readability (*P*<.001) and understandability (*P*=.002; Multimedia Appendix 8). Significant differences in terms of quality, usability, and reliability could not be detected (*P*=.06-.76). However, the LIDA scores were marginally in favor of oncology expert domains.

Discussion

Principal Findings and Comparison With Prior Work

The websites that we have systematically identified provided information on melanoma immunotherapy as the main subject or reported on aspects of cancer immunotherapy in general. Nearly half of the identified websites were published in 2017, and the other half in the years before. The majority of websites could be assigned to providers of scientific medical information or the general public press and Wikipedia.

We assessed the quality of the individual website information as medium–low to medium–high, and we found only 2 website domains from the health care sector that displayed a quality certification. These findings are similar to those of Bari et al [19], who found a low use of quality certificates on German websites (in 4 out of 21), providing general Web-based information on melanoma. An explanation for this persisting low presence of certified websites might be that webmasters have to register, apply, and—following the acceptance—pay for certification. For example, to acquire the HONcode certificate, webmasters recurrently have to apply for certification. In addition, from the second HONcode membership, a fee is due [36]. Hence, the awarding process of such quality certificates proclaiming trustworthiness should be kept in mind, and either their presence or their absence should be critically appraised. However, the 2 domains we found providing quality certificates received the above-average quality of information, usability and reliability scores, and thereby can be seen as a kind of certificate affirmation.

Score deductions resulting in an overall mediocre quality of the websites' content mainly resulted from incomplete and sometimes superficial reporting about melanoma immunotherapy, characterized by missing information on possible treatment consequences for the patients' quality of life, on the consequences of nontreatment, and on unclear scientific evidence for different aspects of treatment. Conversely, more effort was made to describe the effects and benefits of treatment; this is a fairly known problem with Web-based cancer information [20-22,37-39], which makes reporting one-sided and, thus, withholds important information for treatment decision making. However, this may not apply to all websites considered. Highly variable content and quality of websites providing general melanoma information have been reported recently [40].

In terms of content, websites offered to the general public provided only some aspects of melanoma immunotherapy, whereas websites offered by and to oncology experts included more detailed and substantial information. In addition, oncology expert domains marginally met more reliability and usability criteria. Overall, the 30 domains demonstrated high usability but low reliability and even lower readability. The low readability may be attributed to a frequent application of medical terms, which are not explained in layperson's terms. In addition, sentences were sometimes very long and nested, especially in oncology expert websites, which makes the readability more complicated. This pattern of high usability but low reliability and readability has also been found to be typical for websites providing cancer information [20,21,24,39], including those providing information on melanoma [16,19]. It is fundamental that patients can easily read treatment text and understand the medical terms to benefit from the information. Furthermore, an indication of the sources quoted and their recency should routinely be provided on a website to enhance reliability and trustworthiness. Another problem that should also be addressed in this context is that among the websites published before 2017, there were websites offering information dating back to 2007. As immunotherapy is such a novel innovation and because a lot of progress has been evolved since the approval for melanoma treatment with immune checkpoint-inhibiting agents, such as ipilimumab in 2011, the content of such old websites is questionable and unreliable.

In general, and if appropriate, the identified websites showed good efforts to make their contents understandable by applying various visual aids and supportive structuring elements (eg, illustrations, paragraphs, simple numbers, and short sections of texts). However, we found very few elements of actionability. In this regard, the most visible German websites on melanoma immunotherapy were in line with other patient education materials that were previously assessed by the same tool [41,42]. However, the application of more elements of actionability and interactivity (eg, checklists, videos, and webinars) may facilitate the users' handling and understanding of difficult website content and is highly recommended.

Overall, we found that websites that addressed the general public were superior in terms of the popularity and visibility compared with oncology expert domains. They applied more elements to support the understandability and their information provided on immunotherapy was easier to read for laypersons but more superficial in terms of the content. However, we found no discrepancy between the visibility and quality of websites, as this was the case in a previous study on German Web-based cancer information [39].

Strengths

To date, no work has been published with a comprehensive and thorough assessment of the most visible German websites providing information on melanoma immunotherapy. Our results updated the currently available evidence on the Web-based melanoma information quality. Three reviewers have independently assessed the websites using a variety of validated instruments, yielding an overall good interrater agreement. We have not only assessed the websites subjectively (eg, by using tools like DISCERN, PEMAT, or LIDA) but also evaluated them objectively by using tools like FRES, SISTRIX, or ALEXA, which measure the values quantitatively. As immunotherapy is such a novel treatment approach and given its complexity, a comprehensive assessment of the most visible websites addressing this topic is of high relevance for both patients and physicians.

Furthermore, 2 researchers have searched the search engines Google, Bing, and Yahoo because these websites are searched from the most patients and the public for general cancer information [12-15]. In addition, it is interesting to note that the 2 researchers were at different geographical locations of Germany when searching the 3 search engines. Hence, we might have identified a full overview on websites because of different GPS data affecting the algorithms of the search engines. Therefore, our identified websites might be more comprehensive.

Limitations

We are aware that this study has some limitations. First, the websites identified represent only a snapshot of the time when we searched the 3 search engines in July 2017. Bearing in mind that immunotherapy is a quite novel approach with a lot of ongoing progress involved and considering the fast-moving nature of the internet, one might not identify the identical websites as we identified. However, we are confident that the majority of websites will still be available at a later time. Second, we might have either overestimated or underestimated FRES values, as we only extracted a sample of 200-500 words (or 4-5 sentences) to determine the score. It may be possible that the calculated value might differ when using the entire number of words available on the website. However, regarding the consistency, we have stuck to our predefined number of words. Third, we did not include websites of restricted access (eg, asking for log-in). Therefore, we might have failed to identify further websites that were only available when having access. Hence, the list of identified websites might be incomplete. However, we believe that patients with melanoma would not consider those websites and would rather acquire information from easily-accessible websites. Finally, the DISCERN, LIDA, and PEMAT assessment was a result of subjectivity introduced by the individual perspectives of the 3 reviewers. However, the high interrater agreement suggests that most of the independently detected deficits were apparent to all of the reviewers and, thus, may be problematic for others.

Conclusions

In general, German websites on immunotherapy for patients with melanoma provide inexpensive and easily accessible means to acquire disease- and treatment-specific information. We found the most visible among them to be user-friendly and understandably structured. However, the optimization of the most visible websites is desirable; in particular, improvement of the information readability and more provision of meta-information to increase the reliability. We suggest that the ideal websites should be a hybrid and should include both oncology expert parts for completeness, content-related integrity, and details, as well as general public press parts for the visibility and comprehensibility to be beneficial for more patients.

Conflicts of Interest

JB, TS, and LR have no conflicts of interest to declare. CB has been a member of advisory boards of or received speaker's fees by Amgen, AstraZeneca, BMS, Merck, MSD, Novartis, Regeneron, Roche, and Sanofi-Aventis. FM has been a member of advisory boards of or received speaker's fees by Amgen, BMS, Merck, MSD, Novartis, and Roche.

Multimedia Appendix 1

Flowchart of the website identification process according to the PRISMA guidelines.

[PNG File, 178KB - cancer_v4i2e10676_app1.png]

Multimedia Appendix 2

The summary of information about German websites on melanoma immunotherapy analyzed in this study.

[PDF File (Adobe PDF File), 153KB - cancer_v4i2e10676_app2.pdf]

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Multimedia Appendix 3

Summary of the individual DISCERN item assessment of the most visible German websites (n = 45) on melanoma immunotherapy.

[PNG File, 123KB - cancer_v4i2e10676_app3.png]

Multimedia Appendix 4

The assessment summary of the most accessible German websites on melanoma immunotherapy.

[PDF File (Adobe PDF File), 33KB - cancer_v4i2e10676_app4.pdf]

Multimedia Appendix 5

Results of LIDA assessment on usability and reliability of German website domains (n = 30) on melanoma immunotherapy.

[PNG File, 41KB - cancer_v4i2e10676_app5.png]

Multimedia Appendix 6

Interrater agreement.

[PNG File, 65KB - cancer_v4i2e10676_app6.png]

Multimedia Appendix 7

Readability (Flesch Reading Ease scores) differences between the 45 websites.

[PNG File, 98KB - cancer_v4i2e10676_app7.png]

Multimedia Appendix 8

Differences between oncology expert domains and general public domains.

[PNG File, 80KB - cancer_v4i2e10676_app8.png]

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Abbreviations

FRES: Flesch Reading Ease Score
IQR: interquartile range
NMSC: nonmelanoma skin cancer
PEMAT: Patient Education Material Assessment Tool

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<u>Original Paper</u>

Reliability of Cancer Treatment Information on the Internet: Observational Study

Ryo Ogasawara[1*], MD; Noriyuki Katsumata[2*], MD; Tatsushi Toyooka[1], MD; Yuko Akaishi[1], MD; Takaaki Yokoyama[2], MD; Gemmu Kadokura[2*], MD

[1]Nippon Medical School, Tokyo, Japan

[2]Department of Medical Oncology, Nippon Medical School Musashikosugi Hospital, Kawasaki City, Japan

[*]these authors contributed equally

Corresponding Author:
Noriyuki Katsumata, MD
Department of Medical Oncology
Nippon Medical School Musashikosugi Hospital
1-396, Kosugi-machi, Nakahara-ku
Kawasaki City, 211-8533
Japan
Phone: 81 44 733 5181 ext 3040
Fax: 81 44 711 8726
Email: nkatsuma@nms.ac.jp

Abstract

Background: Finding the correct medical information in a flood of information from the internet is a significant issue for patients with cancer.

Objective: We investigated the reliability of the information on cancer treatment methods available on the internet based on an evaluation by medical oncologists, medical students, and cancer survivors.

Methods: Using Google and Yahoo as the search engines, we carried out the information search using 2 keywords, "cancer treatment" and "cancer cure," and the top 20 information sites were identified. A similar search was conducted on 5 types of cancer. The reliability of the information presented was rated on a 3-level scale (A, B, or C). Level A referred to reliable sites (providing information complying with the clinical practice guidelines for various types of cancer), Level B included sites not falling under either Level A or Level C, and Level C comprised dangerous or harmful sites (providing information on treatment not approved by the regulatory authority in Japan and bombastic advertisements without any relevant clinical evidence). The evaluation was conducted by medical oncologists, medical students, and cancer survivors. The consistency of the information reliability level rating between the medical students or cancer survivors with that of the medical oncologists was assessed by using the kappa value.

Results: A total of 247 sites were evaluated for reliability. The ratings provided by the medical students' group were as follows: Level A, 12.1% (30/247); Level B, 56.3% (139/247); and Level C, 31.6% (78/247). The ratings provided by the cancer survivors' group were as follows: Level A, 16.8% (41/244); Level B, 44.7% (109/244); and Level C, 38.5% (94/244). The ratings provided by the oncologists' group were as follows: Level A, 10.1% (25/247); Level B, 51.4% (127/247); and Level C, 38.5% (95/247). The intergroup rating consistency between the medical students' group and oncologists' group was 87.4% (216/247, kappa=0.77) and that between the cancer survivors' group and oncologists' group was 76.2% (186/244, kappa=0.61).

Conclusions: Of the investigated sites providing information on cancer treatment on the internet, the percentage of sites that seemed to provide harmful information was much higher than that of sites providing reliable information. The reliability level rating was highly consistent between the medical students' group and the medical oncologists' group and also between the cancer survivors' group and the medical oncologists' group.

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Introduction

With the recent advances in cancer treatment, the therapeutic options (surgical treatment, drug therapy, radiotherapy, etc) are expanding and becoming more complicated. Therefore, for patients with cancer, selection of the appropriate treatment options is a significant issue.

Cancer patients seek information about cancer diagnosis, diagnostic tests, treatment options, complications, prognosis, etc, and they often search for information by themselves on the internet. The percentage of people with access to the internet now exceeds 80%, and the number of internet users has continued to increase year after year [1]. However, in Japan, according to one report, the probability of internet users finding correct information on the internet using search engines such as Google Japan and Yahoo Japan does not exceed 50%, and 10% of the information accessed by the search are advertisements [2]. Thus, sufficient information on the methods available for cancer treatment is not available on the internet or in publications that are easily accessible by cancer patients. Furthermore, many of the treatment methods described in websites on the internet are not reliably effective, and advertisements overemphasizing their efficacy are often found. It is not uncommon for unapproved treatments without any evidence of efficacy (eg, high dose vitamin C therapy, some kinds of immune cell therapy) to be provided at various private clinics as a treatment not covered by health insurance, necessitating high out-of-pocket payments by the patients. Incorrect information is found in abundance on the internet, which can cause misunderstanding and erroneous knowledge in patients.

In Japan, it is difficult for cancer patients to select the correct information from the internet. There is also a report suggesting that the health literacy of the Japanese population is lower than that of Europeans [3]. Therefore, we conducted this study to investigate the current status and reliability of the information on cancer treatment available on the internet, with the goal of devising appropriate educational campaigns on standard cancer treatments in Japan.

Methods

Recruitment

The internet search engines Google and Yahoo were employed to collect information from the internet. The search was conducted using the 2 keywords "cancer treatment" and "cancer, cure" (both in Japanese expressions), and the top 20 sites providing the information needed were identified. A similar search was also done on each of 5 major types of cancer (lung cancer, breast cancer, stomach cancer, colorectal cancer, and liver cancer).

All the information obtained was evaluated for reliability according to 2 criteria: (1) The source of information is described and the sources are based on reliable cancer practice guidelines (Japan Society of Clinical Oncology; Japanese Society of Medical Oncology; Japanese Society for Palliative Medicine; National Cancer Center for Cancer Control and Information Services, Japan; Cancer Information Japan, Japanese version of the Perceived Deficits Questionnaire; Japanese version of the National Comprehensive Cancer Network Guidelines; the Medical Information Network Distribution Service Guideline Center; etc) and (2) The information is not approved by the regulatory authority in Japan, markedly deviates from cancer practice guidelines, includes bombastic advertisements without any relevant clinical evidence, and can be considered as being potentially harmful to patients (eg, sites guiding patients to medical facilities or the like that provide treatments that are not approved, are not acknowledged as standard therapy, or are not designated as frontier therapy by the government and sites having links to food supplement marketing or advertisement pages, etc)

Using the aforementioned criteria, the reliability of the information was rated on a 3-level scale as follows: Level A: reliable sites, satisfying criterion (1) and not apparently falling under (2); Level B: falling under neither Level A nor C; and Level C: dangerous or harmful sites, not satisfying (1) and evidently falling under (2), and unclassified sites that do not describe any treatment method.

The evaluation was conducted by a medical students' group (3 medical students: RO, TT, and YA) and a cancer survivors' group (3 cancer survivors: Kimiko Ohi, Yumi Higure, and Yukari Tanaka). The cancer survivors provided consent for participating in this study as volunteers (2 women aged between 50 and 59 years and 1 woman aged between 60 and 69 years; 2 were university graduates, and 1 was a junior college graduate). Before performing the evaluation, each member of the group received a 30-minute lecture from a medical oncologist (NK) about the evaluation method. If all 3 members of the group gave the same rating, that rating was adopted as the reliability level for the site concerned. If the rating differed among the members, the reliability level of the site was finally decided through discussion among the members. There were 3 medical oncologists (2 board-certified medical oncologists and 1 not certified) who also individually rated the reliability level of each site. If the rating differed among the oncologists, the rating to be finally adopted was decided through discussion among the oncologists.

Statistical Analysis

Data were analyzed using IBM SPSS Statistics version 20 (IBM Corp, Armonk, NY, US). The categorical data for each keyword was analyzed by the chi-square test and the Friedman test. The consistency of rating between each of the cancer survivors' and medical students' group and the medical oncologists' group was evaluated through calculation of the kappa value. The consistency of rating between any 2 groups was analyzed by determining the Cohen kappa coefficient and that among the 3 groups was analyzed by determining the Fleiss kappa coefficient [4]. Interpretations of the kappa statistic were based on the criteria described by Landis and Koch [5], that is, the level of reliability was defined as follows: kappa values of 0.81-1.00, near-perfect or perfect agreement; 0.61-0.80, substantial agreement; 0.41-0.60, moderate agreement; 0.21-0.40, fair agreement; and 0.01-0.20, slight agreement.

Results

The top 20 sites hit by the search using each engines (Google Japan and Yahoo Japan) were evaluated after the elimination of duplications. The search was conducted on June 15, 2016. Among the 480 sites accessed, the top 20 sites hit by the search using the keywords "cancer, cure," "lung cancer treatment," "lung cancer," "breast cancer treatment," "breast cancer cure," "stomach cancer treatment," "stomach cancer, cure," "colorectal cancer treatment," "liver cancer treatment" and "liver cancer, cure" were completely consistent between Google and Yahoo, and the sites hit by the search conducted using the keywords "cancer treatment" and "colorectal cancer, cure" were partially consistent between Google and Yahoo. These sites were counted as duplications and excluded from evaluation. When the search was made using the keyword "breast cancer treatment," a link to 1 of the 20 top sites was lost during the evaluation, and this site was excluded from the analysis, with the remaining 19 sites included in the analysis. There were 3 sites hit by the Yahoo search using the keywords "colorectal cancer, cure" that were not evaluated by the cancer survivors' group. In total, 247 sites were evaluated by both the oncologists' group and medical students' group, and 244 sites were evaluated by the cancer survivors' group as the top 20 sites yielded by the Google and Yahoo searches using the aforementioned keywords.

Out of the 247 sites, the oncologists' group provided a Level A rating for 25 sites (10.1%), Level B rating for 127 sites (51.4%), and Level C rating for 95 sites (38.5%; Figure 1); the medical students' group gave a Level A rating for 30 sites (12.1%), Level B rating for 139 sites (56.3%), and Level C for 78 sites (31.6%; Figure 2); and the cancer survivors' group provided a Level A rating for 41 sites (16.8%), Level B rating for 109 sites (44.7%), and Level C rating for 94 sites (38.5%; Figure 3). The number of sites rated as Level A was the smallest for the oncologists' group, differing significantly from that for the cancer survivors' group (oncologists' group vs medical students' group: $P=.47$, oncologists' group vs cancer survivors' group: $P=.03$, medical students' group vs cancer survivors' group: $P=.16$).

Of the 124 sites hit by the search using the keyword "treatment," 22 sites (17.7%) were rated as Level A, 62 sites (50.0%) as Level B, and 40 sites (32.3%) as Level C. Of the 123 sites yielded using the keyword "cure," 3 sites (2.4%) were rated as Level A, 65 sites (52.8%) as Level B, and 55 sites (44.7%) as Level C. The number of sites with Level A rating was higher among the sites hit using the keyword "treatment," than among the sites hit using the keyword "cure" ($P<.001$).

According to cancer type, the rating by the oncologists' group for the 20 sites hit using the keyword "lung cancer treatment" was Level A for 2 sites (10%), Level B for 12 sites (60%), and Level C for 6 sites (30%). The ratings for the sites by the oncologists' group were as follows: among the 20 sites hit using the keyword "lung cancer, cure," Level A for 0 sites (0%), Level B for 11 sites (55%), and Level C for 9 sites (45%); among the 19 sites hit using the keyword "breast cancer treatment," Level A for 3 sites (16%), Level B for 14 sites (74%), and Level C for 2 sites (11%); among the 20 sites hit using the keyword "breast cancer, cure," Level A for 0 sites (0%), Level B for 15 sites (75%), and Level C for 5 sites (25%); among the 20 sites hit using the keyword "stomach cancer treatment," Level A for 6 sites (30%), Level B for 6 sites (30%), and Level C for 8 sites (40%); among the 20 sites hit using the keyword "stomach cancer, cure," Level A for 1 site (5%), Level B for 11 sites (55%), and Level C for 8 sites (40%); among the 20 sites hit using the keyword "colorectal cancer treatment," Level A for 6 sites (30%), Level B for 11 sites (55%), and Level C for 3 sites (15%); among the 20 sites hit using the keyword "colorectal cancer, cure," Level A for 1 site (5%), Level B for 10 sites (50%), and Level C for 9 sites (45%); among the 20 sites hit using the keyword "liver cancer treatment," Level A for 2 sites (10%), Level B for 13 sites (65%), and Level C for 5 sites (25%); among the 20 sites hit using the keyword "liver cancer, cure," Level A for 1 site (5%), Level B for 9 sites (45%), and Level C for 10 sites (50%). The number of sites rated as Level A was larger among the sites yielded using the keyword "treatment" than among the sites yielded using the keyword "cure" (lung cancer: $P=.15$, breast cancer: $P=.06$, stomach cancer: $P=.04$, colorectal cancer: $P=.04$, and liver cancer: $P=.55$).

The Friedman test found no significant difference for each keyword among the 3 groups except the keyword "lung cancer, curable," $P=.005$, and "liver cancer, curable," $P=.03$.

The number of sites for which the rating was consistent among all 3 members of each group was analyzed. Among the analyzed sites, the ratings were consistent among all 3 members of the cancer survivors' group for 155 sites (155/244, 63.5%; Fleiss kappa for 3 raters=0.61, 95% CI 0.56-0.66), among all 3 members of the medical students' group for 201/247 sites (81.4%; Fleiss kappa for 3 raters=0.78, 95% CI 0.72-0.83), and among all 3 members of the oncologists' group for 232 sites (232/247, 93.9%; Fleiss kappa for 3 raters=0.92, 95% CI 0.87-0.98; Table 1).

If the rating differed among the members of a group, the reliability level of the site concerned was finally decided through discussion among the members. Among the 247 sites (244 sites for the cancer survivors' group), the number of sites whose reliability level finally adopted through discussion was consistent with the rating by the oncologists group was 186 (186/244, 76.2%) for the cancer survivors' group (Cohen kappa unweighted=0.61, 95% CI 0.51-0.69) and 216 (216/247, 87.4%) for the medical students' group (Cohen kappa unweighted=0.77, 95% CI 0.70-0.84; Table 2).

Figure 1. Evaluation by medical oncologists' group of the top 20 sites hit by Google search (June 15, 2016).

Rank	Cancer treatment	Cancer, curable	Lung cancer treatment	Lung cancer, curable	Breast cancer treatment	Breast cancer, curable	Stomach cancer treatment	Stomach cancer, curable	Colorectal cancer treatment	Colorectal cancer, curable	Liver cancer treatment	Liver cancer, curable
1	C	C	B	B	A	B	A	B	A	B	B	C
2	B	C	B	B	B	B	A	B	A	B	A	C
3	C	B	A	B	B	B	B	B	A	B	C	C
4	B	C	C	C	A	B	A	C	A	C	B	B
5	C	B	C	C	A	B	B	B	B	B	C	C
6	C	C	B	B	B	B	B	C	B	B	B	C
7	C	B	C	B	B	B	C	C	A	C	B	C
8	C	B	C	C	B	C	B	B	A	C	B	B
9	C	C	B	C	B	B	C	B	B	A	B	C
10	B	C	B	B	B	C	A	A	B	C	B	B
11	B	C	B	B	B	B	A	C	C	C	B	B
12	C	B	B	B	B	B	A	C	B	B	A	B
13	A	B	A	C	B	B	C	C	C	C	B	B
14	A	B	B	B	B	B	C	C	B	B	B	B
15	B	C	C	C	B	B	C	B	B	B	C	B
16	A	C	B	C		C	C	B	C	C	C	C
17	C	C	B	C	B	C	C	C	B	B	C	C
18	C	C	B	B	C	B	C	B	B	B	B	A
19	C	C	C	C	B	C	B	A	B	C	B	B
20	C	C	B	B	C	B	B	C	B	B	B	C

Figure 2. Evaluation by a medical students' group of the top 20 sites hit by Google search (June 15, 2016).

Rank	Cancer treatment	Cancer, curable	Lung cancer treatment	Lung cancer, curable	Breast cancer treatment	Breast cancer, curable	Stomach cancer treatment	Stomach cancer, curable	Colorectal cancer treatment	Colorectal cancer, curable	Liver cancer treatment	Liver cancer, curable
1	C	C	A	B	A	B	A	B	A	B	B	C
2	B	C	A	B	B	B	B	B	A	B	A	B
3	B	C	A	B	B	B	B	B	A	B	C	C
4	A	B	B	C	A	B	A	C	A	B	C	C
5	C	B	C	C	A	B	B	C	B	C	C	C
6	C	B	B	B	B	B	B	B	B	B	B	C
7	C	B	C	B	B	B	C	C	A	B	B	C
8	B	C	C	C	B	C	B	B	A	B	B	B
9	C	C	B	C	B	B	C	B	A	A	B	C
10	B	C	B	B	B	C	A	B	B	C	B	B
11	B	C	B	B	B	B	A	C	C	C	B	B
12	C	B	B	B	B	B	A	C	B	B	A	B
13	A	B	A	B	B	B	C	C	C	B	B	B
14	A	C	B	B	B	B	B	C	C	B	B	B
15	B	C	C	B	B	B	C	B	A	B	C	B
16	A	C	B	B	B	B	C	C	B	C	C	C
17	C	C	B	B	B	B	B	C	C	B	B	C
18	B	C	B	B	B	B	C	B	B	B	A	A
19	C	C	C	C	B	C	B	A	C	C	B	B
20	C	C	B	B	C	B	B	C	B	B	B	C

Figure 3. Evaluation by cancer survivors' group of the top 20 sites hit by Google search (June 15, 2016).

Rank	Cancer treatment	Cancer, curable	Lung cancer treatment	Lung cancer, curable	Breast cancer treatment	Breast cancer, curable	Stomach cancer treatment	Stomach cancer, curable	Colorectal cancer treatment	Colorectal cancer, curable	Liver cancer treatment	Liver cancer, curable
1	C	B	B	B	A	B	A	B	A	B	C	C
2	B	C	B	C	B	B	C	B	A	C	A	C
3	C	C	A	B	B	B	B	B	A	B	B	C
4	A	C	C	C	A	B	A	C	A	C	A	B
5	C	B	C	C	B		A	C	B	C	C	B
6	C	B	B	B	B	B	B	B	A	B	C	C
7	C	B	C	C	B	B	C	C	A	B	B	B
8	C	C	C	C	B	C	A	A	B	A	B	A
9	C	C	B	B	B	B	B	B	A	A	A	C
10	C	B	B	B	B	C	A	C	A	B	B	B
11	B	B	C	C	B	B	A	C	C	B	B	B
12	C	B	B	B	B	B	A	C	B	B	B	B
13	A	B	A	C	B	B	C	C	C	B	B	A
14	A	C	A	C	B	B	B	C	C	B	A	A
15	C	C	C	C	B	B	C	A	A	A	C	B
16	A	B	B	C	B	C	C	B	C	C	C	B
17	C	C	B	B	A	B	B	C	B	B	C	B
18	B	C	B	B	C	C	C	B	B	B	C	C
19	C	B	C	C	B	C	C	A	C	C	C	B
20	C	C	B	B	C	B	B	C	B	C	B	C

Table 1. Consistency of rating among persons within each group.

Search engine and keyword	Frequency of consistency			Total number of sites, n
	Cancer survivors	Medical students	Medical oncologists	
google "cancer treatment"	10	13	17	20
yahoo "cancer treatment"	2	5	5	5
google "cancer, curable"	6	16	17	20
google "lung cancer treatment"	11	17	18	20
google "lung cancer, curable"	11	20	20	20
google "breast cancer treatment"	15	13	19	20
google "breast cancer, curable"	14	20	19	19
google "stomach cancer treatment"	18	17	18	20
google "stomach cancer, curable"	15	18	19	20
google "colorectal cancer treatment"	13	15	19	20
google "colorectal cancer, curable"	14	18	20	20
google "liver cancer treatment"	14	11	19	20
google "liver cancer, curable"	12	15	19	20
yahoo "colorectal cancer, curable"	N/A[a]	3	3	3
Kappa	0.6145	0.7813	0.9296	N/A

[a]N/A: not applicable.

Table 2. Consistency of rating by medical oncologists.

Search engine and keyword	Cancer survivors, n	Medical students, n	Total number of sites, n
google "cancer treatment"	17	16	20
yahoo "cancer treatment"	5	5	5
google "cancer, curable"	13	16	20
google "lung cancer treatment"	16	17	20
google "lung cancer, curable"	17	17	20
google "breast cancer treatment"	18	18	20
google "breast cancer, curable"	17	18	19
google "stomach cancer treatment"	14	17	20
google "stomach cancer, curable"	17	19	20
google "colorectal cancer treatment"	15	17	20
google "colorectal cancer, curable"	12	15	20
google "liver cancer treatment"	13	19	20
google "liver cancer, curable"	12	19	20
yahoo "colorectal cancer, curable"	N/A[a]	3	3
Kappa	0.6063	0.7747	N/A

[a]N/A: not applicable.

Discussion

Principal Findings

Cancer is an intractable disease and is often incurable. In the present age, the widespread use of smartphones allows easy access to information on the internet, and 60% of Japan obtains health information from the internet [6]. When patients desire information about health, they more often check the internet fist than ask their doctors [7]. Cancer patients also browse the internet often to collect information about cancer [8]. A similar tendency is seen across the world [7]. However, the information available on the internet is often harmful to patients, and there is a report that more than 10% of sites on the internet offering

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information on lung cancer in Japan recommend alternative therapies [2].

In this study, the number of sites given a reliability rating of Level B or C was larger than the number of sites given a rating of A in each of the evaluations made by the oncologists' group, medical students' group, and cancer survivors' group. This indicates that information on treatment methods based on the relevant guidelines is difficult to obtain from the internet and that the reliability level of the available information on cancer treatment methods on the internet is low in Japan. A report from the United States also shows that there are many sites offering unreliable information on the internet and includes a statement that about half (50%) of the drugs introduced with exaggerative phrases such as "miracle" or "cure" in Google News related to anticancer drugs that were not approved by the Food and Drug Administration, with the patients risking being guided toward adopting treatments of unproven reliability [9]. In this study, however, the prior 30-minute lecture on the evaluation method provided by a medical oncologist resulted in a high consistency of the rating between the cancer survivors' group and the oncologists' group (kappa=0.61) and between the medical students' group and the oncologists' group (kappa=0.77), although the consistency between the cancer survivors' group and oncologists' group was slightly lower than that between the medical students' group and the oncologists' group.

Limitations

This study had several limitations. A 5-level scale of evidence is widely used for critical appraisal for medical information [10]. The validity of the 3-level scale employed in this study remains to be established. The percentage of sites given a reliability rating of Level A was low (10%) in this study, probably because the criteria for Level A adopted in the site information rating step were slightly stringent (requiring guideline-based information and specification of the information source). According to the study reported by Goto et al, about 40% of the sites yielded by Google and Yahoo searches using the keyword "lung cancer" were accorded the highest rating of "acceptable" when a 3-level scale was employed [2]. In addition, the review process has a bias because it is judged by a limited number of each evaluation group. The 2 groups of medical school students and cancer survivors could have some background information about cancer and treatment and

receiving the lecture for the evaluation method before scoring websites could have introduced bias. Moreover, more diversified medical experts will be needed for judging the collected data. Furthermore, since the information available on the internet continues to change, and the sites hit as leading sites vary from day to day, extrapolation of the findings from this study to other situations, in general, would probably be unreasonable.

In Japan, physicians can provide health care services not covered by health insurance (ie, services that would require full payment by the patients themselves). Therefore, information on numerous treatment methods, with an emphasis on cancer treatment, is available on the internet. Factors possibly serving as the background for such a situation include: (1) cancer treatment based on guidelines has not spread widely in Japan (as reflected by the small number of sites given a rating of Level A), and (2) under such circumstances, patients with cancer are likely to attempt treatment whose efficacy has not been established if even a slight possibility of cure is promised so that patients can have accurate knowledge about established treatment methods and can be discouraged from seeking unreliable treatments, it may be important to organize educational campaigns across the country and enable cancer patients to select appropriate information from the vast amount of information available on the internet.

This study was designed to evaluate the capability of medical students and cancer survivors to correctly evaluate the information available on the internet. After the medical students and cancer survivors received a lecture to make them aware that cancer treatment based on guidelines on cancer management is the most desirable, they provided ratings that were highly consistent with the ratings provided by the oncologists. This result indicates the importance of dissemination of the information contained in cancer management guidelines among cancer survivors as well as of educational campaigns for the society.

Conclusions

Although the reliability level of the information on cancer treatment available on the internet seems to be low in general, the results of the 3-level evaluation method employed in this study suggest that judgment of the reliability of individual internet sites can be made relatively easily, even by individuals with poor medical knowledge.

Conflicts of Interest

None declared.

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<u>Original Paper</u>

How to Optimize Health Messages About Cancer on Facebook: Mixed-Methods Study

Priscila Biancovilli[1,2], MSc; Claudia Jurberg[2,3], PhD

[1]Doctoral School of Health Sciences, University of Pécs, Pécs, Hungary

[2]Laboratório de Imunologia Tumoral Dra. Ottilia Affonso Mitidieri, Instituto de Bioquímica Médica Leopoldo de Meis, Universidade Federal do Rio de Janeiro, Rio de Janeiro, Brazil

[3]Fundação Oswaldo Cruz, Instituto Oswaldo Cruz, Rio de Janeiro, Brazil

Corresponding Author:
Priscila Biancovilli, MSc
Doctoral School of Health Sciences
University of Pécs
Vörösmarty utca 4
Pécs, 7621
Hungary
Phone: 36 (72) 513 678
Email: biancovilli@bioqmed.ufrj.br

Abstract

Background: Incidence rate of cancer is increasing worldwide, with longer life expectancy being one of the main causes. Yet, between 30% and 50% of cancer cases are preventable, and early detection contributes to a better prognosis. This makes health communication strategies essential. Facebook, the world's most used social networking site in 2017 and 2018, can be a useful tool for disseminating powerful messages on health promotion, prevention, and early detection.

Objective: We aimed to (1) offer ways of optimizing health messages about cancer on Facebook, focusing on topics, such as risk factors, prevention, treatment, early diagnosis, and cure, and (2) investigate which aspects of these messages generate greater engagement.

Methods: To verify what generates greater engagement in topics related to cancer on Facebook, we analyzed 16 Brazilian pages with the main theme of cancer. We performed a manual analysis of texts, content, and engagement rates. Finally, we developed a software program to operationalize the analysis of Facebook posts. The tool we devised aims to automate the analysis of any Facebook page with cancer as the main theme.

Results: We analyzed 712 posts over a 1-month period. We divided the posts into the following 8 categories: "Testimonies or real-life stories," "Solidarity," "Anniversaries," "Science and health," "Events," "Institutional," "Risk factors," and "Beauty." The pages were also organized into groups according to the type of profile to which they belonged (ie, hospitals or foundations, informative, nongovernmental organizations, and personal pages).The results showed that the categories generating greater engagement in Brazil were not those with the highest percentage of cancer-related content. For instance, in the "Informative" group the "Testimonies or real-life stories" category generated an engagement of 79.5%. However, only 9.5% (25/261) of the content within the relevant time period dealt with such topics. Another example concerns the category "Science and health." Despite being the one with the highest number of posts (129/261, 49.4%), it scored 5th in terms of engagement. This investigation served as the basis for the development of a tool designed to automate the analysis of Facebook pages. The list of categories and keywords generated by this analysis was employed to feed the system, which was then able to categorize posts appearing on a Facebook page. We tested the system on 163 posts and only 34 were classified incorrectly, which amounts to a 20.8% error rate (79.2% accuracy).

Conclusions: The analysis we conducted by categorizing posts and calculating engagement rates shows that the potential of Facebook pages is often underutilized. This occurs because the categories that generate the greatest engagement are often not those most frequently used. The software developed in this research may help administrators of cancer-related pages analyze their posts more easily and increase public interest as a result.

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Introduction

Background

Cancer is an umbrella term encompassing a group of >200 diseases that have in common the disordered growth of cells invading tissues and organs [1]. The number of cancer-related deaths worldwide increased from 6 million in 2000 to 7.6 million in 2007 [2]. In 2012, there were 8.2 million cancer-related deaths [3], and in 2018, it is estimated that this disease will be responsible for around 9.6 million deaths. While about 1 in 6 deaths globally is due to cancer [4], Brazil has an incidence rate of 205.5 cases of cancer per 100,000 inhabitants, thus ranking tenth in South America and the Caribbean region [3].

For prevention purposes, it is important to reiterate that changes in lifestyle and habits of the population may reduce the likelihood of disease onset. As reported by Anand et al, "Only 5%-10% of all cancer cases can be attributed to genetic defects, whereas the remaining 90%-95% have their roots in the environment and lifestyle. The lifestyle factors include cigarette smoking, diet (fried foods, red meat), alcohol, sun exposure, environmental pollutants, infections, stress, obesity, and physical inactivity" [5]. There is, thus, evidence that prevention is the most cost-effective, long-term strategy for controlling the onset of cancer [6].

In addition to the importance of adopting a healthy lifestyle for prevention, it is crucial to increase early detection in individuals who already exhibit symptoms of the disease. Indeed, when some types of cancer are diagnosed in the early stages, the chances of treatment success and cure (for, at least, 5 years after diagnosis) increase dramatically. According to *Cancer Research UK*, some types of cancer can be treated much more easily if detected early, for example, bowel, breast, ovarian, and lung [7].

Facebook and Health Communication

Facebook is currently the social networking site with the highest number of active users; in June 2017, it reached 2 billion monthly active users [8]. Every minute, 510,000 comments are posted, 293,000 statuses are updated, and 136,000 photos are uploaded [9]. The most common forms of interaction are reactions (eg, when a user clicks on one of the emojis representing emotions, such as love, surprise, sadness, and anger), comments (eg, when a user writes a text under a post), and shares (eg, when a user shares another person's post on his or her Facebook profile). Brazil ranks third in the world per the number of Facebook users (130 million), following India (270 million) and the United States (210 million) [10]. Several Facebook pages worldwide are devoted to health promotion. Here, we characterize a "Facebook page" as a public profile created by businesses, organizations, celebrities, or anyone seeking to promote themselves publicly through social media [11].

The active search for health information is associated with greater knowledge of health and with positive behavioral change; that is, individuals tend to become healthier when they are better informed [12]. A number of studies have already explored health-related pages on Facebook to verify the effectiveness of this communication strategy [13-15]. This body of research shows that there is a significant degree of user responsiveness to the topics posted on these pages, suggesting that there is still considerable room for growth in this type of discussion.

Facebook and Cancer

The use of Facebook as a platform for disseminating health messages focused on cancer treatment, early diagnosis, and prevention has been overlooked in the scientific literature. One of the few papers dealing with this theme [16] analyzed about 13,000 comments posted by visiting users on 3 Brazilian cancer-related pages. It was observed that on these pages there was a strong presence of comments employing religious terms such as "God," "faith," "Lord," "blessed," "save," and "pray." Notably, most of the comments were written by women, and the content of the messages was found to be overwhelmingly positive.

A related study conducted in the United States [12] looked at the National Cancer Institute page to identify the most effective strategies for engaging the audience. The researchers reviewed the posts and comments made on this page and found that "audience engagement is associated with the format of cancer-related posts. Specifically, photo posts received significantly more reactions, comments and shares than videos, links, and status updates (posts that contain only texts)" [12].

