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# JMIR Cancer

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Impact Factor (2024): 3.3  
Volume 3 (2017), Issue 1 ISSN 2369-1999 Editor in Chief: Naomi Cahill, PhD, RD

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Original Paper

# Deconstructing Cancer Patient Information Seeking in a Consumer Health Library Toward Developing a Virtual Information Consult for Cancer Patients and Their Caregivers: A Qualitative, Instrumental Case Study

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## Abstract

**Background:** Cancer patients and their caregivers want information about their disease and are interested in finding health information online. Despite the abundance of cancer information online, it is often fragmented, its quality is highly variable, and it can be difficult to navigate without expert-level knowledge of the cancer system. The Patient & Family Library at the Princess Margaret Cancer Centre offers a broad collection of high-quality cancer health information and staff are available to help patrons refine their questions and explore information needs that they may not have considered.

**Objective:** The purpose of this research study was to deconstruct patrons' information-seeking behaviors in the library to assess the feasibility of replicating the services provided in the library through a Web app, extending the service beyond the walls of the cancer centre. The specific aims of this research were to understand (1) how patrons approach information seeking in the library (interface design), (2) how patrons communicate their informational needs (information categorization and metadata requirements), and (3) what resources are provided to address the patrons' information needs (collection development).

**Methods:** We employed a qualitative, instrumental case study to deconstruct patrons' health information-seeking behavior. The study population included patients, the librarian, and library volunteers. Ethnographic observation was conducted at the library over 3 days and key informant interviews with library staff were conducted to address the first aim. A closed card-sorting activity

was conducted to address the second aim and the library shift logs and Search Request Forms (SRFs) were reviewed to address the third aim.

**Results:** A total of 55 interactions were recorded during the ethnographic observation and nine semistructured interviews were conducted during the key informant interviews. Seven library patron personas were identified: (1) Newbie, (2) Seasoned, (3) Direct, (4) Window Shopper, (5) Collector, (6) Information Seeker, and (7) Distressed. A total of 83 participants completed the closed card-sorting exercise. The participants' conceptual clusters within the similarity matrix overlapped with the groupings created by the librarian, with a few differences. A total of 161 entries in the library shift log and 65 SRFs were analyzed to determine what resources were given to patrons. Most resources that patrons received were available online (61%), although almost half of these required special access (47%).

**Conclusions:** The study findings suggest it is possible to replicate library functions in a Web app with a few exceptions that cannot be replicated online. These elements include access to journal articles or other content behind paywalls and the librarian's ability to encourage further discussion through empathy and active listening. Discussion with the librarian could serve to refine and predict needs through observing information seekers and to provide immediate connection to spiritual care and psychosocial support for patrons in distress.

(*JMIR Cancer* 2017;3(1):e6) doi:[10.2196/cancer.6933](https://doi.org/10.2196/cancer.6933)

## KEYWORDS

patient education; information-seeking behavior; health literacy; Internet; consumer health information

## Introduction

It is well established that patients want and need information pertaining to their cancer [1-3]. Benefits of having their information needs met include having a better understanding of their disease, improved ability to cope, reduced anxiety, and satisfaction with treatment choices and health outcomes [4-9]. However, many patients do not know what information they may need because they are not familiar with medical protocols or cancer treatment. Furthermore, studies have shown that the amount and type of information desired varies depending on personal preference and phase in the cancer trajectory [7,9-11].

While health care providers are patients' preferred source for health information [4,9], the Internet is becoming a prominent source for health-related information [8,9,12-16]. Finding and accessing good-quality health information online remains a problem for many patients [17,18]. Some challenges reported in the literature include the following: large amounts of health information available online can cause information overload [19,20], patients do not feel well equipped to assess the quality and credibility of information found online [7,19], the language level used is often far above the recommended grade 6 level for consumer health information [18,21], and there is a discordance between the design of most health information websites and the approach to searches that health information seekers employ [22,23]. A 2015 survey of patients with chronic health conditions found that approximately half of participants had difficulty finding health information, had low confidence in their searching abilities, and wanted support or guidance to find health information on the Internet [24,25]. Previous studies have also found that patients prefer health information websites that are recommended or created by trusted hospitals or health institutions [4,7,26].

The Princess Margaret Cancer Centre is the largest cancer centre in Canada and is located in downtown Toronto, Ontario. The Patient & Family Library (PFL) at the Princess Margaret Cancer Centre offers a broad collection of high-quality cancer health

information. As part of their role, the librarian conducts *information consults* to help people find resources, understand and refine their information needs, and explore other possible information and support resources. Unfortunately, information consults can only be provided within the library. The ultimate aim of this study is to collect information to extend this service beyond the walls of the cancer centre by replicating the information consult online in the form of a *virtual information consult* (VIC). To do so requires a better understanding of the process behind the information consults and a better understanding of patient health information-seeking behaviors. A research study was conducted to deconstruct the information consults, specifically to understand the following: how patrons approach information seeking in the PFL, how patrons communicate their information needs, and what types of resources are provided to address the patron's information needs. Based on these findings, the research team has assessed the feasibility of building an online format. Each study aim from above will also help inform, respectively, the interface design, the language and information categorization, and the online resource collection.

The PFL assists patrons, often patients or their caregivers, in finding health information they may need throughout the cancer care trajectory. The PFL houses a variety of health-information materials in a variety of formats—pamphlets, lendable books, DVDs, and CDs—that patrons can browse on their own or with the assistance of a trained library staff member. Brief interactions between staff and patrons—a patron asks a simple question resulting in a straightforward response—happen quite frequently and are manually tracked in the PFL shift log. When a patron's information needs require a more in-depth discussion, the librarian may conduct an information consult with patrons to help them understand and refine their information needs, find resources to meet their needs, and explore other topics that the patron may not have considered. These information consults usually consist of a 10-15-minute conversation between the patron and the librarian and are tracked in the PFL shift log. Complex information requests that are not readily addressed by

the PFL's resource collection can be submitted to the librarian using a Search Request Form (SRF). To respond to an SRF query, the librarian searches for current and credible resources online and, when needed, scientific literature to address the patron's request, and creates a tailored information package including a cover letter. Patrons can pick up the package or receive it by mail or through email. These services are only available to patrons who visit the PFL.

## Methods

### Overview

A qualitative, instrumental case study was employed to deconstruct and examine how patrons seek and find health information in the PFL. Qualitative case study methodologies employ a variety of qualitative methods to answer "how" and "why" questions about complex phenomena within the context they occur [27,28].

### Study Sample

The study sample was comprised of target end users of VIC. A convenience sample of patients (from initial diagnosis to long-term follow-up), caregivers, and PFL staff from the Princess Margaret Cancer Centre were recruited to participate in the different phases of this research study, described below. Potential participants were excluded if they were under the age of 18, were not fluent in English, or unable to provide informed consent.

### Data Collection and Analysis

#### *How Patrons Approach Information Seeking in the Patient & Family Library (Interface Design)*

##### Ethnographic Observation

Ethnographic observation was conducted to gain a better understanding of how library patrons get from point of entry to finding/receiving resources that address their information needs. The ethnographic observation was conducted in collaboration with the University Health Network's Healthcare Human Factors (HHF) group, a diverse team of human factors specialists who are trained in human factor principles, design, and evaluation, including usability evaluations and ethnographic studies on clinical users and their environments. Two members of the HHF group independently observed the interactions between library staff and patrons visiting the PFL over the course of 3 days. During each interaction, the observers recorded details of the visitor's movements throughout the PFL, including any conversation the visiting patron may have had with PFL staff. The observers did not directly interact with visiting patrons. Following each interaction, the observers conducted a short debrief with the librarian to ensure that the nature of the interaction was accurately recorded. The observers conducted thematic analyses of the recorded interactions and personas emerged. The observers discussed the themes at length and once satisfied that they had captured the various approaches to information seeking and had categorized them appropriately, presented their findings to the study team to discuss and refine the personas. The study team supported the findings and only two changes were made. The first change was to collapse two

personas into one, as there was much overlap between the two; the second change was to refine the names assigned to the personas in an effort to make them more descriptive.

### Key Informant Interviews

Semistructured interviews were conducted in person with the PFL library staff to complement the findings from the ethnographic observation. Informants were recruited through an email describing the study and inviting them to participate in the interview. During the 60-minute interview, informants were asked open-ended questions intended to capture the kinds of discussions that occurred between the library staff and patrons, with a particular focus on how the library staff assisted patrons in identifying and/or expressing their information needs, and what resources were provided. Interviews were audio recorded and transcribed, and a thematic analysis was performed on the transcripts.