Another study published in 2017 [17] implemented a Facebook-based intervention, the main goal of which was to induce users to reduce or stop smoking; the researchers concluded that the interaction between users led to a decrease in the number of cigarettes smoked per week. This result indicates that a Web-based environment of social support and engagement may be beneficial for participants' health.

Finally, another paper [18] studied the Facebook platform to understand "the most commonly used terms and phrases relating to breast cancer screening and the most commonly shared website links that other women interacted with." The study concluded that on this social media, women "shared and reacted to links to commercial and informative websites regarding breast cancer and screening"; this result may provide clues for the development of messaging strategies addressing the importance of early detection of breast cancer.

Despite the studies mentioned above, little research is available on the best ways to engage the public in health communication on social media, both in Brazil and worldwide. Academic analyses are even scarcer with respect to cancer-related communication; this might have a negative impact on the Facebook pages of hospitals, nongovernmental organizations (NGOs), and informational organizations, which may end up reaching a lower percentage of the audience than their potential. Therefore, the objectives of this study were to offer ways of

optimizing health messages about cancer on Facebook, with special emphasis on topics such as risk factors, prevention, treatment, early diagnosis, and cure, and to investigate which aspects of these messages generate greater engagement in the audience. Notably, the metric of engagement on Facebook is based on the number of reactions, shares, and comments for a post.

Methods

This study comprised a qualitative and quantitative study [19] with a descriptive purpose [20], not starting from an *a priori* hypothesis.

Choosing and Organizing Facebook Data

To verify what generates greater engagement in cancer-related topics on Facebook, we analyzed 16 Brazilian pages with the main theme of cancer. In 2017, we studied these pages 2 times over a 1-month period, from March 14 to April 14 and then from April 15 to May 15. With respect to the page selection for this study, we proceeded as follows:

1. We typed the word "cancer" in Facebook's internal search engine ("câncer" in Portuguese) and selected the "Pages" option.
2. We disregarded pages that were not written in Brazilian Portuguese. We also disregarded pages referring to "Cancer" as an astrological sign. To ensure that the pages were actually Brazilian, we also read the posts to attain better identification of the geographical origin of the page; this was done by either recognizing the way in which Portuguese was written (ie, by looking at the differences between European, African, or Brazilian Portuguese) or seeing that the authors themselves mentioned living in Brazil.
3. To select the pages, we first considered those with a higher number of followers, and then we looked at the updates. Notably, to enter our survey, the page should have, at least, 2 weekly updates in the selected 4-week period. We ended up selecting 15 pages, which were divided into the following categories: personal pages, newsletters, hospitals or foundations, and NGOs.
4. Finally, we analyzed a Facebook page created by us, the purpose of which was to inform the public about the prevention and early diagnosis of cancer. We called this page "Acubens, museu de cancer" ("Acubens, cancer museum" in English).

It is worth noting that in our research, we did not select pages that specifically addressed prevention or early detection. Our intention was rather to identify how Brazilian Facebook pages dealt with cancer-related topics. We include the name of each page, the number of followers in 2017 and a content description in Multimedia Appendix 1.

For our analysis, we used the social media monitoring tool Quintly (quintly.com) because it allows the monitoring of multiple media at the same time, even when a user is not an administrator of the relevant pages. Quintly organizes the publicly available information of all pages (ie, the number of followers, reactions, comments, and shares) in charts and tables,

showing, for example, how many new followers a certain page has acquired, or the number of posts created in a selected time period. This service also provides a user with the complete listing of the posts for all the selected pages, collecting the data in a table that indicates the date, time, and type of post. The types of post are sorted into the following categories: photo (any image file), video, event (invitations to events, with the option to accept or decline), status (text-only posts), or link (posts including a Web address redirecting to an external page). These post type definitions mirror those offered by Facebook itself.

Content Analysis of Posts and Engagement Rate

The analysis of the posts was conducted following the methodology proposed by Bardin [21], which consists of a type of inductive analysis [22]. In our case, 2 researchers performed the analysis independently. We conducted the process of content analysis as follows:

1. *Preanalysis*: It comprised careful and systematic reading of all the text in posts to identify the most relevant categories.
2. *Categorization*: It involved the creation of relevant categories so that all individual posts would fit into, at least, one. In this study, the 2 researchers created their categories independently and subsequently worked together to create a final list. In the case of discrepancy between the 2 initial lists, the 2 researchers discussed the categories concerned until consensus was reached.
3. *Interpretation*: It involved the study of the data and development of inferences [21,23].

After the content analysis process, the 2 researchers created a list of keywords for each category. It was not possible for the same word to feature in more than one category. Moreover, very general words that could fit into any of the categories, such as "cancer" or "chemotherapy," were not taken into consideration. After the 2 researchers created their lists independently, they met to check similarities and differences and finally a unique list based on consensus was created.

To obtain a more holistic view of the categories, we also established the total impact that each would have, termed as the "engagement rate". This value considered 3 metrics for each page. We calculated the weighted average reactions, shares, and comments for each post in the 16 relevant pages, assigning a weight of 0.05 for reactions, 0.2 for shares, and 0.75 for comments [23]. The weights created for the calculation of the total engagement took into consideration that the type of engagement (ie, liking, commenting, or sharing) follows a hierarchy according to the amount of effort required by the user to undertake it. For instance, liking a post is usually considered low engagement because it is the simplest and quickest among the 3 available actions, sharing is rather considered a medium form of engagement because a Facebook user identifies with the content to the point that he or she wants to share it on his or her page. Finally, we regard commenting as a high form of engagement; in this case, a Facebook user needs to reflect on the topic in question, draft text, and state his or her opinion publicly.

Elaboration of a System That Automates the Analysis

Our previous analysis of Facebook pages [23], as well as this study, served as the basis for the development of a tool designed to automate the analysis of any cancer-related Facebook page.

The tool developed constitutes a software program created in JavaScript that allows users to organize different types of Facebook posts according to metrics. While some of these metrics are publicly available (eg, reactions, shares, and comments), others are only accessible by page administrators. The metrics employed by our software are as follows: post reach (how many people viewed that post); post clicks (how many users clicked to read the full text); post hides (how many people hid the page content after reading the post, or reported the page as spam); reactions; shares; comments; engagement (weighted average engagement = number of clicks + reactions × 0.05 + shares × 0.2 + comments × 0.75); and engagement rate (engagement divided by reach). The software then enables the creation of a ranking according to each of these metrics. The ranking can be created by considering all the posts published in a relevant period or by filtering according to the categories to be analyzed.

Moreover, within the software, we created a database of categories and a dictionary of keywords, which were developed by the researchers in an earlier phase of this work; this list is editable, and categories or words may be added or removed at any time. Notably, our system can only "read" complete words, and it does not consider compound or root words. This means that the keywords list contains all the possible variations of a particular word—singular, plural, masculine, and feminine. From these data, the system is then able to tag posts and fit them into categories. If a post uses keywords belonging to more than one category, the system will fit the post into the category exhibiting the highest number of keywords.

Our software is also able to predict the engagement rate that a post would have based on the engagement rates of the previous posts on a given page. More specifically, if a text features keywords that have generated high engagement in previous posts, the likelihood of this new post also having high engagement increases.

Results

Content Analysis of Facebook Pages

The 16 Facebook pages that we analyzed produced a total of 712 posts in the relevant 1-month period. As mentioned above, all the pages were organized in groups according to the profile to which they belonged (ie, hospitals or foundations, informative, NGOs and personal pages).

In our previous study [23], we analyzed the texts of 3 Brazilian pages about cancer over a 6-month period (January-June, 2014)

and created 8 categories as follows: "Testimonies or real-life stories" (people writing about their experience of cancer or any real-life story); "Solidarity" (posts asking people to make a donation, such as blood or hair); "Anniversaries" (when the main subject of the post was the celebration of some important date); "Science and health" (posts about scientific discoveries, academic research, and progress in treatment); "Events" (when the page administrator organized or publicized some event); "Institutional" (when an institution wrote about itself); "Risk factors" (when the posts addressed habits increasing the risk of cancer, such as smoking); and "Beauty" (posts about makeup, clothes, or hairstyles).

Although we added new pages in this later analysis, we did not have to create new categories with respect to those listed above, indicating that despite the authors and page administrators being different, the spectrum of topics within the theme of cancer remained similar.

The results presented in Table 1 show the analysis of the page performance divided by the following group: hospitals or foundations, informative pages, NGOs, and personal pages.

Facebook Analytics Software Development

The software we developed for the content analysis of Facebook posts and its classification into categories has a simple and intuitive interface, illustrated in the following Figures 1-3. In Figure 2 darker squares indicate greater the engagement, and in Figure 3 bigger font indicates higher frequency.

Initially, we entered in the software the 8 categories we created, as well as the keywords corresponding to each of these categories. Then, we tested the software through analysis of the page "Acubens, cancer museum," which was created over the course of 6 months by our research group on the *Oncobiology Program* at the Federal University of Rio de Janeiro. Our goal was to verify whether the tool could actually tag the posts in the correct categories. Over this time period, the page presented 163 published posts. In the first stage of this investigation, 2 researchers categorized all posts manually. Then, the results of the manual classification were compared with that performed automatically by the software. This way, the researchers could verify whether the tool could correctly categorize the posts. Of 163 posts, only 34 were classified in the wrong categories by the tool. This corresponds to an error rate of 20.8% (or 79.2% accuracy). Table 2 summarizes the results of the automated analysis performed by the software and the number of errors found for each category. The errors are deducted from the comparison between the manual analysis done by the researchers and that performed by the software.

The percentage of errors is considered acceptable. Indeed, according to the literature [24-28], the accuracy of multiclass text classification (when texts are classified into ≥3 categories) ranges from 46.9% to 83%.

Table 1. Averages of reactions, shares, and comments and weighted average engagement of 16 the pages.

Group	Post, n (%)	Reactions, mean	Shares, mean	Comments, mean	Weighted average engagement
Hospitals or foundations (n=109)					
Solidarity	11 (10)	524	346.9	21.4	111.6
Anniversaries	0 (0)	N/A[a]	N/A	N/A	N/A
Institutional	57 (52.2)	825.1	161.3	56.4	115.8
Testimonies or real-life stories	2 (1.8)	179	26.5	3	16.4
Science and health	20 (18.3)	1263.3	440.5	47	186.5
Events	18 (16.5)	283.7	52.5	13.8	35.1
Beauty	0 (0)	N/A	N/A	N/A	N/A
Risk factors	1 (0.9)	219	57	12	31.3
Informative pages (n=261)					
Solidarity	19 (7.3)	1400.7	227.9	43	147.9
Anniversaries	29 (11.1)	2209.9	717.4	27	274.2
Institutional	26 (9.9)	397.3	72.8	5.7	38.7
Testimonies or real-life stories	25 (9.6)	1976.5	79.9	108.8	196.4
Science and health	129 (49.4)	143.4	50.7	3.8	20.1
Events	28 (10.7)	114.8	28.4	30.4	34.2
Beauty	1 (0.3)	85	19	3	10.3
Risk factors	4 (1.5)	76.2	26.5	2.2	10.8
Nongovernmental organizations (n=156)					
Solidarity	76 (48.7)	559.8	24.3	16.2	45.0
Anniversaries	8 (5.1)	1641	108.3	33.8	129.1
Institutional	27 (17.3)	620.6	37.8	15.7	50.4
Testimonies or real-life stories	11 (7.1)	505.8	24.5	11.3	38.7
Science and health	0 (0)	N/A	N/A	N/A	N/A
Events	33 (21.1)	305.3	84.2	18	45.6
Beauty	1 (0.6)	124	0	4	9.2
Risk factors	0 (0)	N/A	N/A	N/A	N/A
Personal pages (n=186)					
Solidarity	53 (28.5)	1885.2	32.8	48.9	135.5
Anniversaries	9 (4.3)	1320.7	10.8	29.7	90.5
Institutional	26 (13.9)	340.2	8.7	7.4	24.3
Testimonies or real-life stories	68 (36.6)	236.6	18.4	26.7	35.6
Science and health	0 (0)	N/A	N/A	N/A	N/A
Events	10 (5.3)	401.6	8.8	11.6	30.5
Beauty	19 (10.2)	149.7	8.3	5.9	16.6
Risk factors	1 (0.5)	20	1	2	2.7

[a]N/A: not applicable.

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Figure 1. Screenshot of the "posts" tab, displaying the complete list of page posts. (Source: Created by Corbata Informática, 2016).

Figure 2. Screenshot of the "Heat map" tab, displaying the days and times of higher engagement on a particular page. (Source: Created by Corbata Informática, 2016).

Figure 3. Screenshot of the "Word cloud" tab, showing the words used more frequently on a given page. (Source: Created by Corbata Informática, 2016).

Table 2. Results of the automated analysis of the page "Acubens, cancer museum" and the number of errors compared with the manual analysis.

Category	Posts analyzed by the tool, n (%)	Errors per category, n (%)
Beauty	1 (0.6)	1 (2.9)
Science and health	95 (57.2)	4 (11.7)
Anniversaries	17 (10.2)	10 (29.4)
Testimonials	25 (15)	14 (41.1)
Events	1 (0.6)	1 (2.9)
Risk factors	11 (6.6)	1 (2.9)
Institutional	6 (3.6)	1 (2.9)
Solidarity	10 (6.0)	2 (5.8)

Discussion

Content Analysis of Facebook Pages

In this study, we observed that the categories that generated the greater level of engagement were not those with the highest percentage of posts. For example, in the "Informative pages" group, the "Testimonies or real-life stories" category generated an engagement of 196.4 However, only 9.6% (25/261) of the page content in the period of analysis dealt with such topics. The category with the highest number of posts in the "Informative" group was "Science and health" (129/261, 49.4%); yet, this category was ranked only 6th with respect to engagement.

We observed a similar pattern in the "NGOs" group. While the category generating the greatest engagement was "Anniversaries" (129.1), only 5.1% (8/156) of the page content fell into this category. Within this group of pages, the most frequent category was "Solidarity," with 48.7% (76/156) of posts. However, the average engagement rate for these posts

was 45, around 2.8 times lower than the most successful category and scoring fourth in the average engagement ranking.

Another category with a relatively low presence among the analyzed posts was "Science and health"; this category, along with "Risk factors," is directly related to topics such as cancer prevention, well-being, and early diagnosis. In the "NGOs" group and on personal pages, nothing was published on the subject. However, in the "Hospital or foundation" group, this category ranked second in terms of average engagement, indicating that people looking for information on hospitals and foundations are more likely to be interested in these topics than people visiting other cancer-related pages. Hence, we suggest that the administrators of hospitals or foundations devote more space to this subject on their Facebook pages.

Furthermore, to increase engagement, it is crucial that the page administrators adopt strategies to incentivize their users to comment more often, as this is the type of participation that demands greater intellectual effort. Given that users who comment invest more time in a post, this is probably the reason

why the average number of comments is lower than the average number of shares and reactions across all categories.

Some of the most common strategies used to generate more comments on Facebook consist of asking users questions and responding to all the comments [29]. As Porto emphasized, "The more a user interacts with a particular content producer, the greater the chances of that producer appearing in the user's news feed" [30]. To increase user engagement, it is, therefore, crucial for the page to encourage similar actions.

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The category "Science and health" had the largest number of posts (n=95), but it was also the one for which the software committed a small number of errors—only 2. Although the software cannot draw on images or videos that come with the publication, textual analysis proved sufficient for our purposes. In the "Risk factors" category, there was only one error out of 11 posts. An example of text that was correctly classified in the "Science and health" category is as follows:

> *Cancer can be fought with cell transplantation from healthy subjects. Scientists have discovered that it is possible to fight cancerous tumors by using cells from the immune system of a healthy person and transplanting them in the body of a person with the disease. The research was conducted by the Cancer Institute of the Netherlands and the University of Oslo in Norway and published last week by the journal Science. The researchers noted that by inserting components of a healthy donor's immune system cells into the cells of a patient with cancer in the laboratory, it is possible to get the patient's body to recognize the tumors and attack them. The research was conducted on 3 patients with melanoma, a type of skin cancer. Read more:http://goo.gl/FgJNvv.* [Translated from Portuguese]

Although the text contains words belonging to other categories, such as "donor" ("Solidarity"), the software was able to classify the post in the appropriate category, given that most of the words in this section concern "Science and health."

The classification errors made by the software occurred largely because the tool was not able to analyze the context surrounding a sentence. For instance, the following post was interpreted as "Anniversaries," despite having been classified as "Institutional" by the researchers:

> *Any day is a day to break a taboo. Let's talk about cancer. Today's message was recorded with Manoel Gomes and he suggests we see the world in a more positive way. Watch the video by clicking on the link below [link] Get to know @Toda Poesia at [link].* [Translated from Portuguese]

The mistake arguably happened because the word "day" appears 2 times and it is the only word in this post that also appeared in the keyword list. After this error, we may consider including the word "project" in the "Institutional" category as several publications from "Acubens, cancer museum" in this category contain this word.

Limitations

With respect to content analysis, one of the limitations concerned the fact that we restricted the study to pages produced in Brazilian Portuguese. We did this out of interest in gaining a better understanding of what is produced on social media about cancer in Brazil and what generates engagement among Brazilians. However, future studies should analyze more broadly the content generated in other countries and languages.

With respect to the software, one limitation concerned the difficulty in choosing the words for each category, as some of them could belong to more than one. In many cases, we had to make choices based on the evaluative criteria of the researchers. However, it may very well be that people with different experiences and writing styles could have classified words in other categories. Another limitation, already mentioned above, may be that the software does not understand the context and, therefore, is unable to capture irony, jokes, ambiguous wording, or figurative language. Moreover, the system is not able to recognize common typing errors.

Despite these limitations, our software could be of help to many research groups and Facebook page administrators wishing to gain a better understanding of what their audience wants and what generates engagement. Other features of the software, such as the "Heat map," will also be of great value in this process.

Conclusions

Categorizing posts and calculating engagement rates revealed that the potential of Facebook pages is often underutilized. This may be because the categories generating the greatest engagement are not those used most frequently. In contrast, we have noticed that in some cases, the most attractive category in terms of engagement is among the least published. For instance, it is worth noting that many pages had only a few posts in the "Science and health" category, despite this being one of the most popular. Indeed, along with "Risk factors," "Science and health" comprises the most relevant categories for public health issues, such as cancer prevention, early diagnosis, and well-being. Given that a high number of cancer cases are related to environmental and lifestyle issues, it is crucial to talk more about prevention and risky behaviors on social media.

However, this study shows that personal pages and the "NGOs" group did not produce any messages about "Science and health." The "NGOs" group also failed to produce any content on "Risk factors". Our results suggest that NGOs should include more information about science, health, and risk factors and also set out to promote them more vigorously.

Within the "Hospital or foundation" group, the category "Science and health" was the one that generated the highest weighted average engagement. However, only 18.3% (20/109) of the posts within this group of pages fell into this category. Our suggestion is that page administrators of hospitals or foundations give more space to this subject.

The software developed in this study may certainly help research groups interested in studying cancer-related topics. In addition, the keyword dictionary on cancer could help people who are interested in delving deeper into this topic. Moreover,

researchers and groups willing to create new categories and dictionaries could take advantage of our tool to gain a better understanding of what type of content engenders greater engagement among target audiences, thereby collecting information to produce more attractive Web-based content.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Name of each page, number of followers in 2017 and content description.

[PDF File (Adobe PDF File), 39KB - cancer_v4i2e11073_app1.pdf]

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Abbreviations

NGO: nongovernmental organization

Original Paper

A Rapid Process for Identifying and Prioritizing Technology-Based Tools for Health System Implementation

Emily R Dibble[1*], BA; Bradley E Iott[1,2,3*], MPH, MS; Allen J Flynn[1], PharmD, PhD; Darren P King[4], MD; Mark P MacEachern[5], MLIS; Charles P Friedman[1,2,3], PhD; Tanner J Caverly[1,6,7], MD, MPH

[1]Department of Learning Health Sciences, Medical School, University of Michigan, Ann Arbor, MI, United States

[2]School of Information, University of Michigan, Ann Arbor, MI, United States

[3]Department of Health Management and Policy, School of Public Health, University of Michigan, Ann Arbor, MI, United States

[4]Division of Hematology and Oncology, Department of Internal Medicine, University of Michigan, Ann Arbor, MI, United States

[5]Taubman Health Sciences Library, University of Michigan, Ann Arbor, MI, United States

[6]Ann Arbor Veterans Affairs Center for Clinical Management Research, Ann Arbor, MI, United States

[7]Department of Internal Medicine, Medical School, University of Michigan, Ann Arbor, MI, United States

[*]these authors contributed equally

Corresponding Author:
Tanner J Caverly, MD, MPH
Department of Learning Health Sciences
Medical School
University of Michigan
300 North Ingalls Street, 1161 NIB
Ann Arbor, MI,
United States
Phone: 1 7342228958
Email: tcaverly@med.umich.edu

Abstract

Background: Health system decisions to put new technologies into clinical practice require a rapid and trustworthy decision-making process informed by best evidence.

Objective: This study aimed to present a rapid evidence review process that can be used to inform health system leaders and clinicians seeking to implement new technology tools to improve patient-clinician decision making and patient-oriented outcomes.

Methods: The rapid evidence review process we pioneered involved 5 sequential subprocesses: (1) environmental scan, (2) expert panel recruitment, (3) host evidence review panel, (4) analysis, and (5) local validation panel. We conducted an environmental scan of health information technology (IT) literature to identify relevant digital tools in oncology care. We synthesized the recent literature using current evidence review methods, creating visual summaries for use by a national panel of experts. Panelists were taken through a 6-hour modified Delphi process to prioritize tools for implementation. Findings from the rapid evidence review panel were taken to a local validation panel for further rapid review during a 3-hour session.

Results: Our rapid evidence review process shows promise for informing decision making by reducing the amount of time and resources needed to identify and prioritize adoption of IT tools. Despite evidence of improved patient outcomes, panelists had substantial concerns about implementing patient-reported outcome tracking tools, voicing concerns about liability, lack of familiarity with new technology, and additional time and workflow changes such tools would require. Instead, clinicians favored technologies that did not require clinician involvement.

Conclusions: Health system leaders can use the rapid evidence review process presented here to usefully inform local technology adoption, implementation, and use in practice.

KEYWORDS

patient reported outcome measures; evidence-based practice; decision support systems, clinical; medical informatics applications; practice guidelines as topic; evidence review; expert panel; health information technology; oncology care model; clinical decision support

Introduction

Background

Computerized tools that aid patient-provider communication and share medical knowledge are proliferating. Many such tools have also been demonstrated in randomized trials to improve clinical care [1]. These include tools that can support patient self-management (SM) [2], patient decision aids [3], point-of-care clinical decision support [4,5], and Web-based tools that can connect health care teams and patients outside of traditional face-to-face clinic visits, such as tools that automate collection of important patient-reported outcomes (PROs) and feed this information to the clinical care team [6]. These knowledge transfer and communication tools can be broadly categorized as PROs and SM tools. There is high enthusiasm that such tools can help make clinical care more safe, effective, and patient-centered [7].

Despite increasing optimism about the potential for PRO and SM tools to improve clinical care, there are many barriers to their successful implementation [8,9]. These tools can be complex, with multiple components that engage not only patients but also multiple members of the clinical care team [10]. Determining how they best fit into a local health system context is often unclear [11]. Furthermore, the extent to which these tools have been tested varies. Relatively, few have been found effective in clinical practice outside of initial efficacy trials, whose purpose is to consider performance in ideal situations [8,12,13]. At the same time, it is not practical for hospital and health system personnel to spend years formally evaluating these and other systems before implementing them.

Objective

Health systems and larger clinical communities interested in taking advantage of promising PRO and SM tools need a rapid but still systematic and trustworthy process for identifying, prioritizing, and adapting tools for local implementation [9,14]. Methods of rapid analysis have been developed to aid pragmatic application of research, such as ethnographic style analysis [15,16] and assessment of health technology literature [17,18]. To our knowledge, however, no methods exist to address our question "How can health systems rapidly identify and evaluate technology-based tools that claim to improve clinical care to prioritize them for local use?"

One area where PRO and SM tools have growing policy impetus is oncology care. For example, the Oncology Care Model (OCM) is a pay-for-performance model that emphasizes PRO measures and is being implemented by 192 practices and 14 payers nationwide, including our own academic cancer center [19].

Figure 1. Revised Design and develOpment, Testing early iterations, Testing for effectiveness, Integration, and implementation (DoTTI) framework.RCT: randomized controlled trial.
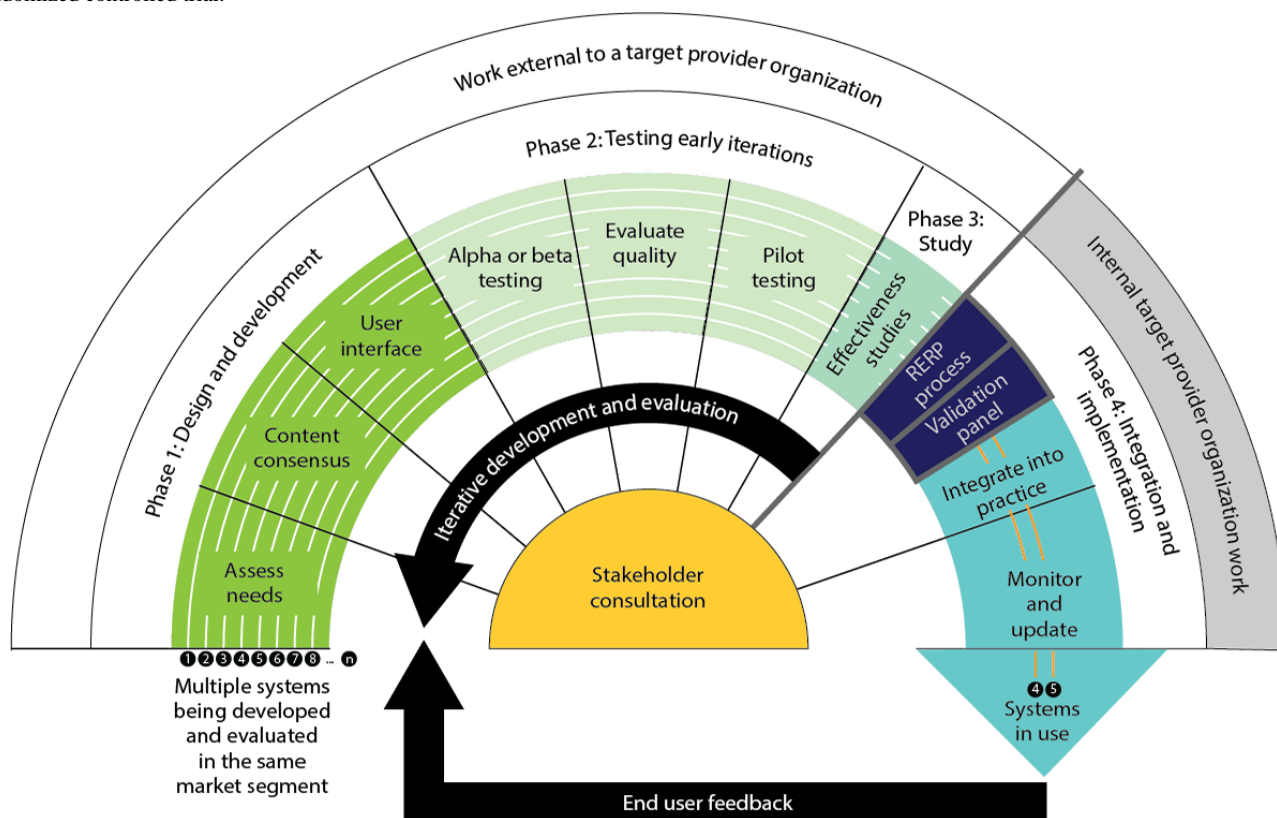
Thus, OCM provided an ideal test case for developing and evaluating a rapid evidence review process to review PRO and SM tools, with a goal of enabling experts to (1) rapidly evaluate evidence for complex computerized tools and (2) prioritize which tools are put into practice. We called this novel process the rapid evidence review panel (RERP) for PRO and SM tools. This methodology study describes our novel evidence review process and how it worked in the context of prioritizing, for local use, complex computerized tools to improve the patient experience of cancer care. We intend for this to be an efficient process that can rapidly unfold at the organizational level.

The RERP process is just 1 important step in a multistep user-centered framework for developing and implementing new tools. The RERP process is not meant to encompass aspects of tool development or evaluation activities around actual tool implementation. Rather, the focus of RERP process is on rapid and pragmatic evidence review that can be conducted within busy health systems. The goal of the RERP process is to help health system leaders prioritize, using current best evidence, which existing tools may be the most feasible and important to implement. The RERP process is important because, if health systems are able to adopt such a process in a systematic and ongoing fashion, it opens a potential path for important new technologies to be adopted more quickly. The RERP process fits within the larger *Design and develOpment, Testing early iterations, Testing for effectiveness, Integration and implementation* (DoTTI) development and evaluation framework, as portrayed in Figure 1 [20]. The DoTTI framework offers a complete development model for digital tools for patient use. The involvement of patients as stakeholders in the development of PRO and SM tools is essential to ensure that tools meet patient needs and expectations.

Methods

Overview

We developed our process to take advantage of existing measures, rapid evidence review methods, consensus-based decision-making methods, and rapid qualitative analysis methods [17,18,21]. The process we developed attempts to streamline the information provided to an expert panel and enable the panel to meet just twice to evaluate and prioritize multiple interventions, once in a 1-hour introductory teleconference and again in a face-to-face 5-hour meeting. This time frame may be adjusted according to the quantity of manuscripts needing to be reviewed.

Given this limited amount of time, it is not practical or efficient for panelists to review full manuscripts, fully review the literature, or individually evaluate evidence. Instead, the RERP process makes use of established evidence review tools and frameworks to ensure a rapid process that is also credible. By shifting the labor to a smaller project team that can collect and synthesize relevant information in advance of expert panel review, the expert panel's evidence review can be accelerated. Our project team consisted of an oncology subject matter expert, an evidence-based medicine expert, a project manager, and a research specialist. Our project team required approximately 3

months to assemble the evidence presented in the RERP meeting.

We then used a rapid template-based coding method using the tailored implementation for chronic disease (TICD) framework and developed a categorization scheme for interventions to rapidly interpret the expert evaluations from the RERP [22]. Our aim was to use these findings to inform local effectiveness, implementation, or hybrid studies [23]. We describe each step of the RERP process in detail (Figure 2) below.

Step 1: Conduct a Rapid Environmental Scan to Identify Promising Tools

A number of procedures exist to conduct rapid reviews of scientific literature [17,18,21]. We chose to conduct a thorough environmental scan (Figure 3) [17]. We first sought to identify the relevant topic domains. In the context of OCM's incentives to improve the patient experience of cancer care, we focused on PRO and SM tools related to improving cancer and cancer treatment–related symptoms. We identified symptom domains by reviewing all published care guidelines from major professional organizations writing guidelines for any aspect of the cancer care continuum (prevention, screening, diagnosis, treatment, and prognosis). Our review included the following organizations: American Society of Clinical Oncology, National Comprehensive Cancer Network, European Organization for Research and Treatment of Cancer, National Cancer Institute, US Preventive Services Task Force, American Academy of Hospice and Palliative Medicine, American Cancer Society, and the Oncology Nursing Society. This review established the set of possible symptom domains for further study (see Multimedia Appendix 1). From this larger set of symptoms, we prioritized those that applied to multiple different cancers treated in a cancer center to be more relevant to a broader group of patients (eg, we included chemotherapy-induced nausea and vomiting, but excluded highly disease-specific symptoms such as lymphedema in breast cancer patients). Such highly disease-specific symptoms are certainly important for consideration but were not the focus of our review.

An informationist then performed a systematic search for PRO and SM tools that targeted one or more of the selected symptom domains and evaluated in randomized controlled trials (RCTs; search strategy described in detail in Multimedia Appendix 2). We chose to focus our search on randomized controlled efficacy trials because an initial search identified few to no implementation or effectiveness studies of PRO and SM tools in these domains. The search strategy we developed to identify PRO and SM tools will be of particular interest to those interested in implementing PRO and SM tools and is described in detail in Multimedia Appendix 2. Moreover, the standardization and internal validity of RCTs aid a rapid and rigorous expert panel evaluation. However, we recognize the need to sometimes move beyond the RCT, particularly in the context of complex interventions such as decision support, where local context and clinical workflows are likely to be key factors in determining the success of the intervention [24-26]. In the absence of large pragmatic trials and implementation studies, single-center and multicenter efficacy studies are likely the best starting points for identifying promising tools.

Figure 2. Rapid evidence review panel (RERP) process. This diagram shows each step of the RERP process.

A content expert on the project team (DK) then reviewed the abstracts of all RCTs retrieved by the search strategy. Our criteria for selecting a local content expert are as follows: (1) clinical expertise in oncology, (2) interest in technology-enabled interventions to improve the patient experience of cancer care, and (3) time and ability to work closely with the evidence-based medicine expert and conduct a thorough review. Although the content expert led the abstract review process, the process also included weekly meetings with an evidence-based medicine expert (TC) to review the abstracts and rationale for inclusion or exclusion. The content expert excluded interventions that were not technology and knowledge based or were not targeting one of the selected symptom domains. Afterwards for further review, he selected those interventions reporting at least some evidence of efficacy in the abstract. Full manuscripts were retrieved for these trials and were read in full by the oncologist. Some manuscripts were excluded at this stage because of the limited clinical relevance of the findings. The oncologist then assigned *effect size* and *reach* scores to each RCT based on a process developed by the National Cancer Institute (ie, using the Research-Tested Intervention Programs review process) [27]. Those RCTs with combined scores (effect size+reach) of greater than or equal to 4 were presented to the RERP as the final product of this environmental scan. In total, 14 RCTs fit the above criteria for presentation to the RERP. Finally, a member of the team with experience in evidence-based evaluation (TJC) applied quality of evidence scoring to each RCT following the Grading of Recommendations, Assessment,

Development, and Evaluation (GRADE) working group approach [28]. GRADE outcomes' tables were created for the primary outcomes of each RCT (see tables in Multimedia Appendix 3).

Step 2: Expert Panel Recruitment

2a. Identify the Target Population to Conduct the Rapid Expert Review

The target population for the evidence review process can be local or national level, depending on goals for future implementation and effectiveness studies. Ideally, an initial national-level process to prioritize the most promising tools can be followed by local validation, which focuses much more on how high-priority tools need to be adapted to fit local clinical contexts and workflows. Targeting a national group of experts for initial prioritization has several advantages. First, a national panel lends itself to focusing on what might generally work to improve the patient experience rather than details of what might be practical in a particular context. Second, it allows the project team to obtain the perspective of clinical experts from multiple different geographic areas and a variety of clinical settings. Third, it allows health systems to incorporate expertise from beyond the boundaries of their own system, which enhances potential for solutions that can be used and evaluated at multiple institutions. Finally, a national panel allows health information technology (IT) companies developing technological interventions to evaluate the types of software most likely to be accepted by their customers.

Figure 3. Environmental scan showing the components of Step 1 of the rapid evidence review panel, the environmental scan. RCT: randomized controlled trial; NCI: National Cancer Institute; RE-AIM: reach, effectiveness, adoption, implementation, and maintenance.
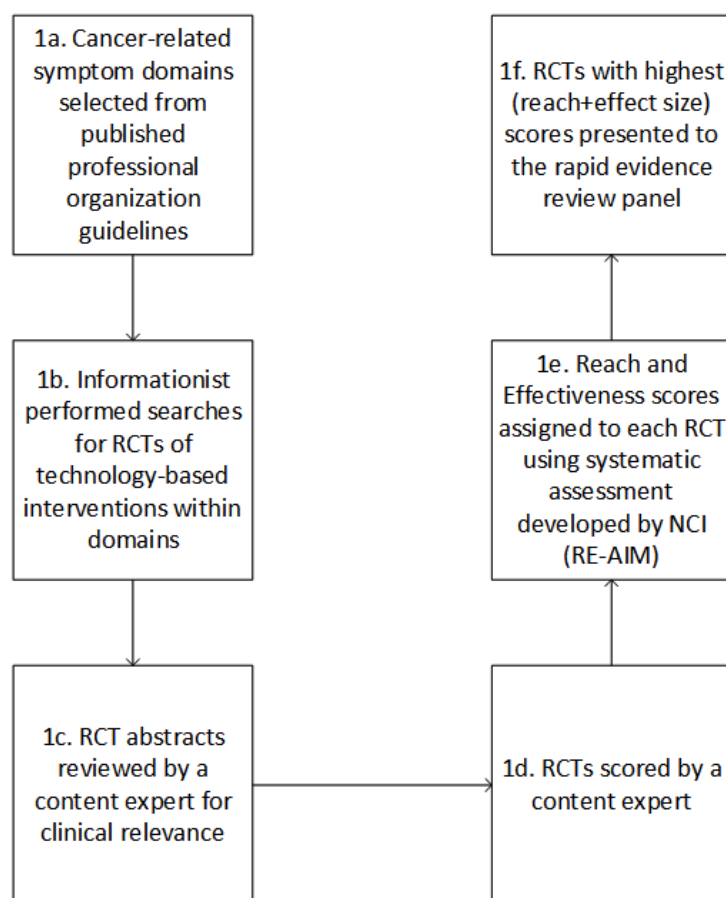
The panel meeting of national experts can be held, if resources allow, at a national society meeting for practitioners in the area of interest to expand convenience for panelists and increase the number of experts willing and able to participate. The RERP meeting, focusing on the patients' experience of cancer care, was held at the 2017 annual meeting of the American Society for Clinical Oncology (ASCO).

2b. Recruit the Appropriate Mix of Participants

To identify potential panel participants, we looked for practitioners with expertise in the area of interest from across the nation. We sought to recruit panelists who practice in the field in which the intervention will be implemented and have first-hand knowledge of the topic and clinical workflows. We also considered whether to include patient representatives on the panel to provide insight into patient needs, preferences, and knowledge that can further inform the impact and feasibility of the technologies being considered. However, given the goal of evidentiary review at this stage, we chose to focus on clinical experts for this initial evidence review and prioritization. To select expert panelists, we first contacted national leaders within the domains of using technology in oncology care and improving the patient experience of cancer care. We asked these national leaders to nominate clinical oncologists with research or clinical interest in the patient experience of cancer care and PROs, such

as monitoring and improving symptoms related to adverse effects of chemotherapy, cancer-related fatigue, comorbid depression, and anxiety. We then reached out to nominees to invite their participation. The final national panel comprised a convenience sample of clinical oncology leaders who were able to attend the annual meeting of ASCO in 2017. We identified 16 experts in medical oncology from across the United States, including physicians in both community oncology practices and academic medical centers. Our final panel consisted of 8 medical oncologists with a range of expertise relevant to the patient experience of cancer care and technology's role in facilitating patient experience. Participants were recruited through direct contact by the principal investigator and coinvestigators and subsequent snowball sampling. If resources allow, panelists can be compensated for their time.