#### *How Patrons Communicate Information Needs (Information Categorization and Metadata Requirements)*

A card-sorting exercise was performed. Card sorting is a technique that is often used in Web development to better understand users' mental models by examining how individuals view items as relating to each other and how they group items into categories [29]. A closed card-sorting exercise was used to determine how similar the conceptual categories patients used to group information were to the conceptual categories used by the librarian.

The titles and descriptions of 50 resources from the PFL catalog were randomly selected to be used during the card-sorting exercise. Each card included the full title of the resource and a brief description—one or two sentences—to describe the type of information contained in each resource. The format (ie, book, video, website, etc) was not included on the card. The subject headers under which each resource was cataloged in the PFL were used as the categories into which participants could choose to sort the cards.

Participants for the card-sorting exercise were recruited by staff in the PFL and passively through recruitment posters distributed throughout the hospital. An invitation to participate in this research study was also sent to an electronic distribution list of patients and caregivers who had previously consented to be sent invitations to participate in research.

OptimalSort software (Optimal Workshop) was used to administer the card-sorting exercise, facilitate data collection, and record responses. The OptimalSort interface displayed the names of the 50 resources on cards to participants. As with typical closed card-sorting exercises, the participants were instructed to sort the 50 cards into the categories provided using drag and drop. Some examples of titles of resources selected for card sorting included *How to use your feeding tube*, *Food safety for patients with weakened immune systems*, and *Introduction to radiation therapy*.

The same 50 cards were also sorted by the librarian into the PFL categories to provide a basis to compare patient conceptual groupings to those used in the PFL. A similarity matrix was

created with the aggregate participant card-sorting results; it was then reordered using the librarian's groupings to allow for easier comparison. If participants' conceptual categories were a match with the librarian's, we expected to see clusters of agreement along the diagonal axis, corresponding within each category.

### ***What Resources Are Provided to Patients and Caregivers (Collection Development)***

Document analysis, including a retrospective review of 1 month of the most recent PFL shift logs and 5 months of the most recently submitted SRFs, was conducted to provide insight into the information resources given to patrons and the types of topics requested. An additional review of these information resources was conducted to determine how many were available online. A descriptive analysis was performed on the quantitative data and a thematic and keyword analysis was performed on the qualitative data.

## **Results**

### **How Patients and Caregivers Seek Information (Interface Design)**

A total of 55 interactions were recorded during the ethnographic observation and nine semistructured interviews were conducted during the key informant interviews. A total of seven library patron personas were identified by the HHF researchers based on the ethnographic observation data. Personas emerged based on a combination of familiarity with the PFL, motivation for visit (where available), and specific information-seeking behavior. The personas were further supported when cross-referenced with the data extracted from the key informant interviews and shared with the study team. Patrons transition between different personas depending on their experience and information needs at different times. The personas identified included the following: (1) Newbie, (2) Seasoned, (3) Direct, (4) Window Shopper, (5) Collector, (6) Information Seeker, and (7) Distressed. Once the personas were established, the study team discussed Web apps that could be used to serve the needs of each type of persona. Descriptions of personas, information-seeking considerations for each persona, and the corresponding Web app recommendations are shown in [Table 1](#).

**Table 1.** Description of personas, information-seeking considerations, and Web app recommendations.

Persona	Description	Information-seeking considerations	Corresponding Web app recommendation
Newbie	New visitor to the PFL <sup>a</sup> , looking for general information, possibly feeling overwhelmed, and not yet aware of the ample services and information available to them	Exploratory search strategy	Results filtering Topic-based menu options Support/tips section for using Web app Contact-us option
Seasoned	Familiar with the library and what it offers; require little assistance from the library staff and often come in looking for a specific resource	Focused search strategy	Search bar (with fuzzy search)
Window Shopper	Explore pamphlet racks and the front display table; unlikely to interact with the library staff and some may not enter the PFL	Exploratory search strategy	Card display with featured items enabling quick information scanning A-Z list of resources
Direct	Knows exactly what they are looking for, often coming in with a specific resource title request or a recommendation from a clinician; less likely to explore the library	Focused search strategy	Search bar (with fuzzy search) Ability to download and save resources
Collector	Some familiarity with the PFL and comes in to find information on a specific topic; collect as much as they can on that topic and do not seek anything further	Exploratory search strategy	Topic-based menu options Ability to download and save resources
Information Seeker	Engages in an information consult with the librarian and seeks as much information as possible; typically leaves the PFL with a comprehensive set of resources	Focused search strategy	Topic-based menu options Contact-us option
Distressed	Visibly upset and preoccupied; may seek either general or specific information, but not so much information that it overwhelms them; may also need someone to talk to such as the library staff, spiritual care, or psychosocial support	Varied	Clear social support section (including audio-based mindfulness exercises and clear list of support services) Neutral color palette and single font type

<sup>a</sup>PFL: Patient & Family Library.

## How Patrons Communicate Information Needs (Information Categorization and Metadata Requirements)

A total of 83 participants completed the closed card-sorting exercise. To aid with identifying categories, card pairings that were paired by 27 or more participants were color coded. These highlighted cells were then compared to the librarian's categories to determine if cards were sorted similarly between the participants and the librarian.

The participants' conceptual categories within the similarity matrix overlapped with the conceptual categories created by the librarian, with only a few differences. Participant

categorization of 10 of the 50 cards did not agree with the categorization used by the librarian, as seen in [Textbox 1](#). In these few cases, the librarian's conceptual categories were broader in comparison to those of the participants. For example, the librarian categorized the resource *How to use your feeding tube* under the category *Self-management*, while many participants categorized it under *Eating*. The librarian also categorized several resources that related to coping with cancer under the broad category *Coping*, while many participants assigned multiple categories to these resources, including *Healing*, *Testimonials*, and *Help*. Examples of the conceptual categories of participants that matched with those of the librarian include the following: *Side Effects*, *Prevention*, and *Treatments*.

**Textbox 1.** The 10 resources that did not match in the participants' and librarian's conceptual categorizations.

Card titles

1. How to Use Your Feeding Tube
2. Relaxation Therapy
3. Caregiver Stress
4. Anti-Cancer
5. Living with Advanced Cancer
6. Spiritual Care
7. Coping With Cancer—Psychosocial Oncology
8. The Healing Journey
9. Where's Mom's Hair?
10. When a Parent Has Cancer

## What Resources Are Provided to Patients and Caregivers (Resource Collection Development Policy)

A total of 161 entries in the PFL shift log and 65 SRFs were analyzed to determine what resources were given to PFL patrons. The PFL shift logs recorded simple queries on topics ranging from health information and support to directions in and around the hospital. The most common types of resources distributed to address these queries were pamphlets (distributed in 93% of the queries), books (distributed in 16% of these queries), and e-books (distributed in 2% of these queries).

The queries recorded in the SRFs were for cancer information (33%), specific treatment information (32%), clinical trials and/or research articles (20%), and rare cancer information (15%). The most common types of resources provided to address SRFs were credible cancer websites (62%), followed by research articles and clinical trial webpages (48%), which require special access to use. Fewer queries required books, pamphlets and brochures (38%), classes, events and support groups (23%), or contact information of a health professional (9%). Most search request resources were available online (61%); however, 47% of these resources were not available to the general public.

## Discussion

### Principal Findings

After deconstructing how patrons seek information in the PFL, examining the mental models they use to categorize health

information, and reviewing the types of resources provided by PFL staff, we determined it was feasible to develop an online complementary tool that can assist cancer patients and caregivers in finding high-quality cancer health information. However, it is not possible to replicate all of the PFL functions in entirety.

Seven patron personas were observed in the PFL that underline the different ways that patients and caregivers approach information seeking, complementing previous research that found that users seek health information by using a focused or an exploratory approach [23,30,31]. Focused searchers use specific keywords and refine their search until they find the answer they are looking for [32,33]. The Direct, Seasoned, and Information Seeker personas identified in our study appear to use focused search strategies to find health information. Exploratory searchers are less confident about what they are looking for [23,31,34] and may explore a variety of information during their search [30,32]. The Newbie, Window Shopper, and Collector personas identified in the study appear to use exploratory search strategies to find health information.

The needs of six personas—Newbie, Direct, Seasoned, Collector, Window Shopper, and Information Seeker—may be met by including certain features in the VIC interface design. Conducting a search is the most common starting point for consumers seeking health information [13,21,35,36]. A search box would likely be sufficient for the Direct and Seasoned personas who approach information seeking with confidence, though a “fuzzy search” function should be added to allow for

misspelling. The Newbie persona may begin with a search, but find they need assistance narrowing down their results, a strategy employed by many health information seekers called *orienteeing* [37]. The search results page could contain a number of filters to guide users in refining the results to better meet their information needs. The Window Shopper persona is unlikely to conduct an in-depth search using the search bar, but there is evidence that search engine advertisements can provide teachable moments for users who rarely go beyond the first page of search results [38]. Thus, resource “advertisements” on the VIC landing page may provide Window Shoppers with sufficient information to meet their needs. The Collector and Information Seeker personas seek out everything available on a specific topic. To aid in this information-seeking behavior, topic-based menu options should be constantly present on the interface to encourage these personas to dig deeper within the search [39]. Additionally, subject headings could be displayed alongside resources returned in a search query to assist the Collector and Information Seeker personas in determining all topics related to their query. Displaying the subject headings along with the resources may also assist the Newbie with orienteeing.