2c. Introduce Participants to the Topic and Prepare Them for the Work Ahead

A short introductory meeting is helpful to set the tone for the expert panel, present background information, and allow panelists to ask questions and learn what to expect. For the introductory meeting, we held an hour-long teleconference 1 week before the RERP meeting in which we introduced ourselves and the panelists, gave the rationale for the project,

and explained the panel members' responsibility and what would take place during the RERP meeting.

The purpose of the RERP is for expert practitioners to evaluate the potential feasibility and impact of putting complex technological interventions into clinical practice. We defined the goal of our panel as helping oncologists and health systems nationwide evaluate the feasibility and impact of utilizing trial-tested PRO and SM tools to improve the patient experience of cancer care. On the basis of our decision to focus on symptoms common across many cancers, we asked participants to consider feasibility and impact for the *average patient* in the *average care setting*. We aimed to have applicability to the largest portion of oncology patients rather than focusing on rare or specialized cases.

Step 3: Conduct the Rapid Evidence Review

We used a modified Delphi panel process. Modified Delphi panels are widely used in health research as a method to elicit group judgment that includes multiple rounds of rating, panelist discussion of judgment, and group facilitation to mitigate bias [29]. The modified Delphi was chosen as the best method of evaluation because it is seen as credible, widely used, and can

quickly elicit expert consensus. Using the modified Delphi strategy, we conducted the RERP meeting in 3 parts: an introduction, initial rating, and rerating. We allowed time for discussion and questions in each part.

3a. Creation of Study Summary Diagrams

For technological interventions in clinical care, there will likely be a standard set of *actors*, whereas the clinical actions may vary by intervention. Actors may include the technology, the patient or caregiver, or the clinician. When visualizing a complex intervention from a published trial, it is important to only include aspects that comprise the technological intervention and not aspects arising from the trial itself (eg, consent forms). Each actor will send, receive, and/or process information in some way. We presented the technology's name and described its function in as much detail as possible. We described the frequency of patient contacts and detailed the information that patients provided to the technology or staff. In addition, we specified how the clinical team implemented the intervention. Symbols indicated whether staff interacted with technology and whether a social media network or patient forum was present (see Figure 4 for an example diagram [30] and Figure 5 for a key to the diagram).

Figure 4. Example intervention diagram and flowchart. Diagram mapping out the Choice ITPA intervention in [30]. The patients selects from 18-preset problem categories via a Web-based system called Choice ITPA. The system tailors delivery of symptom questions based on patient responses. The patient rates their symptom, and the Choice ITPA system creates an assessment summary rank patient symptoms by priority, which is delivered to the clinician. Choice ITPA: Interactive Tailored Patient Assessment.
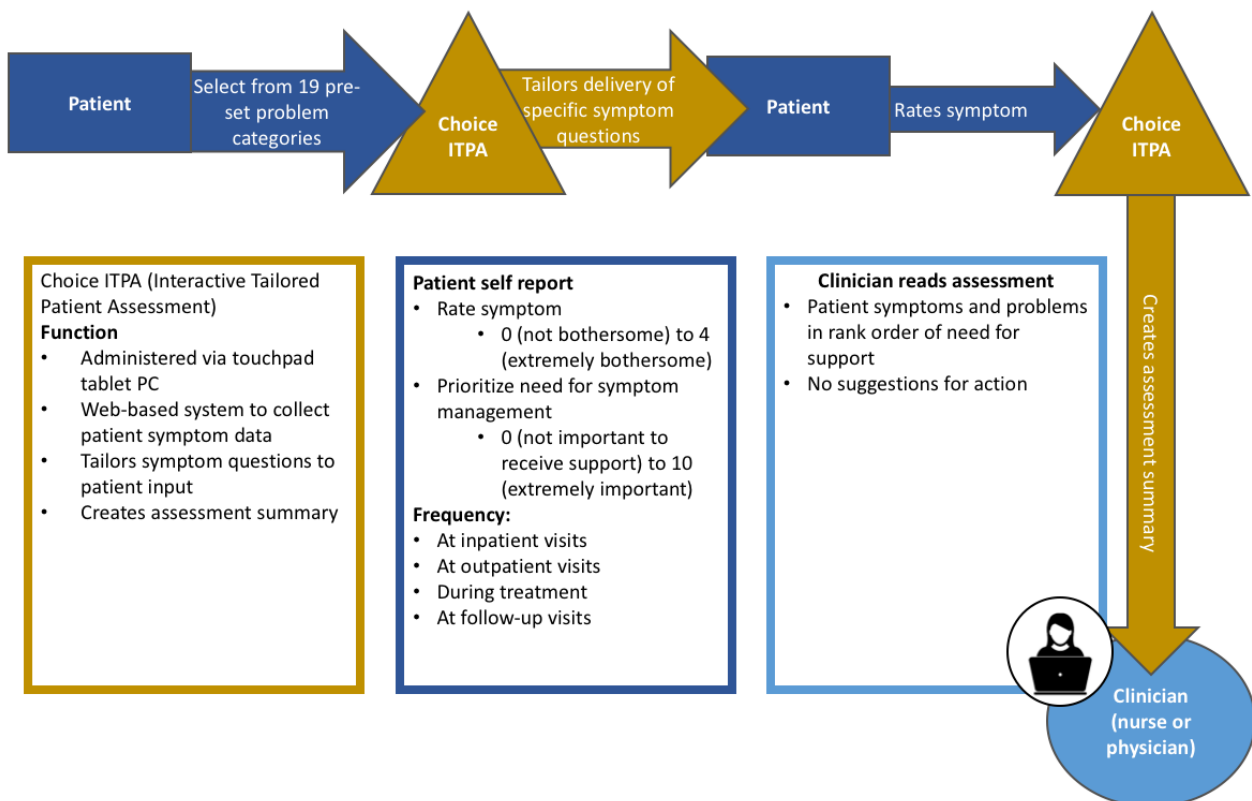
Figure 5. The key allows the intervention of any patient-reported outcome (PRO) or self-management (SM) tool to be mapped out, with a focus on the role of the technology, patient or caregiver, and staff (including providers).

Intervention Description Key
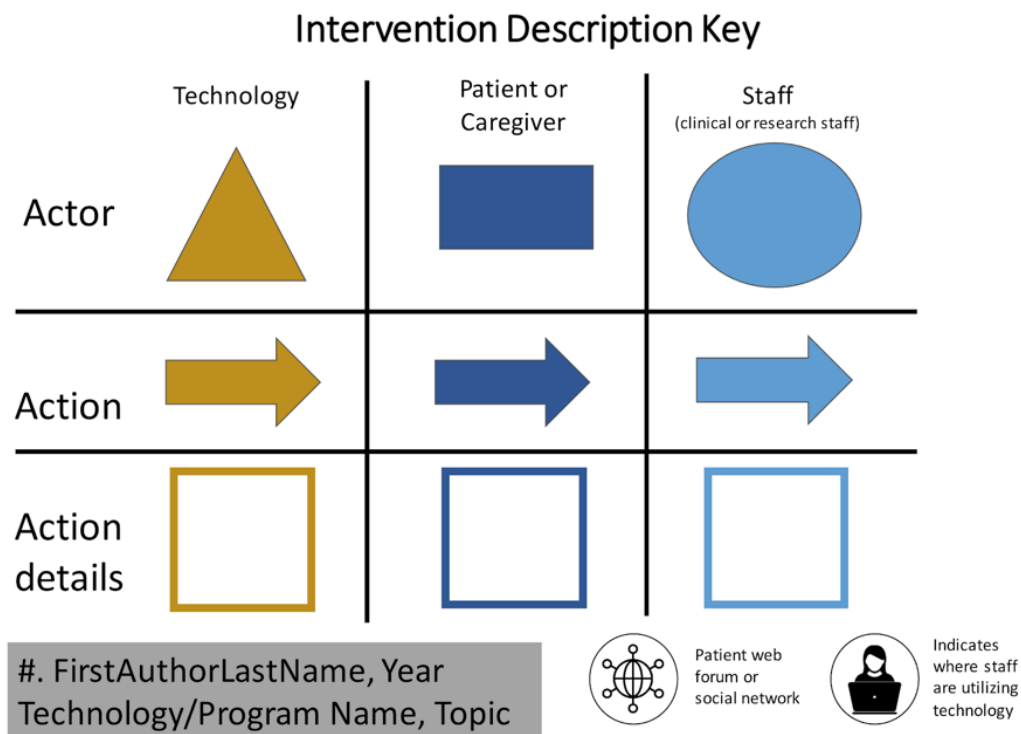
Textbox 1. Impact criteria.

Criteria 1: Impact

1. Evidence exists that using the intervention is likely to improve patient outcomes.

2. Actions are consistent with high-quality care.

3. Using the intervention is likely to affect many patients or have a significant impact on a smaller number of patients.

4. Intervention fills a gap: current rates of intervention's actions are likely to be low.

Textbox 2. Feasibility criteria.

Criteria 2: Feasibility

1. Actions are likely to be accepted by providers.

2. Actions fit with current workflows or workflows can be easily redesigned to fit.

3. Actions are consistent with current system incentives.

4. Actions will be accepted or welcomed by patients.

3b. Rapid Evidence Review Panel Introduction

The goal of the RERP introduction is to remind the participants of the goals of the session and key concepts and terms and quickly set the stage for the focused discussion and rating that follows. Our project team led a brief introduction of the panel and its purpose. In addition, we defined feasibility and impact and how these concepts would be rated during the session (see Textboxes 1 and 2).

3c. Rating

Maintaining a brisk pace is crucial to evaluate more than a handful of interventions. We allocated an average of 10 min per intervention; this included 4 min for material presentation, 4 min for clarifying questions, and 2 min for private rating. It is reasonable to expect that the first few interventions will take longer as panelists adjust to the specifics of the topic area and the panel structure. With the highly structured approach described below, our panel of medical oncologists was able to complete initial ratings of interventions from 14 RCTs in an average of 10 min per intervention.

What information is necessary to evaluate an intervention? Rapid evidence review requires highly structured information. For each intervention, the project team presented preprepared material, including a study synopsis, GRADE tables of evidence quality, and a visual description of the intervention. Examples

of the structured materials are provided in the Web-based supplementary materials. To review each RCT, the panelists were shown a series of slides on a large projection screen. Slides included background information about each technological intervention and RCT, including how many patients used the technology in total and how many settings the system had been implemented in. Each panelist also had a binder with all information from the slides that they were able to reference throughout the review process. Table 1 shows a detailed description of all materials provided to each panelist (Table 1).

This structured information allows the panelists to quickly understand key aspects of the study and intervention, which they can then discuss while project staff takes notes on their comments. Finally, the panelists rated the intervention's feasibility and its impact on a scale of 1 to 9, where 1 to 3 indicated low impact or feasibility, 4 to 6 indicated uncertain or equivocal impact or feasible, and 7 to 9 indicated highly feasible or high impact (Table 2) [28].

3d. Rerating

The project team compiled the panelist's ratings according to modified Delphi panel methods [31]. For each intervention, the project team presented the median score and counts for both feasibility and impact and indicated the level of panelist agreement (agree, disagree, or equivocal). After viewing their own and the group's overall ratings and level-of-agreement, the panelists rediscussed the interventions. We prompted them to explain the rationale behind their initial rating, especially if it was higher or lower than the median. Research staff took notes on the discussion. Finally, the panelists completed a final rating of each intervention.

We followed the criteria outlined by Fitch et al to calculate agreement and disagreement [29]. For 8 panelists, counts indicated agreement when no more than 2 panelists rate the indication outside the 3-point region (1-3; 4-6; and 7-9) containing the median. Counts indicated disagreement when at least three panelists rate the indication in the 1 to 3 region *and* at least three panelists rate it in the 7 to 9 region. Otherwise, agreement level was determined to be equivocal. To accelerate the processing of ratings and levels of agreement for real-time use during the session, we prepared an Excel spreadsheet to automatically calculate and present median scores and counts to panelists.

Table 1. Materials for rapid evidence review panel (RERP) process.

Material	Purpose	Description	Project example	Source	Preparation time (per intervention)
Synopsis	Introduce the intervention and its context in a research study or guideline	A 5-sentence synopsis of the intervention and how it was originally tested or presented	Synopses were presented for all 14 RCTs[a] based on the content of study abstracts	Study abstracts or society guidelines	5 min to standardize abstract content
GRADE[b] tables	Evaluate quality of evidence and strength of recommendations	A common, sensible, and transparent approach to grading quality (or certainty) of evidence and strength of recommendations, which is now considered the standard in guideline development [28]	GRADE tables were used to evaluate quality of evidence for each of the 14 RCTs whose interventions panelists considered	GRADE working group [28]	10 min
Intervention flowchart	Present the intervention in a manner that allows for understanding of workflow impact, separate from study design	A standardized system for creating a visual representation of each intervention to describe the role of the technology, patient or caregiver, and clinician or research staff in the intervention	See Figures 4 and 5	Generated by research team from published manuscript	25 min
RE-AIM questions[c]	Encourage participants to evaluate aspects of interventions that would affect implementation	Four questions adapted from RE-AIM that address the ability to move research into action	Panelists were prompted to consider the following 4 questions after the presentation of each intervention: What are barriers to reaching the target population?; What are some unintended consequences of this intervention?; What are some barriers to adoption by sites and organizations?; and What are the staff and skills needed for implementation?	National Cancer Institute's RTIPs RE-AIM scoring criteria [27]	<1 min
Published manuscript	Ability to reference original manuscripts for clarification	Full manuscript or guideline	Full published manuscripts of each RCT were made available for panelists during the RERP[e] and were utilized several times to verify details of study design	Original manuscript or guideline	<1 min
Scales information	Ability to verify scale content, validity, and reliability	Scale items and reliability and validity information for all scales (those used in all interventions and study analyses)	Although we had scale information available, it was not used by panelists	Scales used were identified from the original manuscript and items, and reliability and validity were located from scale authors	30 min

[a]RCT: randomized controlled trial.

[b]GRADE: Grading of Recommendations, Assessment, Development, and Evaluation.

[c]RE-AIM: Reach, Effectiveness, Adoption, Implementation, and Maintenance Framework.

[d]RTIPs: Research-Tested Intervention Programs

[e]RERP: rapid evidence review panel.

3e. Qualitative Supporting Information

Beyond prioritizing interventions quantitatively, understanding the rationale for panelists' ratings can provide insights for local implementation. To collect these qualitative data, 2 members of the project team took notes during the discussion of key points by the panelists. Although recordings and transcripts are generally regarded as preferable for qualitative research [32], notes are preferable here because the time, effort, and resources required for transcription interfere with the goals of rapid analysis. Finally, we asked panelists for feedback on their

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participation in the RERP process using a short survey instrument, which included space for free text comments.

Step 4: Analysis—How Are Expert Evaluations From the Rapid Evidence Review Panel Interpreted?

There are 3 tasks for data analysis: (4a) *prioritize interventions* for implementation, (4b) *identify features* of the interventions that contribute to positive or negative perceptions of feasibility or impact, and (4c) *identify perceived barriers to and facilitators for* putting the intervention into practice.

4a. Prioritize

We ranked the interventions based on the panelists' ratings. We determined this ranking by ordering the interventions according to the panel's second (final) round of ratings using median scores and level of agreement for impact and feasibility. In determining the ranking, we weighted impact and feasibility equally and gave agreement second priority.

Depending on the project, stakeholders may consider the quantitative ranking described above as sufficient for determining which tools to prioritize for implementation. To decide whether this is sufficient, teams should consider the specificity required for meeting their aims. If simply recommending a *type* of system, then perhaps completing a prioritization is enough. However, if attempting to develop or implement a specific software and the team is interested in more specific details about *why* the rankings fall as they do, project teams should consider the benefits of additional analysis.

4b. Identify Intervention Features

We also wanted to identify features of the interventions that contributed to positive or negative perceptions of the intervention's feasibility and impact. This analysis allowed us to understand the types of tools and features that might be perceived as higher priority for implementation. We categorized each intervention as being primarily 1 of the 3 types: *SM Support*, *PROs*, and *communication.* Moreover, 2 interventions were classified with a secondary type. The project team generated a set of 17 codes to describe the features of the interventions; codes were generated from the original manuscript, and the diagrams designed to explain each intervention to the panelists and the panelists' discussion. We then coded the RCTs based on which of the 17 features they possessed. All features were coded based on the information provided in the original manuscripts. We understand that scientific manuscripts do not contain full details of the computerized tools they describe and acknowledge that certain features or details are omitted in the RERP process. We also calculated the number of features described for each intervention. In addition, the notes from the panelists' discussion were coded for presence of endorsement or opposition to each of the identified features, and the number of features endorsed or opposed was recorded for each intervention.

4c. Identify Barriers and Facilitators

To identify perceived barriers to and facilitators for putting the interventions into practice, we conducted a content analysis of notes from the panel session using the Tailored Implementation for Chronic Disease (TICD) checklist [22]. The TICD checklist was developed from a systematic review of the literature in implementation science. It was designed to identify barriers and facilitators to implementation of health improvement interventions. Moreover, 2 members of the research staff read through discussion notes and coded per the TICD checklist. The raters then met and reconciled coding disagreements. From the final codes, themes were identified.

Step 5: Local Validation Panel for Evaluation of Effectiveness

The purpose of the RERP process is to identify high-priority PRO and SM tools for further study and/or implementation. Although systematically identifying and prioritizing the most promising tools is an important first step, successfully implementing these complex tools will still require adaptations based on detailed knowledge of local workflows and context. After identifying SM and symptom tracker tools as effective, impactful, and feasible through the RERP process, we hosted a validation panel with a diverse set of stakeholders within our health system. These included hospital and clinical leadership, hematologists, oncologists, nurses, nurse educators, physician assistants, patient navigators, and other professionals from the University of Michigan Rogel Cancer Center. Using evidence summaries provided to them, these panelists were asked to validate, for locally focused purposes, the knowledge generated previously by a national panel of experts about the feasibility and impact of software tools intended to help improve the patient experience of cancer care. In addition, after having reviewed and commented on the scientific evidence about these tools and its meaning to a national group of oncologist experts, these panelists were asked to review and comment on an early design concept for a user customizable decision support app with features of SM and symptom tracker tools.

Results

Environmental Scan and Evaluation of Evidence Quality

We were able to rapidly review 14 manuscripts about computerized tools related to the OCM using our method. Panelists' feedback indicated that participation was valuable and intuitive. What follows are the results we gained by doing so.

Our environmental scan and evidence review process yielded 14 RCT-tested interventions associated with at least moderate impact and reach. Evidence quality was variable, with most trial outcomes graded as being based on low to moderate quality evidence. Multimedia Appendix 3 provides the evidence review of the 14 RCTs from our environmental scan.

Rapid Evidence Review Panel Step 4a: Prioritize

Participants rated interventions on impact and feasibility (Table 2). Agreement increased from the first to the second rating. Overall, most interventions were ranked more highly after discussion.

Table 2. Scoring schema for potential impact or feasibility and confidence in a given impact or feasibility rating.

Scores	Potential impact or feasibility	Confidence
7-9 (high)	High potential	Moderate to high (minor concerns only)
4-6 (equivocal)	Potential	Lower (major concerns)
1-3 (low)	No or low potential	—

Table 3. Outcomes of study ratings.

Study	Type	Agreement		Median		
		Rating 1	Rating 2	Rating 1	Rating 2	Final rank
Feasibility						
1	PRO[a]	Equivocal	Equivocal	5	6	—
2	PRO	Equivocal	Equivocal	3	4	—
3	SM[b]	Agree	Agree	8	8	—
4	SM or Communication	Agree	Agree	7	7	—
5	PRO	Agree	Agree	5	4	—
6	PRO	Equivocal	Equivocal	4	4	—
7	PRO	Agree	Agree	6	6	—
8	PRO	Equivocal	Equivocal	4	4	—
9	PRO	Equivocal	Agree	6	5	—
10	SM	Equivocal	Equivocal	7	7	—
11	Communication or SM	Equivocal	Equivocal	4	4	—
12	PRO	Equivocal	Equivocal	6	5	—
13	SM	Equivocal	Agree	8	8	—
14	SM	Agree	Agree	8	8	—
Impact						
1	PRO	Equivocal	Equivocal	5	5	6
2	PRO	Equivocal	Equivocal	7	7	3
3	SM	Agree	Agree	8	8	1
4	SM or Communication	Equivocal	Equivocal	7	7	2
5	PRO	Equivocal	Agree	5	5	4
6	PRO	Equivocal	Equivocal	6	6	6
7	PRO	Equivocal	Equivocal	7	7	3
8	PRO	Equivocal	Agree	5	5	5
9	PRO	Equivocal	Equivocal	4	4	5
10	SM	Equivocal	Agree	6	6	3
11	Communication or SM	Equivocal	Equivocal	3	3	7
12	PRO	Agree	Agree	6	5	5
13	SM	Equivocal	Agree	7	7	1
14	SM	Equivocal	Equivocal	7	7	2

[a]PRO: patient-reported outcome.

[b]SM: self-management.

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Table 4. Average scores for feasibility and impact of different study designs based on second panelist's ratings.

Study type	Feasibility	Impact
PRO[a]	4.72	5.23
SM[b]	7.18	6.64
Communication	5.07	5.00

[a]PRO: patient-reported outcome.

[b]SM: self-management.

Rapid Evidence Review Panel Step 4b: Identify Intervention Features

We found that these complex interventions contained multiple features and that the panel had opinions about many of these features. We identified clear differences in how interventions were ranked based on the type of intervention being studied. We identified 3 main types of interventions among the 14 RCTs reviewed related to improving the patient experience of cancer care:

Self-Management (SM) Tools

Interventions with the primary function of providing resources and information to patients that involved no or limited clinician involvement supported patient SM and often provided patients with educational materials and were primarily patient facing.

Patient-Reported Outcomes (PROs)

Some of the interventions with the primary function of collecting PROs and transmitting that information to the clinician in some format to assist with treatment had additional components, such as decision support for patients and/or to help clinicians deal with the patient-reported information or functions to trigger notifications to clinicians when certain thresholds had been reached. These interventions contained both patient- and clinician-facing components.

Communication

Interventions with the primary function of facilitating patient-provider communication were both clinician- and patient-facing. Considering the ratings from 4a and the 3 main types of interventions identified in 4b (Table 3), SM support interventions consistently received highest rankings (average rating for feasibility=7.18 and average rating for impact=6.64; see Table 4).

Rapid Evidence Review Panel Step 4c: Identify Implementation Barriers and Facilitators

Using the TICD framework, 6 major constructs were identified as barriers to implementation: quality of evidence, cultural appropriateness, patient behavior, availability of necessary resources, information systems, and payer or funder policies. No themes were identified as major facilitators. SM support interventions were seen as having fewer barriers to implementation, including being more appropriate for the workflow, more in line with patient behavior, carrying less legal risk, and having better evidence for their success.

Taken together, the results of this mixed-methods analysis allowed us to not only understand which specific interventions were considered most high priority but also to learn that SM support interventions may be perceived as more impactful and feasible to implement.

Discussion

Overview

The slow progress from research to practice is well documented [33,34]. The approach we describe here, a rapid evidence review for PRO and SM tools, is intended to balance the goals of rigor and efficiency for an evidence-based method to prioritize promising communication and decision-support technologies. Clinical experts found the evidence review structure to be engaging and the content sufficient to make judgments, and they were able to quickly and effectively prioritize a heterogeneous set of PRO and SM tools.

We observed that the RERP panel strongly favored implementation of SM and communication tools over PRO tools and indicated that this was largely because of less need for clinician involvement and lower legal risk. In addition, panelists expressed much skepticism about the feasibility of implementing PRO tools, despite high evidence of their success in the RCTs. We observed increased levels of agreement in the second round of rating, which is an expected feature of the modified Delphi process, after panelists come together and discuss the rationales for their initial ratings [31].

Health systems cannot put all effective tools into practice, no matter how promising. This prioritization process can be used by health systems and practices seeking to employ PRO and SM tools as the basis for local implementation studies or larger pragmatic effectiveness studies. Furthermore, the results of our evaluation highlight how our medical oncology experts favored SM support tools over tools utilizing PROs. This is surprising given what seems to be growing evidence of the effectiveness of these interventions to improve quality of life [35] and perhaps even lifespan [36]. Technological, workflow, cultural, and legal barriers caused our panel to evaluate these technologies as less feasible and impactful. Further evaluation of PRO and SM tools will help elucidate the extent to which these views about the challenges of implementing PRO-based tools are shared across institutions. Local evaluation can help clarify expectations and planning for implementation at individual institutions. Finally, the use of a systematic evidence review method such as that described here can help ensure that decision making for the implementation of new tools considers both the experience of relevant clinical experts and empirical findings from a diverse body of research literature. In addition, barriers exist that are because of the nature of PRO and SM tools and the research

reporting process. Inadequate reporting of technology interventions makes evidence review difficult [37]. Furthermore, rapid technological change can outpace conducting and publishing RCTs, which further outpaces evidence review [38]. However, this further emphasizes the need for a rapid process to facilitate evidence being translated into practice as soon as the evidence is available.

Limitations

Our rapid evaluation process has limitations. Although the RERP process was designed to limit the amount of time and resources it takes to complete the review and prioritization process, the time it takes to prepare the materials and synthesize evidence for the panelists is still nontrivial creating a potential barrier if resources are limited. However, a relatively small project team could follow our process and accomplish the majority of the work before convening the RERP. As the amount of evidence to review increases, the amount of preparation time needed may increase.

The focus of this particular rapid evidence review was on the clinician-facing aspects of existing tools, particularly the feasibility and impacts of integrating these complex technologies into clinical workflows. However, we recognize that this is only a first step in implementing new technologies. Fully successful implementation also requires incorporation of patient viewpoints [39-41]. For example, patient engagement is necessary to ensure that these tools strike the right balance between providing patients' information and protecting their privacy [42]. Technology developers and health system leaders tasked with implementing and evaluating new tools need a robust process that incorporates all key stakeholders, including patients [39-41].

Although the RERP process provides a method to address the critical question, "Which PRO and SM tools should we prioritize for further study and implementation?," it does not solve all of the challenges health systems face when seeking to use these complex tools to improve clinical care. It is likely that implementation challenges, both resulting from infrastructure limitations and clinician concerns, have limited utilization of these tools. To scale up use of PRO and SM tools in different clinical contexts nationally, a computational infrastructure that can support interoperable applications is necessary to support data collection and curation. PRO and SM tools may be an excellent use case for machine-encoded, computable biomedical knowledge curation, and execution platforms.

In the context of a relatively narrow and recent area of study, technology-based communication and support tools to improve the patient experience of cancer care, we identified numerous RCT-tested tools. To achieve the important task of improving the patient experience of cancer care, we needed a systematic and trustworthy process for identifying and prioritizing the most promising tools for further study and implementation.

Although health systems focused their efforts solely on tools with randomized trial evidence showing they can improve patient-important outcomes, the number of potential tools will likely exceed the system's capacity to put them into practice. Moreover, these technologies can be complex. Integrating novel tools into clinical workflows has proven challenging [43]. Thus, even more than with other types of interventions, randomized trial's evidence of the tool's ability to improve outcomes may not translate into effectiveness in real-world settings. The RERP process presents a method to streamline the process of guideline review and data collection while maintaining a rigorous evidence-based grounding. We took advantage of multiple existing frameworks to streamline our process while maintaining rigor: current evidence searches and environmental scan procedures [17,44], the National Cancer Institute's Research-Tested Intervention Program's review process, the modified Delphi panel process, the GRADE ratings and summary of findings tables, and the TICD coding framework. Using these existing frameworks for each part of the evidence search and review process allowed for a systematic process that was feasible to complete within approximately 4 months.

In addition, the identification of potential useful features or perceived implementation barriers by experts (4b and 4c) may help health system leadership understand how the high-priority tools need to be adapted before implementation. The evaluation of the benefits and drawbacks of specific features of tools may inform the design or configuration of new technologies before implementation. For example, a system architect may consider deleting or modifying some features seen as barriers and including other features viewed as helpful. Thus, important next steps include taking the findings of an RERP to a local group of decision makers for validation and to determine how tools need to be adapted to fit a local context.

Conclusions

Before PRO and SM tools, or other digital tools, may be broadly used, proper assessment of their potential feasibility and impact using an RERP process may be beneficial. The RERP process presented here may enable health care administrators to make more efficient and effective decisions about the implementation of novel technologies in clinical practice.

Conflicts of Interest

None declared.

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Multimedia Appendix 1

Symptom domains identified for the environmental scan.

[PDF File (Adobe PDF File), 13KB - cancer_v4i2e11195_app1.pdf]

Multimedia Appendix 2

Detailed information on environmental scan search strategy.

[PDF File (Adobe PDF File), 64KB - cancer_v4i2e11195_app2.pdf]

Multimedia Appendix 3

Grading of recommendations, assessment, development, and evaluation tables of evidence for each of the 14 randomized controlled trials selected for panelist review.

[PPTX File, 86KB - cancer_v4i2e11195_app3.pptx]

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Abbreviations

ASCO: American Society for Clinical Oncology
DoTTI: Design and develOpment, Testing early iterations, Testing for effectiveness, Integration, and implementation
GRADE: Grading of Recommendations, Assessment, Development, and Evaluation
IT: information technology
OCM: Oncology Care Model
PRO: patient-reported outcome
RCT: randomized controlled trial
RE-AIM: Reach, Effectiveness, Adoption, Implementation, and Maintenance Framework
RERP: Rapid Evidence Review Panel
RTIPs: Research-Tested Intervention Programs
SM: self-management
TICD: Tailored Implementation for Chronic Disease

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Original Paper

An Interactive Web Portal for Tracking Oncology Patient Physical Activity and Symptoms: Prospective Cohort Study

Michael Marthick[1], BS, MPH; Haryana M Dhillon[2], PhD; Jennifer A Alison[3,4], PhD; Bobby S Cheema[5], PhD; Tim Shaw[6], PhD

[1]Chris O'Brien Lifehouse, Camperdown, Australia

[2]Centre for Medical Psychology & Evidence-based Decision-making, School of Psychology, University of Sydney, Sydney, Australia

[3]Faculty of Health Sciences, University of Sydney, Sydney, Australia

[4]Sydney Local Health District, Sydney, Australia

[5]School of Science and Health, Western Sydney University, Penrith, Australia

[6]Research in Implementation Science and eHealth Group, Faculty of Health Sciences, University of Sydney, Sydney, Australia

Corresponding Author:
Michael Marthick, BS, MPH
Chris O'Brien Lifehouse
119-143 Missenden Road
Camperdown,
Australia
Phone: 61 028 514 0763
Email: michael.marthick@lh.org.au

Abstract

Background: Physical activity levels typically decline during cancer treatment and often do not return to prediagnosis or minimum recommended levels. Interventions to promote physical activity are needed. Support through the use of digital health tools may be helpful in this situation.

Objective: The goal of the research was to evaluate the feasibility, usability, and acceptability of an interactive Web portal developed to support patients with cancer to increase daily physical activity levels.

Methods: A Web portal for supportive cancer care which was developed to act as a patient-clinician information and coaching tool focused on integrating wearable device data and remote symptom reporting. Patients currently receiving or who had completed intensive anticancer therapy were recruited to 3 cohorts. All cohorts were given access to the Web portal and an activity monitor over a 10-week period. Cohort 2 received additional summative messaging, and cohort 3 received personalized coaching messaging. Qualitative semistructured interviews were completed following the intervention. The primary outcome was feasibility of the use of the portal assessed as both the number of log-ins to the portal to record symptoms and the completion of post-program questionnaires.

Results: Of the 49 people were recruited, 40 completed the intervention. Engagement increased with more health professional contact and was highest in cohort 3. The intervention was found to be acceptable by participants.

Conclusions: The portal was feasible for use by people with a history of cancer. Further research is needed to determine optimal coaching methods.

Introduction

Physical activity levels typically decline during cancer treatments such as chemotherapy or radiation therapy and often fail to return to prediagnosis or minimum recommended levels [1]. Patients report symptoms and side effects, primarily cancer-related fatigue, as a significant barrier to increasing physical activity levels [2-3]. These factors present a challenge for health professionals to increase physical activity levels in cancer populations. Integrating physical activity and exercise prescription into routine clinical care is supported by various national and international statements and guidelines that

emphasize the importance of contact with an exercise professional with expertise in cancer care [4-5].

In order to promote physical activity, health professionals, particularly exercise professionals, may suggest the use of commercially available physical activity trackers to their patients. However, data monitoring by health professionals for a large number of patients who use such trackers can be difficult because individual patient data is not readily available as it sits with the patient.

Digital health interventions such as the use of Web portals have been shown to be beneficial by supporting engagement in health and wellness activities in individuals with chronic diseases, including people with a history of cancer. A Web portal is generally seen as a secure website that brings information from various sources together in a uniform way [6-7]. Web portals can have many uses including patient access to personal medical records, appointments, medications, communication with health professionals, and decision support tools [8-12].

Patients who use Web portals may have greater engagement in their treatment, increased treatment satisfaction, and better communication with their health professional care team. This includes a method to record and track patient-reported outcome (PRO) measures [6-9,13]. These factors may contribute to facilitating positive health behavior change.

The use of an integrated clinician-patient Web portal, with a mechanism for automated real-time data transfer, may provide the ability to track physical activity and patient-reported symptoms such as fatigue and provide an opportunity to positively impact behavior change through messaging. The use of messaging, including personalized coaching messaging, has emerged as a promising approach to promoting positive behavior change [10,11]. However, the feasibility of Web portals to support physical activity behavior change in people with a history of cancer has not been evaluated.

The aim of the study was to assess the feasibility of using a Web portal with activity monitoring and personalized messaging for people diagnosed with and treated for cancer.

Methods

Study Design

This was a prospective, longitudinal cohort study to determine user feasibility of a Web portal in cancer patients. The study protocol has been published previously [12].

Web Portal

An interactive Web portal was developed that included integration of real-time wearable activity device data, collection of PROs and symptom information, the provision of educational material, and individualized coaching messaging to support behavior change by encouraging patient engagement in physical activity. The Web portal enabled remote monitoring of physical activity for use by both clinician and patient, along with symptom and health-related quality of life (HRQoL) tracking capabilities. The Web portal also allowed for educational emails, summary messaging, and individual personalized messages to be sent to participants.

Activity and Sleep Tracker

The Misfit Shine activity monitor was used in this study. The Shine was chosen due to its long battery life. Participants enrolled in the study could also opt to bring their own device from the Misfit, Garmin, or Fitbit product ranges.

Study Population

The inclusion criteria were (1) diagnosed with any cancer, at any stage of treatment receiving or had received anticancer therapy within the last 12 months, (2) aged 18 years or older, (3) Eastern Cooperative Oncology Group performance status 0 to 2, (4) had internet or mobile phone access, (5) willing to complete the intervention and follow-up in English, and (6) provided written informed consent. Participants were excluded if they were unable or had limited ability to speak English or had any condition that would compromise their ability to understand the participant information or give informed consent.

Recruitment

Potentially eligible patients registered with the cancer center were invited to participate by a member of their health care team between March and June 2017. Following eligibility check and consent, participants were enrolled serially into one of three cohorts without randomization. Cohort 1 was provided Web portal access and given a wearable activity tracker (Misfit Shine) for 10 weeks. Cohort 2 was provided Web portal access, an activity tracker, and an additional weekly automated summary message via the Web portal detailing average symptom and physical activity scores over the past week, along with specific educational material such as information on cancer-related fatigue and nutrition. Cohort 3 received the same content as Cohort 2 plus personalized behavioral change messaging from an accredited exercise physiologist (MM). Messages were sent weekly through the Web portal to the participants' email. Each participant received a 20- to 30-minute face-to-face onboarding and setup session.

Primary Outcome

The primary outcome was the feasibility of the program. The intervention was deemed feasible if a compliance rate of more than 70% was observed. Compliance comprised two measures:

- Log-ins: a patient was defined as compliant if they had more than 2 log-ins to record symptoms over the 10-week study period
- Questionnaires: a patient was defined as compliant if they completed the follow-up questionnaire at week 10.

For the Web portal to be deemed feasible, more than 70% of the participants needed to comply with both criteria.

Secondary Outcomes

The secondary objectives of the study were to describe the number of individuals who were eligible, took up the program, and completed the program; compute the rate of goal attainment as set by the exercise physiologist in week 2; and measure participant satisfaction, acceptability with the intervention, self-efficacy related to change in lifestyle factors, and changes in PROs including symptom and HRQoL scores. For cohorts 2

and 3, median daily step count was recorded and weekly email engagement measured.

At the initial face-to-face session, baseline PROs were completed on the Web portal, with follow-up questionnaires administered remotely. Three validated PRO measures were used: symptom tracking scale—Edmonton Symptom Assessment Scale (ESAS) [14], HRQoL tool—Functional Assessment of Cancer Therapy–General (FACT-G) [15], and self-efficacy scale— Cancer Behavior Inventory–Brief Version (CBI-B) [16]. An additional study-specific feedback questionnaire was remotely administered via a Web survey to assess participant satisfaction with the intervention, focused on the Web portal and activity tracker.

Data Analysis

Baseline demographics are summarized as number and percentage for categorical variables and mean and standard deviation or median and interquartile range (IQR) for continuous variables depending on the distribution. The number of compliant participants within each cohort is summarized as number and percentage. The number and percentage of patients who attained their step goal was summarized weekly and by cohort, along with the median number of weeks taken to attain goals. Daily step count was summarized at weeks 1 and 10 for each cohort as mean and standard deviation or median and IQR. The mean difference and 95% confidence interval for physical activity between weeks 1 and 10 is provided. HRQoL scores are summarized as median and IQR or mean and standard deviation at the initial and week 10 visit for each cohort group. The mean difference between time points is displayed alongside the 95% confidence interval. The number and percentage of opened emails is summarized for cohorts 2 and 3 by each week of the study, and the number of personalized messages opened by cohort 3 is summarized as number and percentage. The number of symptoms reported was used to investigate the association between baseline characteristics and engagement with the Web portal. A Mann-Whitney U test was used to compare the number of symptoms between categorical variables.

Participants were invited to complete a semistructured qualitative interview after completing the study in order to provide feedback regarding their perception of the acceptability of the intervention and experience in using the Web portal. Interviews were conducted by an experienced qualitative researcher (AJ) via telephone and audio recordings. Interviews were transcribed verbatim and analyzed thematically [17] using a framework approach [18]. Three coders (MM, JA, HMD) coded the data independently. Qualitative data were used to augment quantitative findings in this paper.

Permission to conduct this study was granted by the Royal Prince Alfred Hospital Human Research and Ethics Committee (X16-0051). All participants provided written informed consent.

Results

Participant Characteristics

A total of 59 patients were invited to participate, and 83% of those (49/59) were recruited to the study. The first 17 participants were entered into cohort 1 in month 1, the second 17 into cohort 2 in month 2, and final 15 into cohort 3 in month 3. Recruitment numbers for each cohort were lower than planned (n=20) due to delay in the Web portal development, and 80% (39/49) of participants had data included in the analysis. There were no data predictive of patients lost to follow-up. Figure 1 shows the study flow chart.