Addressing the needs of the Distressed persona is more challenging as technology cannot replace human interaction and immediate connection to psychosocial support that is possible in the PFL. No studies have examined the effectiveness of online self-help interventions for cancer-related distress; however, there is significant evidence to suggest mindfulness-based stress reduction programs are effective interventions for managing cancer-related distress [40-44]. These interventions are typically in-person classes that meet over the course of several weeks. One reported study assessed the feasibility of conducting a mindfulness-based stress reduction program for cancer patients online and found the effects were similar to in-person programs [45,46]. We propose including an audio-based guided mindfulness exercise on the VIC interface to provide immediate support for the Distressed persona. Advertised alongside this mindfulness exercise, we can include a list of psychological and spiritual support services, linking to basic service information and details on how a patient can get a referral. Future research could examine the effectiveness of our approach in reducing distress in the moment.

When examining how patrons organize health information, it was determined that the mental model they used was similar to that used by librarians in the PFL, and thus categorizing information using the subject headings used in the PFL would not hinder users’ ability to find information. The conceptual clusters created by the participants were not a precise match for those used in the PFL; however, the differences may be attributed to the data collection method. The protocol limited the categorization of each resource to precisely one category, requiring participants to use their judgment to determine best fit. In practice, the PFL catalog associates multiple subject headings to each resource. Differences in conceptual clusters may also be attributed to differing familiarity of the resources included in the card-sort activity. The librarian had in-depth knowledge of each resource in the activity while participants’

knowledge was limited to the title and brief description provided on the card.

In examining the resources provided to patrons by PFL staff, most were related to cancer topics including information on rare types, specific treatments, and clinical trials, with more than half of these resources available online. Previously, the research team determined that the collection development policy for the PFL should focus on relevance to patron population, credibility, currency, and accessibility of the content and its format [47]. The same criteria could be applied to an online catalog, though the scope of *accessibility* would need to broaden to include digital accessibility. In many cases, the information provided in the PFL is already accessible online, though not within a single Web app. All pamphlets created by Princess Margaret Patient Education are available on the Princess Margaret Cancer Centre website, as are details about support services, specialized programs, classes, and active clinical trials that take place at Princess Margaret Cancer Centre. Digital complements of information from external organizations are often available online as webpages or downloadable PDFs. An online public access catalog, also published on the Princess Margaret Cancer Centre website, allows users to browse the PFL lendable materials, though they must visit the PFL to pick up the resource. Digital accessibility becomes a challenge with respect to restricted-access websites, as it is not technically feasible to support public access to content behind paywalls or restricted areas. While it is not feasible to catalog these particular types of resources in VIC, the contact information of the PFL could be included to help facilitate patient access to this content or provide support should a search be too complex to be handled with VIC.

Since the completion of the study, an interface prototype of VIC has been built, tested with users, and refined through several iterations. Next steps involve collaborating with Web developers to build the VIC database and user interface. Future studies will involve evaluating the VIC interface.

## Conclusions

The purpose of this study was to deconstruct the health information-seeking behavior of patrons of the PFL to determine the feasibility of building a Web app that could assist patients and caregivers with finding high-quality cancer health information. Through observing daily operations in the PFL, seven patron personas were identified that describe how patients and caregivers approach information seeking. The subject headings used by the librarian were compared to groupings used by patrons and we found that they were a close match. The majority of resources given to patrons were available online.

The study findings suggest it is possible to replicate the services of the PFL in a Web app, with a few exceptions. The elements that cannot be replicated online include access to journal articles or other content behind paywalls and the librarian’s ability to encourage further discussion through empathy and active listening. Further discussion with the librarian could serve to refine and predict needs through observing information seekers and provide immediate connection to spiritual care and psychosocial support for patrons in distress.

## Acknowledgments

We are grateful for the support of the Princess Margaret Cancer Foundation Stella Ruth Feitelson Fund and to Craig Olmstead and Stephanie Kischak for their assistance.

## Conflicts of Interest

None declared.

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## Abbreviations

**HHF:** Healthcare Human Factors

**PFL:** Patient & Family Library

**SRF:** Search Request Form

**VIC:** virtual information consult

*Edited by H Wu; submitted 01.11.16; peer-reviewed by X Han, M Mazzocut, S Chang; comments to author 29.11.16; revised version received 19.01.17; accepted 28.02.17; published 24.05.17.*

*Please cite as:*

*Papadakos J, Trang A, Cyr AB, Abdelmutti N, Giuliani ME, Snow M, McCurdie T, Pulandiran M, Urowitz S, Wiljer D  
Deconstructing Cancer Patient Information Seeking in a Consumer Health Library Toward Developing a Virtual Information Consult  
for Cancer Patients and Their Caregivers: A Qualitative, Instrumental Case Study  
JMIR Cancer 2017;3(1):e6  
URL: <http://cancer.jmir.org/2017/1/e6/>  
doi: [10.2196/cancer.6933](https://doi.org/10.2196/cancer.6933)  
PMID: [28539305](https://pubmed.ncbi.nlm.nih.gov/28539305/)*

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Original Paper

# Adolescent and Young Adult Cancer Survivorship Educational Programming: A Qualitative Evaluation

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## Abstract

**Background:** This program evaluation considers the need for increased professional and patient education for adolescent and young adult (AYA) cancer survivorship. Due to the high incidence of late effects of cancer treatment among AYA cancer survivors, knowledge sharing and communications are needed throughout the transition from cancer care into community care. AYA survivors are likely to need developmentally appropriate psychosocial care as well as extensive follow-on surveillance by physicians who are educated and aware of the likely chronic conditions and late effects that may occur in these patients.

**Objective:** The objective of this study was to evaluate the outcomes of the After Cancer Care Ends, Survivorship Starts for Adolescent and Young Adults (ACCESS AYA) programming. The intent of the ACCESS AYA program was to build health literacy around AYA survivorship issues and to stimulate improved communications between survivors and health care providers. This paper addresses the central research question of “How did the ACCESS AYA program increase health literacy, communications, and understanding among AYA survivors and providers?”

**Methods:** The primarily qualitative evaluation included a brief introductory survey of participant awareness and effectiveness of the ACCESS AYA project serving as a recruitment tool. Survey respondents were invited to participate in in-depth interviews based on interview guides tailored to the different stakeholder groups. The evaluation used the Atlas Ti qualitative database and software for coding and key word analyses. Interrater reliability analyses were assessed using Cohen kappa analysis with Stata 12.1 (StataCorp LLC) software.

**Results:** The key themes, which included survivor wellbeing, health care professional education, cancer advocates role and education, hospital and community-based resources, and the role of societal support, are presented in a concept map. The interrater reliability scores (ranging from 1 to minus 1) were .893 for first cycle coding and .784 for the second cycle. In the brief quantitative survey based on a scale of 1 to 5 with 5 as high, the 22 respondents rated their level of awareness of the project with a mean 3.2 (CI 3.02-3.45) and project effectiveness with a mean of 4 (CI 3.72-4.27).

**Conclusions:** This study contributes to understanding of the ACCESS AYA survivor community in central Texas and the health care professionals and advocates who aid them in their efforts to a new normal life and wellbeing in their survivorship. The results of the evaluation highlight the need to continue to build both survivor and professional resources to address the unique impact of cancer on AYA cancer survivors.

(*JMIR Cancer* 2017;3(1):e3) doi:[10.2196/cancer.5821](https://doi.org/10.2196/cancer.5821)

**KEYWORDS**

cancer survivorship; adolescent and young adult; qualitative; mixed methods; evaluation

## Introduction

### Overview

In the United States, improvements in overall cancer survival rates experienced by adolescent and young adult (AYA) cancer survivors ages 15 to 39 years have not kept pace with survival rates for adults and pediatric patients. Despite improvements in treatment modalities for many of the cancers that affect AYAs, survival rates for many common cancers experienced by AYAs continue to be concerning [1-6]. Further, AYA cancer survivors face long-term risks from their cancer care, including excess risks of mortality, incidence of secondary primary neoplasms, cardiovascular disease, neuroendocrine and neurocognitive dysfunction, and psychosocial effects [4-7]. Intellectual and psychosocial concerns such as depression and anxiety also affect this group, as they frequently suffer developmental, cultural, and educational setbacks as a result of their cancer treatment [7]. Researchers speculate that the lack of improvement in AYA survival may be due to a combination of factors including deficiencies in care [1,2].

The LIVESTRONG Young Adult Alliance's position statement on quality care for AYAs suggests that there are gaps in both provider and survivor education to address the unique needs of AYA cancer survivors [8]. Since 2006, with the publication of the National Cancer Institute (NCI) and LIVESTRONG Foundation's first joint progress review group statement in AYA oncology, AYAs have received increased attention as a population that experiences disparities in care, including poorer survival rates overall than both older and younger cancer patients [1-9]. These reports indicate the need to enhance both quality of life (QOL) and care quality for AYA cancer survivors and call for providers and hospital systems to address the specific health and psychosocial needs of AYAs. To achieve this will require increased education for both providers and survivors. Educational emphases include topics such as the management of cancer survivorship and late effects including awareness of concerns for fertility and body image issues; recognition of the unique context of psychosocial growth and development among AYA survivors; assessment of and attention to cognitive, psychiatric, and psychosocial effects and needs; improved transition to off treatment care, including education of community provider; and referral to available age-appropriate information and support services when indicated [7-9].

Yet, today, few resources exist to train community medical professionals on the unique survivorship needs of AYA cancer survivors. AYA survivorship clinics and educational programs needed to ensure that AYA survivors and caregivers are aware of late effects of treatment and have access to resources to support improved QOL are lacking in most communities [7-9]. This lack of information underscores the need for integrated programs that (1) train providers and educate survivors, (2) establish networks and shared models of care with transition paths from treatment to community care, and (3) build health promotion tools to support improved quality of life among AYA cancer survivors.

### After Cancer Care Ends, Survivorship Starts for Adolescents and Young Adults Program

To meet the need for focused education, the After Cancer Care Ends, Survivorship Starts for Adolescent and Young Adults (ACCESS AYA) program was designed as a strategic combination of provider and survivor education directed at community health care providers, AYA survivors, their families, and cancer patient advocates. The program's professional medical education was targeted at community and hospital-based family practice and internal medicine physicians and nurses. These are the professionals most likely to provide follow-up medical care to AYA cancer survivors who have transitioned from oncology care into community care [8]. ACCESS AYA focused on 3 elements of professional education: (1) formal, accredited continuing medical education program (CME), (2) a half-day live educational CME session that included case studies and presentations on AYA late effects, and (3) a series of medical briefs, AYA Prompt Evidence Assessment and Review of the Literature Service, known as AYA PEARLS. Examples of the PEARLS are provided in [Multimedia Appendix 1](#).

Feelings of isolation and lack of peer support have been identified as important issues and concerns among AYA cancer survivors, both during their time in treatment and posttreatment [7]. To address this need, the ACCESS AYA program produced 2 annual, half-day interactive, educational sessions for survivors, friends and family, and community cancer advocates. During the project operating period, an estimated 4000 central Texas AYA survivors, 15,000 physicians, and 18,500 nurses across Texas received information about the ACCESS AYA program via mail, email, or print materials. As reported in the project's final report to the Cancer Prevention and Research Institute of Texas (CPRIT), the project's funder, direct interpersonal contact was made with approximately 325 AYA cancer survivors; 785 health care professionals, including nurses, physicians, and residents; and over 175 cancer advocates and care givers (ACCESS AYA Final Report, submitted to CPRIT as personal communication by Deborah Vollmer Dahlke, November 2013).

Use of mHealth social and digital media was an innovative element in the survivor public education efforts. The ACCESS AYA grant supported marketing and dissemination of the AYA Healthy Survivorship iPhone app. Over 850 users downloaded the Healthy Survivorship app from the Apple App Store during the project period. The app provides an interactive AYA survivor health and well-being assessment and links to the Children's Oncology Group's *Health Links*, several of which are offered both in English and Spanish. Both the iPhone app and its companion website ([www.healthysurvivorship.org](http://www.healthysurvivorship.org)) offer AYA survivors links to the LIVESTRONG and Journey Forward cancer survivorship care plans. This program was conducted in collaboration with the Communities of Texas Cancer Activity Resource Education Support (CTxCARES), a Centers for Disease Control and Prevention (CDC) Cancer Prevention and Control Research Network-funded project at Texas A&M School of Public Health.

The primary aim of this study was to share results from the evaluation of ACCESS AYA, which addressed several key

research questions based on semistructured interviews with 4 sets of stakeholders: AYA survivors, health care providers including both nurses and physicians, hospital administrators, and leaders of cancer survivor advocacy groups. The central research question was “How did the ACCESS AYA program increase health literacy, communications, and understanding among AYA survivors and providers?” The concept of health literacy as used in ACCESS AYA is reflective of AYA survivors’ ability to function in the health care environment and, as such, depends on the characteristics of the AYA survivors, their health care providers, and the health care system in which they operate. Thus, health literacy is a dynamic state that may depend on the awareness of the patients of their medical problems and the concomitant knowledge and awareness of the health care provider. An individual’s health literacy may vary depending on care needs, the health care provider’s knowledge, and the policies and procedures and capabilities of the health care system. In the case of AYAs, a major health literacy concern among survivors, providers, and the system is the lack of awareness of late effects of cancer care including medical, emotional, and psychosocial late effects.

Specific subquestions to this inquiry focused on the common barriers that AYA survivors experience and the stakeholders’ perceptions of opportunities for sustaining and expanding AYA survivorship education programs. The qualitative themes and analyses of this study reflect and build upon the findings from the periodic and final quantitative evaluations and reports that were submitted to CPRIT and the Seton Healthcare Family executives. The quantitative assessments were important, as they reported on numbers of survivors and health care professionals served and the types and numbers of print and digital health materials delivered throughout the project period (ACCESS AYA Final Report, submitted to CPRIT as personal communication by Deborah Vollmer Dahlke, November, 2013).

This evaluation seeks to provide deeper insights into what the ACCESS AYA participants valued and to build a richer understanding of what elements of the educational programs were most important across the spectrum of stakeholders. Additionally, the stakeholders’ responses to question about what barriers continue to affect them can help identify areas for additional communication and educational programming. Finally, the themes and areas of discussion for sustainability and future development can be used to inform future system and policy changes.

### **After Cancer Care Ends, Survivorship Starts for Adolescents and Young Adults Theoretical Framework**

The ACCESS AYA program’s educational efforts were focused on improving the AYA survivors’ well-being and supporting

changes in their behavior as well as changes in health care professionals’ knowledge and clinical practice behaviors. We anticipated that the effects of the educational programming would extend into the broader clinical, social, cultural, and political environments of the survivors and providers. Based on the social ecological framework for behavioral health by McLeroy et al, the research team identified 5 levels of societal influence in order to construct a theoretical model (see [Figure 1](#)) for use in our analyses of the interview narratives [10].

In line with this framework, our social ecological model places the AYA survivors at the center, where physical characteristics, attitudes about survivorship, knowledge, and values exist in relationship to individual health and well-being. The AYA survivors’ educational node in the framework encompasses critical interpersonal relationships with clinicians, parents, partners, friends, and peers, including social media relationships that may influence the survivors’ care and health behaviors both at home and in clinical settings.

On the right side node are the influences of the health care professionals’ education, based on the rationale established in the LIVESTRONG and other AYA studies [7-9] that the knowledge base of physical and psychosocial late effects can influence care and treatment, awareness of transitional needs, and use of survivorship navigation services to support and sustain survivor well-being. The surrounding layer of the Seton Healthcare Family organization and community-based health care represents the organizational norms, culture, and resources of the community health care environment.

In the closer of 2 outer rings, the cancer advocacy groups represent a powerful and contributing sphere of influence in AYA cancer survivorship including physical, financial and social support, research efforts, resource sharing, and dissemination. The final outer ring indicates the levels of societal support for cancer survivor well-being including policies for insurance, financial and social support, and cultural attitudes and values that affect how AYA survivors are perceived and supported or left isolated in the workplace, at school, and in the community.

Each of these levels, or spheres, in the theoretical framework is laden with value judgments of the research team, the interviewers, and the individuals being interviewed. As such, this narrative evaluation of the ACCESS AYA program is naturally influenced by the social context and values embedded in each group as they relay their perceptions of the program effects, barriers, and potential for sustainability.

**Figure 1.** After Cancer Care Ends Survivorship Starts for Adolescents and Young Adults (ACCESS AYA): Theoretical Framework.

## Methods

### Subject and Setting

The ACCESS AYA project participants were clinicians, AYA cancer survivors, caregivers, and cancer advocates affiliated with the Seton Healthcare Family in Austin, Texas. The evaluation participants were participants in ACCESS AYA project activities who were invited to complete a brief study survey and to participate in in-depth interviews.