Participants were mostly female (38/49, 78%) with a history of breast cancer (27/49, 55%), the median age was 54 years, and 24% (12/49) were receiving concurrent chemotherapy. Median time since last intensive anticancer therapy was 3.5 (IQR 0-12.5) months. The majority (43/49, 88%) had at least one comorbidity. Most participants (33/49, 67%) had not used an activity monitor previously, and the majority (40/49, 82%) were supplied with an activity monitor by the study investigators. Patient demographics are summarized in Table 1.

Primary Outcome

Feasibility Measures

The number of log-ins and completed questionnaires are shown in Table 2. Feasibility increased across the cohorts, with cohort 1 having the least number of participants (7/17, 35%) and cohort 3 having the most (12/14, 86%) meeting the two criteria for feasibility. Feasibility criteria were met for cohort 3 only.

Participant Acceptability of Intervention

Twelve themes were identified from the data, with 4 themes directly applicable to the feasibility and acceptability of the intervention. Participants in the study generally reported a high level of acceptability for the intervention.

> *It was really, really positive and it was really helpful in terms of making a progressive recovery.* [Participant 4, cohort 2]
>
> *I think from both mental and physical point of view it was really worthwhile for me.* [Participant 1, cohort 3]

Secondary Outcomes

Symptom Logging

The mean number of log-ins to report symptoms increased in each of the cohorts depending on the level of interaction. Cohort 1 had a mean of 11 log-ins (range 0-52), cohort 2 had a mean of 17 log-ins (range 0-104) and cohort 3 had a mean of 50 log-ins (range 3-121). Figure 2 shows the number of log-ins to record symptoms per week across cohorts.
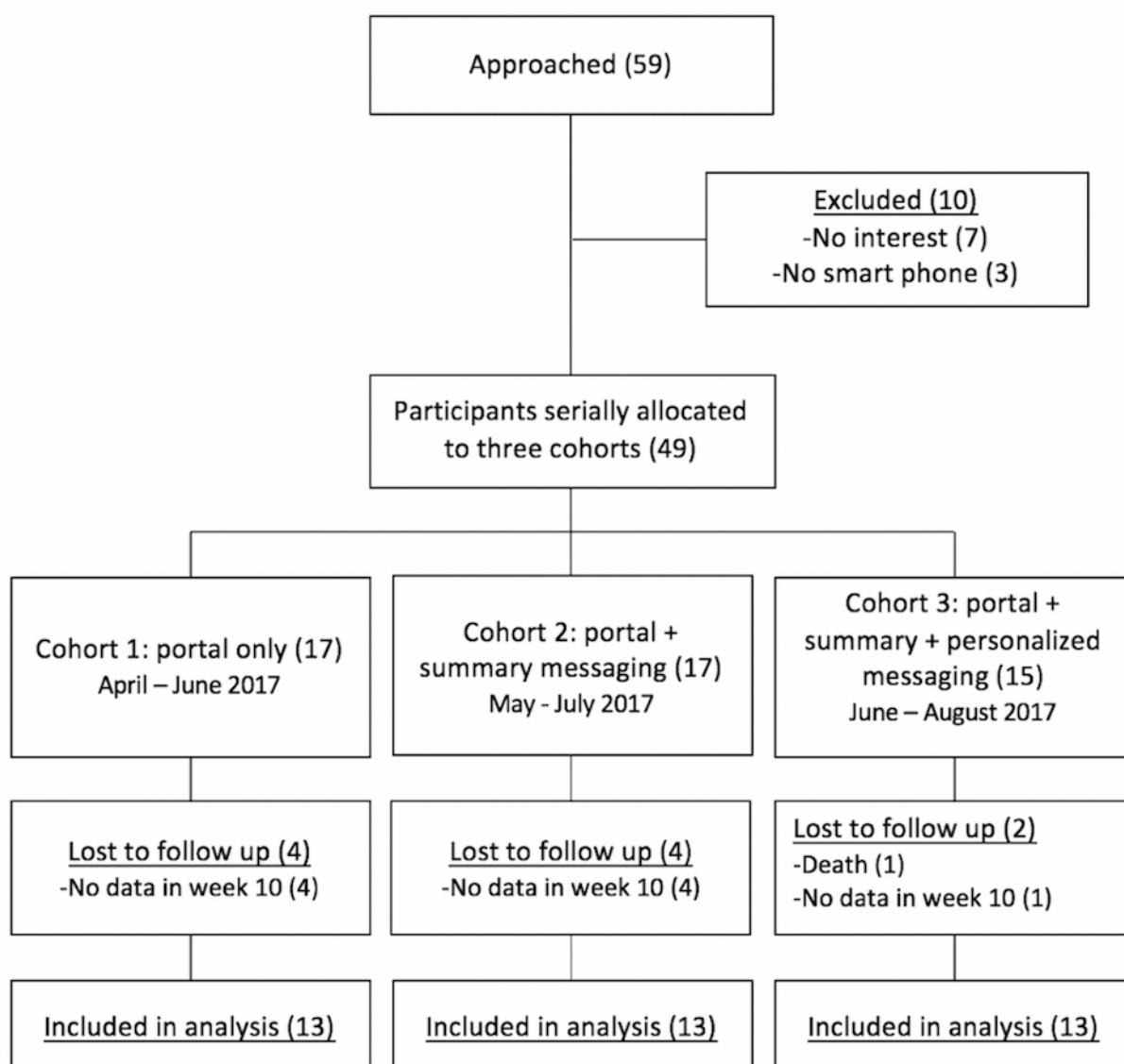
Figure 1. Study flow chart.

Table 1. Summary of participant baseline characteristics by cohort.

Characteristics	Cohort 1 (n=17)	Cohort 2 (n=17)	Cohort 3 (n=15)	Total (N=49)
Age in years, mean (SD)	56 (10.0)	51 (10.9)	56 (12.4)	54 (11.0)
Gender, male, n (%)	2 (12)	4 (24)	5 (33)	11 (22)
Diagnosis, n (%)				
Hematological	1 (6)	2 (12)	5 (33)	8 (16)
Breast	12 (71)	12 (71)	3 (20)	27 (55)
Prostate	1 (6)	1 (6)	1 (7)	3 (6)
Colorectal	2 (12)	—[a]	1 (7)	3 (6)
Lung	—	—	2 (13)	2 (4)
Other	1 (6)	2 (12)	3 (21)	6 (12)
Current chemotherapy, n (%)	3 (18)	5 (29)	4 (27)	12 (24)
Treatment history, n (%)				
Chemotherapy	11 (65)	7 (41)	13 (87)	—
Radiation therapy	11 (65)	5 (29)	2 (30)	—
Recent surgery (<6 weeks)	16 (94)	10 (59)	8 (53)	—
Current hormonal therapy	7 (41)	7 (41)	4 (27)	—
Immunotherapy	1 (6)	1 (6)	1 (7)	—
Time since last treatment, months, median (range)	5.95 (0.1-13.5)	1.38 (0-13.1)	2.17 (0-12.3)	3.5 (0-12.1)
Comorbidities, number				
0	2 (12)	2 (12)	2 (13)	6 (12)
1	4 (24)	8 (47)	7 (47)	19 (39)
2	7 (41)	4 (24)	4 (27)	15 (31)
3	4 (24)	3 (18)	2 (13)	9 (18)
Travel time to cancer center, minutes, median (range)	24 (5-45)	35 (10-120)	37 (5-240)	32 (5-240)
Previous use of activity tracker, n (%)	4 (24)	7 (41)	5 (33)	16 (33)
Activity tracker, n (%)				
Supplied with Misfit Shine	15 (88)	12 (71)	13 (87)	40 (82)
Using own Garmin or Fitbit	2 (12)	5 (29)	2 (13)	9 (18)

[a]Not applicable.

Table 2. Feasibility of study intervention.

Characteristics	Cohort 1 (n=17), n (%)	Cohort 2 (n=17), n (%)	Cohort 3 (n=15), n (%)
Log-ins, Web portal data logs (>2)	7 (41)	11 (65)	15 (100)
Questionnaires, completed at follow-up	12 (71)	11 (65)	12/14[a] (86)
Log-ins and questionnaires combined	6 (35)	11 (65)	12/14[a] (86)

[a]One patient death reported during study period.

Figure 2. Mean log-ins to record symptoms per week for each cohort.

Figure 3. Proportion of participants who attained their step goal.
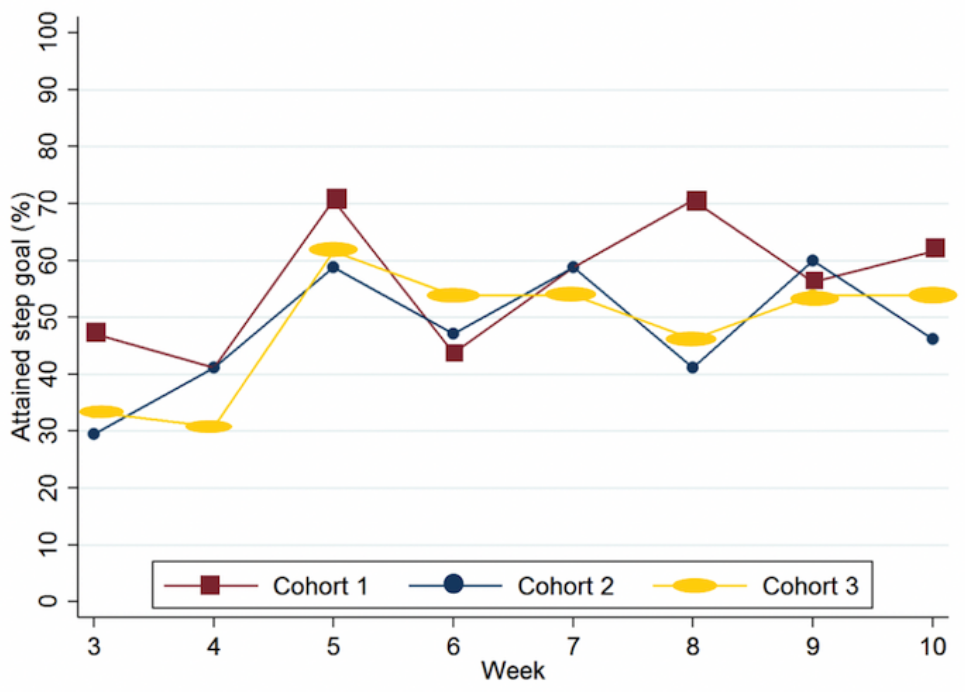
Goal Attainment

The number of patients who attained their daily step count goal are summarized for each week of the study in Figure 3. Week 1 and 2 of the intervention were used to work out an attainable goal, therefore data for weeks 3 to 10 are shown. A number of participants in each cohort had no activity tracker data as the weeks progressed, suggesting the activity tracker was no longer in use. At week 10 of the intervention, we received activity tracker data from 76% (13/17) of participants in cohort 1, 76% (13/17) of participants in cohort 2, and 93% (13/14) of participants in cohort 3, noting one participant died in cohort 3.

Activity Tracker Data

Daily step count has been summarized at week 1 and week 10 for each cohort in Table 3.

Acceptability of Device

The activity tracker given to participants (Misfit Shine) was generally well received, with participants stating they liked it and found it acceptable to use.

> *Yes. I absolutely love the thing that you wear on your arm. I'm just elated. I think it's really motivating and I really enjoyed having that.* [Participant 3, cohort 1]

> *Absolutely, absolutely I loved it. It was really good to see exactly what it took to get to my goal each day and I love it. To the point I'm going to get another one and it's going to be a part of my life to have a fitness tracker now.* [Participant 3, cohort 3]

Some participants reported concerns about the accuracy of the device, in particular sleep tracking.

> *So, I don't think the [sleep] data is accurate, so I didn't bother.* [Participant 3, cohort 2]

Patient-Reported Outcome Questionnaires

Changes in PRO questionnaire results from the initial intake (week 1) to end of program (week 10) are summarized below for each of the 3 cohort groups.

The ESAS was used to report pre-post symptom changes such as fatigue and pain and is reported in Table 4. A lower ESAS score indicates a lower symptom burden.

Change in patient-reported self-efficacy was reported using the CBI-B. A lower CBI-B score reflects improved self-efficacy. At a 95% confidence interval, cohort 1 had a change in score of –0.33 (–15.2 to 14.6), cohort 2 had a change of –6.78 (–21.9 to 8.3), and cohort 3 had a change of –2.18 (–11.9 to 7.6).

Change in patient-reported HRQoL was reported using the FACT-G and reported in Table 5. Lower scores on FACT-G indicate better HRQoL across 4 domains.

Weekly Email Learning Engagement

The most accessed educational topic was sleep (week 6) with 95% (16/17) and 93% (13/14) of participants in cohorts 2 and 3 opening the email, respectively, followed by nutrition (week 3) with 80% (14/17) and 93% (14/15) in cohorts 2 and 3, respectively, opening the email (see Table 6). A majority of participants in both groups engaged with educational content each week.

Practitioner Weekly Time

Participants in cohorts 1 and 2 received no direct health professional contact following onboarding. Cohort 3 received weekly personalized coaching messaging for which time data were collected. Weekly, the mean time spent by the health professional to interact with each participant was 11 minutes.

Acceptability of Web Portal Educational Content

Cohorts 2 and 3 had access to a curated selection of Web portal educational information including written and video content. The participants perceived the portal educational content to be acceptable.

> *I thought it was really good, the information was presented in a glaring manner.* [Participant 4, cohort 2]

Some respondents reported they would have preferred tailoring of content to their stage of cancer treatment and care.

> *Some of the stuff I might have been interested in two and a half years ago, but it's not so relevant to me now.* [Participant 5, cohort 3]

Acceptability of Personalized Messaging

Qualitative interview data for those participants in cohort 3 who received personalized messaging revealed it was acceptable and provided additional motivation to help them use the Web portal and attain goal.

> *And it actually made me happy. It gave me a sense of achievement, especially when the [exercise physiologist] would send the message saying, "Wow, you've matched your goals. Well done." I felt a lot of pride in myself.* [Participant 1, cohort 3]

> *...it made me just push myself and even on days when I didn't want to walk I thought no my steps were down and I should get out there and go for a walk and so on.* [Participant 3, cohort 3]

Reflecting on the lack of interaction, some participants in cohorts 1 and 2 remarked they would have liked more contact with their health professional throughout the study.

> *...but if someone motivated me to say, "Would you like to come in and have a look at that app again and I'll show you what it does. And let's see how you're going with it," then that might have...I might have engaged with it a bit more...or at all.* [Participant 3, cohort 1]

Table 3. Secondary outcome: change in daily step count.

Daily step count	Cohort 1, median (IQR)[a]	Cohort 2, median (IQR)	Cohort 3, median (IQR)
Week 1	7549 (4835-10,138)	7193 (4206-9998)	6862 (4980-9202)
Week 10	8889 (6545-11,358)	7762 (5566-11,311)	8579 (6060-11,008)

[a]IQR: interquartile range.

Table 4. Secondary outcome: change in patient-reported symptom scores (Edmonton Symptom Assessment Scale).

Symptom	Cohort 1			Cohort 2			Cohort 3		
	Week 1 (n=17), median (IQR)[a]	Week 10 (n=11), median (IQR)	Change, median (IQR)	Week 1 (n=17), median (IQR)	Week 10 (n=11), median (IQR)	Change, median (IQR)	Week 1 (n=15), median (IQR)	Week 10 (n=11), median (IQR)	Change, median (IQR)
Pain	2 (0 to 3)	4 (1 to 5)	0 (0 to 1)	2 (0 to 3)	0 (0 to 2)	0 (–3 to 0)	2 (0 to 5)	1 (0 to 1)	–1 (–2 to 0)
Fatigue	4 (2 to 5)	5 (2 to 7)	0 (–1 to 3)	4 (3 to 5)	3 (2 to 4)	–1 (–2 to 2)	4 (0 to 5)	1 (1 to 2)	0 (–4 to 1)
Nausea	0 (0 to 0)	1 (0 to 3)	1 (0 to 3)	0 (0 to 2)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)
Depression	0 (0 to 1)	1 (0 to 3)	0 (0 to 2)	0 (0 to 3)	1 (0 to 4)	0 (0 to 1)	0 (0 to 1)	0 (0 to 1)	0 (0 to 0)
Anxiety	1 (0 to 2)	1 (0 to 3)	0 (–1 to 0)	0 (0 to 3)	1 (0 to 3)	1 (0 to 2)	0 (0 to 3)	0 (0 to 0)	0 (–3 to 0)
Drowsiness	2 (0 to 3)	2 (0 to 5)	3 (0 to 4)	0 (0 to 3)	0 (0 to 4)	0 (–3 to 1)	0 (0 to 4)	1 (0 to 3)	0 (–1 to 2)
Shortness of breath	0 (0 to 2)	0 (0 to 3)	0 (–1 to 1)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 3)	0 (0 to 2)	0 (–2 to 1)
Appetite	0 (0 to 2)	0 (0 to 4)	1 (0 to 2)	3 (0 to 5)	2 (0 to 4)	0 (–3 to 1)	1 (0 to 3)	0 (0 to 4)	0 (–1 to 0)
Sleep	5 (3 to 5)	2 (0 to 5)	0 (–3 to 0)	5 (3 to 6)	4 (3 to 5)	0 (–2 to 0)	5 (1 to 8)	2 (1 to 4)	–1 (–3 to 1)
Feeling of wellbeing	4 (2 to 5)	3 (3 to 4)	0 (–1 to 1)	4 (3 to 5)	3 (3 to 6)	–1 (–2 to 1)	3 (2 to 5)	2 (1 to 3)	0 (–1 to 1)
Financial distress	0 (0 to 2)	0 (0 to 2)	0 (–1 to 1)	1 (0 to 5)	1 (0 to 5)	0 (–2 to 1)	0 (0 to 3)	0 (0 to 2)	0 (0 to 0)
Spiritual pain	0 (0 to 0)	0 (0 to 3)	0 (0 to 1)	0 (0 to 1)	0 (0 to 1)	0 (–1 to 0)	0 (0 to 2)	0 (0 to 1)	0 (0 to 0)
Sadness	2 (0 to 2)	2 (1 to 4)	1 (0 to 2)	1 (0 to 2)	1 (0 to 6)	0 (0 to 2)	0 (0 to 3)	0 (0 to 1)	0 (–2 to 0)
Vomiting	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)
Numbness/tingling	3 (1 to 3)	3 (3 to 4)	0 (–1 to 1)	0 (0 to 1)	0 (0 to 2)	0 (0 to 1)	1 (0 to 3)	1 (0 to 4)	–1 (–1 to 0)
Dry mouth	0 (0 to 2)	0 (0 to 2)	0 (0 to 0)	0 (0 to 2)	0 (0 to 0)	0 (–1 to 0)	0 (0 to 4)	0 (0 to 1)	0 (–2 to 0)
Memory	4 (3 to 5)	5 (4 to 6)	0 (0 to 2)	4 (2 to 5)	4 (2 to 5)	0 (–1 to 1)	2 (1 to 3)	1 (0 to 2)	0 (–1 to 1)
Distress	0 (0 to 3)	0 (0 to 2)	0 (–2 to 0)	0 (0 to 1)	2 (0 to 3)	2 (0 to 3)	0 (0 to 1)	0 (0 to 0)	0 (0 to 0)

[a]IQR: interquartile range.

Table 5. Secondary outcome: change in patient-reported quality of life (Functional Assessment of Cancer Therapy–General).

Domain	Cohort 1			Cohort 2			Cohort 3		
	Week 1 (n=17), median (IQR)[a]	Week 10 (n=17), median (IQR)	Change, median (IQR)	Week 1 (n=17), median (IQR)	Week 10 (n=17), median (IQR)	Change, median (IQR)	Week 1 (n=15), median (IQR)	Week 10 (n=15), median (IQR)	Change
Physical	7 (5 to 10)	2 (0 to 8)	–2 (–8 to 0)	7 (5 to 12)	0 (0 to 4)	–4 (–10 to 0)	4 (2 to 11)	3 (0 to 10)	0 (–4 to 0)
Social	22 (16 to 24)	11 (0 to 22)	–9 (–17 to 0)	21 (15 to 23)	0 (0 to 18)	–10 (–22 to –3)	22 (16 to 24)	15 (0 to 21)	–3 (–11 to 0)
Emotional	7 (5 to 8)	6 (0 to 9)	0 (–6 to 1)	6 (5 to 10)	0 (0 to 6)	–3 (–7 to 1)	5 (5 to 11)	6 (0 to 9)	0 (–5 to 1)
Functional	17 (13 to 20)	12 (0 to 16)	–8 (–14 to 0)	14 (12 to 17)	0 (0 to 16)	–4 (–13 to 1)	16 (7 to 18)	14 (0 to 19)	0 (–7 to 2)

[a]IQR: interquartile range.

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Table 6. Secondary outcome: percentage of emails opened.

Week and topic	Cohort 2 (n=17), n (%)	Cohort 3 (n=15)[a], n (%)
Week 1: Introduction	14 (82)	11 (73)
Week 2: Fatigue	13 (76)	12 (80)
Week 3: Nutrition	14 (82)	14 (93)
Week 4: Exercise	10 (59)	13 (87)
Week 5: Emotional health	12 (71)	11 (79)[a]
Week 6: Sleep	16 (94)	13 (93)[a]
Week 7: Pain	11 (65)	12 (86)[a]
Week 8: Qi Gong	14 (82)	11 (79)[a]
Week 9: Finances	12 (71)	13 (93)[a]
Week 10: Completion	11 (65)	11 (79)[a]

[a]After week 4, n=14 due to patient death during study period.

Participant Survey Feedback

Overall, the participant satisfaction with the intervention was high, with 83% (33/40) of respondents extremely satisfied or moderately satisfied with the intervention. Satisfaction with the activity tracker (Misfit Shine) was high, with 77% (31/40) of respondents extremely or moderately satisfied with using the device. In addition, 73% (29/40) of respondents found the Web portal extremely or moderately easy to use.

Discussion

Principal Findings

The results of this study demonstrate the feasibility of using a remote digital health intervention to track and promote physical activity levels and function and that personalized coaching messaging appears to increase participant engagement. The Web portal was found to be acceptable by the majority of participants, and satisfaction with its use was high across all cohorts. Participants accessing the Web portal varied widely in engagement, but overall participants in cohorts 2 and 3 interacted more with the Web portal compared to cohort 1.

The attrition rate was lowest in cohort 3, which had personalized contact, and highest in cohort 1, which had no personalized contact. This suggests simply giving patients access to a tool such as the Web portal was not sufficient to keep patients engaged for more than a short time. Regular interaction between patients and health professionals such as that provided by personalized messaging may lead to increases in participant accountability and may be a key method to improving engagement. Personalized messages are seen to be most effective when tailored to each patient rather than generalized to broader audiences [10,11,19].

The impact of messaging on engagement of participants was clear from the qualitative responses, where they were stated to be motivational and helpful. Further focus on the frequency, length, and content of personalized messaging will be an important development area for the future.

This research also builds on previous studies, such as those conducted by Huh et al [20] and Rosenberg et al [21], which indicated that patients support the idea of their care team having access to their wearable activity data. Health professionals often do not have access to these data sets without the patient bringing in their device to a consultation. This presents problems for patients who are living in rural and remote areas and may increase the need for face-to-face appointments. In our study, the information from the wearable devices was able to be accessed remotely, which enabled more individualized feedback to cohort 3.

Our study showed that real-time monitoring of symptoms and treatment-related side effects can be reported through remote systems and the use of these systems is acceptable, which is consistent with previous research [22-23]. Furthermore, in addition to increased patient HRQoL, a recent randomized controlled trial reported that there may be additional benefits to patients' overall survival for those who monitor their symptoms longitudinally [24].

PRO completion rate for cohorts 1 and 2 was lower than for cohort 3. Only two automated attempts to encourage participants to provide follow-up PRO data were made to each cohort during the study. Further individualized contact may be needed to collect such data when using remote models of care.

The usefulness of educational material is likely to be dependent on participants' stages of disease, cancer treatment, and trajectory. Tailoring of educational content in this Web portal was insufficient to account for individual needs and stages of treatment, recovery, and health literacy. This finding is supported by previous reviews in various populations that indicate digital health interventions need to focus on increasing personal relevance of content [25-27]. Further research is needed to determine which type of educational content is most appropriate and useful at various time points in a patients' care pathway.

The inclusion of qualitative interviews provided important insights into participant perspectives of the intervention. These

data have been helpful in conceptualizing changes to the Web portal, the intervention, and future research studies. Codesigned health systems have been shown to increase functionality, specificity, and uptake [28].

Reduced physical activity levels during cancer treatment can lead to increased symptom burden and, consequently, reduced quality of life. There is no single solution to facilitate positive behavior change across a population of people with cancer in active treatment; however, the innovative use of technology may benefit a proportion of the population.

Limitations

More participants in cohorts 2 and 3 were receiving chemotherapy during the study period, and cohort 1 participants had been off treatment longer than the others. Since these differences were not accounted for in the data provided, it is unknown what impact they had on the findings.

The study also had small group sizes and heterogeneous cancer diagnoses of the participants. Broad inclusion criteria were appropriate for this feasibility study to increase generalizability to the larger population of cancer survivors. However, future studies may need to consider the specific requirements of different cancer diagnoses and stages of disease in order to provide appropriately tailored interventions effectively.

All participants had access to a mobile phone, which may define them as different from the general cancer population and could result in overestimation of the feasibility and acceptability of the program. However, only 6% of screened participants were excluded due to lack of a mobile phone, suggesting that the study group was representative of the general cancer population in regard to the use of mobile phones.

The utility of Web portals for clinicians and clinician-patient relationships is an important benefit of such systems. This study did not include data review or interactions with medical specialists and was limited to interactions with an exercise physiologist.

Future Iterations

Development of an automated alert algorithm focused on a combination of PRO measures, symptom tracking, and activity monitor data could improve functionality of the Web portal. For example, if pain above a set value for a set number of days were reported, this would trigger a clinical message to the patient's care team for investigation. Alerts and flagging mechanisms triggering clinician intervention for patients with cancer to report their symptoms have been shown to be effective in several studies; however, none of these studies included integration of wearable activity monitor data [29-32].

The Web portal was not fully integrated into care pathways and the hospital electronic medical record (EMR) as this integration was cost- and time-prohibitive when developing this study. Integration of data into the EMR is a potential area of future development for this Web portal. EMR integration provides opportunity for multiple members of the patient's care team to provide remote monitoring and support. Integration of remote tracking data into the EMR also increases clinical metrics available to clinicians to inform decision making and referral practices. For example, a patient reporting cancer-related fatigue corresponding with low physical activity levels could be appropriately referred to a local exercise oncology professional for individualized exercise counseling and prescription.

Further studies may also consider the inclusion of health economic data. Health professionals are typically time poor, and although this study indicated that weekly time spent for each participant receiving coaching was minimal, future research should report this in greater detail as well as the travel time saved by patients.

Our findings from this prospective cohort study indicate it is a feasible digital health tool for people with a history of cancer. Tailored messaging is needed to maximize engagement in this population. It is anticipated that the results of this pilot will inform the design of an adequately powered randomized controlled trial assessing the efficacy of this intervention.

Authors' Contributions

All authors contributed to the conception of the study. MM analyzed the data and wrote the manuscript. All authors read the manuscript, provided edits, and approved its final version.

Conflicts of Interest

None declared.

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Abbreviations

CBI-B: Cancer Behavior Inventory–Brief Version
EMR: electronic medical record
ESAS: Edmonton Symptom Assessment Scale
FACT-G: Functional Assessment of Cancer Therapy–General
HRQoL: health-related quality-of-life
IQR: interquartile range
PRO: patient-reported outcome

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Novel mHealth App to Deliver Geriatric Assessment-Driven Interventions for Older Adults With Cancer: Pilot Feasibility and Usability Study

Kah Poh Loh[1], BMedSci, MBBCh BAO; Erika Ramsdale[1], MD; Eva Culakova[2], PhD; Jason H Mendler[1], MD, PhD; Jane L Liesveld[1], MD; Kristen M O'Dwyer[1], MD; Colin McHugh[1], MD; Maxence Gilles[1], BS; Terri Lloyd[1], BS; Molly Goodman[1], BS; Heidi D Klepin[3], MD, MS; Karen M Mustian[2], PhD, MPH; Rebecca Schnall[4], RN, PhD; Supriya G Mohile[1], MD, MS

[1]Division of Hematology/Oncology, James P Wilmot Cancer Institute, University of Rochester Medical Center, Rochester, NY, United States
[2]Department of Surgery (Cancer Control), James P Wilmot Cancer Institute, University of Rochester Medical Center, Rochester, NY, United States
[3]Section on Hematology/Oncology, Department of Internal Medicine, Wake Forest Baptist Health, Winston Salem, NC, United States
[4]School of Nursing, Coumbia University, New York City, NY, United States

Corresponding Author:
Kah Poh Loh, BMedSci, MBBCh BAO
Division of Hematology/Oncology
James P Wilmot Cancer Institute
University of Rochester Medical Center
601 Elmwood Avenue
Box 704
Rochester, NY, 14642
United States
Phone: 1 4133069767
Email: kahpoh_loh@urmc.rochester.edu

Abstract

Background: Older patients with cancer are at an increased risk of adverse outcomes. A geriatric assessment (GA) is a compilation of reliable and validated tools to assess domains that are predictors of morbidity and mortality, and it can be used to guide interventions. However, the implementation of GA and GA-driven interventions is low due to resource and time limitations. GA-driven interventions delivered through a mobile app may support the complex needs of older patients with cancer and their caregivers.

Objective: We aimed to evaluate the feasibility and usability of a novel app (TouchStream) and to identify barriers to its use. As an exploratory aim, we gathered preliminary data on symptom burden, health care utilization, and satisfaction.

Methods: In a single-site pilot study, we included patients aged ≥65 years undergoing treatment for systemic cancer and their caregivers. TouchStream consists of a mobile app and a Web portal. Patients underwent a GA at baseline with the study team (on paper), and the results were used to guide interventions delivered through the app. A tablet preloaded with the app was provided for use at home for 4 weeks. Feasibility metrics included usability (system usability scale of >68 is considered above average), recruitment, retention (number of subjects consented who completed postintervention assessments), and percentage of days subjects used the app. For the last 8 patients, we assessed their symptom burden (severity and interference with 17-items scored from 0-10 where a higher score indicates worse symptoms) using a clinical symptom inventory, health care utilization from the electronic medical records, and satisfaction (6 items scored on a 5-point Likert Scale for both patients and caregivers where a higher score indicates higher satisfaction) using a modified satisfaction survey. Barriers to use were elicited through interviews.

Results: A total of 18 patients (mean age 76.8, range 68-87) and 13 caregivers (mean age 69.8, range 38-81) completed the baseline assessment. Recruitment and retention rates were 67% and 80%, respectively. The mean SUS score was 74.0 for patients and 72.2 for caregivers. Mean percentage of days the TouchStream app was used was 78.7%. Mean symptom severity and interference scores were 1.6 and 2.8 at preintervention, and 0.9 and 1.5 at postintervention, respectively. There was a total of 27 clinic calls during the intervention period and 15 during the postintervention period (week 5-8). One patient was hospitalized

during the intervention period (week 1-4) and two patients during the postintervention period (week 5-8). Mean satisfaction scores of patients and caregivers with the mobile app were 20.4 and 23.4, respectively. Barriers fell into 3 themes: general experience, design, and functionality.

Conclusions: TouchStream is feasible and usable for older patients on cancer treatment and their caregivers. Future studies should evaluate the effects of the TouchStream on symptoms and health care utilization in a randomized fashion.

Introduction

Scope of the Problem

Older adults are more likely to receive cancer treatments with the increasing availability of these treatments possessing superior toxicity profiles and greater ease of administration. Compared to their younger counterparts, older adults have a higher prevalence of comorbidity, disability, and geriatric syndromes (eg, falls, functional decline, and delirium), putting them at an increased risk of treatment-related toxicities and adverse outcomes such as hospitalization and death [1-4]. A geriatric assessment (GA) is a compilation of reliable and validated tools to assess essential domains that are predictors of morbidity and mortality [5]. A GA can also guide interventions based on the impairments noted on the assessment, such as delivery of specific diet recommendations for nutritional deficits, referral to physical therapy and promotion of physical activity for physical performance problems, and assessment of medication adherence for patients with multiple health problems and are on many medications [6,7]. These evidence-based recommendations have been shown to improve outcomes such as nutritional status, frailty, and chemotherapy tolerance in older adults [8-11]. Nevertheless, implementation of GA-driven interventions is low in the oncology community [12,13].

Mobile health (mHealth) apps have the potential to monitor and deliver GA-driven interventions at home. Recent advances in information technology have allowed health care professionals to utilize apps in clinical practice [14,15]. In the cancer setting, mHealth apps have been designed for various uses which include providing education and support [16], monitoring symptoms and facilitating symptom reporting [17-20], monitoring medication adherence [21], promoting physical activity [22,23], and monitoring nutritional status and surgical care [24]. These apps collectively support a number of GA-driven interventions, but generally they are specialized to have a single focus (such as promoting physical activity), and only a limited number of them have been tailored specifically to older adults with cancer who have complex health care needs and for their caregivers who themselves frequently have health issues [25].

Study Objectives

In this study, we utilized the TouchStream app [26]. It was designed by TouchStream Solutions (Rochester, New York, United States) with the goal of helping people live independently. Currently, it is being used primarily for patients with developmental disabilities. To evaluate if older adults with cancer can use the technology, we conducted this study to (1)

evaluate the feasibility and usability of the TouchStream app to deliver GA-driven interventions and (2) identify barriers to use and issues with existing design and functionality. As an exploratory aim, we gathered preliminary data on symptom burden and health care utilization.

Methods

Study Design, Setting, and Sample

This prospective single-arm pilot study was conducted at the University of Rochester Medical Center (Rochester, New York, United States) from January to December 2017. Patients were recruited if they were aged ≥65 years, diagnosed with a solid tumor or hematologic malignancy, on systemic cancer treatment, able to understand and speak English, able to provide informed consent, and had a life expectancy of 6 months or greater. Patients were given the option to select a caregiver to participate in the study. A caregiver was defined as "a valued and trusted person in a patient's life who is supportive in health care matters by providing valuable social support or direct assistive care." The caregiver accompanies the patient to medical appointments, can listen and give thoughtful advice, and might be a family member, partner, friend, or professional caregiver. Caregivers had to be ≥21 years and able to understand spoken English and provide informed consent. Patients and caregivers were not required to have electronic devices with internet access to participate in the study as internet access was provided through the device using a wireless carrier.

The TouchStream App

The TouchStream app was developed by TouchStream Solutions (Rochester, New York, United States). The app displays a list of activities entered from the Web portal and arranges them by the time of day (Figure 1). These activities include doctor appointments, medication reminders, monitoring, vital signs (eg, weight, blood pressure), surveys (eg, symptoms), contingency plans (eg, fever, constipation), and physical activity (in the form of daily steps). The study team entered activities tailored to the patient onto the Web portal before the start of the study based on the GA impairments (Table 1). At the appropriate date and time, the tablet speaks through a voice avatar reminding patients/caregivers to complete these activities. The app is connected to a Web portal (Figure 2). The Web portal is used to enter or remove activities, and it can be accessed using a desktop or laptop computer. The home page of the Web portal displays the patient's information and a list of activities followed by the date and time and whether the tasks have been completed. This display allows the caregivers/patients and the study team

to monitor for completion and compliance. All information entered on the Web portal is transferred to the app and vice versa. TouchStream stores data on both the tablet and TouchStream server. On the tablet, the data is encrypted, and the back-end server hosts a Microsoft Structured Query Language Server Database.

Study Procedures

Once informed consent was obtained, all patients completed baseline questionnaires (on paper) that captured demographics and clinical information, their previous experience with electronic devices (ie, if they have access to any electronic devices and the total hours spent per week using these devices), and a symptom survey (see "Outcomes"). Clinical information was cross-checked with the electronic medical records for accuracy. Caregivers (available for 13 patients) also provided information on baseline demographics and their experience with electronic devices. All patients also underwent a baseline GA included measures of comorbidity (Older Americans Resources and Services (OARS) physical health section [27]), physical function (activities of daily living (ADL) [28], instrumental activities of daily living (IADL) [29], number of falls in the past year and Short Physical Performance Battery (SPPB) [30]), cognition (Blessed Orientation-Memory-Concentration (BOMC) [31] and Montreal Cognitive Assessment (MoCA) [32]), number of medications, social support (Medical Outcomes Study (MOS) Social Support Survey [33]), nutritional status (body mass index (BMI) and self-reported weight loss in the past 6 months) [34,35], and psychological status (Geriatric Depression Scale-15 (GDS-15) [36]). All measures were self-reported except for SPPB, BOMC, and MoCA that were performed by a study coordinator. The GA was performed to uncover baseline impairments as well as to guide interventions or activities delivered through the TouchStream app (Table 1). The list of

GA-driven interventions was based on a prior study and represented a consensus from geriatric oncology experts on how GA can guide nononcologic interventions [6]. Based on this, we selected interventions that can be delivered through the mobile app and adapted them for our study.

After the baseline assessment, the study team entered activities tailored to the patient onto the Web portal. Patients and caregivers were provided with a touchscreen tablet connected to a data plan for internet access and preloaded with the TouchStream app in addition to chargers and instruction manuals for use at home. Patients were initially also provided with a speaker and a cable that connects the speaker to the tablet, but these were removed during the study period for simplicity. A stylus was also provided for use if patients had difficulty with the touchscreen. The study team provided a brief tutorial on how to use the TouchStream app and Web portal to both the patients and caregivers. Patients were then asked to use the app for the following 4 weeks, and caregivers were asked to assist the patients if needed. Patients and caregivers were also given the option to access the Web portal to enter additional activities if they wished to during the study period.

They were asked to place the tablet at a place of choice (eg, kitchen, living room, bedroom, or study room). Any activities delivered through the app were for the patients and primarily informational for the caregivers. Patients were encouraged to bring the tablet with them when they left the house. The study team accessed the Web portal at least once weekly and on an as-needed basis to enter new activities and monitor existing activities. If any concerns were noted (eg, patient-reported pain for several days in a row), the study team communicated these concerns to the primary oncology team. During this time, the study team and TouchStream Solutions were available to both the patients and caregivers for questions and technical assistance.

Figure 1. Tablet showing the interface of the mobile application.

- "**To do'**" includes: Medication, Weight, Blood Sugar and Blood Pressure activities.
- "**Appointment**" includes: Social Events and Doctor appointments.

Table 1. Geriatric assessment domains, tools, and interventions.