### Research Approach

The criteria and approach for this qualitative evaluation are based in the constructivist models suggested by Guba and Lincoln with criteria including [11,12]:

- Credibility (ie, faithful descriptions or interpretations of human experiences)
- Fittingness (ie, how a study findings fit outside the study and if viewers will find the evaluation results meaningful in their own experience)
- Auditability (ie, if the study is detailed in such as way that it can be replicated)

Audibility can be enhanced through description of the project and clear explanations and justification of (1) study rationale; (2) articulation of the researchers' views on the subject; (3) purposes and goals of the study; (4) description of participant engagement; (5) mutual influences among the researchers,

participant, and stakeholders; and (6) explicit details of data collection, analyses, and transformation [12]. Using these criteria as guidelines and as a statement of the evaluators' philosophical approach to the evaluation, the remainder of this report describes the data analyses, findings, and results and a discussion of future directions.

### Sampling Methodology and Survey for After Cancer Care Ends, Survivorship Starts for Adolescents and Young Adults Evaluation Participation

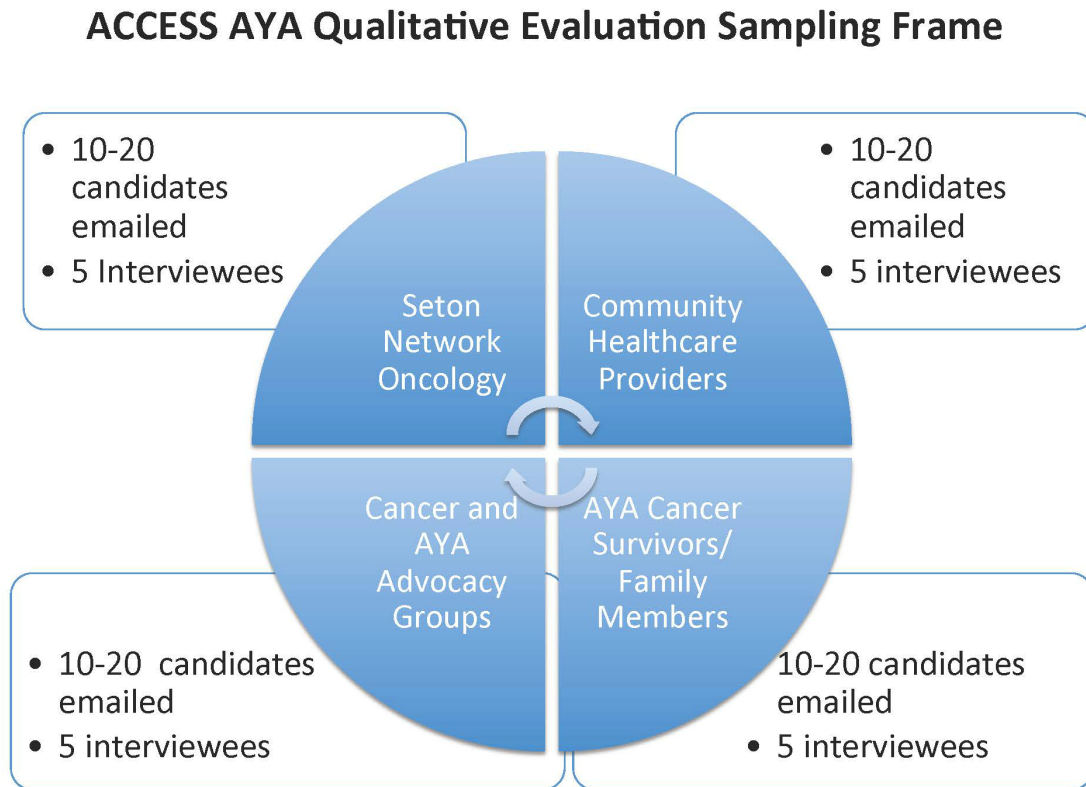
The sampling methodology, described in the sampling frame in Figure 2, was designed to include approximately 20 participants, 5 from each of the following groups: (1) health care administrators and executives from Seton Network Oncology; (2) community health care providers (ie, doctors and nurses); (3) AYA survivors, caregivers, and family members; and (4) community cancer advocates. The rationale for including these groups in the sampling frame is that they reflect the groups of participants in the ACCESS AYA program. These groups are also described in the project's theoretical model (Figure 1).

The initial contact with the participants was via an email that included a survey to ascertain their willingness to participate, an online consent process, and information on how to contact informants who agreed to participate in the evaluation process. This survey also assessed respondents' awareness of the ACCESS AYA programs and their perceptions about program effectiveness using a 5-point Likert scale. In addition to the

email request, a request for interested AYA survivors to participate in the research study with a link to the survey was

posted on a Facebook page operated and maintained by central Texas AYA survivors.

**Figure 2.** After Cancer Care Ends, Survivorship Starts for Adolescent and Young Adults (ACCESS AYA) sampling frame.



### Evaluation Team and Interview Guides and Methodology

The evaluation team included 4 investigators: 2 investigators conducting the interviews and 2 different investigators analyzing the raw data and providing the coding and analyses of the materials. The coding was done under the guidance of an experienced qualitative researcher, and all members of the team have experience in health behavior research in cancer survivorship. A general interview guide was developed and tailored with questions specifically relevant to each type of participant. The semistructured interview questions were designed with reference to Stufflebeam's context input process product (CIPP) model of evaluation practice [13,14]. The CIPP model considers evaluation an essential component of improvement efforts and adapts well to qualitative evaluation of programs like ACCESS AYA where there is a need to include context, input, process, and impact statements with deep engagement of a variety of stakeholders.

The interview guide questions for health care professionals and AYA cancer survivors are provided in Tables 1 and 2, respectively. The researchers and research assistants individually or jointly conducted 20- to 30-minute telephone interviews with

study participants. Joint interviews were held to assist the interviewers in taking notes as well as in making a recording of the interview. In these situations, 1 interviewer led with questions while the second interviewer listened in via speaker phone. All telephone interviews were recorded with the participant's agreement, and each participant confirmed they had understood and agreed to the consent process. Once consent agreement was confirmed, the interviewers no longer used the participant's names so that the recorded and transcribed interviews would remain anonymous to the research team coding the interviews.

The researchers conducting the interviews were experienced health behavior professionals who sought to apply an open and receptive aspect to accommodate positive, neutral, and negative attitudes articulated by the participants. The tape-recorded interviews were transcribed by an external contractor and returned as text documents. The transcribed interviews were coded by the type of participant (ie, physicians, nurse, hospital executive, advocate, or AYA survivor). In cases where a participant had more than one role (eg, both survivor and advocate), the interviewers asked the participant to respond to the questions specific to 1 role, to the greatest extent possible.

**Table 1.** Health care professional interview guide.

Question	Interview questions
1	In what ways have Seton's professional and patient education programs on AYAs helped you understand the needs of these survivors?
2	In what ways have you shared information on the ACCESS AYA cancer survivorship professional or patient education program with your colleagues or staff?
3	In what ways, if any, has information or education materials about AYA cancer survivors changed the way in which you do your job?
4	What barriers or challenges are you aware of regarding how AYA cancer survivors are cared for or treated in central Texas?
5	Has the information or education regarding AYA cancer survivors changed how you think about or treat other cancer survivors? If so, can you provide examples?
6	What opportunities or challenges do you believe exist in sustaining or expanding programs for educating AYA cancer survivors and their families/caregivers?
7	Do you have any additional thoughts or information you would like to share as part of this evaluation of the ACCESS AYA grant?

**Table 2.** Interview guide for cancer survivor, family member, or caregiver.

Question	Interview questions
1	In what ways have Seton's education programs on AYA cancer survivorship helped you as a survivor (or as a caregiver or family member)?
2	Have you shared any of the information or educational materials, including the videos or the AYA iPhone app with other AYA survivors, caregivers, or family members? Can you share a story?
3	In what ways, if any, has information or educational materials about AYA cancer survivors helped you (for example, learning about healthy diets or physical activity for AYA survivors)?
4	What barriers or challenges are you aware of regarding how AYA cancer survivors are cared for or treated in central Texas?
5	Has the information or education regarding AYA cancer survivors changed how you think about or treat other cancer survivors? If so, can you provide examples?
6	What opportunities or challenges do you believe exist in sustaining or expanding programs for AYAs?
7	Do you have any additional thoughts or information you would like to share as part of this evaluation of the ACCESS AYA grant?

Once transcribed, the interview narratives were read and checked for accuracy by the first author and a research assistant prior to coding. The electronic files were loaded into Atlas.ti version 7 (Atlas.ti GmbH) for coding and analysis.

The descriptive coding and framework followed fundamental approaches of identifying themes, developing codebooks, and constructing models guided by the theoretical frameworks provided by Miles et al and Saldaña and assessed statements about the merit, worth, satisfaction, and significance of the educational programming for the evaluation [15,16]. These themes were present in the interview guide questions, thus supporting efforts to code statements in interviews to specific themes. In the first cycle of coding, both descriptive and in vivo codes were applied. The coding process started with both researchers independently reading the transcripts and then discussing early findings. First cycle coding themes were developed independently from the interview guide, and additional themes emerged during the second cycle coding process.

Memos were inserted into the Atlas.ti database. Data analysis for the evaluation was informed by an analytical approach suggested by Creswell in efforts to grasp the themes and essential meaning of the stakeholder comments [17].

During the first and second stages of analysis, both research team members independently coded and met with a senior researcher to discuss findings. Any differences or disagreements in coding or thematic analysis were resolved through discussions among the research team members. The interrater reliability scores (ranging from 1 to minus 1) were .893 for the first cycle and .784 for second cycle. The Cohen kappa scores were derived using Stata 12.1 statistical analysis software (StataCorp LLC). Quotations from the stakeholders were further categorized based on coding domains associated with the evaluation's theoretical framework. As a third stage, a concept map was generated using the codes and themes generated by both first and second cycle coding. Concept maps can provide a useful alternative to code and word-based text analysis in response to open-ended survey questions [18].

## Results

### Overview

A total of 22 participants responded to the study evaluation survey. However, only 18 participated in the qualitative interviews (scheduling conflicts accounted for loss of 3 subjects, and 1 participant declined to be interviewed). The available demographic information was limited by the personal data collection requirements established under the evaluation



institutional review board (IRB). Among the 5 participants from the Seton Network Oncology practice, a male nurse, a female AYA nurse navigator, a male medical oncologist, a male palliative care physician, and a female internal medicine physician were interviewed. Among the 4 participants from community health care were a female cancer administration hospital executive, a male cancer program manager, a female community-based surgical oncologist, and a female dietician

who worked with cancer patients. The cancer advocacy participants, all of whom were also cancer survivors, included 3 female advocates and 1 male advocate from community-based cancer advocacy groups. The AYA cancer survivors included 4 AYAs (2 males and 2 females) and one female AYA caregiver.

Table 3 provides the results of the initial email survey and the methodology used to assess the participants' perceptions of the program and recruit participants for the telephone surveys.

**Table 3.** Survey of awareness and effectiveness of the After Cancer Care Ends, Survivorship Starts for Adolescents and Young Adults (ACCESS AYA) program (N=22).

Question	Mean <sup>a</sup>	Standard error	95% CI
Level of awareness	3.2	0.098	3.02-3.43
ACCESS AYA program effectiveness	4	0.132	3.72-4.27

<sup>a</sup>The response scale was 1 to 5, with 5 as the high score.

### After Cancer Care Ends, Survivorship Starts for Adolescents and Young Adults Coding Results and Concept Map

Table 4 provides examples of the first cycle descriptive codes and their relationship to the theoretical model. Focal areas for

the first cycle code reflect perceived participant areas of concerns and needs from the interview transcripts.

**Table 4.** List of first cycle codes and focal areas.

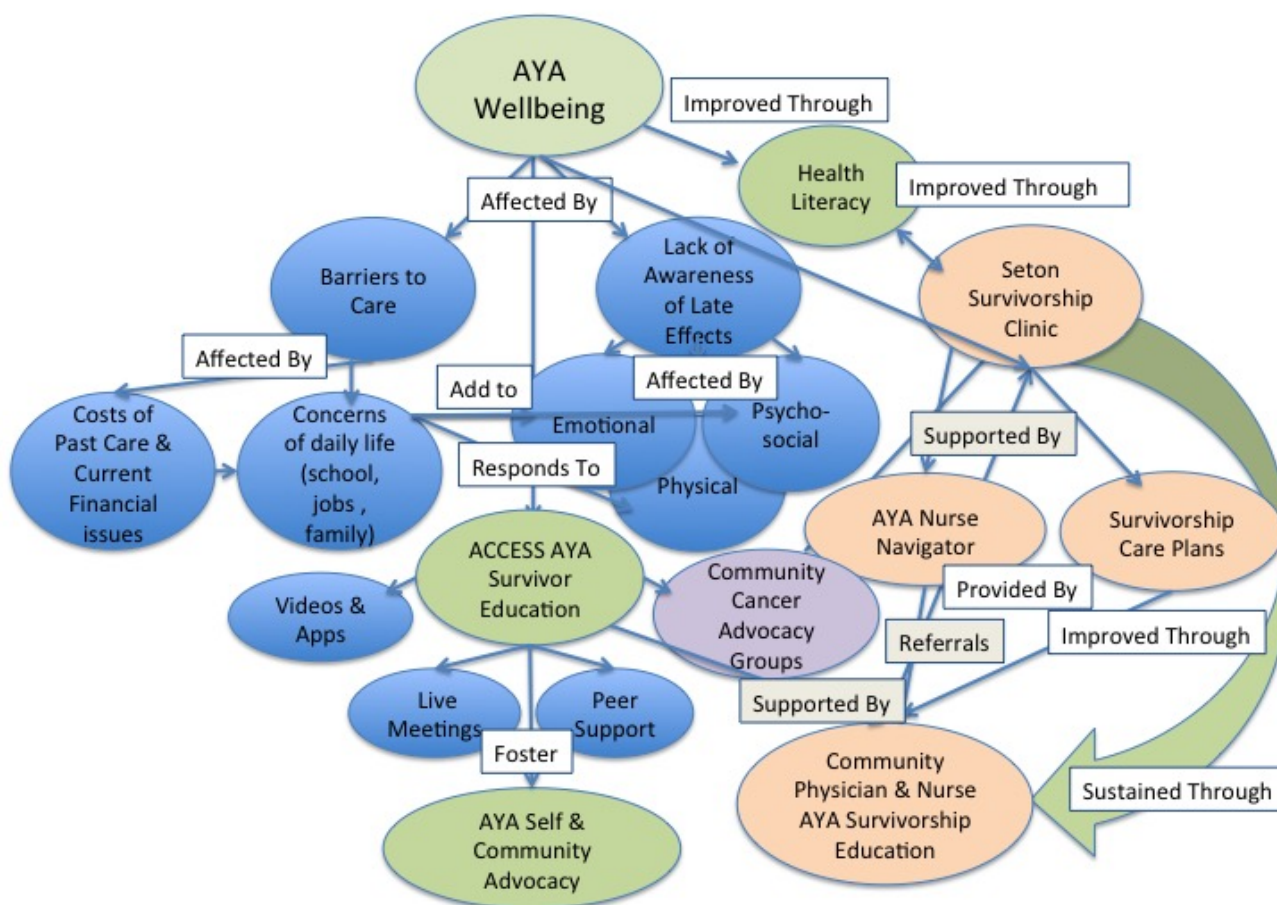
Framework region and first cycle descriptive codes	Focal area
<b>AYA survivor well-being</b>	
Barriers to care and lack of access to care	Physical concerns
Awareness of late effects	
Use of care plans	
<b>Educational needs</b>	
Personal reflection on survivorship	Psychosocial concerns
Need for community and peer sharing	
<b>Needs of daily living</b>	
Costs of past care	Financial and insurance concerns
<b>AYA survivor education</b>	
Need for survivorship education	Health literacy
AYA use of apps and digital technology	
Use of survivorship plans	
<b>Information-sharing practices</b>	
AYA self advocacy	Training and education
Lack of ability to communicate with physicians	
<b>Health care professional education</b>	
Age-appropriate care	Survivor education and training
Lack of awareness of late effects	Provider education and training
Lack of knowledge of AYA needs	Provider time constraints
Lack of knowledge of Seton AYA clinic	
AYA population sparseness and fragmentation	
CME uptake and professional education programs	
<b>Survivorship clinic</b>	
Referrals and transitions in care	Insurance coverage concerns
Coordination with navigators	
Use of survivorship plans with patients	
<b>Cancer advocates</b>	
Advocates role in information sharing	Information gathering and sharing
Attitudes about AYA research	Delivery of resources
Lack of knowledge of Seton and other community programs	
Family and caregiver needs	
Lack of survivorship care plans	
Lack of information for nonmedical needs	
<b>Seton Healthcare Family and community physicians</b>	
Impact of AYA educational programs	Financial and human resources
Improved knowledge of Seton AYA program	Sustainability
<b>Political, economic, and cultural societal support</b>	
AYA political advocacy	Resources

Framework region and first cycle descriptive codes	Focal area
American College of Surgeons requirements for survivorship care plans	Influence and power Practice change

The results of the second cycle coding are represented in the ACCESS AYA evaluation concept map (Figure 3). These were generated using the codes and themes from the second cycle coding. In the ACCESS AYA map, the major themes and aims of the program are explored including survivor well-being, the

use of survivor and provider education to support health literacy, and communication. An unexpected consequence of the ACCESS AYA programming that emerged as part of the evaluation was the increased desire among AYA survivors to engage in self and community advocacy.