Domain	Tool	Score signifying impairment	Interventions/activities
Comorbidity	OARS[a] physical health section	• ≥5 illnesses that affected them by a "great deal" • ≥3 illnesses that affected them by "somewhat," or vision/hearing rated as "fair, poor, or totally blind/deaf"	• Access to a list of the patient's medical conditions
Physical function	• ADL[b] • IADL[c] • Fall history • SPPB[d]	• Any ADL or IADL impairment • Fall(s) within the past year • ≤9 on SPPB	• Handouts on energy conservation via the tablet with reminders • Exercise and fall counseling provided through the tablet • Daily steps monitoring and reminders for increasing physical activity[e]
Cognition	• BOMC[f] • MoCA[g]	• >4 on BOMC • <26 on MoCA	• Reminders for medications and appointments
Polypharmacy	No. of total medications	≥5 medications	• Medication (scheduled and as needed) reminders and monitoring • Provide instructions including dosages, frequencies, and indications for all medications to patients and caregivers • Automated reminders to caregivers if patients missed their medications
Social support	MOS[h] medical social support	Any deficit noted	• Easy access to caregiver and health care teams' contact information
Nutrition	BMI[i]	• BMI of <21 • >5% weight loss in the last six months	• Provide recommendations and reminders for hydration • Nutritional handouts
Psychological health	GDS-15[j]	≥5 on GDS-15	• Monitoring of distress and mood
All patients	__[k]	—	• Cancer treatment information including regimen and dose • Contingency plans related to their treatment (eg, constipation, diarrhea, and fever) • Symptom monitoring

[a]OARS: Older Americans Resources and Services.

[b]ADL: activities of daily living.

[c]IADL: instrumental activities of daily living.

[d]SPPB: Short Physical Performance Battery.

[e]Patients were encouraged to enter the number of steps during the study if they have a step counter. If they did not have a step counter, they were asked to enter the approximate number of steps based on distance walked.

[f]BOMC: Blessed Orientation-Memory-Concentration.

[g]MoCA: Montreal Cognitive Assessment.

[h]MOS: Medical Outcomes Study.

[i]BMI: body mass index.

[j]GDS-15: Geriatric Depression Scale-15.

[k]Not applicable.

Figure 2. Interface of the Web portal

Textbox 1. The system usability scale questionnaire.

1. I think I would like to use this system frequently.

2. I found the system unnecessarily complex.

3. I found the system was easy to use.

4. I think I would need the support of technical person to be able to use this system.

5. I found the various functions in this system were well integrated.

6. I thought there was too much inconsistency in this system.

7. I would imagine that most people would learn to use this system very quickly.

8. I found the system very cumbersome to use.

9. I felt very confident using the system.

10. I needed to learn a lot of things before I could get going with this system.

At the end of the study period, patients and caregivers returned to meet with the study team for a semistructured interview (approximately 30 minutes to an hour) to obtain feedback about the app, including functionality, design, and barriers to use. The interviews were audio-recorded. Both patients and caregivers also completed postintervention assessments that included usability and symptom surveys.

Outcomes

The primary outcome was usability assessed by the system usability scale (SUS). The SUS is a standardized questionnaire commonly used to assess participants' perceptions of usability of an electronic system or device [37,38]. The scale consists of 10 items, and each item is rated on a 5-point Likert scale (Textbox 1). A score higher than 68 is considered above average in the evaluation of mHealth apps [37,38].

Other feasibility metrics included recruitment rate (no. of subjects recruited divided by the no. of patients approached), retention rates (no. of subjects consented who completed postintervention assessments), the percentage of days the tablet was turned on, and percentage of days subjects used the app.

The scores for each question are converted to a new number using the following formula: odd-numbered questions are calculated as the scale position minus 1, and even-numbered questions are calculated as 5 minus the scale position. The scores are added together and multiplied by 2.5 to get the final score, with a range of 0 to 100.

Additionally, as prespecified in the protocol, for the last 8 patients enrolled in the study, we gathered data on patients' and caregivers' satisfaction as well as patients' symptom burden and health care utilization. The modified satisfaction survey consisted of 6 items, and patients and their caregivers (if available) rated each question on a 5-point Likert scale, with a total score of 30 and a higher score indicating greater satisfaction [39]. Symptom burden was assessed using a clinical symptom inventory [40]. Patients were asked to rate the severity of 11 symptoms (eg, pain, nausea, disturbed sleep) at its worst in the past week from 0 (not present) to 10 (as bad as you can imagine). They were also asked to rate how the symptoms had interfered with their lifestyle in 6 domains: (1) general activity, (2) mood, (3) work, (4) relations with other people, (5) walking, and (6) enjoyment of life. Health care utilization during the

study period (week 1 to 4) and postintervention period (week 5-8) was obtained from the electronic medical records by the study team. Utilization metrics captured included numbers and types of clinic calls, number of missed appointments, and hospitalizations.

Analyses

Descriptive analyses (count, mean, SD, range, and percentage as appropriate) were used to describe the study sample demographics and GA findings, feasibility metrics, and outcomes. Qualitative interviews were transcribed. Two coders reviewed and coded these transcripts using conventional content analysis [41], focusing on users' experiences and their feedback on the design and functionality of the app including ease and barriers of use. Any discrepancies were resolved through discussion.

Results

Baseline Characteristics

From January to December 2017, 30 patients were approached and 20 patients and 14 caregivers consented to the study (recruitment rate 66.7%). Two patients and 1 caregiver did not complete baseline assessment (1 patients did not provide any reason while another patient had "too much going on"), resulting in a total sample of 18 patients and 13 caregivers. Table 2 shows the baseline characteristics for patients and caregivers. Mean ages of the patients and caregivers were 76.8 (SD 5.4, range 68-87) and 69.8 (SD 13.5, range 38-81), respectively. The majority of patients were male (15/18, 83%) while most caregivers were female (12/13, 92%). They were predominantly white (patients: 16/18, 89%; caregivers: 11/13, 85%) and married (patients: 13/18, 72%; caregivers: 11/13, 85%). More than half of the patients (12/18, 67%) and caregivers (7/13, 54%) completed college or university education. Many patients (15/18, 83%) had at least one caregiver at home, most of whom were their spouses or significant others (14/18, 78%).

Concerning the type of cancer, 78% (14/18) of the patients had hematologic malignancies. Most of these patients were on hypomethylating agents. The mean number of GA impairments was 4.6 (SD 1.9, range 1-7), 17% (3/18) had up to two impairments, 39% (7/18) had three to five impairments, and 44% (8/18) had six or more impairments. Table 2 shows impairments in the various domains.

Experience With Electronic Devices

Most patients and caregivers had access to electronic devices, with desktop and laptop being the common (Table 2). Among the patients, 8 of 18 (44%) had access to a mobile phone and 3 of 18 (17%) had access to a tablet or iPad. Among the caregivers, 8 of 13 (62%) had access to a mobile phone and 4 of 13 (31%) had access to a tablet or iPad. Over half (10/18, 56%) of the patients and (9/13, 69%) of the caregivers spent more than five hours a week on their own electronic devices.

Retention Rate, Usability, Feasibility, and Satisfaction

During the study period 1 of the 18 (6%) patients left as she was no longer interested in the study. Another (1/16, 6%) patient and (1/13, 8%) caregiver had hearing difficulties and did not want to continue being involved in the study. One of the 13 (8%) caregivers did not complete the postintervention assessment due to the inability to come to the study visit. The retention rates for patients and caregivers were 89% (16/18) and 85% (11/13), respectively.

The mean SUS score was 74.0 (SD 14.5, range 22.5-100.0) for patients and 72.2 (SD 22.2, range 45.0-92.5) for caregivers. Mean percentage of days the tablet was turned on was 88.7% (SD 14.1, range 47-100), and the mean percentage of days the mobile app was used was 78.7% (SD 18.6, range 37-100). Ninety-four percent used the app for more than 50.0% of the study days.

Mean satisfaction scores of patients (n=8) and caregivers (n=5) with the TouchStream app were 20.4 (SD 6.6) and 23.4 (SD 8.1), respectively (Table 3).

Symptom Burden and Health Care Utilization

Mean symptom severity score was 1.6 (SD 1.0, range 0.2-4.6) at preintervention and 0.9 (SD 0.6, range 0-3.5) at postintervention. Mean symptom interference score was 2.8 (SD 1.2, range 0-4.2) at preintervention and 1.5 (SD 1.5, range 0-5.3) at postintervention.

Among the 8/18 (44%) patients for whom health care utilization was assessed, there was an average of 3.4 (total=27, SD 3.1, range 1-12) clinic calls during the intervention period (week 1-4) and 1.9 clinic calls (total=15, SD 1.6, range 0-5) during the postintervention period (week 5-8). The majority of phone calls were related to appointments, followed by symptom reporting, and medication advice. One of 18 (6%) patients was hospitalized during the intervention period (week 1-4) and 2/18 (11%) patients during the postintervention period (week 5-8). Two of 18 (11%) patients had missed appointments due to factors unrelated to cancer or its treatment during the intervention period, and none during the postintervention period.

Semistructured Interviews

Theme 1: General Experience

Many patients (10/16, 63%) and caregivers (8/11, 73%) appreciated and enjoyed the experience, and saw the value of the TouchStream app. Four patients (4/16, 25%) commented that the app would be good for someone living alone and 1 patient (6%) suggested that it would be helpful for home care nurses to help with home monitoring. It could also be useful patients who have memory impairment. One patient thought that the app helped him connect to the team more easily.

> *It is an exceptionally good idea to have a companion on the team. You extended the team back into my house, and that was great.* [Patient #13, male]

Table 2. Baseline demographic and clinical characteristics, geriatric assessment impairment, and patient/caregiver experience with electronic devices.

Variables	Patient (n=18), n (%)	Caregiver (n=13), n (%)
Demographic and clinical characteristics		
Age in years, mean (SD, range)	76.8 (5.4, 68-87)	69.8 (13.5, 33-81)
Gender		
Male	15 (83)	1 (8)
Female	3 (17)	12 (92)
Race		
White	16 (89)	11 (85)
Other	2 (11)	2 (15)
Marital status		
Married	13 (72)	11 (85)
Long-term committed significant other	2 (11)	1 (8)
Widow	3 (17)	0
Divorce	0	1 (8)
Education level		
Postgraduate	5 (28)	4 (31)
College/university	7 (39)	3 (23)
Some college/university	4 (22)	3 (23)
High school/GED[a] or lower	2 (11)	3 (23)
Caregiver(s) at home[b]		
Spouse/significant other	14 (78)	—
Child/children	1 (6)	—
Grandchild/grandchildren	2 (11)	—
None	3 (17)	—
Caregiver(s) not living at home[b]		
Child/children	5 (28)	—
Other relative(s)	3 (17)	—
Friend(s)	2 (11)	—
None	9 (50)	—
Relationship with the patient		
Spouse/significant other	—	11 (85)
Child/children	—	1 (8)
Other relative	—	1 (8)
Cancer subtype		
Leukemia	8 (44)	—
Myelodysplastic syndrome	4 (22)	—
Lymphoma	2 (11)	—
Solid tumors (esophagus, prostate, and lung)	4 (22)	—
Treatment		
Hypomethylating agents	11 (61)	—
FOLFOX[c]-based	2 (11)	—
Rituximab-based	2 (11)	—

Variables	Patient (n=18), n (%)	Caregiver (n=13), n (%)
Other	3 (17)	—
Geriatric assessment impairment		
Comorbidity (OARS[d])	12 (67)	—
ADL[e] (≥1 impairment)	0	—
IADL[f] (≥1 impairment)	9 (50)	—
Falls (≥1 in the past year)	5 (28)	—
Objective physical function (SPPB[g]; ≤9)	14 (78)	—
Cognition (BOMC[h] or MoCA[i])	10 (56)	—
Polypharmacy		
≥5 medications	16 (89)	—
Nutrition (% weight loss or BMI[j])	7 (39)	—
Depression (GDS-15[k]; ≥5)	5 (28)	—
Social support (MOS[l])	4 (22)	—
Experience with electronic devices		
Access to electronic devices[b]		
Desktop	9 (50)	10 (77)
Laptop	11 (61)	5 (39)
Mobile phone	8 (44)	8 (62)
Tablet/iPad	3 (17)	4 (31)
Total hours spent/week on own device(s)		
0-5	8 (44)	4 (31)
6-10	4 (22)	3 (23)
11-15	3 (17)	4 (31)
16-20	1 (6)	1 (8)
>20	2 (11)	1 (8)

[a]GED: General Equivalency Development.

[b]Total percentage does not equal to 100%.

[c]FOLFOX: folinic acid, fluorouracil, and oxaliplatin.

[d]OARS: Older Americans Resources and Services.

[e]ADL: activities of daily living.

[f]IADL: instrumental activities of daily living.

[g]SPPB: Short Physical Performance Battery.

[h]BOMC: Blessed Orientation-Memory-Concentration.

[i]MoCA: Montreal Cognitive Assessment.

[j]BMI: body mass index.

[k]GDS-15: Geriatric Depression Scale-15.

[l]MOS: Medical Outcomes Study.

Table 3. Patients' and caregivers' satisfaction scores with the TouchStream mobile app.

Statements and possible score (range 1-5)	Mean, (SD, range)
Patients (n=8)	
Overall satisfaction using the app	3.8 (1.2, 2-5)
The app helped improve the care coordination for my cancer	3.6 (1.3, 1-5)
The app helped with my appointments	3.0 (1.5, 1-5)
The app helped with my medications	3.6 (1.2, 1-5)
The app helped me with the management of side effects from cancer treatments	3.0 (1.4, 1-5)
I would recommend TouchStream to my family and friends	3.4 (1.2, 1-5)
Total (possible range 5-30)	20.4 (6.6, 7-30)
Caregivers (n=5)	
Overall satisfaction using the app	4.2 (1.8, 2-5)
The app helped improve the care coordination for his/her cancer	3.6 (1.7, 1-5)
The app helped with his/her appointments	3.5 (1.9, 1-5)
The app helped with his/her medications	4.6 (0.9, 1-5)
The app helped him/her with the management of side effects from cancer treatments	3.4 (1.7, 1-5)
I would recommend TouchStream to my family and friends	3.8 (1.8, 1-5)
Total (possible range 5-30)	23.4 (8.2, 10-30)

Three patients (3/16, 19%) already had involved caregivers who provided the same services as the tablet, although the caregivers themselves appreciated the mobile app. One patient (6%) felt that his primary oncology team was already very responsive. Another patient (6%) also commented that the app might be challenging for someone who is computer illiterate. Also, the app was challenging for patients who were immobile, as the tablet was set up in one place at home. Those who were still working or spending most of their time outdoors were not able to attend to the activities unless they brought the tablet with them, and they preferred the idea of a mobile phone-based app. Three patients (3/16, 19%) suggested integration with wearable technologies (eg, smartwatch).

> *I like something a little more mobile, like my iPhone, like an app on my iPhone. This (the tablet) is big but I am always near it to use it and I did answer the questions, maybe not right at the time but near it.* [Patient #5, male]

Theme 2: Design

The majority of patients/caregivers did not encounter any major barriers with the design and commented that it was easy to use (1 patient was technologically illiterate and was not able to use it). The brightness and the font and screen sizes were appropriate for this age group. Only 1 patient utilized the instruction manuals, and most commented that they only needed a few days to get used to the app. After that, they were able to use it regularly.

Three patients (3/18, 19%) had difficulty with the touchscreen and 2 of these patients were able to use it with a stylus. One patient did not like touchscreen devices and preferred to interact with a device through a physical button. One patient did not like the monotone voice from the tablet and wanted additional selections, while one caregiver (1/11, 9%) preferred the monotone voice as it could not be confused with someone in the house. One patient preferred a smaller screen size while another patient preferred one that was bigger.

> *I used the stick [stylus], I tried my finger and I realized it wouldn't always respond. I did eye screening for little kids [for my job] and you have to punch in all these things, and I do it with my finger on a touchscreen so I am used to doing that but this screen didn't seem to respond to my finger.* [Patient #20, male]

Theme 3: Functionality

The various functions including appointment, medication, and nutritional reminders were helpful to some patients and caregivers. The medication reminders (scheduled and as needed) encouraged patients/caregivers to think about the indications for the medications and whether these medications were necessary. The daily step reminders made patients conscious of their physical activity. However, these reminders were not sufficient enough to promote physical activity in and of themselves. One patient suggested that exercise recommendations from his oncologist would be helpful in combination with the app. Contingency plans related to their treatment (eg, constipation, diarrhea, fever) were helpful for patients who were receiving their first few cycles of treatment but not for those who had been receiving treatment for a longer period. The list of activities was beneficial for them to keep track of things. The reminders when conveyed through the voice avatar or listed on the tablet also generated conversation between patients and caregivers and other family members and friends who were not involved in the care of the patients.

It may be helpful for the caregiver to know what you have done and when. They can check the tablet because you (the patient) may not want to talk about it or may not have remembered. [Caregiver #13, female]

Three patients (3/16, 19%) already had a system to keep track of activities such as appointments and medications, and therefore did not find the reminders helpful. The symptom survey was overall not very helpful to patients and caregivers, as no feedback was provided on the tablet after they filled out the survey. However, 1 patient did recommend optional daily symptom surveys, recognizing that symptoms can fluctuate and may be missed by more infrequent surveys. Patients also preferred the ability to enter open-ended answers in the surveys. They were unable to ignore the reminders or erase their answers on the surveys or tasks once they had been filled out. One patient also did not want to be continuously reminded that she was sick.

It would be nice to have some daily jokes or something educational... to just always be reminded that you are sick, you need to do this, you need to do that; you know we have many stuff going on. [Patient #4, female]

Only 1 patient (1/16, 6%) and 2 caregivers (2/11, 18%) accessed the Web portal to add or remove activities. Patients and caregivers thought that the health care team should be responsible for entering these activities, and would prefer that the TouchStream system be integrated with their electronic medical records.

Discussion

Principal Findings

In this pilot study, we demonstrated that the TouchStream mobile app is a usable and feasible platform with which to deliver GA–driven interventions for older adults with cancer and their caregivers. Many older patients and caregivers own electronic devices, and they are open to participating in studies testing a mobile technology device. We also showed that it is feasible to monitor symptoms and health care utilization in this vulnerable population as part of a clinical study.

Mobile technologies are increasingly used for health purposes even among older adults who have demonstrated a lower uptake of technologies compared to younger adults [42]. These technologies have the potential to assist in care coordination activities for older adults with cancer. However, most mobile apps are not designed specifically for this population who have complex health care needs. In addition, caregivers who are involved in the care of older adults with cancer are rarely included in studies evaluating mobile technologies. In this study, we gathered input and identified barriers to the use of a mobile app from the patients' and caregivers' perspectives. These barriers are currently being used to refine and improve the TouchStream system. Also, we propose a set of recommendations for future studies that aim to evaluate apps for older adults with cancer focusing on general issues as well as the design and functionality of the app (Table 4).

Additions to the Literature

Using the Delphi technique, Mohile and colleagues [6] previously developed an algorithm to help guide nononcologic interventions based on the GA. These interventions were converted to activities and were tailored for each patient based on their GA findings. Multiple mHealth apps intended to enhance and promote self-management have been designed for patients with chronic illnesses including cancer, though most of them have generic functions and are not tailored to individual patients [43,44]. Our approach is novel and innovative as we tailored the interventions to the patients.

Table 4. Recommendations for future studies utilizing a mobile technology device.

Domain	Recommendations
General	• Coordinate study visits with clinic or treatment appointments • Simplify instructions and accompanying accessories (eg, a built-in speaker with a range of volume, one cable, and video demonstration) • Ensure internet access is reliable • Engage caregivers and treatment team including homecare nurses if possible
Design	• Provide stylus for touchscreen devices or utilize devices with buttons or a remote • Provide a list of voice options • Provide the options for smartphone and tablet-based app (for both patients and caregivers) • Provide a mobile device with varying screen sizes • Ensure the screen color, font size, and brightness are appropriate for the study population
Functionality	• Tailor the interventions and activities to each individual • If symptom reporting is incorporated, ensure that feedback is provided after symptoms have been reported • When surveys are administered, allow users to enter open-ended answers and to change or erase answers • Interface the app with electronic health records (to ensure consistency of information) • Provide a digital activity tracker when exercise intervention is recommended with the ability to sync exercise data from the tracker to the app automatically • Provide an option for users to enter activities through the mobile application in addition to the Web portal • Set an appropriate frequency for reminders (to ensure compliance but not to overburden users) • Incorporate nonmedical functions such as social and educational activities and daily jokes or words

In our patient and caregiver interviews, many expressed appreciation and valued the experience. Our goal is to optimize this platform using their feedback and suggestions to allow incorporation of other GA-driven interventions that can be delivered through the mobile app (eg, cognitive rehabilitation for cognitive impairment, cognitive behavioral therapy for psychological impairment, MedicAlert bracelet that interacts with the app).

Study Limitations

Our study has several limitations. First, this is a single center study with a small sample size and predominantly male patients and female caregivers. During accrual, a higher number of female patients did not want to participate. A common reason provided was that they already had a system in place to help with managing their care. Our sample was also highly educated. All of these may limit generalizability to a larger population of patients with cancer. Second, we did not statistically compare the changes in outcomes due to the heterogeneity of our patient population and small sample size. We acknowledge that symptoms and health care utilization are highly dependent on the type of cancer, the stage of the disease, and the treatment(s) administered, and our sample had varying durations of treatment ranging from one month to several years. Third, patients and caregivers were provided with the tablet for approximately 4 weeks with a relatively short follow-up. For future studies, we plan to extend both the intervention and follow-up periods.

Conclusion

In conclusion, we demonstrated that the TouchStream mobile app is feasible and usable for older patients undergoing cancer treatment and for their caregivers. Older patients and their caregivers value the experience of using an app in the management of their care, but the design and functionality of mobile technologies need to be adapted and tailored to their needs. Future studies should evaluate the effects of the TouchStream app on symptoms and health care utilization in a randomized fashion.

Authors' Contributions

KPL and SGM were responsible for study concepts and design. KPL, JHM, JLL, KMO, CM, M Gilles, TL, and M Goodman acquired data. KPL, CM, and EC analyzed the data. KPL prepared the initial draft. All authors reviewed and approved the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

ADL: activities of daily living
BMI: body mass index
BOMC: Blessed Orientation-Memory-Concentration
FOLFOX: folinic acid, fluorouracil, and oxaliplatin
GA: geriatric assessment
GDS-15: Geriatric Depression Scale-15
GED: General Equivalency Development
IADL: instrumental activities of daily living
mHealth: mobile health
MoCA: Montreal Cognitive Assessment
MOS: Medical Outcomes Study
OARS: Older Americans Resources and Services
SPPB: Short Physical Performance Battery
SUS: system usability scale

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<u>Original Paper</u>

A Novel Mobile Phone App (OncoFood) to Record and Optimize the Dietary Behavior of Oncologic Patients: Pilot Study

Till Orlemann[1], MD; Dejan Reljic[1], MA; Björn Zenker[2], Dipl-Inf; Julia Meyer[1], Dipl-Stat; Bjoern Eskofier[3], PhD; Jana Thiemt[3], MSc; Hans Joachim Herrmann[1], PhD; Markus Friedrich Neurath[4], MD; Yurdagül Zopf[1], MD

[1]Hector Center for Nutrition, Exercise, and Sports, Department of Internal Medicine 1, University Hospital Erlangen, Friedrich-Alexander University Erlangen-Nürnberg, Erlangen, Germany

[2]Embedded Systems Institute, Department of Informatics, Friedrich-Alexander University Erlangen-Nürnberg, Erlangen, Germany

[3]Machine Learning and Data Analytics Lab, Department of Computer Science, Friedrich-Alexander University Erlangen-Nürnberg, Erlangen, Germany

[4]Department of Internal Medicine 1, University Hospital Erlangen, Friedrich-Alexander University Erlangen-Nürnberg, Erlangen, Germany

Corresponding Author:
Till Orlemann, MD
Hector Center for Nutrition, Exercise, and Sports
Department of Internal Medicine 1
University Hospital Erlangen, Friedrich-Alexander University Erlangen-Nürnberg
Ulmenweg 18
Erlangen,
Germany
Phone: 49 913 1854 5204
Email: till.orlemann@uk-erlangen.de

Abstract

Background: Catabolism and tumor-specific therapy lead to reduced nutrient intake and weight loss in cancer patients. Maintaining a specific individualized diet can be challenging for the patient as the nutritional counseling options are limited. Monitoring of nutrient intake and frequent feedback are, however, vital for successful nutritional therapy because they support the patient's compliance and realization of dietary therapeutic goals.

Objective: This study aimed at investigating the feasibility and applicability of a novel mobile phone app to assess and evaluate dietary behaviors in oncologic patients.

Methods: To determine dietary habits and food preferences in oncologic patients, initially 1400 nutritional records were evaluated and analyzed. The results provided the basis for creating a nutritional mobile phone app. Key requirements for the app included simple handling, recording the daily intake, and a comparison of nutrient targets and current status. In total, 39 cancer patients were recruited for the study; 15 patients dropped out prior to the study. All patients received a nutritional anamnesis, nutritional analysis, and nutritional counseling. Individual energy and nutrient aims were defined. The intervention group (n=12) additionally used the app. Weight and body composition of each group were evaluated after 4 weeks.

Results: The app group gained significantly more weight (P=.045; mean weight 1.03 kg vs –1.46 kg). Also, skeletal muscle mass showed a significant increase in the app group (P=.009; mean skeletal muscle mass 0.58 kg vs –0.61 kg) compared with the control group. There was no significant difference between groups relating to the daily protein intake (P=.06). Additionally, there was a decrease in macronutrient intake during the study period in the control group.

Conclusions: Our study indicates that patients who track their daily dietary habits using a mobile phone app are more likely to reach their nutritional goals than the control patients. Further large-scale studies are needed to confirm these initial findings and test the applicability on a broader basis.

KEYWORDS

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Introduction

The nutritional status of cancer patients has a significant influence on morbidity and mortality [1,2]. Cancer-induced inflammatory and catabolic processes lead to a progressive degradation of the muscle mass and the body's fat deposits [3]. Up to 20% of cancer patients die as a result of weight loss and physical wasting [4]. In addition to tumor cachexia, loss of appetite, malabsorption and reduced nutrient uptake increase weight loss and further accelerate a decline in skeletal muscle mass [5]. Due to the anabolic resistance and increased turnover of muscle proteins, the need for high-quality proteins and amino acids is significantly higher in cancer patients [6]. An early start to nutritional therapy and stabilization of the body composition reduce morbidity and mortality in cancer patients [2]. According to national and international guidelines, screening of the nutritional status is recommended at the beginning of cancer-specific therapy as well as along the course of the disease [7,8]. Patients with suspected malnutrition should be given qualified nutritional therapeutic counseling to optimize their normal diet, and artificial nutrition should be provided if necessary [8]. Several studies have shown the benefits of nutritional care in cancer patients in relation to numerous aspects (malnutrition, quality of life, complications, mortality) [9-12].

The basis of any nutritional therapeutic concept is to record the individual nutrient intake of the patient. In this context, various dietary assessment methods are available. Retrospective methods have the disadvantage that their reliability strongly depends on the memory performance of patients (eg, 24-hour recall interviews, diet history interviews, or food frequency questionnaires). The gold standard of prospective nutritional protocols has long been the weighing protocol, but this is a burden for patients as all food must be weighed and recorded before being consumed. Therefore, prospective estimation records of food consumption are more patient-friendly. In Germany, for example, the Freiburg Diet Record (FB-DR) is one of the most commonly used estimation records, for which a computer-based evaluation procedure was developed (PRODI software, Nutri-Science GmbH). The database for the FB-DR is the Federal Food Key 3.02 developed by the German Federal Research Institute for Nutrition and Food. In the nutritional questionnaires of the FB-DR, patients record their diet on a standardized sheet. All estimation protocols have an acceptable expenditure of time because a tally list is used to note the food and drinks patients consumed during the course of the day. Qualified nutritionists use the records to determine the current energy and nutrient intake (micro- and macronutrients) of patients. This is important for individualized nutritional counseling and therapy. The food diaries are also used to detect preferences of patients for certain foods. However, none of the usual nutritional records has been developed specifically for cancer patients. Recording of the nutrient intake of oncologic patients would be very important, since dietary habits may change due to the specific disease situation and cancer therapy. National and international guidelines recommend a high-protein diet to counteract tumor cachexia and progressive muscle breakdown [8]. Due to issues relating to the disease and its

therapy, appetite and taste disorders complicate the diet [13]. Thus, a special nutritional profile is typically present that must be individually tailored. However, in clinical routine, the resources for professional nutritional counseling for cancer patients are rather limited.

Mobile phone apps play an increasing role in the everyday use of electronic devices. Patient-specific data can be recorded and analyzed. These mobile phone apps are already being used successfully in other areas of nutrition consultation, and their benefit has been demonstrated in several studies [14-18].

However, in the field of oncology, comparable studies are rare and data about the usage of electronic aids are currently missing, especially the use of dedicated apps on mobile phones. Continuous monitoring of ingested nutrients and supporting individual nutritional goals by capturing individual dietary habits and dynamic changes during disease progression and tumor therapy are the target criteria of a mobile phone app for cancer patients. Therefore, the primary aim of this study was to evaluate the feasibility and applicability of a novel mobile phone app to assess and evaluate the nutritional status of patients with cancer diseases. Furthermore, we aimed at gaining first insights into whether the app may contribute to an improved nutritional status in cancer patients.

Methods

Patient Recruitment

Initially, 1400 nutritional records of 186 cancer patients from different oncology departments at University Hospital Erlangen were evaluated. The patients received nutritional care at the Hector Center for Nutrition, Exercise, and Sports in the Department of Internal Medicine 1 at the University Hospital Erlangen. For a detailed analysis of nutrient intake, an analysis of the FB-DR nutritional sheets was completed using PRODI version 6.2 organizational software for nutritional counseling and therapy (Nutri-Science GmbH). With the FB-DR, the energy and nutrient supply can be determined by using common kitchen dimensions. Including age, gender, and the number of documented days, a nutritional analysis was carried out using the DACH (Germany–Austria–Switzerland) reference values (German Society for Nutrition, Austrian Society for Nutrition, Swiss Society for Nutrition Research, Swiss Society for Nutrition). The analysis of the text logs was done externally in Java (Oracle Corporation) and Python (Python Software Foundation). The presence or risk of malnutrition was recorded using Nutritional Risk Screening 2002 [7,19-21].

The evaluation of the prospectively collected dietary charts allowed for optimizing the food selection and digital input of the daily diet into the app. The detailed recording of individual nutritional habits of cancer patients made it possible to detect foods missing from the FB-DR and preferences in food selection and develop the widest possible food choices for programming the app, based on the preferences of cancer patients. The nutritional goals were defined based on current national and international guideline recommendations on cancer nutrition [8].

Figure 1. Design of study. BIA: bioimpedance analysis.
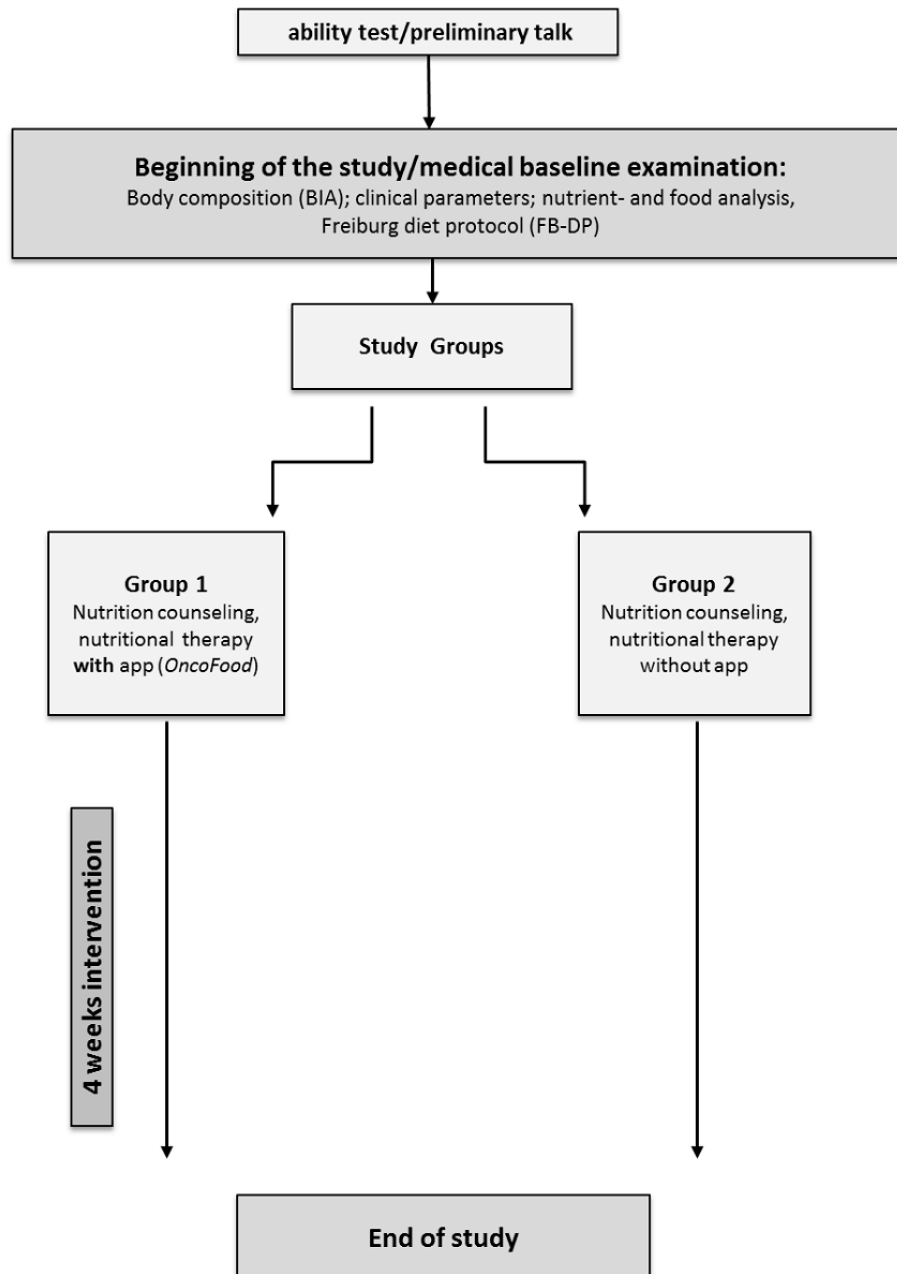
Study Design

This study (see Figure 1 for flow diagram) recorded food intake over a 4-week period. After an initial nutritional analysis, both groups received professional nutritional advice with the aim to achieve the individually determined energy and nutrient requirements. Because of its explorative character, no explicit case number estimation was made.

In group 1 (app group), food intake was initially recorded using the FB-DR. In addition to the paper protocol, the participants were provided with a mobile phone with an Android operating system and the OncoFood app for nutritional documentation. To ensure that no entries were forgotten, the app reminded the user with an acoustic signal. The patient had the opportunity to check the current state and development of their energy and nutrient supply in the app.

In group 2 (usual care), food intake was recorded using a standardized paper record (FB-DR). Study participants completed the protocol for 3 days according to a given classification of the different foods. The nutritional analysis of the documented food was completed using PRODI software. The patients implemented the nutritional aims for the next 4 weeks by themselves.

Setup of the App

OncoFood for Android mobile phones was developed in Java with Android Studio specifically for this study and programmed for the mobile phone Huawei Y6 (Huawei Technologies Co Ltd). Mobile phone selection was based on the average battery life and acquisition costs. Of course, the app can also be used on any other Android-based mobile phone. The app contains a database of more than 1300 nutrition facts for foods based on

the German Nutrition Society's nutritional value table [22]. The version used was updated based on the Federal Food Key 3.02.

Oncologic patients require high-calorie fluids, so 24 artificial, high-calorie liquids were added to the database with the appropriate nutritional values. Furthermore, foods listed by the cancer patients but missing from the top 200 foods in the FB-DR nutritional protocols in the preliminary evaluation were added. For each listed food, the water, energy, proteins, fat, carbohydrates, and fiber components were stored, which allowed a detailed nutritional calculation. Subjects were asked to enter the ingested foods and drinks into the app daily. The foods could either be entered by the screen keyboard or voice input. The last recorded foods could be saved and quickly revisited in a favorites list. Alternatively, the food could be selected from 16 categories such as fruit or bread spread. Compound and regularly scheduled meals (eg, spaghetti Bolognese, lasagna, or bread and butter) could be selected and saved for later reuse. The app reminded patients to enter their food intake every day at 9 am, 1 pm, and 7 pm. In case of a missed entry, the reminder function went off every 3 minutes (between the hours of 8 am and 10 pm only). Once a week, at 5 pm, patients were reminded with an acoustic signal to enter weight and appetite parameters collected to record the clinical status of the patient.

Use of the App

After individual nutritional status was recorded, OncoFood was configured individually for each patient by a physician and a nutritionist. For this purpose, nutritional goals and current weight were entered into the app (Figure 2). The mobile phone was then given to the patient. Patients entered consumed food daily; meals were stored separately and presented in an overview

(Figure 3). Once the food was entered, charts showed whether patients reached their daily nutritional goals (Figure 4). The use of traffic light colors and symbol diagrams helped patients interpret what they had achieved. For example, a green cup represents the fact that a nutritional goal has been achieved with a nutrient. This aimed at motivating the patient to adhere to their nutritional plan.

Bioimpedance Analysis

Bioimpedance analysis (BIA) is an easy-to-use, noninvasive method for determining the body composition of a patient. Each patient, regardless of group affiliation, received a measurement at the beginning and end of the study. The BIA is based on the measurement of body resistance against an electrical alternating current caused by the application of a voltage source. The BIA device used (Medical Body Composition Analyzer [mBCA], seca GmbH) is a multifrequency (5, 50, and 100 kHz) device with a hand/foot resistance of <300 ohm and a sandwich resistance of <30 ohm. Based on measured resistance and reactance values, the device calculates body cell mass and extracellular mass including intracellular water and extracellular water. In addition, the body fat mass is determined and the phase angle is calculated. The phase angle from the BIA measurement has been reviewed in several clinical trials and shown to be a useful prognostic marker for various diseases such as cirrhosis, HIV infection, and cancer [23]. With the modification of the phase angle to the standardized phase angle, its statement becomes more specific because it is related to the population (age, body mass index, nationality) [24]. The prognostic statement of the phase angle becomes more precise through the modification.

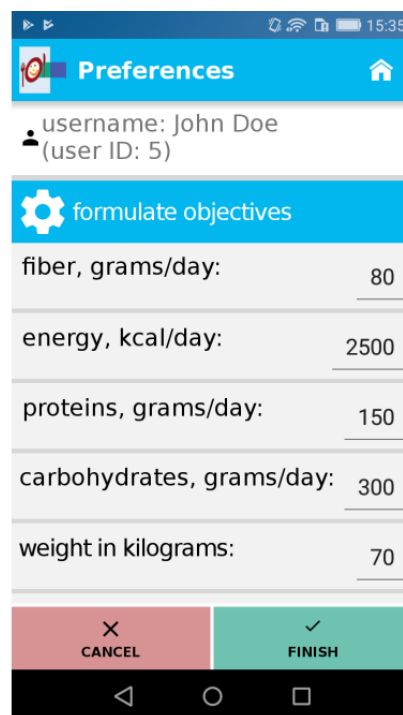**Figure 2.** Nutritional goals and weight.