Figure 3. After Cancer Care Ends, Survivorship Starts for Adolescent and Young Adults (ACCESS AYA) evaluation concept map.



**Illustrative Quotes from the After Cancer Care Ends, Survivorship Starts for Adolescents and Young Adults Evaluation Interviews**

**Well-Being**

As mapped out in Figure 3, our evaluation interviews indicated that for many AYA survivors, their concerns about debt from the cost of their care and the economic impact that cancer has had in their lives affect their overall well-being. Some survivors indicated that their financial status was a barrier to their adherence to follow-up care and care for late effects. AYAs also expressed concerns about how their cancer experience affected their ability to function in their daily lives at school, work, and in relationships.

A young brain cancer survivor shared her frustrations about the transition from being in treatment to the new normal of survivorship and her concerns about the ongoing financial costs of cancer care and survivorship.

*What would be really helpful is to figure out financial help because that's kind of one of the big things. It just costs so much for all the treatment . . . the biggest thing is trying to get back to normal routines because you're used to just being home and dealing with your sickness. [AYA survivor and program participant]*

For AYA survivors, the concept of well-being is transient, and late effects of care may affect them emotionally as well as physically and mentally [19,20]. They may struggle with the affects of their treatment across all the areas of the social

ecological framework, physically, intellectually, socially, and financially. Several of the ACCESS AYA evaluation participants expressed concerns about the effects of their treatment on their mental capacity and worried about how that might affect their future employment and educational opportunities. Well-being among survivors was also expressed in changed awareness and increased empathy for those they encounter.

*A lot of people might not even realize how sick people might be and not even look it. I think my experience has made me more aware and less judgmental. [AYA survivor; ACCESS AYA participant]*

When asked to address the benefits of the ACCESS AYA program, several survivors commented on the value of being more informed and connected to the community of AYA survivors. According to Sansom-Daly and Wakefield Schroevers, positive social support is strongly protective against the distress and depression that may affect AYA cancer survivors, and many AYAs suffer from post-traumatic stress conditions [20].

*I appreciated the connection point, to meet some more people . . . doctors are brilliant and all, there are things that they simply don't understand because they've never been through it . . . there's a difference between science and experience. [AYA survivor/ACCESS AYA program participant]*

### **Adolescent and Young Adult Survivor Education**

The ACCESS AYA educational programming for survivors covered medical and clinical issues, survivor advocacy, self-efficacy, and opportunities for social engagement with other survivors in real time and in virtual online space. Both patient and professional education programs stressed the importance of the development and use of survivorship care plans as a way to improve health literacy among both the providers and survivors.

*My memory is really, really bad, so it [the care plan] helps me to have a lot of information to hand over to my doctors. I have probably 8 to 12 different medical people trying to keep me well and going. So, it's hard to keep up with all that. It helped me along the way when I can't remember stuff. [AYA cancer survivor; ACCESS AYA participant]*

The ACCESS AYA Summits were half-day meetings designed to provide opportunities for interactions with peers, health care professionals, and community cancer advocates. The agendas included a variety of interactive elements including physical activity, cooking demonstrations, and physician presentations on screening and surveillance for second cancers and late effects such as cardiotoxicity.

*. . . some of it has been some good practical stuff on how to deal with finances, emotions, the insurance, second opinions, keeping records. My favorite part, honestly, is that it connects you to other people, both experts in the medical field and other people who have been through it . . . [AYA cancer survivor/ACCESS AYA program participant]*

### **Adolescent and Young Adult Advocacy**

A consistent theme throughout the ACCESS AYA education effort was the importance of self-advocacy and advocacy training. The educational seminars included survivor-led discussions on self-advocacy in dealing with the medical community and in life situations as well as engagement in social advocacy for AYA survivorship concerns.

*I think that the benefit of a young person understanding and knowing that they are actually part of a larger community, they're not alone, that they're part of this community, they're part of something bigger and they can make a difference, I think is incredibly powerful and can be helpful to their own sort mental and emotional healing. [AYA cancer survivor/cancer advocate]*

The shared passion and desire to participate in social advocacy among the AYA survivor community is perhaps an unintended consequence of the ACCESS AYA educational program. Several of the AYA survivor participants stated that as a result of learning about national AYA advocacy organizations in the ACCESS AYA programs like Critical Mass and the OMG Stupid Cancer Annual Conference, they are now participating in advocacy at a national level.

### **Health Care Professional Education**

Education of health care professionals appeared to be one of the more challenging aspects of the ACCESS AYA program. The initial plan of offering free online and digital video disc (DVD) CME materials to physicians and nurses was deemed successful only for the nursing professionals. Despite multiple attempts to deliver the CMEs to physicians, uptake was minimal. The innovation of creating the Prompt Evidence Assessment and Review of the Literature Service (PEARLS), both as 1-page briefs and short YouTube videos that included cases and evidence-based facts on AYA survivorship, offered improved dissemination of the professional education materials. Over 450 PEARLS packets containing 3 1-page PEARLS, DVDs with the AYA CME courses, and materials on Seton's AYA survivorship clinic and navigation were delivered to central Texas physician offices and clinics, and 345 physicians and nurses participated in clinic discussions about the PEARLS' content.

The PEARLS were delivered both as links from the Seton Survivor Center website and delivered directly to clinics and offices with brief presentations to the clinical staff. A qualitative assessment of the PEARLS dissemination effort is reported on elsewhere. A community physician commented on the difficulty of continuing education and the PEARLS as a delivery mechanism.

*So, the education probably has to come case-by-case. That is the way most of us learn anyway. A lot of people are getting a lot of education off emails, webcams and this kind of short vignette. [Community physician]*

There were differing perceptions in the value and opportunity for providing physician education, as is evidenced by comments from a second community-based physician.

*I think it's a challenge, frankly, to educate any professional once they've finished their training. I just think that a lot of people are so busy and so overwhelmed with just workload that taking time for professional education that isn't mandated by their specialty board, it's just not going to happen. [Community physician]*

A cancer survivor advocate, who also served on the ACCESS AYA advisory group, had a differing opinion regarding health care professional education.

*I think educating professionals is a real problem in the young adult community. Because the young adults patient population is fragmented between adult and pediatric and community and academic, I think anything that we can do to break down those walls is what we have to do to move the field forward and to improve the care and treatment of these young adult patients. [Cancer advocate and ACCESS AYA advisory board member]*

Despite these concerns, there was dispersion of the professional training through the system as evidenced by resident training programs for AYA cancer survivorship provided by a Seton staff physician and via comments from both nurses and physicians about sharing the ACCESS AYA materials with staff and colleagues.

Concerns for the complexity of care of AYA patients and comments about the need for better transitions of patients from cancer care to community care were themes in the health care professional interviews. Both physicians and nurses expressed concerns about lack of time for education as well as the relatively few numbers of AYA survivors among their practice populations.

In addition to delivering information and education, an ACCESS AYA goal was practice change in health care. A community-based palliative care physician reflects on changes in her practice behavior as a result of the ACCESS AYA programming.

*I've tried to be more deliberate about preparing patients for survivorship while they're in treatment. I think systematically what we used to do is treat the patients, and then be a little befuddled as to why they weren't feeling great afterward, either physically or emotionally or both. I've started to be more deliberate about trying to prepare patients for when they finish treatment . . . I have gotten more tuned into the need for behavioral health support for patients who are not yet in survivorship . . . the bigger questions of meaning and comorbid mental health problems are harder, a lot harder. [Community palliative care physician]*

According to the views of both the health care professionals and health care administrators, the ACCESS AYA program was successful in creating the content and materials for professional education but struggled in dissemination and adoption. The delivery of the video and print PEARLS were perhaps the most successful elements of the program in that they delivered

evidence-based information in a timely and succinct manner and required little investment of time from the health care providers.

### **Community Cancer Advocacy Groups**

Cancer advocacy groups and advocacy leaders frequently take on the role of bridging between the medical community and the patients and their families. They are frequently supported both financially and through provider provision of education programs and training in the community by hospital systems and community physicians. Modeled partially on the success of breast cancer advocacy, AYA advocacy groups work to ensure that the unique medical, psychosocial, supportive, and educational needs of teenagers/ayas living with cancer are met. The roles of advocacy groups include bringing individuals interested in change together and providing coordinated education and support services as well as policy analysis and response. Increasingly, AYA cancer advocacy groups deliver the bulk of their services through social media [21]. Much of the focus of the national AYA advocacy groups is to bring researchers together with survivors to support increased recognition of the unique needs of this population including developing specialist facilities for treatment and survivorship, addressing concerns for delayed diagnosis, and seeking to improve access and quality of care. Central Texas is home to both the national headquarters of the LIVESTRONG Foundation, with its strong focus on AYA survivorship, and the newly formed Critical Mass AYA advocacy group.