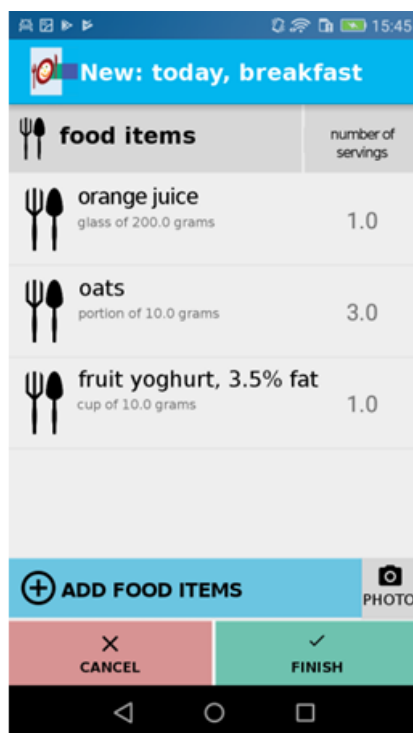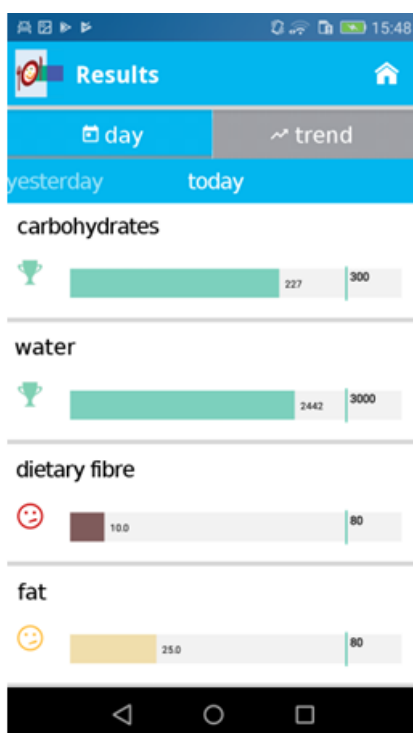**Figure 3.** Daily input of consumed food.

Figure 4. Record of daily nutritional goals met.

Statistics

For categorical variables, numbers and percentages were determined and tested for baseline differences using the chi-square test. For continuous variables, averages and standard deviations were calculated at the beginning and end of the study in both groups (app subjects, controls). All the nutritional variables were given in the actual amount relative to the agreed target size. All continuous variables were tested with the Wilcoxon sign-rank test for differences within the groups before and after intervention. Differences in the final and starting values were calculated and tested using the Mann-Whitney U test. All analyses were performed with the statistical package R version 3.3.1 (R Foundation for Statistical Computing).

Results

Key Findings

Of the FB-DR protocols initially evaluated to interpret the dietary habits of cancer patients, 47.8% (89/186) were of women and 51.2% (97/186) were of men. Patients with different tumors (prostate, breast, esophagus, bronchi, stomach, pancreas, kidneys, liver, ovaries, colon, cecum, rectum, papillae, blood and hematopoietic system, lymphatic system, skin, or pleura) were included in the study. The mean age of the patients was 58.4 years (range 27-90 years). An average nutritional risk score of 3 points was determined.

Averages of 7.5 (SD 4.7) protocols per patient were completed. Although more than 7 protocols per patient were analyzed, no additional nutritional information could be evaluated. In particular, there were no differences in the number of specified foods recorded using the protocols (59.2 [SD 23.6]; Figure 5). Missing among the top 10 (Tables 1-3) foods most frequently mentioned in the FB-DR were beef and pork and their by-products. Drinks, fruit and fruit preparations, bread products, and dairy products were often consumed. Of the 172 foods listed in the FB-DR, 169 were recorded by the patients.

Out of the top 200 foods cited by our cancer patients as being preferred foods, 31 were missing from the FB-DR. Three foods (liquors, hamburgers, and cheeseburgers) that can be marked in the FB-DR were not even selected by oncologic patients (Table 4).

Figure 5. Increase in the number of different foods in terms of the number of protocols delivered.
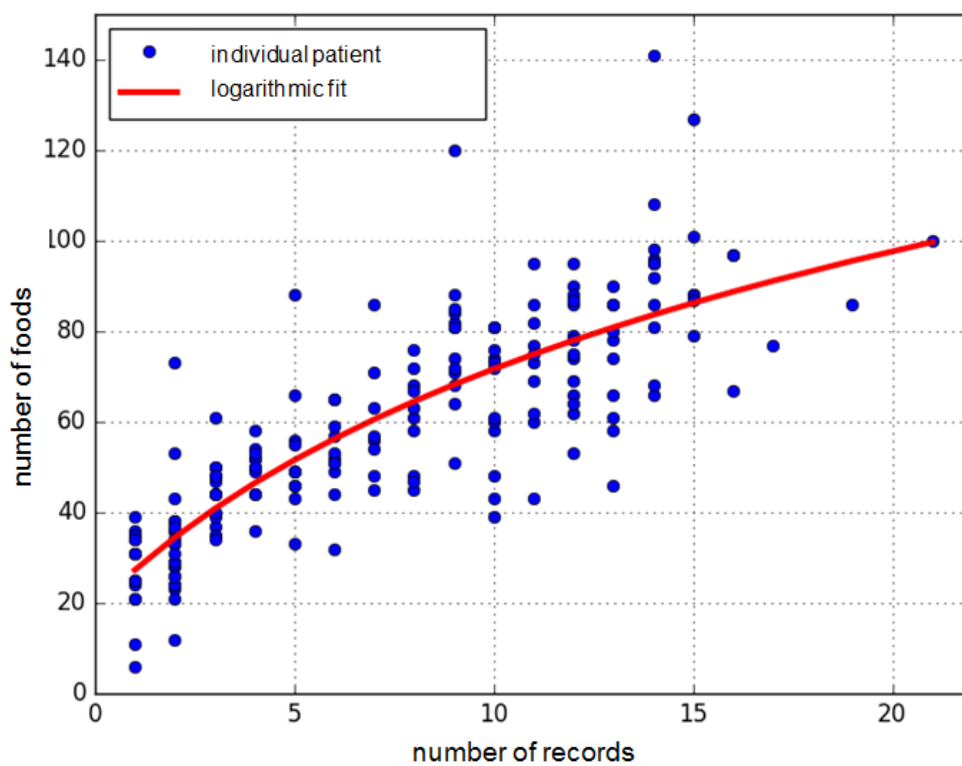
Table 1. Top 10 food choices documented by the participating cancer patients (excluding water and tea).

Position	Food	Terms (N)
1	Butter	155
2	White coffee	147
3	Coffee	136
4	Apple	126
5	Tomato	123
6	Milk, 1.5% fat	108
7	Banana	104
8	Espresso	94
9	Hen's egg, cooked, with salt	83
10	Carrot	80

Table 2. Top 10 most consumed drinks documented by the cancer patients (including water and tea).

Position	Food	Terms (N)
1	Water	520
2	Herbal tea	266
3	Mineral water	206
4	White coffee	147
5	Coffee	136
6	Milk, 1.5% fat	108
7	Espresso	94
8	Coffee cream, 10% fat	63
9	Apple spritzer	59
10	Soft drinks	57

Table 3. Top 10 food choices documented by the cancer patients (excluding drinks).

Position	Food	Terms (N)
1	Butter	155
2	Apple	126
3	Tomato	123
4	Banana	104
5	Hen's egg, cooked, with salt	83
6	Carrot	80
7	Cucumber	79
8	Rye whole grain bread	74
9	Jam	71
10	Red pepper	70

The app's food database was programmed based on recorded nutrition protocols and the database of the German Nutrition Society [22]. Of the 39 patients (15 men and 24 women) originally recruited, 15 patients cancelled their participation before initiating the study. The most common reason for this was an inpatient admission. A total amount of 24 participants took part in the app study during the 4-week intervention. Twelve participants were assigned to a control group and 12 patients to the app group. This is still an appropriate sample size for this pilot investigation [25]. The group of patients suffering from a gastrointestinal tumor (n=16) was most frequently represented. Significant differences could be identified with regard to the achievement of the defined nutritional therapeutic goals. Thus, the protein and fat intake in the control group at the end of the study does not differ compared with the start of the study ($P=.91$). Fiber intake ($P=.34$), carbohydrates ($P=.27$), and total energy intake ($P=.42$) even show a worsening of the initial situation after 4 weeks. The patients who used OncoFood during the 4-week period achieved more than 100% of nutritional goals, especially with regard to protein and fat intake, as well as the total amount of energy (Figures 6 and 7) in comparison with the control cancer patients. They also achieved an adequate carbohydrate intake. The amount of fiber alone fell slightly compared with the previous value. The evaluation of the data shows a significant increase in skeletal muscle mass ($P=.009$; mean skeletal muscle mass 0.58 kg vs –0.61 kg; Figure 8) and fat-free mass ($P=.03$; Figure 9) for the app-using patients during the 4-week treatment. Weight gain and body mass index during the study period were significantly higher in the app subjects ($P=.045$; mean weight 1.03 kg vs –1.46 kg; Figure 10).

Table 4. Foods from the top 200 list from cancer patients that are not in the Freiburg Diet Record compared with foods from the Freiburg Diet Record that are not in the top 200 list of foods from cancer patients.

Position	Food
1	Liquor[a]
2	Hamburger[a]
3	Cheeseburger[a]
74	Formula diets
130	Pretzel
139	Vegetarian pastries
153	Gingerbread
158	Fried egg
159	Linseed
161	Malt beer
164	Doughnut
166	Soy milk
169	Avocado
170	Apple puree
172	Protein bread
173	Cheesecake
174	Mozzarella
175	Cappuccino
176	Lamb
177	Scrambled eggs
178	Tiramisu
182	Apple spritzer
183	Wheat bran
184	Espresso
185	Fruit salad
187	Feta cheese
190	Kefir
191	Goat cheese
192	Pita bread
193	Smoothie
194	Whole grain toast
195	Shandy
199	Tomato juice
200	Shrimp

[a]Foods in the Freiburg Diet Record that are not in the top 200 list.

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Figure 6. Four-week overview of nutritional goals reached by cancer patients using the app.
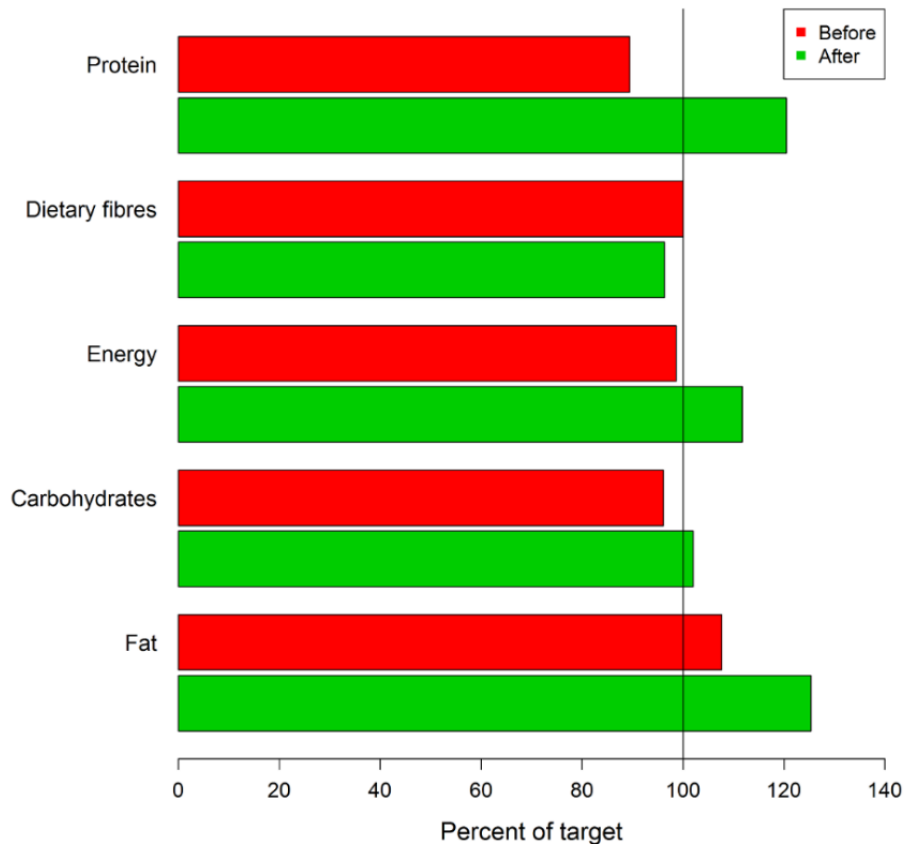
Figure 7. Four-week overview of nutritional goals reached by control group cancer patients.
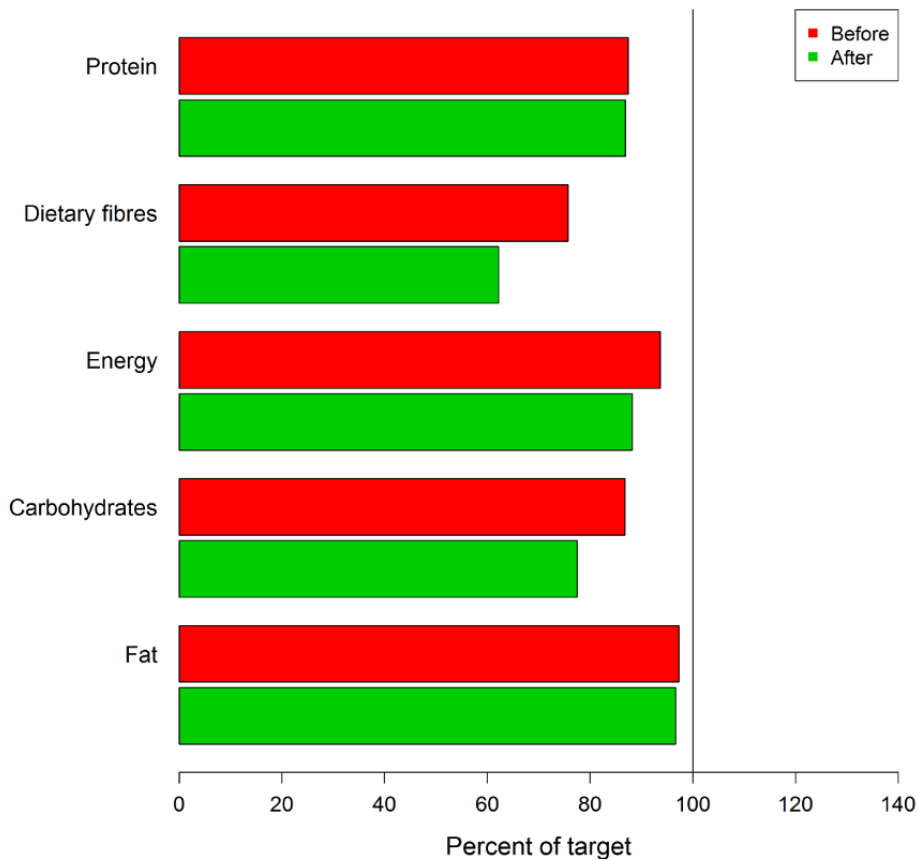
Figure 8. Skeletal muscle mass before and after intervention (app vs control).
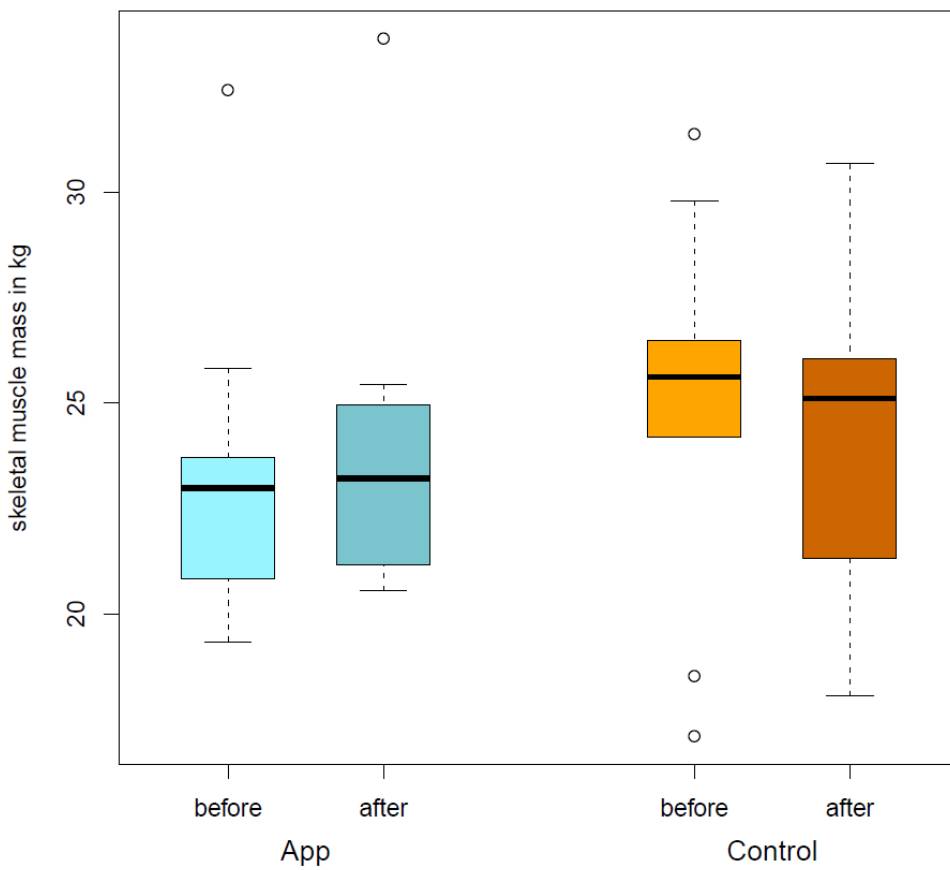
Figure 9. Fat-free mass index before and after intervention (app vs control).
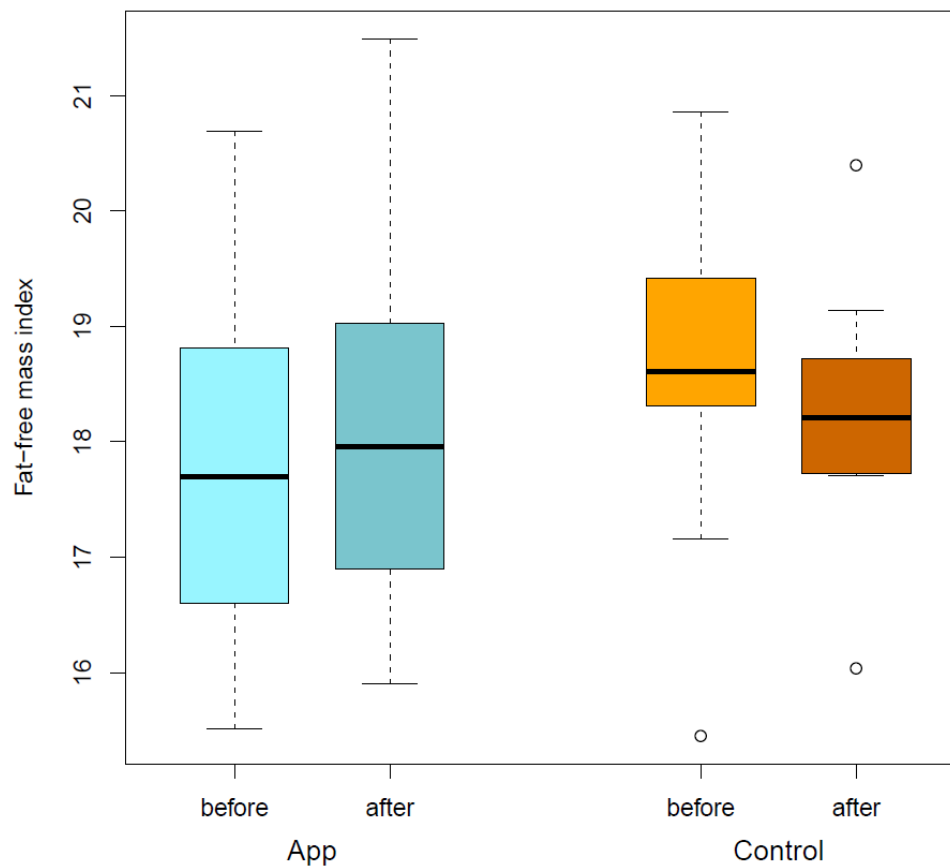
Figure 10. Weight before and after intervention (app vs control).
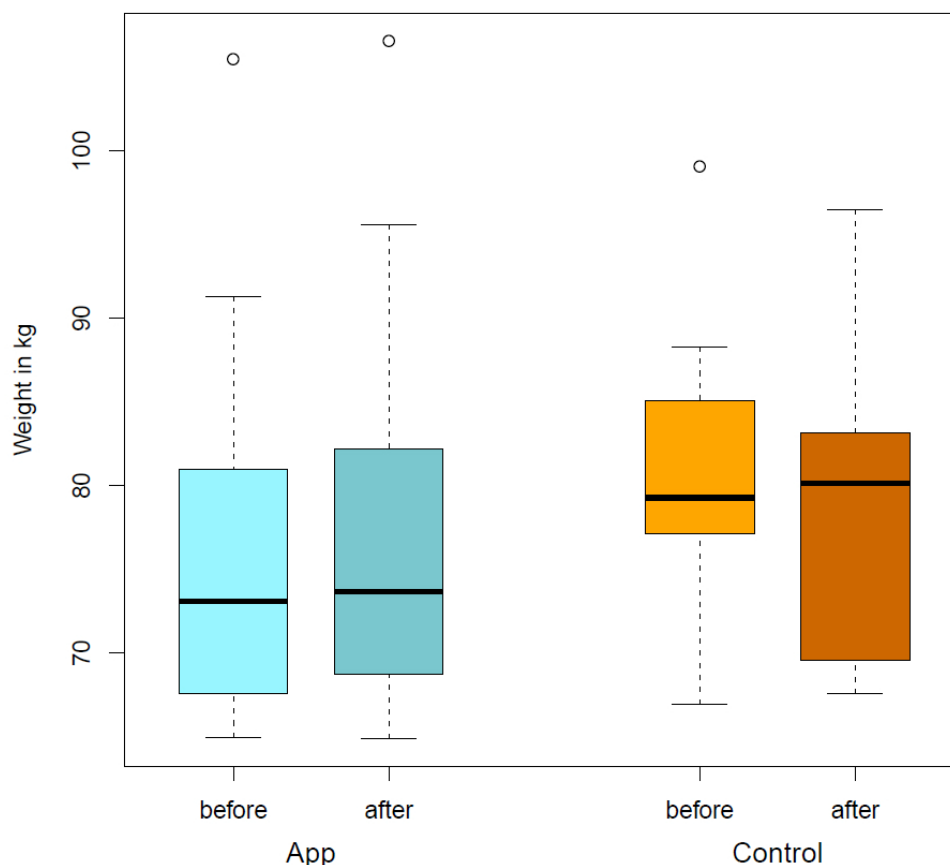
Challenges Using the App

The Android devices are owned by the clinic and were configured with a parental control app, allowing the subjects to access nothing but the OncoFood app and simplifying the task for them. Still, getting used to the new phone and app required effort and could be challenging for the individual subject. Nevertheless, the patients adapted easily to the phones and the OncoFood app running on them.

Users' Opinions

The patients in the group using OncoFood were asked to provide suggestions for improvement as well as positive and negative feedback. One particularly positive bit of feedback was that all meals in the database of the app were available. Also, the overview of the daily goal of nutrient intake was praised. Some noted that using the app would take too much time. One request was that the voice input of the app (via an activated internet connection) should also work offline. Additionally, many users also wished for recipe suggestions and the ability to make changes to existing and past data on foods and prepared meals.

Discussion

Principal Findings

On the basis of nutritional protocols, we were able to present for the first time that cancer patients not only show a changed diet but, in particular, have insufficient protein intake than is necessary for them. The analysis of standardized nutritional protocols showed that meat, for example, was not listed among

the 25 most commonly consumed foods by tumor patients. Fish consumption was named last. However, not all of the preferred foods consumed by cancer patients were found in the standardized nutritional protocol. With adapted nutritional documentation and individualized nutritional care, the use of app assistance was associated with optimized nutritional status and could stabilize the body composition in cancer patients compared with conventional nutritional assistance.

Meat consumption has a higher priority in the healthy population compared with cancer patients. Meat is considered to be an important source of protein and contains a relevant amount of vitamins, trace elements, and minerals. A disturbed taste perception in cancer patients seems to be responsible for the avoidance of meat. In particular, the taste disturbance with the quality of bitter seems to increase the aversion to meat proteins [26]. This is especially unfavorable, as cancer patients require increased protein intake to counteract muscle breakdown caused by systemic inflammation and malignancy catabolic status.

A systematic recording of nutrition is the basis of nutritional treatment. We could show that standardized nutritional protocols such as the FB-DR may require special attention to specific dietary needs of specific disease populations. Among the 200 foods most commonly consumed by cancer patients, 31 foods were not included in the nutritional protocol. Artificial foods, such as enteral nutrition, were completely missing on the FB-DR. The results of our cancer database nutrition protocols served as a basis to optimize the food documentation of the OncoFood app.

The possibilities of nutritional counseling are often very limited in clinical practice due to the lack of sufficient consultation hours and human resources. In clinical routine, paper documentation is used to record the nutritional status, which is often completed retrospectively. This can lead to missing information about the daily food consumption.

A timely and detailed review of nutrient intake is very difficult to implement with the analogue protocol. In addition, the 1 to 3 day nutritional protocols do not provide complete records of the patient's actual nutrition as a function of disease progression. In particular, tumor patients may have extremely high fluctuations in terms of nutrient uptake due to their tumor-specific therapy and the dynamic course of their disease. Not only the tumor cachexia but also the antitumor therapy (eg, chemotherapy, radiotherapy, or surgical therapy) influence food intake. A timely and continuous recording of these fluctuations in nutrient uptake by conventional nutritional protocols will hardly be possible.

So far, only Coughlin et al [27] have used a mobile phone app to record the nutritional status and activity levels in breast cancer patients. In this study, the participants were provided with an app that stores the information from 2 commercially available apps (Fitbit device for monitoring physical activity and the LoseIt! mobile phone app for monitoring and tracking diet and nutrition) and additionally contains information and tips for the prevention of breast cancer.

However, the patients did not initially receive professional dietary advice from dieticians who conducted an individual nutritional analysis and nutritional goals calculation as in our study. The data collection was based on the inputs of the patients in commercially available apps that were not specifically designed for cancer patients. Comparable to the OncoFood app used in our study, users were given a nutritional goal and a reminder to improve their compliance. In contrast to the OncoFood app, the option of a voice function was not available. A detailed analysis on which database the nutritional recommendation was based on was not reported. The use of apps in cancer patients has been studied mainly for the detection of cancer pain [28]. The benefits of the electronic input and regular monitoring of nutritional treatment were also reflected in our results. We could demonstrate that app users were able to achieve their previously defined nutritional therapeutic goals. The protein and fat intake as well as the total amount of energy were achieved more than 100%.

Compared with the app users, patients with conventional nutrition monitoring could not improve their nutritional status. In some cases a deterioration of the diet was recorded, so that the agreed nutritional goals could not be achieved. Thus, the protein and total energy intake of the control patients at the end of the study period was lower than at the beginning.

The skeletal muscle mass of patients with conventional nutritional intervention decreased over the 4-week study period (P=.06). In contrast, close monitoring of the nutritional status in the app group even resulted in significant weight gain (P=.05). In particular, skeletal muscle mass was significantly improved (P=.03).

Optimal management of nutritional therapy with significant improvement in body composition can otherwise only be shown with very close nutritional supervision. However, this proves to be difficult to perform in clinical routine. Time constraints, organizational circumstances, and socioeconomic aspects don't allow an optimal and individual management of the patient. In this feasibility study, we could demonstrate that individually defined nutritional goals have a relevant influence on the eating behavior of the patients. Due to the easy handling and operation of the app, there was a high level of compliance and acceptance among our cancer patients. This allowed a fast and effective response to any changes in the nutritional needs of cancer patients. The considerable advantage of a mobile phone–controlled app has already been confirmed for other diseases, some of them lifestyle diseases such as diabetes mellitus, hypertension, and obesity [15,29-31].

For example, Ryan et al [15] developed a mobile phone app for people with type 1 diabetes. The aim was to positively influence glucose metabolism by giving patients the opportunity to incorporate the daily glucose measurements in an app and thus to provide a history overview.

There were also time advantages over traditional personal documentation by the patient. In the long term, the app users in this study showed an improvement in glucose parameters in type 1 diabetes patients. In contrast to our study, however, a nutritional recommendation based on type 1 diabetes was not offered.

Using new technology is one way to bridge the gap between what patients need and what health care can offer. This study evaluated a new digital health care platform. The use of a mobile phone app can be an effective and feasible method to improve the nutritional status of cancer patients.

Limitations

Since the tumor collective in our study was very heterogeneous, it would be interesting to investigate the app for a uniform tumor disease. In addition, the 4-week study period can only provide an overview. Therefore, a longer observation period should be chosen in future studies. Prospectively, we want to shed light on the physical activity of tumor patients, so further studies are required.

Conclusion

In accordance with national and international guidelines, cancer patients should follow a high-protein diet. We were able to show that closely guided nutrition therapy on a digital platform can not only improve the realization of the nutritional aims but also stabilize weight and skeletal muscle mass. The app was rated predominantly positively by the patients in terms of user satisfaction. Also, in relation to time and personnel costs, it offers advantages compared with traditional nutritional counseling and therapy. The app may be used in addition to conventional nutritional advice and therapy but also as a replacement for conventional therapy in every oncology patient. Further evaluation of the OncoFood app should be tested for validation in a larger collective of cancer patients.

Acknowledgments

Conflicts of Interest

None declared.

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Abbreviations

BIA: bioimpedance analysis
FB-DR: Freiburg Diet Record

Original Paper

The Implementation Effectiveness of a Freely Available Pediatric Cancer Pain Assessment App: A Pilot Implementation Study

Perri R Tutelman[1,2], BHSc (Hons); Christine T Chambers[1,2], PhD; Jennifer N Stinson[3,4], RN-EC, PhD; Jennifer A Parker[2], PhD; Melanie Barwick[3,4], PhD; Holly O Witteman[5,6], PhD; Lindsay Jibb[7], PhD; Hayley C Stinson[2], MSW; Conrad V Fernandez[1,2], MD; Paul C Nathan[3,4], MD, MSc; Fiona Campbell[3,4], MD; Karen Irwin[8]

[1]Dalhousie University, Halifax, NS, Canada
[2]IWK Health Centre, Halifax, NS, Canada
[3]University of Toronto, Toronto, ON, Canada
[4]The Hospital for Sick Children, Toronto, ON, Canada
[5]Laval University, Quebec, QC, Canada
[6]Ottawa Hospital Research Institute, Ottawa, ON, Canada
[7]University of Ottawa, Ottawa, ON, Canada
[8]Cancer Knowledge Network, Milton, ON, Canada

Corresponding Author:
Christine T Chambers, PhD
IWK Health Centre
Centre for Pediatric Pain Research
5850/5980 University Avenue
Halifax, NS, B3K 6R8
Canada
Phone: 1 902 470 6906
Email: christine.chambers@dal.ca

Abstract

Background: Pain Squad is an evidence-based, freely available iOS app designed to assess pain in children with cancer. Once research-based technologies such as Pain Squad are validated, it is important to evaluate their performance in natural settings to optimize their real-world clinical use.

Objective: The objective of this study was to evaluate the implementation effectiveness of Pain Squad in a natural setting.

Methods: Parents of 149 children with cancer (aged 8-18 years) were contacted to invite their child to participate. Participating children downloaded Pain Squad on their own iOS devices from the Apple App Store and reported their pain using the app twice daily for 1 week. Participants then emailed their pain reports from the app to the research team and completed an online survey on their experiences. Key implementation outcomes included acceptability, appropriateness, cost, feasibility, fidelity, penetration, and sustainability.

Results: Of the 149 parents contacted, 16 of their children agreed to participate. More than a third (6/16, 37.5%) of participating children returned their pain reports to the research team. Adherence to the pain assessments was 62.1% (mean 8.7/14 assessments). The 6 children who returned reports rated the app as highly feasible to download and use and rated their overall experience as acceptable. They also reported that they would be willing to sustain their Pain Squad use over several weeks and that they would recommend it to other children with cancer, which suggests that it may have potential for penetration.

Conclusions: While Pain Squad was well received by the small number of children who completed the study, user uptake, engagement, and adherence were significant barriers to the implementation of Pain Squad in a natural setting. Implementation studies such as this highlight important challenges and opportunities for promoting the use and uptake of evidence-based technologies by the intended end-users.

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Introduction

Pain is a prevalent symptom experienced by children with cancer [1-4]. For children with cancer, pain can result from a variety of sources (eg, treatments, procedures, the disease itself) [5-7], and when undermanaged, can have deleterious impacts on many domains of their health and functioning [8-12]. Significant resources have been dedicated to the development and validation of tools to assess and treat pain in children with cancer. These include physical and psychological interventions [13-15], symptom assessment scales [16-18], and mobile health (mHealth) apps [19-22].

One mHealth tool developed specifically to assess pain in children with cancer is Pain Squad, a gamified pain assessment mobile phone app [19,23]. Pain Squad enables children and adolescents to report their pain twice daily on an iOS device (eg, iPhone or iPad) in real-time by responding to a 22-item multidimensional pain assessment [19]. The pain assessment includes questions on pain intensity, interference, duration, location, and pain management strategies used (Figure 1). Within the app, users play the role of law enforcement officers and are promoted to various ranks based on adherence. Pain reports are stored locally on the user's device and can be downloaded or emailed to their health care professional. Stinson et al developed the app using a comprehensive user-centered design approach [23] and subsequently evaluated its psychometric properties in 106 children and adolescents with cancer. Pain Squad was found to be a valid, reliable, and feasible pain assessment device for children and adolescents between the ages of 8-18 years undergoing cancer treatment [19]. While there are over 50 apps for pediatric pain in the Apple App Store [24], Pain Squad is currently the only evidence-based and freely available iOS cancer pain assessment app for children and adolescents.

Despite the rigorous development of tools such as Pain Squad to assess and manage pain in pediatric oncology, symptom audits reveal that as many as 92% [25] of children with cancer have pain, and many do not benefit from the best available evidence-based approaches to pain care [26]. This phenomenon, known as the knowledge-to-action gap, refers to failure of the translation of the best available research evidence to be used in regular clinical practice [27]. Knowledge-to-action gaps have been described in many areas of medicine and health, and the availability of mHealth tools shown to be valid and reliable in research studies is no exception. In fact, a 2014 systematic review found that none of the 34 pain apps published in peer-reviewed journals were available to end-users [28] (since the time of the review, Pain Squad has become the only freely available pediatric pain iOS app). Apps like Pain Squad, which aim to measure patient-reported outcomes and experiences to better tailor care to each patient, are of little clinical use if they are not used by patients. Failure to ensure uptake is a barrier to the provision of evidence-based care [29].

Implementation science has emerged as a field of study to better understand uptake of new interventions. Defined as, "the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice" [30], implementation science seeks to identify theories, processes, strategies, and outcomes to enable the use of evidence-based practices in natural contexts. While efficacy studies of pain management tools traditionally measure clinical outcomes to assess the performance of the intervention (eg, participant pain, quality of life, functional disability) [19,20,31], implementation studies evaluate outcomes associated with the performance of the tool in a real-world setting (eg, acceptability, adoption, cost, penetration) [32,33]. Pain Squad's validity as a pain assessment tool in pediatric oncology has been previously evaluated in tightly controlled research studies [19,23]. However, research examining the implementation effectiveness of Pain Squad is needed to determine its performance in natural settings and to guide and promote its uptake into routine pediatric oncology practice. Thus, the objective of this study was to evaluate the implementation effectiveness (ie, acceptability, appropriateness, cost, feasibility, fidelity, penetration, and sustainability) of the Pain Squad app in a naturalistic context.

Figure 1. Screenshots of the Pain Squad Pain Assessment (note that users can scroll for additional answer options for the multiple choice questions).
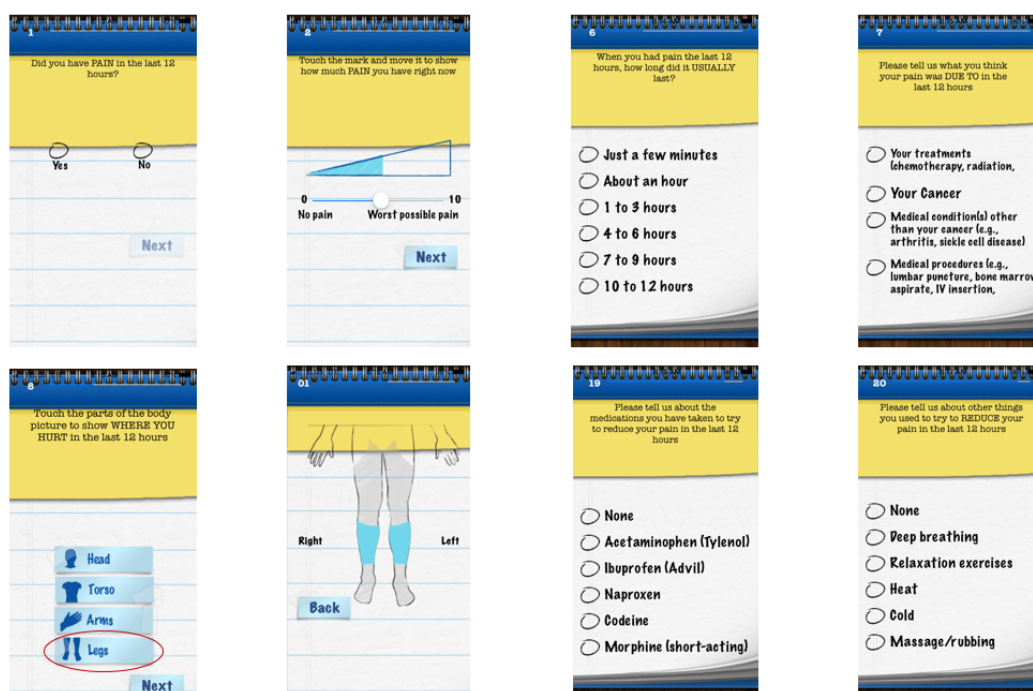
Methods

Participants

We accessed child participants by contacting parents who had participated in a larger online project [7] and consented to be contacted for future research (n=149). These parents received an invitation for the current study via email. Their children were eligible to participate if they (1) were between the ages of 8-18 years, (2) had a history of cancer, (3) were currently undergoing cancer-related treatment or were a cancer survivor, (4) had experienced any pain in the past week, (5) had a personal iOS device, and (6) could read and understand English. There were no geographic restrictions. One reminder email was sent 48 hours after the initial invitation.

Procedure

Parents who replied to the invitation email expressing interest in participating were emailed a consent form and an investigator-developed document with information for their child on how to use Pain Squad. Children were asked to download the app from the iTunes store onto their iOS device and complete pain assessments twice daily on the app for a minimum of 1 week. Users are able to customize the timing of their pain assessments within the app to coincide with their schedules, so long as the assessments are scheduled 12 hours apart. Pain Squad sends users push notifications to their device at the time of their scheduled reports, after which they have 30 minutes to complete the report or else it is counted as missed. The app was designed this way by the developers to capture children's pain assessments in real-time and reduce the impact of recall bias [19,23]. In the Pain Squad information document, participants were reminded to ensure their notification settings were turned on for Pain Squad to ensure they received the reminders to complete the reports. This study used the publicly

available version of Pain Squad that stores all data directly on the individual's device. Thus, participants were required to use the built-in email feature to send their pain report to the research team after the testing period (Figure 2). Previously published studies using Pain Squad used the research version of the app, which has server connectivity providing researchers with direct access to participants' pain assessments, and provided participants with study iOS devices preloaded with the Pain Squad app [19] (the team that developed the app removed server connectivity from the public version of the app for data security reasons). Children in this study were required to download the app onto their own devices mimicking the realistic end-user experience. Participants were reminded via email midway through the week to continue using the app and to submit their reports at the end of the week. Participants who did not submit their reports were sent two follow-up emails. Two months later, children and their parents who submitted reports were emailed a link to a follow-up survey to collect their demographic information and ask about their experience using Pain Squad. Children who submitted pain reports received a Can $25 gift card to an online retailer. Those who completed the follow-up survey were entered into a prize draw to win an additional Can $25 gift card. This study was approved by the institutional research ethics board of the IWK Health Centre, Nova Scotia, Canada.

Measures

#### Participant Recruitment, Retention, and Adherence

Recruitment was evaluated by the response rate to the invitation email and proportion of participants agreeing to participate. Retention was assessed based on the proportion of final reports received by the research team, and adherence was assessed as the proportion of pain assessments completed of a possible 14 (two reports daily for 7 days).

Figure 2. Screenshots from the publicly available version of Pain Squad demonstrating the process of emailing a pain report.
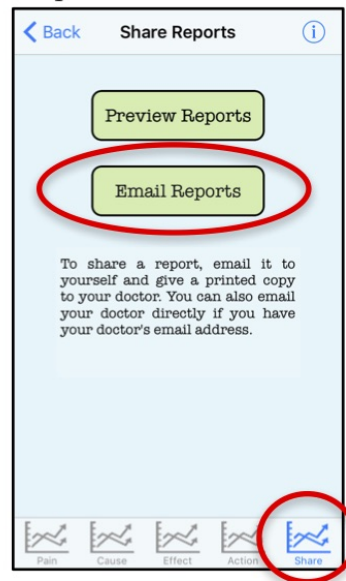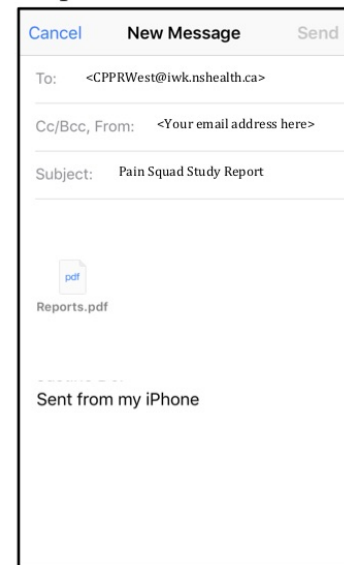

Implementation Effectiveness

Participants answered 10 questions (rated on a scale of 1-5) to assess key implementation outcomes including acceptability (ie, participant satisfaction), appropriateness (ie, perceived usefulness), feasibility (ie, utility), penetration (ie, spread), and sustainability (ie, maintenance) as described in Proctor's taxonomy [32]. Questions were adapted from the Acceptability E-Scale (AES), a 6-item questionnaire that assesses the acceptability of electronic self-report symptom tools on a 5-point scale [34]. The AES has been found to be valid and reliable and has been used previously with pediatric oncology populations [31,35]. Two questions were derived from the acceptability questionnaire used by Jibb et al in a pilot study of the Pain Squad+ app [31], and two questions were developed by the research team. Consistent with published cut-off values for the AES, a mean score >3 on any item indicated a positive evaluation [34] and scores ≥4 were considered high [35]. Other implementation outcomes including cost and tool fidelity (ie, technical difficulties reported by participants, use of the app as intended) were assessed by the research team.

Open-Ended Questions

Two open-ended questions ("What was your favorite part about using the Pain Squad app?" and "What was your least favorite or the most challenging part about using the Pain Squad app?") were included in the follow-up survey.

Demographic Information

In the follow-up survey, parents were asked to report on their child's date of birth, sex, cancer diagnosis, time since diagnosis, country of residence, remission status, and ethnicity.

Data Analysis

Descriptive statistics including frequencies, means, standard deviations, and ranges summarized the quantitative data. Content analysis was used to summarize the qualitative responses according to the procedure outlined by O'Cathain and Thomas [36].

Results

Participant Recruitment, Retention, and Adherence

Of the 149 parents invited to participate, 28 parents (18.8%) replied to the email, of whom 16 (57.1%) of their children agreed to participate. Ten of the 28 parents who replied to the email indicated that their children were ineligible to participate due to their age (n=7), lack of pain in the past week (n=2), and no access to an iOS device (n=1). Two parents replied to the email indicating that their children were not interested. After the 1-week period, more than a third of participants (6/16, 37.5%) returned their reports to the research team. Figure 3 depicts the flow of participants through the study. A total of 52 pain assessments were completed by the 6 participants. Out of a possible 14 assessments per child, children completed an average of 8.7 (62.1%) assessments (SD 4.18, range 4-15). One participant completed more than the minimum amount of reports (a total of 15). As described in Table 1, the 6 children who returned their Pain Squad reports were almost all female and in remission (information on any current disease directed therapies was not available). Children ranged in age from 8-17 years old and resided in Canada (n=2), the United States (n=2), and the Netherlands (n=2). One participant was diagnosed 1-2 years prior to participating, 4 participants were diagnosed 2-5 years prior to participating, and 1 participant was diagnosed 5-10 years prior to participating. All parents identified their children as Caucasian.

Figure 3. Flow of participants through the study.
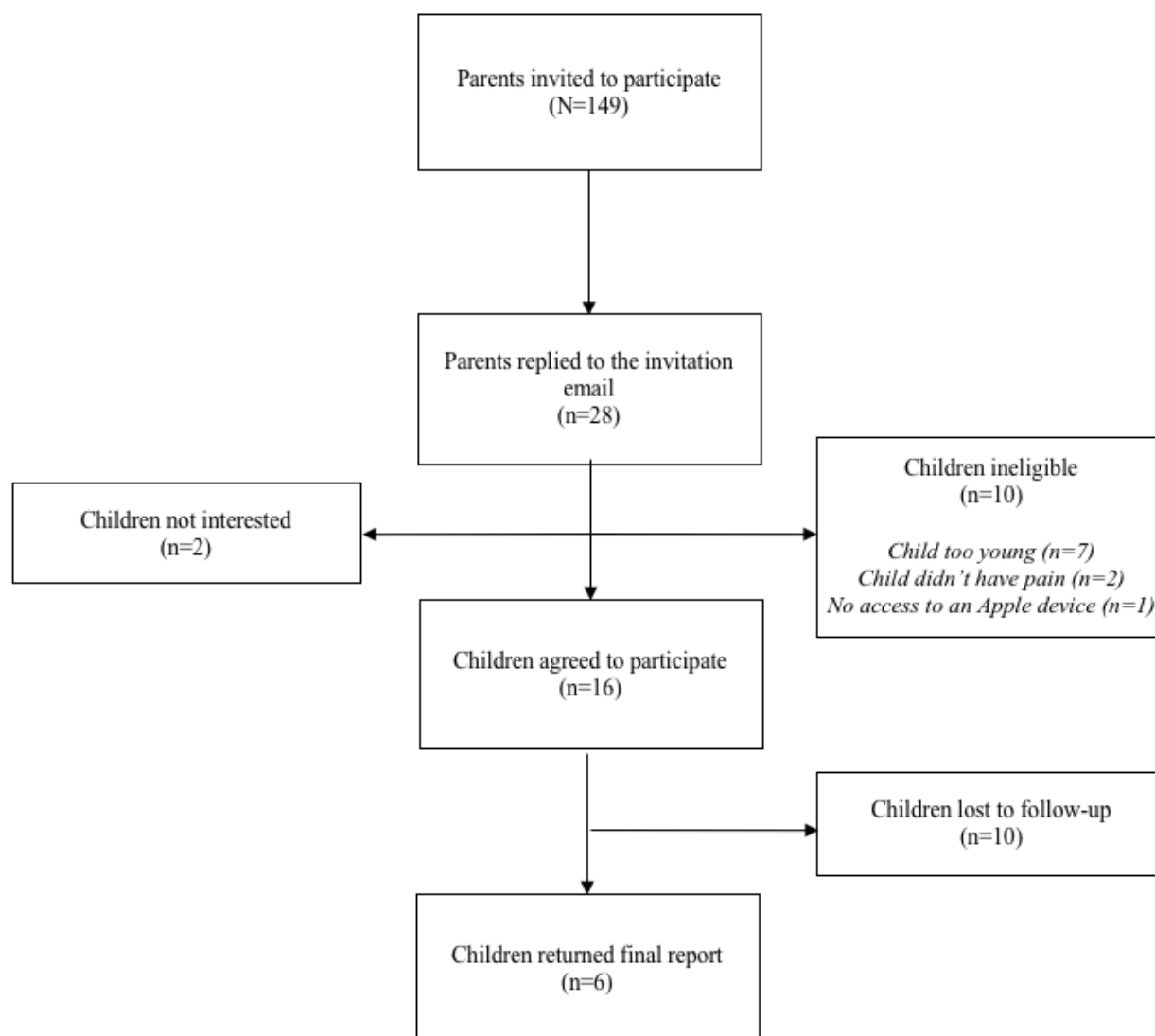
Table 1. Characteristics of participants who returned reports.

Participant	Age, years	Sex	Diagnosis	Remission	Completed reports, n[a]
1	15	Female	Osteosarcoma	Yes	8
2	8	Female	ALL[b]	No	8
3	17	Female	Germ cell tumor	Yes	5
4	14	Male	ALL[b]	Yes	15
5	9	Female	ALL[b]	Yes	4
6	13	Female	Brain tumor	Yes	12

[a]14 possible reports.

[b]Acute lymphoblastic leukemia.

Implementation Effectiveness

A summary of the participants' ratings on key implementation outcomes are provided in Table 2. Overall, participants provided positive evaluations for 9 of the 10 outcomes and high evaluations for 5 of those outcomes. Participants rated Pain Squad as being highly feasible to download and use and rated their experience using it as acceptable. Ratings of the app's appropriateness varied. Participants rated the app's helpfulness with describing pain positively, although the average rating of the app's helpfulness with treating pain was evaluated negatively. Participants' responses demonstrated a potential for wide penetration of the app, reporting on average that they would be highly likely to recommend Pain Squad to another child with cancer. In terms of sustainability, one participant

reported that they would be willing to use it for the same amount of time, while the others indicated that they would be willing to use it for longer. There was no direct cost associated with implementing Pain Squad as it is freely available on the Apple App Store. With respect to fidelity, no participants reported any major technical issues using the app. However, difficulty did occur when participants tried to download the app on an iPad (as opposed to iPhone), as an extra step was required in the Apple App Store interface. The app was also not used entirely as intended by participants. As mentioned above, only 6 of 16 participants returned reports to the research team, and on average, fewer than the 2 required pain assessments were completed per day. Also, it was noted that 2 participants reported higher levels of pain for their "least" compared to their "worst" pain scores in a pain assessment (pain data not reported).

Open-Ended Responses

Five participants (5/6, 83%) provided comments in the open-ended questions of the follow-up survey.

Favorite Part of Using Pain Squad

Regarding participants' favorite part of using Pain Squad, 3 participants discussed the app's features and usability.

> The rewards and the "promotions." Thought it was cool to be "promoted."

> It was very easy to fill in and did not take a lot of time.

One participant acknowledged the app's usefulness as their favorite feature:

> I liked all of the questions the app asked me, they helped describe my pain, which is pretty hard.

Least Favorite or Most Challenging Part of Using Pain Squad

Timing of the assessments necessitated participants having their iOS device with them, and this was identified as the least favored or most challenging part of the Pain Squad experience by 2 participants. For instance, participants described:

> Being in the right place at the right time was sometimes difficult – remembering as well. My phone is not always with me.

Table 2. Survey questions evaluating key implementation outcomes.

Question	Associated implementation outcomes	Answer choices	Possible scores, range	Actual scores, range	Mean score (SD)	n
Items from the Acceptability E-Scale						
How easy was Pain Squad for you to use?	Feasibility	N/A[a]	1-5	3-5	4.17 (0.75)	N/A
How understandable were the questions?	Acceptability	N/A	1-5	3-5	3.83 (0.75)	N/A
How much did you enjoy using Pain Squad?	Acceptability	N/A	1-5	2-5	3.67 (1.20)	N/A
How helpful was Pain Squad in describing your pain?	Appropriateness	N/A	1-5	1-5	3.50 (1.38)	N/A
Was the amount of time it took to complete Pain Squad acceptable?	Acceptability	N/A	1-5	4-5	4.67 (0.52)	N/A
How would you rate your overall satisfaction with Pain Squad?	Acceptability	N/A	1-5	4-5	4.33 (0.52)	N/A
Items from Jibb et al						
How helpful was Pain Squad in treating you pain?	Appropriateness	N/A	1-5	1-4	2.33 (1.03)	N/A
How long would you be willing to use Pain Squad?	Sustainability	Same amount of time	N/A	N/A	N/A	1
		2 weeks	N/A	N/A	N/A	1
		4 weeks	N/A	N/A	N/A	0
		6 weeks	N/A	N/A	N/A	1
		≥8 weeks	N/A	N/A	N/A	3
Investigator-developed items						
How easy was it to download Pain Squad from the App store to your device?	Feasibility	N/A	1-5	3-5	4.00 (0.90)	N/A
How likely would you be to recommend Pain Squad to another child with cancer?	Penetration	N/A	1-5	4-5	4.33 (0.52)	N/A

[a]N/A: not applicable.

The tricky thing was the timing. It was done during the summer and sometimes we were out or doing things at the time I had to fill it in. It was hard to always be at the iPad when it was time to fill it in. I do not have a phone, so I had to be at my house to do it. It was hard.

Two participants commented on the commitment required. The following quote illustrates this point:

My daughter disliked that she had to fill in the questions daily.

One participant expressed dislike for a feature in the app:

I didn't like that some options didn't have a back button.

Finally, one participant described that the app would have been more relevant and useful at a different stage of their disease:

It would have been great to have had this while in treatment to record pain as there was a lot then.

Discussion

Principal Findings

The objective of this study was to evaluate the implementation effectiveness of Pain Squad, a free evidence-based cancer pain assessment app, in a naturalistic context. Results provide preliminary data to support the use of Pain Squad as a pain assessment tool for children with cancer who have access to an iOS device. However, the study also identified significant barriers and challenges associated with the app's use and uptake by end users.

Similar to what has been reported in other mHealth studies [37,38], we encountered challenges with participant recruitment and retention in this naturalistic context outside of a traditional clinical research trial. Of 149 parents who were invited to participate, 16 agreed for their child to participate, and only 6 had children who completed the study by sending in their pain assessment report at the end of the testing period. This is in contrast to the Pain Squad validation trial, which recruited 92 children and adolescents with cancer and managed to retain all enrolled participants throughout the course of the study [19]. We surmise some key contextual differences may account for these differences. First, the current study recruited and engaged with participants entirely online. Indeed, it is unclear how many of the 149 parents contacted had children meeting the study's eligibility criteria. While emerging research suggests that online recruitment may be advantageous [39], lack of in-person contact is a well-documented limitation of mHealth studies and may negatively influence recruitment, retention, and effectiveness [40]. This challenge was likely compounded in this study by the need to access child participants via their parents. Second, unlike the research version of the app used in past usability, feasibility, and validation studies [19,23], the public version of Pain Squad used in this study does not feature any network or server connectivity, requiring participants to email their final pain assessment report to the research team. Participants did not raise this as a challenge in the open-ended questions; however, it is possible that this extra step was a barrier for study

completion and restricted our ability to collect partial data from participants who started but did not complete the study. Future public versions of Pain Squad should consider the possibility of server connectivity to allow clinicians to access users' pain data without requiring this additional step, or alternatively, adding other ways for users to send in their reports, such as text message, which is a communication method more commonly used by children and adolescents [41]. These contextual differences reflect real-world issues that children downloading and using Pain Squad may encounter in their everyday lives outside of tightly controlled and well-resourced research trial environments. These are challenges that should be considered by the app development community, which may wish to evaluate the differential effectiveness of various app features (ie, report submission via text message). This could be done in a sample of healthy children to prevent undue burden on vulnerable medical populations.

Reporting adherence varied significantly for the 6 participants who submitted report data, ranging from 4-15 assessments. Overall, the average adherence rate in this study was lower than the rate of adherence in previous Pain Squad feasibility and validation studies [19,23]. This "voltage drop," whereby the success of a tool decreases once it is tested in naturalistic settings, has been previously described [42]. This decrease in adherence may be related to the fact that completing pain assessments within 30 minutes of the scheduled time may be difficult to attain or sustain for many children and families but may also reflect other important differences, such as the characteristics of the community-based sample. Hardiker and Grant [43] reviewed factors that influence public engagement with electronic health (eHealth) and found that among adults, engagement with eHealth can vary significantly based on individual characteristics including age, disease severity, motivation to improve one's own health, and the belief that the intervention will improve one's health [43]. The majority of children in our study were in remission, and while pain can remain an issue for childhood cancer survivors, it is often significantly lower in intensity than children who are in active treatment [7,44]. Thus, addressing pain with the app presented lower relative advantage for the participants—a construct described in the Consolidated Framework for Implementation Research [45]. Children in Stinson et al's validation study [19] were in active treatment, and thus, the opportunity for buy-in, relative advantage, and tension for change [45] were presumably more compelling. It is important to note that in both the original validation study [19] and the current implementation pilot, participants' submitted pain reports were used for research purposes only. This lack of potential for improved clinical care may also afford lower relative advantage and is a point of ecological validity that should be addressed in future implementation studies of Pain Squad. Finally, participants in this study were offered a monetary incentive to complete the pain assessments and return their final report to the research team, and this may have been a key feature driving compliance [46,47]. When the app is used in a clinical setting without monetary incentives, researchers and clinicians may experience an additional drop in retention and adherence. Future studies using Pain Squad may wish to conduct a process evaluation to better understand barriers to participant retention and adherence.

This may reveal additional challenges to be considered (eg, preferences for alternative gamification themes or need for further information on the benefits of using the app).

Participants' comments about their experiences using Pain Squad were generally positive (Table 2). They reported the app as acceptable, feasible, sustainable, and having potential for broad penetration. Most participants (5/6) reported they would be willing to use Pain Squad for an extended period of time; however, they described the limited time window for completing pain assessments and the commitment required as challenges. These challenges were also identified by participants in the Pain Squad validation study [19]. Future versions of Pain Squad should take this feedback into account to promote adherence. Further, while the current study was only 1 week in duration, the gamification element of the app terminates after a 2-week period (ie, participants can achieve the highest law enforcement rank after completing 2 weeks of pain assessments). Future versions of the app should also consider additional incentives for longer-term use. Participants' perceptions of the appropriateness of the app were mixed. Participants reported that the app was helpful for describing their pain, but not for treating their pain. This version of Pain Squad collects data on the strategies that participants select to treat their pain but was designed primarily as a pain assessment tool. An enhanced version of Pain Squad, Pain Squad+, provides real-time pain management recommendations according to a standardized pain treatment algorithm in response to pain reported in app assessments and was able reduce pain intensity and interference in an efficacy pilot with 40 children [31]. Building on the results of the current study, it will be important to conduct implementation studies of Pain Squad+ after its effectiveness is demonstrated to optimize its relevance to children with cancer in real-world settings.

Limitations

This work is not without limitations. First, the results of this study describe the experiences of a small number of children with cancer (most of whom were in remission) whose perspectives and experiences may not be representative. As well, the study eligibility criteria required children to have access to an iOS device, which introduced sample selection biases based on socioeconomic status and participants' device brand preferences. Further, the study was limited to the perspectives of the main app user, children with cancer. Future implementation studies should evaluate the perspectives of other users involved such as parents, regarding their role in implementing the intervention, as well as clinicians and organizational administrators to assess other potential barriers and facilitators to the implementation of Pain Squad in clinical settings [48]. The findings of this pilot work could be used to adapt Pain Squad for a full implementation trial to evaluate the effectiveness of various implementation strategies (eg, advertisements and prescription by health care providers) to achieve optimal dissemination and uptake of the app.

Conclusions

In conclusion, this study demonstrated that Pain Squad was generally well received by a small sample of children with cancer in a naturalistic context. However, specific challenges related to user engagement and adherence were revealed that are unique to a naturalistic setting. This work highlights the importance of studying implementation outcomes for evidence-based technologies, such as Pain Squad, to optimize their use when made available to the intended end-users.

Conflicts of Interest

None declared.

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Abbreviations

AES: Acceptability Evaluation Scale
eHealth: electronic health
mHealth: mobile health

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Usability Evaluation of a Mobile Phone–Based System for Remote Monitoring and Management of Chemotherapy-Related Side Effects in Cancer Patients: Mixed-Methods Study

Saeed Moradian[1,2], BSN, MA, PhD (Nursing); Monika K Krzyzanowska[3,4], MPH, MD, MD FRCPC; Roma Maguire[5], BN, MSc, PhD; Plinio P Morita[6,7], PEng, MAsC, PhD; Vishal Kukreti[8,9], MD FRCPC; Jonathan Avery[8], PhD; Geoffrey Liu[8,10], MSc, MD; Joseph Cafazzo[11,12], BASc, PEng, MHSc, PhD; Doris Howell[2,3], BS, RN, PhD

[1]Department of Supportive Care-Research Division, Princess Margaret Cancer Centre, University Health Network, Toronto, ON, Canada

[2]The Lawrence S Bloomberg Faculty of Nursing, University of Toronto, Toronto, ON, Canada

[3]Department of Medical Oncology and Hematology, Princess Margaret Cancer Centre, University Health Network, Toronto, ON, Canada

[4]Institute of Medical Science, Faculty of Medicine, University of Toronto, Toronto, ON, Canada

[5]Department of Computer and Information Sciences, University of Strathclyde, Glasgow, United Kingdom

[6]School of Public Health and Health Systems, University of Waterloo, Waterloo, ON, Canada

[7]Institute of Health Policy, Management and Evaluation, University of Toronto, Toronto, ON, Canada

[8]Princess Margaret Cancer Centre, University Health Network, Toronto, ON, Canada

[9]Division of Medical Oncology and Hematology, Department of Medicine, University of Toronto, Toronto, ON, Canada

[10]Epidemiology Division, Dalla Lana School of Public Health, University of Toronto, Toronto, ON, Canada

[11]Centre for Global eHealth Innovation, University Health Network, Toronto, ON, Canada

[12]Institute of Health Policy, Management & Evaluation, University of Toronto, Toronto, ON, Canada

Corresponding Author:
Doris Howell, BS, RN, PhD
Department of Medical Oncology and Hematology, Princess Margaret Cancer Centre
University Health Network
Toronto, ON,
Canada
Phone: 1 416 946 4501 ext 3419
Fax: 1 416 340 4739
Email: Doris.Howell@uhn.ca

Abstract

Background: As most chemotherapy is administered in the outpatient setting, patients are required to manage related side effects at home without direct support from health professionals. The Advanced Symptom Management System (ASyMS) has been developed to facilitate the remote monitoring and management of chemotherapy-related toxicity in patients with cancer, using patient-reported outcomes questionnaires and a clinician alerting system.

Objective: This study aims to evaluate the usability of the ASyMS, a mobile phone–based technology, from the perspective of Canadian patients with cancer receiving chemotherapy to identify existing design, functionality, and usability issues and elicit their views, experiences, and satisfaction with the ASyMS.

Methods: We used a mixed-method approach to data collection with user-based testing, a think-aloud technique, semistructured interviews, and short answer questionnaires with a purposive sample of 10 patients with cancer. Participants attended usability testing sessions at the Centre for Global eHealth Innovation, University Health Network, and performed specific tasks on the ASyMS device. The test was videorecorded and each task was timed during the test. After the usability sessions, participants completed a posttest questionnaire and participated in a semistructured qualitative interview. A thematic analysis was used to code and categorize the identified issues into themes that summarized the type and frequency of occurrence.

Results: The thematic analysis generated 3 overarching themes as follows: ASyMS user-friendliness; usefulness of ASyMS (content quality and richness); and intention to use. Results from the posttest questionnaire indicated that 80% (8/10) of participants had great motivation to use the ASyMS, 70% (7/10) had positive perceptions of the successful use of the ASyMS, and all (10/10, 100%) had a positive attitude toward using the ASyMS in the future. Most identified design and functionality issues were related

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to the navigation of the ASyMS device and a desire for a more attractive design with advanced functionality and features. The main general design recommendations were as follows: enhance the readability of the screen; implement advance options (eg, search option); and support better navigation.

Conclusions: The ASyMS has shown positive perceptions of patients in usability testing and qualitative interviews. An evaluation of the effects of the ASyMS on symptom outcomes in a clinical trial is needed.

Introduction

Background

Systematic chemotherapy continues to be the main treatment modality for almost all major cancer types [1]. Chemotherapy is associated with a myriad of symptoms and adverse treatment side effects that can range from mild to life-threatening, severe, and disabling [2]. Therefore, early recognition and effective management of these symptoms by both clinicians and patients are critical to reducing physical and psychological treatment sequalae [2].

There is growing evidence in support of using patient-reported outcome measures (PROMs) for improving symptom management [3-5]. The increased number of mobile phone users creates opportunities for developing models of supportive care that use these technologies for monitoring PROMs to improve home-based, proactive "real-time" symptom monitoring and management [6-8]. Several Web-enabled PROMs systems have been trialed in oncological settings [4,8-10] and shown to support patients in managing chemotherapy-related symptoms [3,11], improve symptom control [11,12], and enhance patient-clinician communication [4]. However, few of the current systems have been developed in line with best-practice guidelines in user-centered design nor have verified the system usability during the stages of system development [5,13], which could impact their use by patients and clinical integration in practice settings [14].

The aim of this study, which is part of a larger project to enhance the provision of timely, high-quality, person-centered supportive care, is to evaluate the usability of a mobile phone–based technology, the Advanced Symptom Management System (ASyMS), from the perspective of Canadian patients with cancer (colorectal and lymphoma) receiving chemotherapy in a controlled usability testing environment. The secondary aim of our end-user testing is to explore users' performance and satisfaction with the system interface and their perspectives and experience with the system and the content of ASyMS [9]. In addition, this study assesses the ASyMS against a set of human factors design guidelines and heuristics to increase the likelihood of discovering more design features and function issues that could impact user experience and willingness to use the system.

Advanced Symptom Management System

The ASyMS, one of the more advanced remote monitoring systems, is a mobile phone–based device designed to monitor and manage chemotherapy-related toxicity in the home setting. It enables real-time remote monitoring of cancer symptoms using PROMs [15]. The ASyMs uses innovative risk prediction modeling and decision-support tools that allow for timely, high-quality, person-centered supportive care for better treatment toxicity management [10,16].

Patients using the ASyMS complete an e-symptom PROMs questionnaire to assess the occurrence, severity, and distress associated with each symptom. After completing the questionnaire, patients immediately receive evidence-based, self-care advice on the mobile phone based on the specific symptoms reported, which facilitates the self-management of symptoms. Leveraging evidence-based algorithms, symptoms reported through the device that meet a threshold criteria (ie, high level of severity) trigger alerts to cancer care clinicians, usually nurses, who on the receipt of an alert can view patients' symptom reports on a secure webpage and contact patients directly at home by telephone, enabling the initiation of proactive clinical interventions (Multimedia Appendix 1) [17].

The ASyMS was developed in the United Kingdom based on the extensive patient and clinician engagement, and its utility and acceptability have been tested in UK populations [18,19]. The effect of the ASyMS intervention on patient outcomes is uncertain and is being tested in a large multisite trial in European countries [16]. We undertook a study to test the usability of the ASyMS program to identify its potential for the uptake in a Canadian cancer population. The ASyMS program was installed on an Android mobile phone with a 5.00-inch touchscreen display with a resolution of 720 pixels by 1280 pixels. Figure 1 and Multimedia Appendix 2 show a preview and some features and functions of the ASyMS.

Figure 1. Patient handset screenshots. (Source: Docobo Ltd).

Methods

Study Design

We used a mixed-method approach (qualitative and quantitative data sources) to increase the depth of evaluation and support methodological triangulation to improve the reliability and validity of findings [20]. Mixed-methods also allow for a more comprehensive understanding of participants experience and enable the identification of specific usability issues [20,21]. A usability study evaluates how a specific process or product works for individuals and the extent to which a user can use a product to achieve specific goals (interaction between user and task in a defined environment) [22,23].

Data collection combined user-based testing using a think-aloud technique, semistructured qualitative interviews based on a qualitative descriptive methodology [24], and short answer quantitative questionnaires; all these methods have been used widely for usability testing [25]. Specifically, think aloud is a user-related method for assessing usability where users are encouraged to verbalize their perceptions out loud as they interact with the system [26]. Participants' experiences with the system evaluated through qualitative interviews and questionnaires can inform potential for future uptake [27].

Participants and Setting

Estimation of the sample size for a usability test depends on several variables, including types of test users available, the mission criticality of a system (any factor that is essential for system operation), and problem discovery rate (the number of usability issues that can be uncovered by users) [28,29]. Although, it has been shown that 80% of the usability problems can be detected with 4 or 5 participants in a usability testing

[30], Faulkner [29] found that the minimum percentage of identified usability issues increased from 55% to 82%, and the mean percentage of issues increased from 85% to 95% when the number of participants was increased from 5 to 10. Thus, in this study, we aimed to recruit a minimum of 10 patients. We used a purposive sampling method to ensure maximal variation in end-user characteristics, specifically younger (age <50 years) and older (age >50 years) adult patients with diverse cancer types (colorectal or lymphoma), males and females, and those with and without experience in using mobile technology.

The Institutional Review Board Approval was obtained from the University Health Network (UHN) to conduct the study prior to recruitment (#15-9432). Patients were recruited from ambulatory follow-up clinics at the Princess Margaret Cancer Center, a cancer research center affiliated with the University of Toronto as part of the UHN. The inclusion criteria were that patients received, at least, one cycle of chemotherapy for treatment of their cancer (colorectal or lymphoma), were aged >18, and able to participate in usability testing for "think aloud" in English. All participants gave informed written consent for participation in the study.

Data Collection

The main goal of user-centered methods is to involve real users, elicit their views and experiences of the intervention to identify usability issues [31,32]. To meet the aim of this study, usability sessions were videorecorded from multiple angles, and participants were encouraged to share their thoughts verbally as they progressed through a set of predefined tasks (think aloud) [26]. We aimed to elicit feedback and identify design, functionality, and usability issues. In addition, participant experiences, thoughts, feelings, and satisfaction with the ASyMS were assessed by an audiotaped, semistructured, face-to-face

qualitative interview with participants and through completing a short questionnaire (modified Telehealth Acceptance Measure, TAM), immediately after usability testing sessions (Multimedia Appendix 3).

The TAM questionnaire comprises 10 questions on a Likert scale ranging from 1 to 7; higher scores indicate greater motivation to use telehealth, more favorable perceptions of the successful use of telehealth, greater patients' belief that significant others would like them to use telehealth, and more positive attitude toward using telehealth. The TAM questionnaire is designed to assess patients' motivation to use telehealth and includes questions that are derived from the theory of planned behavior, a model that explains the factors that underpin people's motivation to act [33]. We used this questionnaire to indicate participants' overall motivation and readiness to use the ASyMS device, assess participants' perceived behavioral control, subjective norms, attitudes toward the device, and the extent to which individuals perceive that significant others want them to use the device.

Usability Testing Procedure

Participants attended usability testing sessions at the Healthcare Human Factors labs at the Centre for Global eHealth Innovation, UHN. Each participant was advised that the aim was to test the ASyMS device and not participants. In addition, participants received written and verbal information regarding the testing procedure, and a brief introduction to the ASyMS before usability testing commenced.

Before starting the session, participants completed a demographic questionnaire. Participants were given a case scenario and a simulated symptom experience they might have during one of their chemotherapy cycles. Participants were requested to follow the tasks provided to them on the ASyMS device, representing typical user goals. Throughout testing, each participant was requested to perform specific tasks that consisted of the following: completing the e-symptom questionnaire (PROMs) on the ASyMS device; finding information about side effects and self-care; filling out the anytime section of the symptom questionnaire; and finding a history of side effects (Multimedia Appendix 4). A trained moderator guided participants through the testing procedure but did not intervene or disrupt the thinking-aloud process. Furthermore, from the observation room, behind a one-way mirror, 2 observers watched the interaction, made notes about what was verbalized, and observed to inform the analysis, and ensured the entire session was recorded. Each task was timed during the test.

After the usability sessions, participants completed the posttest questionnaire to assess their perceptions about the usability of the ASyMS (Multimedia Appendix 3). In addition, they participated in a face-to-face interview regarding the utility and acceptability of the ASyMS in managing chemotherapy symptoms, parts of the content or aspects of the system they liked or disliked, and the reason for their response. The complete testing procedure for all steps averaged approximately 2 hours (range 1.5-2 hours).

Data Analysis

The audio and video recordings from the usability and interview sessions were transcribed. The thematic analysis was used to identify all emerging issues and the relations between the themes [34,35]. The identified issues were coded and categorized according to the type and frequency of occurrence [35]. Data collection and analysis continued until no more patterns or themes were emerging from the data [36]. Two members of the research team reviewed the transcripts. Any discrepancies between reviewers were resolved through discussion or the involvement of a third reviewer, if necessary. All qualitative data were coded using NVivo 10 qualitative data analysis software. In addition, a set of variables related to the participants' performance, including the number of errors each participant made, requests for help, the time taken to complete the task, participant feedback, observers and moderator's notes, and reviewing the videos, were used to identify a list of usability issues. Descriptive statistics (means, medians, ranges, frequencies, or percentages) were used to summarize these data.

Results

Participant Characteristics

Table 1 presents the characteristics of the study participants. Of 10 participants, 7 were male and 3 were female, with an average age of 68 (range 18-78) years. Most participants (n=8) had higher education (college or university). All participants had their own mobile phone, of which 70% (7/10) had a smartphone, whereas 30% (3/10) owned a regular cell phone (not a smartphone). In addition, 60% (6/10) of participants mentioned that they were comfortable or very comfortable using these devices; 80% (8/10) were comfortable using the internet.

Quantitative Results

Using the video analysis, the task completion times, the number of errors made by participants while completing tasks, and the number of times they asked for help are shown in Table 2. We followed the TAM developers instructions to score and interpret the TAM (Multimedia Appendix 3). Overall, 80% of participants (8/10) scored >4 on Q2, Q4, and Q5 (mean=5.8), indicating high motivation to use the ASyMS device. In addition, 70% of participants (7/10) scored >4 on Q3, Q6, and Q7 (mean=5.6), indicating they had positive perceptions of the successful use of the ASyMS, and all participants (n=10) scored >4 on Q8 and Q9 (mean=6.1), showing they believed that significant others would like them to use the ASyMS. Furthermore, all participants (n=10) scored ≥5 on Q10 (mean=6.3), suggesting a positive attitude toward using the ASyMS device in future (Table 3).

Table 1. Participants' characteristics (N=10).

Characteristics	Value
Age, median (range)	68 (18-78)
Sex, n	
Male	7
Female	3
Education, n	
High school	2
University or college	5
Postgraduate degree (eg, Doctor of Philosophy)	3
Own a phone, n	
Smartphone	7
Regular cell phone	3
Hours use a computer each week, n	
Not at all	1
1-2 h	1
4-5 h	1
>7 h	7
Comfortable using a smartphone, n	
Not at all	1
A little comfortable	3
Comfortable	4
Very comfortable	2
Comfortable using a computer, n	
Not at all	N/A[a]
A little comfortable	4
Comfortable	3
Very comfortable	3
Comfortable using the internet, n	
Not at all	N/A
A little comfortable	2
Comfortable	4
Very comfortable	4
Cancer type, n	
Gastrointestinal cancer	3
Lymphoma	7

[a]N/A: not available.

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Table 2. Quantitative results (time and SD, errors, and requests for help).

Task	Mean task completion time (SD) in seconds	Frequency of error, n_{error} (n)[a]	Frequency of requests for help, n_{help} (n)[b]
Task 1: Complete e-symptom questionnaire	846 (135)	25 (8)	47 (9)
Task 2: Find information about side effects and self-care	502 (250)	52 (9)	32 (8)
Task 3: Filling out anytime questionnaire	232(124)	35 (10)	37 (10)
Task 4: Find history of side effects	257 (70)	34 (10)	26 (9)

[a]n_{error} represents the number of times an error was made, and n represents the number of people who made the error.

[b]n_{help} represents the number of times a request for help was made, and n represents the number of people who made the request for help.

Table 3. Telehealth Acceptance Measure: Mean scoring.

Participants' characteristics				Behavioral intention item	Perceived behavioral control item	Subjective norm item	Attitude item
No	Age	Sex	Comfortable using a smartphone				
1	68	Female	A little comfortable	7	6.3	7	7
2	78	Male	Not at all	5.7	4.3	5	5
3	18	Male	Very comfortable	6	6.3	5.5	6
4	68	Male	Comfortable	7	6	6	7
5	77	Female	A little comfortable	5.3	3	6.5	6.3
6	59	Male	A little comfortable	3.7	7	7	6.7
7	75	Male	Comfortable	5.3	6	6	5
8	70	Male	Comfortable	7	7	7	7
9	34	Male	Very comfortable	3.7	3	5	6.3
10	55	Female	Comfortable	7	7	6	7

Qualitative Results

The thematic analysis of the interview transcripts and participants' feedback generated 3 overarching themes and related subthemes: ASyMS user-friendliness, with subthemes of design, navigation, and ease of use of the ASyMS; usefulness of the ASyMS (content quality and richness), with subthemes of self-care advice and information on the ASyMS, and appropriateness of the ASyMS questions; and intention to use, with subthemes of acceptance and satisfaction with using the ASyMS in future.

Advanced Symptom Management System User-Friendliness

Both the quantitative and qualitative data from the usability testing identified several design and functionality issues for the ASyMS's device that may negatively impact its efficient use. Each of the recognized issues was mapped to source events (ie, participants' feedback, errors, and moderator observation). Moreover, each of the issues was classified in one of the 8 usability heuristics for mobile devices (ie, match between system and the real world, ease of input, and screen readability) [37].

The identified issues shown in Table 4 mostly relate to the navigation of the ASyMS device.

Table 4. Identified usability issues.

Problem	Category (usability heuristics)	Source
Introduction screen not intuitive nor informative enough	Match between system and the real world	Feedback; Errors; Request for help
Small screen or font size	Screen readability	Feedback; Observations
Lack of effective color scheme	Screen readability	Feedback; Observations
Lack of advance options (eg, search option)	Consistency and mapping	Feedback; Observations
No option to (send a message) chat with a clinician	Ease of input	Feedback; Observations
Problem with editing and no obvious go back option	Ease of input and Consistency and mapping	Feedback; Errors; Request for help; Observations

Participants through usability testing and the interview commented on the need for a more advanced and attractive design, with better functionality and features in ASyMS to better address the needs of end users, as indicated below:

> *Finding where everything is, it's not labeled, so it would be easier if every option was labeled...I think it needs a higher-level menu, which may have to be categorized, which allows me to navigate around through it easily.* [Participant 1]

> *...add a search button. Having a search button just kills so much time. You can access the entire database in like 2 seconds. Saves a lot of time...I wish it had a search button.* [Participant 3]

Some older participants (age>65) commented that they would prefer to use ASyMS on a device with a larger screen (with larger font size) and a more effective color scheme that better draws users' attention toward specific elements on the screen.

> *A bigger screen for people who need glasses...someone like me whose vision is affected needs a bigger screen* [Participant 4]

> *It is always nice for someone in my age if got a bigger text...Of course, if you could make it bigger, would be great.* [Participant 7]

> *I have an iPhone, which the text isn't very much bigger than that, right? Like the text is the same basically. But the screen colors, like this screen color to me (shows iPhone) is a lot easier to read than this (shows the ASyMS's handset).* [Participant 5]

As participants were not familiar with the system prior to the usability session and no tutorial of the ASyMS and its functionalities was given, they often felt insecure about their actions and asked for assistance and approval before performing tasks. Most participants mentioned that they would need some time to learn and get familiar with the ASyMS device before they could start to use it regularly. By the end of the usability sessions, when participants had gained some experience with using ASyMS, all participants agreed that with experience in using the ASyMS, they would get familiar with its features and definitely use it more efficiently, as noted in the following participant quote:

> *If people use this a few times they will be able to (use and) navigate it easily.* [Participant 6]

Usefulness of the Advanced Symptom Management System

Regarding the self-care advice and information provided in the library, almost every participant commented that the ASyMS provides a lot of quality information. Two participants suggested that using the information would be easier if the self-care information was better categorized.

> *The information section, I would rather have that more generalized and categorized. It is easier for the person to use.* [Participant 6]

> *There is no easy way to find information here. You have to read the entire list to get what you want, and probably read more than once. Categorization would improve that.* [Participant 2]

One older (aged 70 years) participant, who felt comfortable using a smartphone and had a high level of education suggested that it would be helpful if the information and advice could be customized to the specific therapy that patients receive. In addition, he commented that the self-care information he sought was not covered in the self-care advice as he experienced different treatment toxicities and suggested to modify and enhance the self-care advice.

> *It would help if you could customize to the individual...the specific therapy they are receiving...There is one major thing, that is the food. One of the problems in my experience, I went through two different regimens of chemotherapy, different elements of the regimens have different food requirements, some for example do not allow caffeine or alcohol or meat products or spices. None of that is here, that would be helpful if me and my wife are about to contemplate dinner and it tells us can I eat such and such, those answers would be helpful in terms of my chemotherapy. This app tells us about chemotherapy in general, whereas different patients have different regimens of chemotherapy...* [Participant 8]

Intention to Use

All participants mentioned that the ASyMS would be a valuable device to use for managing cancer treatment side effects. Results from the modified TAM and the interviews suggested that almost all participants were satisfied and pleased with their experience in using the ASyMS device, and this positively influenced their attitude toward using the ASyMS in the future. Participants indicated confidence that the problem of communication with their health care provider can be solved (to some extent) by using such a device, and it will help participants to manage their symptoms quicker than the other current available options.

> *Clinician is typically in a hurry, not using a lot of words, sometimes very technical words...easy to get snowed...I always try to bring my wife or my son or my daughter, so they can hear what the doctor says and also ask questions. The conversation between me and my doctor is brief and complex. If I have any questions later, I cannot reach them...I call their secretary, who asks that clinician, and gets back to me in a few days...makes it impossible to ask follow-up questions. There is a problem with the nature of this communication, which a system like ASyMS could improve, if it provided for multiple interactions...I can see value in such a system if it provided that capability.* [Participant 10]

> *it actually would give you a pretty good history. And probably you would be able to deal with the nasty symptoms quicker than the other options which is trying to contact your doctor or nurse, and its not that easy.* [Participant 2]

Discussion

Despite the proliferative use of mobile technologies in health care, few Web-enabled PROMs systems have been developed with consideration of their quality through comprehensive and rigorous usability evaluations [38]. While ASyMS has undergone several years of development [17,18], this study has added to the knowledge about usability issues, acceptability, and the potential for the uptake of this mobile technology in Canadian cancer populations to manage the acute effects of cancer treatment.The main general design recommendations (according to usability heuristics) for enhancing features of the ASyMS are as follows: enhance the readability and glanceability of screen; implement advance options (including search option, easy identifiable back option, intuitive pop-up screen option, and advanced navigation options, eg, swiping screens, for expert users); and support navigation by creating an option to customize main menu features, particularly the self-care advice to make it easier to find rather than reading through lengthy text.

Concerns have been raised in the literature that modern technologies, such as mobile devices, may not be entirely appropriate for use by all cancer populations, as it might be considered difficult to use. For example, older adults may experience difficulties when using technologies such as mobile devices or smartphones [39]. However, there has been a growing interest in the design of technologies, including innovative health technology design for older adults, who often manage complex health conditions and multiple chronic illnesses, to provide better and more sufficient supportive care services [40]. Our study findings demonstrated that older participants (>65) were interested and had a positive attitude toward using the ASyMS device, although a few of them mentioned that they prefer to use the ASyMS on a larger device with larger font size. Furthermore, they mentioned that their performance was affected by age-related physical and mental health status. This is also shown in previous research that older adults are interested and capable of using modern technologies for managing health care issues [41-43].

Furthermore, limited experience with aspects of mobile technology did not affect the acceptance of the mobile device in this study. This is also consistent with the result of a recent literature review indicating that mobile devices, such as smartphones, can be ideal tools for novice users who have very little understanding of how software or a system in general works, as users learn how to use a touchscreen after a few tries

[39]. Although none of the participants had previous experience in using the ASyMS device, all of them became proficient during or by the end of usability testing sessions, indicating that the training period does not need to be long; nevertheless, the incorporation of tutorials and training are important to reduce the time needed by users to learn how to use the system [44,45]. The training should focus on the system features that are more problematic, challenging, and complex for users [43], ensuring that patients feel confident in the use of the system.

Besides design issues and problems observed in the usability testing, participants also commented on the ASyMS content to enable self-management of treatment symptoms. Previous research has shown that a higher perception of the content richness in a system has resulted in a higher perception of the usefulness of the system [46]. The content richness is defined as the adequacy of resources that users can access to improve their activity on a particular technology [47]. As noted by Lee and Lehto [48], the content richness is a key significant predictor of the perceived usefulness [49]. Our findings support a need to enhance the self-care advice and personalized tailoring to treatment regimens to better support patients in taking the required actions for symptom self-management. Evidence-based guidelines for symptom management have been developed [50] and best practices in presenting information in an "actionable" format should be considered in the future design of the ASyMS device [51]. Furthermore, as patients have different learning styles, the use of an extensive library of written, audio, and video information resources and patient education materials and guidelines for symptom self-management would be beneficial.

Although the usability considers a combination of factors (including intuitive design, ease of learning, efficiency of use, memorability, error frequency, and user satisfaction [52,53]), one usability evaluation cannot claim to cover all possible and critical usage situations that can possibly occur. Testing the ASyMS in a real-world setting and evaluation of the effectiveness through a trial is needed given high variability in practices [43,54]. We have customized some of the features in the ASyMS device based on the data derived from this study. For instance, we have modified the content of the self-care library to be more action-oriented to foster patient self-management. Currently, a feasibility randomized controlled trial is under way (NCT03335189) that will identify the implementation and context-related issues prior to a larger, multisite randomized controlled trial in Canada.

Conflicts of Interest

None declared.

Multimedia Appendix 1

ASyMS Monitoring System.

[[PDF File (Adobe PDF File), 187KB](#) - [cancer_v4i2e10932_app1.pdf](#)]

Multimedia Appendix 2

Features of ASyMS.

[[PDF File (Adobe PDF File), 682KB](#) - [cancer_v4i2e10932_app2.pdf](#)]

Multimedia Appendix 3

ASYMS Acceptance Measure.

[[PDF File (Adobe PDF File), 42KB](#) - [cancer_v4i2e10932_app3.pdf](#)]

Multimedia Appendix 4

Usability test script.

[[PDF File (Adobe PDF File), 230KB](#) - [cancer_v4i2e10932_app4.pdf](#)]

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Abbreviations

ASyMS: Advanced Symptom Management System
PROM: patient-reported outcome measure
TAM: Telehealth Acceptance Measure
UHN: University Health Network

Original Paper

Assessing Preference Shift and Effects on Patient Knowledge and Decisional Conflict: Cross-Sectional Study of an Interactive Prostate-Specific Antigen Test Patient Decision Aid

Peter Scalia[1], MSc; Glyn Elwyn[1], MD, PhD; Jan Kremer[2], MD, PhD; Marjan Faber[2], PhD; Marie-Anne Durand[1], PhD

[1]The Dartmouth Institute for Health Policy and Clinical Practice, Dartmouth College, Lebanon, NH, United States

[2]Radboud Institute for Health Sciences, Scientific Institute for Quality of Healthcare, Radboud university medical center, Nijmegen, Netherlands

Corresponding Author:
Peter Scalia, MSc
The Dartmouth Institute for Health Policy and Clinical Practice
Dartmouth College
One Medical Center Drive, 5th floor
Lebanon, NH, NH 03756
United States
Phone: 1 603 653 0832
Email: Peter.Scalia@dartmouth.edu

Abstract

Background: Randomized trials of Web-based decision aids for prostate-specific antigen (PSA) testing indicate that these interventions improve knowledge and reduce decisional conflict. However, we do not know about these tools' impact on people who spontaneously use a PSA testing patient decision aid on the internet.

Objective: The objectives of this study were to (1) determine the impact of the Web-based PSA Option Grid patient decision aid on preference shift, knowledge, and decisional conflict; (2) identify which frequently asked questions (FAQs) are associated with preference shift; and (3) explore the possible relationships between these outcomes.

Methods: Data were collected between January 1, 2016, and December 30, 2017. Users who accessed the Web-based, interactive PSA Option Grid were provided with 3 options: have a PSA test, no PSA test, or unsure. Users first declared their initial preference and then completed 5 knowledge questions and a 4-item (yes or no) validated decisional conflict scale (Sure of myself, Understand information, Risk-benefit ratio, Encouragement; SURE). Next, users were presented with 10 FAQs and asked to identify their preference for each question based on the information provided. At the end, users declared their final preference and completed the same knowledge and decisional conflict questions. Paired sample t tests were employed to compare before and after knowledge and decisional conflict scores. A multinomial regression analysis was performed to determine which FAQs were associated with a shift in screening preference.

Results: Of all the people who accessed the PSA Option Grid, 39.8% (186/467) completed the interactive journey and associated surveys. After excluding 22 female users, we analyzed 164 responses. At completion, users shifted their preference to "not having the PSA test" (43/164, 26.2%, vs 117/164, 71.3%; $P<.001$), had higher levels of knowledge (112/164, 68.3%, vs 146/164, 89.0%; $P<.001$), and lower decisional conflict (94/164, 57.3%, vs 18/164, 11.0%; $P<.001$). There were 3 FAQs associated with preference shift: "What does the test involve?" "If my PSA level is high, what are the chances that I have prostate cancer?" and "What are the risks?" We did not find any relationship between knowledge, decisional conflict, and preference shift.

Conclusions: Unprompted use of the interactive PSA Option Grid leads to preference shift, increased knowledge, and reduced decisional conflict, which confirms the ability of these tools to influence decision making, even when used outside clinical encounters.

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Introduction

Randomized trials of Web-based decision aids for the prostate-specific antigen (PSA) screening test have indicated that these tools increase user knowledge, reduce decisional conflict, and reduce interest in having the test in controlled contexts, where users are recruited to use the intervention [1,2]. However, what can we say about users who choose to use Web-based decision aids independent of any study recruitment? Does spontaneous use of a PSA tool have an effect on users' knowledge and decisional conflict and shift their screening preferences?

A recent systematic review of 13 randomized trials assessed the effectiveness of decision aids for decision making in prostate cancer testing [3]. Regardless of the mode of delivery (ie, paper-based, Web-based, or video) the majority of decision aids improved patient knowledge of the PSA screening test and mitigated decisional conflict [3]. An example of a Web-based intervention that induced these positive outcomes is Prosdex, which also lowered the intention to undergo testing by 18% in comparison with participants in the control group who did not receive any decision support intervention [1]. Furthermore, a randomized trial found an almost 10% reduction in PSA screening and a 30% increase in preference for "watchful waiting" for those who used a Web-based decision aid compared to those who viewed public websites [4]. Web-based PSA tools that are tailored to individual participants increased knowledge levels among African American men, improved decision quality, and decreased levels of decision regret at follow-up [5-7].

A Web-based PSA decision aid—"PSA test: yes or no?" Option Grid—is a platform for men seeking information on the Web. It is designed for independent use. Individuals (presumably men) find this tool, independent of any invitation or promotion. This tool provides evidence-based information on the risks and pros and cons of the PSA screening test to help users make a decision that aligns with their preference [8]. The tool assesses user knowledge, level of decisional conflict, and preference before and after viewing the information. A prior study among 82 participants shows that users of the PSA Option Grid tend to become more risk averse, shifting their preference to "not having the test" after viewing risk information associated with the screening test and prostate biopsies [9]. This indicates a real-world impact on screening preference for users who spontaneously use this tool [9].

In a recent study, researchers used Google Analytics to track usage data for users of a Web-based decision aid for early-stage prostate cancer to determine if the tool was helpful and if users would recommend it to others. Although this study analyzed data from an unsolicited sample to determine "real-world" impact, they did not assess outcomes pre- and post decision aid use [10]. As far as can be determined, there has been no assessment of the direct impact of using a Web-based PSA screening decision aid on specific outcomes like preference shift, knowledge, or decisional conflict without actively recruiting or providing incentives to users in a research context.

The aims of this study were to: (1) determine the impact of the Web-based PSA Option Grid patient decision aids on preference shift, knowledge, and decisional conflict; (2) identify which frequently asked questions (FAQs) are associated with preference shift; and (3) explore the possible relationships between these outcomes.

Methods

Design

We conducted an analysis of data from a longitudinal sample derived from the Option Grid website of users who searched for and used the Web-based "PSA test: yes or no?" Option Grid, independent of any invitation. We assessed user preferences regarding PSA screening. We also measured levels of knowledge and decisional conflict before and after using the intervention. Ethical approval for this study was received from the Dartmouth College Committee for the Protection of Human Subjects (STUDY00030776).

Participants

Data from users of the "PSA test: yes or no?" Option Grid collected between January 1, 2016, and December 30, 2017, were eligible for inclusion. Data were excluded if the user exited the Option Grid website prior to completing the entire interactive process or if the user self-identified as female.

Intervention

Based on the 2017 Cochrane systematic review definition of a patient decision aid—"decision aids are intended to provide information and to promote self-help in the treatment decision-making process, which enables the patient to more actively participate in this process, if this is his or her preference"—we identify Option Grid as a patient decision aid [11]. Option Grid is available in static (PDF) and interactive (Option Grid interactive journey) formats. Both the paper-based and interactive versions of the "PSA test: yes or no?" Option Grid were freely available on the optiongrid.org website until March 2018. Users searched for and used the tools independent of any invitation. The tool was not promoted at any time during the study period. The interactive version of Option Grid was intended for independent use, but the information provided could have been used to facilitate a more collaborative discussion with a physician.

On the Option Grid website, users could have searched for the PSA interactive Option Grid using the keyword function or found it on a list of topics they could have browsed through. Once on the PSA Option Grid webpage, users had the option of viewing the PDF version of the PSA Option Grid or starting the "interactive journey." The same information is presented in both versions except the interactive journey presents the information in a sequential interactive method. If the journey was selected, users provided their demographic information such as their age group, gender, ethnicity, and geographic location. Before proceeding, users identified the strength of their preference, their level of decisional conflict, and their level of knowledge. Next, 10 FAQs, always presented in the same order, provided users with evidence-based information on the PSA test (ie, described the test and indicated the chances of having prostate cancer in their lifetime, the significance of having a normal or high PSA level, survival risk, and the

advantages and risks associated with the PSA test), and the risks and side effects associated with prostate biopsies and prostate cancer treatments. Multimedia Appendix 1 illustrates the interface that the user encountered for the first FAQ of the tool. To complete the interactive journey, users identified their final preference and the strength of that preference and completed the same SURE survey and knowledge questionnaire post-PSA Option Grid use.

Outcome Measures

The "self-check" knowledge measure contained 5 items that require a true or false response (Multimedia Appendix 2). The questions were developed in relation to some of the information embedded in the interactive PSA Option Grid. Those questions helped us determine if the user understood the content and learned new information during the interactive journey. Users filled out their responses before and after completing the journey.

Légaré et al developed a short 4-item decisional conflict measure known as SURE (Sure of myself; Understand information; Risk-benefit ratio; Encouragement), in which the user responded yes or no to each of the 4 questions (Multimedia Appendix 3) [12]. The 4 items are based on the 16-item decisional conflict scale and the Ottawa Decision Support Framework. The reliability and validity of SURE was first assessed with French-speaking pregnant women considering prenatal screening for Down syndrome and with over 1000 English-speaking patients in rural New England who were referred to watch condition-specific video decision aids [12]. SURE was found to be a reliable and valid measure to "detect clinically significant decisional conflict" in both groups [12,13]. Results of a secondary analysis of a clustered randomized trial supported the conclusions using a primary care sample: SURE showed "adequate psychometric properties" [13].

We also collected user preference data before and after reading the information associated with each FAQ in the interactive Option Grid (Multimedia Appendix 4).

Data Collection and Analysis

A database stored all responses provided by the user throughout the entire interactive journey; we only analyzed data from users of the interactive version. This included their responses to the knowledge questions, SURE survey, and their preferences pre-and post-Option Grid use.

The 3 preference options were represented in the dataset as 0=having the PSA test, 1=not having the PSA test, and 2=I am not sure. The McNemar test was used to determine if users significantly shifted their preference after completing the interactive journey in comparison with their initial preference prior to viewing the information. Chi-square tests were performed to explore possible relationships between knowledge, decisional conflict, and preference shift.

We conducted a multinomial regression analysis to determine which FAQs were associated with preference shift. We created a dependent variable with 4 categories: 0="having a PSA test" shifted to "not having a PSA test," 1="not having a PSA test" shifted to "having a PSA test," 2="not having a PSA test" preference retained, and 3="having a PSA test" preference retained (reference category). The FAQs represented nominal independent variables and were inserted as factors in the model. Due to the fact that multiple treatment options are being compared for each FAQ, we decided that FAQs with a P value of ≤.02 would be considered statistically significant in terms of shifting user preference [9].

Users received a score from 0 to 5 (a perfect score) on the "self-check" knowledge questionnaires. This score was recorded as a continuous variable in the database. The pre- and post knowledge scores were used in a paired sample t test to determine whether knowledge significantly increased after Option Grid use. The dataset also contained the user's responses (0=no, 1=yes) to each SURE survey item before and after completing the interactive Option Grid. A perfect score indicated that the user was not experiencing clinically significant decisional conflict. A score of ≤3 meant that the user was experiencing clinically significant decisional conflict [13]. A paired sample t test was employed to compare the total pre-and postdecisional conflict scores.

Results

Participant Sample

A total of 467 users accessed the Option Grid website and began using the Web-based, interactive PSA decision aid. However, only 186 users completed the entire interactive journey. Of the 186 completed "journeys" (attrition rate of 60.2%, 281/467), 22 users self-identified as female, leaving a sample of 164 users. The majority of 281 users who dropped out either did so after viewing the first FAQ (118/281, 42.0%) or at the midway point of the journey (66/281, 23.5%). Over half (88/164, 53.7%) of users indicated that they were between the ages of 45-64 years, and over 70.1% (115/164) of the sample self-identified as white or not Hispanic or Latino. The majority (87/164, 53.0%) of the sample resided in North America. See Table 1 for details.

Preference Shift

Prior to being presented with the FAQs, 73.8% (121/164) users selected "having the PSA test" as their initial preference. After completing the interactive journey, 28.7% (47/164) users indicated that they preferred having the PSA test—a decrease of 45.1% (74/164). The number of users who preferred "not having the PSA test" increased from 43 users pre-FAQ to 117 users post-FAQ. Overall, a significant preference shift (P<.001) to "not having a PSA test" occurred after viewing the information embedded in the interactive tool. Figure 1 illustrates the decrease in the number of users who selected "having a PSA test" for each FAQ.

Table 1. User characteristics for the Web-based, interactive "prostate-specific antigen test: yes or no?" Option Grid.

Characteristic	n (%)
Age in years	
18-24	5 (3.0)
25-44	29 (17.7)
45-64	88 (53.7)
>65	42 (25.6)
Ethnicity	
Hispanic or Latino	15 (9.1)
Not Hispanic or Latino	115 (70.1)
Not identified	34 (20.7)
Race	
White	130 (79.3)
Black or African American	11 (6.7)
Asian	12 (7.3)
Native Hawaiian or other Pacific Islander	1 (0.6)
American Indian or Alaska Native	5 (3.0)
Other or not identified	5 (3.0)
Geographic region	
North America	87 (53.0)
South America	8 (4.9)
Europe	59 (36.0)
Africa	1 (0.6)
Asia	5 (3.0)
Australia	4 (2.4)

Figure 1. Percentage of users who declared their preference for each FAQ: have a prostate-specific antigen (PSA) test, not having a PSA test, or not sure.
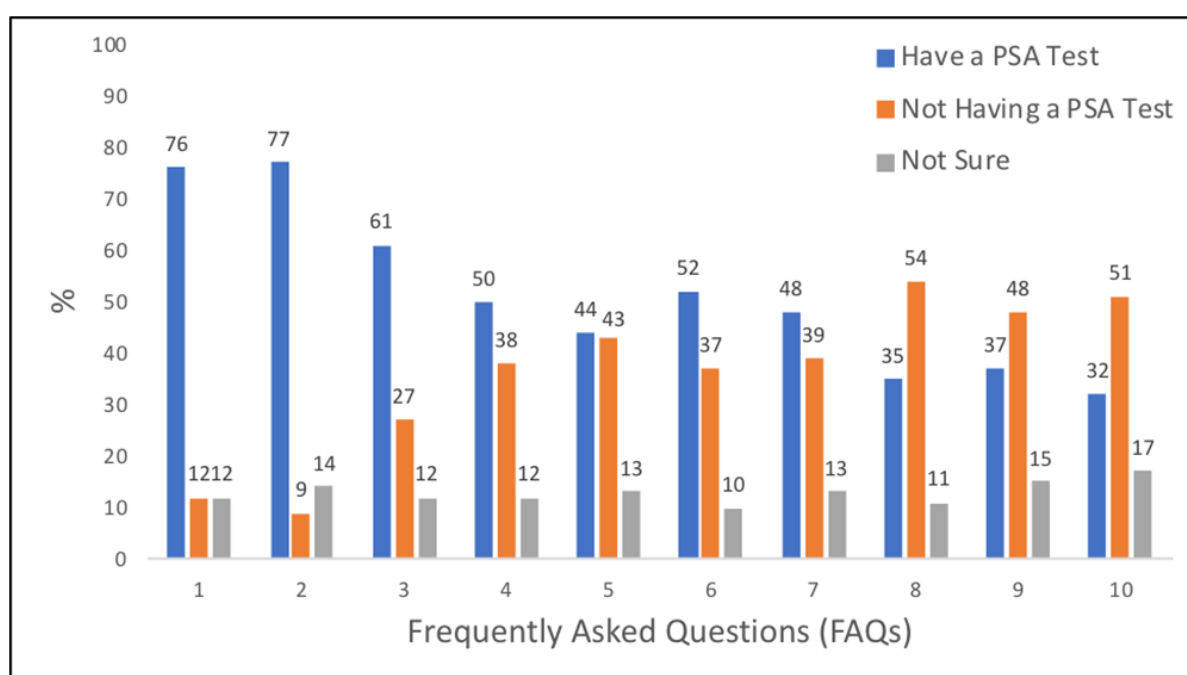
There were 3 FAQs associated with a preference shift from "having the PSA test" to "not having the PSA test," namely, FAQ1, "What does the test involve?" (P=.002); FAQ 3, "If my PSA level is high, what are the chances that I have prostate cancer?" (P=.01); and FAQ 7, "What are the risks?" (P=.01; Table 2). The majority of users in the sample selected "having a PSA test" for FAQ 1, which informed them that the PSA is a blood test that measures the antigen level in the blood from the prostate gland; no information was provided for the "not having a PSA test" option. A slight increase in PSA preference occurred for FAQ 2, where users were presented with the same risk information for both options: 15% of men will develop prostate cancer in their lifetime. Numbers significantly declined for preference of the PSA test at FAQs 3 and 4. When users were presented with the fact that 30% of men with a high PSA level have prostate cancer (FAQ 3), albeit inflammation and infection also increase levels, they shifted their preference to "not having the PSA test." Preference for this option continued with FAQ 4, which stated that 15% of men with a normal PSA have prostate cancer. More users opted for "not having the test" at FAQ 5, which stated that only 0.6% of men who do not have a PSA test die from prostate cancer. FAQ 6 represented an inflection point because this was the only question that reversed the trend (albeit not significantly) of preferences shifting to "having the test." FAQ 6 indicated that 33% of prostate cancers are aggressive, and a small number will benefit from early treatment. FAQ 7 significantly shifted preference. It informed users that the PSA test cannot identify an aggressive form of prostate cancer and that more tests (biopsies) would be needed. The number of users who preferred having the screening test continued to decline after this question until it hit the lowest point at the last question when only 31.7% (52/164) of the sample preferred having the PSA test.

Knowledge

Before viewing the FAQs, 68.3% (112/164) users achieved a perfect score compared with the 89.0% (146/164) users who achieved a perfect knowledge score after viewing the FAQs. The mean post-FAQ knowledge score was 4.88 (SD 0.36) compared with the pre-FAQ knowledge score of 4.64 (SD 0.56). Overall, there was a statistically significant knowledge increase after viewing the Web-based, interactive PSA Option Grid FAQs (t_{163}=−6.70, P<.001).

Decisional Conflict

Before reviewing the FAQs, 89.0% (146/164) users answered "no" to at least 1 of the 4 SURE survey items, indicating decisional conflict. After completing the Option Grid interactive journey, decisional conflict decreased to 42.7% (70/164) users. Overall, the decisional conflict score pre-FAQs was 1.49 (SD 1.38) and post-FAQs was 3.24 (SD 1.03). A statistically significant decisional conflict reduction occurred after viewing the Web-based, interactive PSA Option Grid (t_{163}=−15.234, P<.001). The percentages of users who selected yes for each SURE item are listed in Table 3.

Relationship Between Knowledge, Decisional Conflict, and Preference

Analyses indicated no association or relationship between preference shift and increased knowledge levels (P=.45) or between reduced decisional conflict and preference shift (P=.29). Furthermore, no relationship was established between increased knowledge and reduced decisional conflict (P=.85).

Table 2. Frequently asked questions (FAQs) associated with preference shift for the interactive prostate-specific antigen (PSA) Option Grid decision aid based on the multinomial regression analysis.

Variable[a]	"Having a PSA" shifted to "not having a PSA" (n=76), OR[b] (95% CI)	"Not having a PSA" shifted to "having a PSA" (n=2), OR (95% CI)	"Not having a PSA" preference retained (n=41), OR (95% CI)	P value[c]
FAQ 1: What does the test involve?				.002[e]
Not sure	1.00	1.00	1.00	
Have a PSA test	0.48 (0.07-3.09)	205 (0.00-0.00)[d]	9.7×10^6 (0.00-0.00)[d]	
Not have PSA test	5.9×10^5 (0.00-0.00)[d]	0.00 (0.00-0.00)[d]	7.0×10^{13} (0.00-0.00)[d]	
FAQ 2: What are my chances of having prostate cancer in my lifetime?				.94
Not sure	1.00	1.00	1.00	
Have a PSA test	0.40 (0.04-3.73)	0.00 (0.00-0.00)[d]	0.27 (0.02-4.09)	
Not have PSA test	0.12 (0.00-0.00)[d]	3.89 (0.00-0.00)[d]	0.03 (0.00-0.00)[d]	
FAQ 3: If my PSA level is high, what are the chances that I have prostate cancer?				.01[e]
Not sure	1.00	1.00	1.00	
Have a PSA test	1.02 (0.08-13.63)	236 (0.00-0.00)[d]	0.07 (0.00-1.81)	
Not have PSA Test	0.71 (0.04-13.73)	0.00 (0.00-0.00)[d]	0.26 (0.01-8.23)	
FAQ 4: If my PSA level is normal, can I be sure that I don't have prostate cancer?				.26
Not sure	1.00	1.00	1.00	
Have a PSA test	0.11 (0.01-1.33)	2.81×10^{10} (0.00-0.00)[d]	0.57 (0.02-14.53)	
Not have PSA test	0.33 (0.02-4.71)	94.79 (0.00-0.00)[d]	1.13 (0.04-30.95)	
FAQ 5: Will getting the PSA test lower my chance of dying from prostate cancer?				.07
Not sure	1.00	1.00	1.00	
Have a PSA test	13.43 (0.73-246)	2.06×10^{11} (0.00-0.00)[d]	114.96 (0.78-169.02)	
Not have PSA test	17.69 (0.88-353)	0.00 (0.00-0.00)[d]	223.42 (1.51-330.33)	
FAQ 6: What are the advantages?				.09
Not sure	1.00	1.00	1.00	
Have a PSA test	1.60 (0.09-30.35)	0.00 (0.00-0.00)[d]	1.66 (0.05-51.22)	
Not have PSA test	16.23 (0.70-377)	0.25 (0.00-0.00)[d]	10.72 (0.31-373.95)	
FAQ 7: What are the risks?				.01[e]
Not sure	1.00	1.00	1.00	
Have a PSA test	0.26 (0.01-11.67)	0.00 (0.00-0.00)[d]	0.05 (0.00-2.95)	
Not have PSA test	0.76 (0.02-39.09)	0.00 (0.00-0.00)[d]	0.26 (0.00-17.42)	
FAQ 8: What risks are associated with a prostate biopsy?				.99
Not sure	1.00	1.00	1.00	
Have a PSA test	2.75 (0.05-154)	0.00 (0.00-0.00)[d]	0.98 (0.01-167.57)	
Not have PSA test	4.33 (0.07-255)	7.64 (7.64-7.64)[d]	1.37 (0.01-237.35)	
FAQ 9: What other side effects can I expect from a prostate biopsy?				.89

Variable[a]	"Having a PSA" shifted to "not having a PSA" (n=76), OR[b] (95% CI)	"Not having a PSA" shifted to "having a PSA" (n=2), OR (95% CI)	"Not having a PSA" preference retained (n=41), OR (95% CI)	P value[c]
Not sure	1.00	1.00	1.00	
Have a PSA test	0.25 (0.01-4.33)	0.00 (0.00-0.00)[d]	0.43 (0.01-15.63)	
Not have PSA test	0.24 (0.01-4.27)	0.00 (0.00-0.00)[d]	0.53 (0.02-18.50)	
FAQ 10: What are the risks associated with prostate cancer treatment?				.61
Not sure	1.00	1.00	1.00	
Have a PSA test	0.23 (0.03-1.88)	0.00 (0.00-0.00)[d]	0.50 (0.03-7.45)	
Not have PSA test	0.42 (0.05-3.53)	0.00 (0.00-0.00)[d]	0.39 (0.03-5.95)	

[a]Reference category: "having a PSA test" preference retained.

[b]OR: odds ratio.

[c]Estimated P value for the association between FAQs and preference shift.

[d]The cell sample size was too small; thus, we could not compute OR or CI.

[e]Significantly shifted screening preference.

Table 3. The proportion of users who responded "yes" to each item on the Sure of myself, Understand information, Risk-benefit ratio, Encouragement (SURE) decisional conflict survey before and after viewing the information embedded in the interactive prostate-specific antigen Option Grid.

SURE item	Yes, n (%)	
	Pre	Post
Do you feel sure about the best choice for you?	55 (33.5)	110 (67.1)
Do you know the benefits and risks of each option?	52 (31.7)	156 (95.1)
Are you clear about which benefits and risks matter most to you?	63 (38.4)	136 (82.9)
Do you have enough support and advice to make a choice?	74 (45.1)	129 (78.7)

Discussion

Principal Findings

The Web-based interactive PSA Option Grid decision aid shifted preference toward not having the screening test, increased user knowledge, and reduced decisional conflict. In particular, there were 3 elements of information that induced a shift. First, the description of the PSA test—a blood test that measures the antigen level in the blood from the prostate—was associated with the preference of having the PSA test. Second, FAQ 3 (stating that 30% of men with a high PSA level have prostate cancer, but that inflammation and infection can also increase PSA levels) shifted user preferences to declining the screening test. Lastly, the risks of having the PSA test were presented at FAQ 7, which represents a significant juncture in the "journey" in terms of shifting user preference to not having the PSA test. FAQ 7 stated that it is not possible to know whether a cancer is aggressive with the PSA test alone; a high PSA level means that one would need more tests like biopsies, and biopsies carry risks. No relationships were established between knowledge, decisional conflict, and preference shift.

The main strength of our study is that we obtained information from a self-selected sample of participants who freely accessed the Web-based intervention to better understand whether the effect of using a Web-based tool is replicated in a naturalistic setting (ie, outside of a controlled, incentivized research context). However, we know that a self-selected sample of individuals who access Web-based health information is likely to have a higher computer literacy and educational attainment, which means that we may not have had a representative sample of the greater population. Increasing the sample size and randomizing the FAQs would strengthen the study findings. We recognize that having a more diverse sample may have influenced our findings. Only 6.7% (11/164) participants of our sample identified as African American people, and we know that this patient population is considered to be at high risk for prostate cancer [14]. Further, we were unable to determine whether users were health care professionals or actual patients. Lastly, it is important to note that following data analysis, the interactive PSA Option Grid decision aid (in the Web-based format used for this study) was removed from the Web in March 2018 and is no longer available for public use.

A paucity of data exists on the outcomes associated with the use of Web-based PSA decision aids for individuals spontaneously searching the internet for information. Our study shows that even for a self-selected sample, a Web-based tool increased knowledge and reduced decisional conflict. Our previous work indicated that FAQs 1, 3, and 8 shifted user preferences to not having the PSA screening test. In this study, FAQs 1, 3, and 7 shifted preference in the same direction, confirming that risk information (FAQs 7 and 8 both discuss risk) may be the *active ingredient* in the PSA Option Grid

responsible for the shift [9]. FAQs 7 and 8 discuss the risk of the PSA test and the risk of the prostate biopsy, respectively. Thus, we can infer that men value risk information in their decision making. Our data are also consistent with previous studies suggesting that men who used Web-based decision aids reported higher knowledge and lower decisional conflict and were less likely to want prostate cancer screening [1,2,15,16]. The preference not to undergo screening aligns with the Agency for Healthcare Research and Quality's recommendation, which indicates that the "benefits of PSA-based screening for prostate cancer do not outweigh the harms" [17].

Our study showed no relationship between knowledge, decisional conflict, and preference. This differs from Evans et al's randomized trial that showed a link between increased knowledge and a less favorable attitude toward testing [1]. Although we did not test attitude, we still did not see an association between increased knowledge and preference shift. Rubel et al used a Solomon 4-group design to demonstrate that increased knowledge was related to reduced decisional conflict for those using a prostate cancer screening decision aid [18]. Based on our data, we can infer that men who spontaneously used the Option Grid already had high levels of knowledge to begin with, despite being conflicted about their screening preference. Further investigation is required to better understand the potential associations between these outcomes. We did not collect data on the final screening decision of the user; thus, more research is needed to understand the actual effect of using interactive decision aids on the quality of the real-world decision-making process.

In light of the high attrition rate observed in this study, future work should focus on creating or modifying Web-based patient decision aids to reduce the burden on the user. Many men search the internet for credible health information, but the high attrition rate in our study indicates that interest or engagement is impacted by the time it takes to complete the Option Grid interactive journey. For example, an observational Web-log analysis showed that the mean total time spent on a Web-based decision aid is 20 minutes [19]. Evidently, these tools, which rarely undergo extensive usability testing, can be made easier to use [20]. Furthermore, research should focus on minimizing the "digital divide" [21]. Men who use these tools tend to be white people, highly educated, and reasonably computer literate, with internet access [21,22]. Men exhibiting these characteristics have a significant advantage in terms of access to health information. We need to better understand how to reach men across socioeconomic strata and how to create Web-based tools that are suitable to all demographics, health literacy levels, and computer literacy levels.

Conclusion

The Web-based PSA Option Grid decision aid enabled users to increase their level of knowledge while reducing decisional conflict. The risk information embedded in the tool shifted preference away from having the screening test. Efforts should be made to increase access to evidence-based information for men in all socioeconomic categories. This would lead men to be more informed when communicating with their clinician and would help them make a decision that aligns with their preference.

Conflicts of Interest

GE is the director of &think LLC, which owns the registered trademark for Option Grids patient decision aids. He provides consultancy in the domain of shared decision making and patient decision aids to Access Community Health Network, Chicago (Federally Qualified Medical Centers), and to EBSCO Health Option Grids patient decision aids. GE initiated the Option Grid Collaborative, tools that are hosted on a website managed by Dartmouth College. Existing Option Grids hosted at this website are freely available until such time as the tools have expired. MAD is a consultant to Access Community Health Network and has contributed to the development of the Option Grid patient decision aids, which are licensed to EBSCO Health. MAD receives consulting income from EBSCO Health and may receive royalties in the future.

Multimedia Appendix 1

The interface the user encountered for the first frequently asked question of the Web-based PSA Option Grid patient decision aid.

[PDF File (Adobe PDF File), 60KB - cancer_v4i2e11102_app1.pdf]

Multimedia Appendix 2

The "self-check" knowledge questionnaire that users encountered before, and after completing the interactive journey.

[PDF File (Adobe PDF File), 70KB - cancer_v4i2e11102_app2.pdf]

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Multimedia Appendix 3

The SURE survey presented to users before and after completing the interactive journey to measure decisional conflict.

[PDF File (Adobe PDF File), 46KB - cancer_v4i2e11102_app3.pdf]

Multimedia Appendix 4

Users identify their preference pre-and-post interactive journey.

[PDF File (Adobe PDF File), 47KB - cancer_v4i2e11102_app4.pdf]

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Abbreviations

FAQ: frequently asked question
PSA: prostate-specific antigen
SURE: Sure of myself, Understand information, Risk-benefit ratio, Encouragement

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