*I think that it is not unique to central Texas. I think that a challenge that is faced everywhere is this fragmentation of the young adult patient population and the difficulty in breaking down silos of their care and treatment and service. I find that so often the frustration is people don't get me, they don't understand what it's like to be a young person with cancer. Why am I getting materials for old people? It's different to be in my position. This gives rise to the isolation and the fact that you don't have anyone, if you're socially isolated, to process your experience with. [AYA survivor and cancer advocate]*

A consistent theme among the cancer advocates was their role in the community in sharing and distributing educational resources and programming both via social media and in print and at meetings [21,22]. Several of the cancer advocates participated in the 2 AYA annual summits held during the project and used the venue to both distribute their own information and gather other resources for sharing with their constituencies.

Among the most powerful elements in programs like ACCESS AYA and the Seton Cancer Survivor Center as well as among the advocacy groups are the creation and support for shared communication among of AYA survivors [21,22]. The online Facebook and in-person support community were primarily a creation of the Seton Cancer Survivor Center, but they also reflect the increased emphasis on survivor education and communication from the ACCESS AYA grant efforts. The engagement of the AYA survivors in group meetings further

demonstrates the development of a sustainable community engaged in sharing resources, wisdom, and information.

*I think a lot of people really identified with that because they were able to hang out with people that had, I guess, maybe the same limitations . . . or similar backgrounds to them and they felt more comfortable . . . They really seemed to enjoy the fact that it wasn't all based on the illness or the complications . . . it was based on having fun, being normal and moving on . . . [AYA cancer survivor/ACCESS AYA participant]*

### ***Sustaining After Cancer Care Ends, Survivorship Starts for Adolescents and Young Adults Educational Programs***

Programs like ACCESS AYA face challenges in efforts to sustain and expand their reach due to competition for funding and ongoing challenges in hospital and health care operations. When asked about their thoughts regarding sustainability, most respondents mentioned the competition for funding. However, there are valuable insights regarding what it will mean to sustain survivorship education efforts in emerging areas such as caregiver support and palliative care both for pain management and end-of-life care.

*To make an analogy . . . we prep people for a hurricane. We take care of people during the hurricane, and we may provide some emergency services after the hurricane, but . . . we don't help people rebuild when that hurricane is all through . . . I look at caregivers as a patient population that's emerging and that we are ill-equipped to care for. [Community palliative care physician]*

## **Discussion**

### **Principal Findings**

The results of the evaluation indicate that the program was perceived in a positive light by the members of the representative stakeholder groups interviewed—AYA survivors, clinical health care professionals, administrative health care professionals, and cancer advocates. However, some of the physicians claimed to have not been fully informed of the program and others indicated difficulty in finding time for educational activities given their patient load and clinic demands. Among cancer advocates, there were concerns about the need for additional and ongoing dissemination of the educational materials. Among survivors, most indicated benefits from both the educational program and the navigation and care plan provision services provided by the Seton Survivor Center.

The survivor benefits were in the domains of increased awareness of late effects, use of the app and social media, and increased peer support and engagement. The AYA survivors also indicated increased self-efficacy both for their engagement with physicians and in health care settings and in policy advocacy for the regional and national AYA survivor community.

Among physicians, nurses, and health care administrators, there was clear evidence of increased knowledge of AYA health and

psychosocial concerns and greater awareness of the unique needs of the AYA population. There was evidence of practice change in the way nurses and physicians treated and perceived survivor posttreatment needs, both physical and psychosocial. The high level of effectiveness and value of the nurse navigator and staff of the Seton Survivor Center were remarked upon by both survivors and providers. While the nurse navigator was not directly funded by the CPRIT grant, her engagement in the project as an advisor and collaborator was an important element in the success of the education programming.

The ACCESS AYA program appears to have succeeded in increasing awareness of AYA survivors as a unique population and building a sense of community among AYAs, their caregivers, and advocates. The survivors' self-avowed increased social and political awareness and desires for activism is also an indicator of increased self-efficacy. An unexpected consequence of the ACCESS AYA programming that emerged as part of the evaluation was the increased desire among AYA survivors to engage in self and community advocacy.

These elements tie to the societal support realm in the evaluation's theoretical framework related to building skills and support for political, economic, and cultural aspects of AYA survivorship. Both the cancer advocate and AYA survivor interviews indicated that the participants found value and benefit in the increased sense of community and the potential to take action based on information and education provided by the ACCESS AYA program. There were also indications among the health care professionals that increased advocacy and self-management both for patients and their families was a positive benefit of the ACCESS AYA programming.

ACCESS AYA was designed to address both knowledge gaps and service delivery gaps among AYA cancer survivors and providers. The knowledge gap includes the lack of information and awareness among AYA survivors and providers about the characteristics that make this population unique among cancer survivors. This includes lack of knowledge about disparities in survival, increased mortality, greater incidence of second cancers, awareness of late effects of treatment, and psychosocial concerns that affect quality of life among AYAs. The lack of service delivery includes the lack of age-specific clinics for both cancer care and posttreatment care and programs. The stakeholder groups in the evaluation shared perceptions that were unique to their experience, some reflecting on the ACCESS AYA materials and others on AYA survivorship concerns in general. The delivery gaps identified by the stakeholders suggest opportunities for increased information and resource sharing among health care professionals, both oncologists and community providers as well as among the survivor and advocate stakeholder communities. This finding is supported by Zebrack in his analysis of the service needs of AYA survivors [8]. Across all of the stakeholders, there was general agreement on the importance of programs and educational efforts to ensure the well-being of the survivors. Similarly, there was consensus for the need to building a knowledge base and a community repository of resources to support AYAs in their survivorship efforts. AYA survivor needs regarding information sharing, especially among peers, were assessed in research by Freyer [23]. Among the survivors and cancer advocates, there was

acknowledgment and support for increased social support and peer engagement, which was identified as one of the key research gaps in a recent National Cancer Policy Forum Workshop held jointly by the LIVESTRONG Foundation and the Institute of Medicine [24].

### Limitations

We note that there are limitations in our qualitative approach to evaluating ACCESS AYA. While one of the strengths of qualitative research is the “making of meaning,” the meaning is subject to the authors’ understanding and interpretation. Among the limitations inherent in this study are the small sample size and potential of researcher prejudice and bias, observer effects, and the authors’ ability to present the research in such a way that it could be replicated in the future.

Qualitative analyses and evaluations allow us to share the voices of the stakeholders and participants from an interpretive perspective. In considering the limitations in this evaluation, the research team attempted to recognize the subjectivity of their lenses in viewing the ACCESS AYA project. The selection of the interview participants may be perceived as a limitation, as they were self-selected. The participant sampling frame was well reasoned, and the inclusion of groups of AYA survivors, health care professionals, and advocates was highly relevant to the evaluation research. The views expressed by the AYA survivors may not reflect the perspectives of AYA cancer survivors who prefer to forget about their cancer experience or those who are less affected by late effects of treatment. And, certainly, the specific geographic region of central Texas may limit the generalizability of the research, although the program delivery was diverse and included racial and ethnic groups as well as gay, lesbian, and bisexual AYA survivors.

The assumption was that data collection via a brief phone interview was appropriate for addressing the research objectives, and yet in hindsight this may not have resulted in as rich data responses as longer face-to-face interviews. The limited time for some of the phone interviews was driven by the time constraints of the health care professionals. Limitations may exist in the narrow use of interviews as the primary source of data. However, the research team was familiar with the print and video materials of ACCESS AYA, and team members participated in field observations, providing additional richness and robustness to the evaluation analysis. Finally, the results and data must be appropriately analyzed and the findings adequately corroborated by using multiple sources of information.

### Conclusions

Qualitative studies such as this evaluation have the potential to complement quantitative evaluations by bringing to the forefront the multiple realities of the various stakeholders. The values and benefits of the program evaluated reflect the realities of the lives and work of the participants. What worked in ACCESS

AYA and what challenges and opportunities remain are articulated through the voices of those most affected.

In responding to the evaluation’s primary and secondary research questions regarding the value and benefits of both AYA survivor and professional education, we suggest that overall ACCESS AYA was moderately successful in reaching its intended population but that additional work is needed to continue the educational efforts.

The evaluation and the ACCESS AYA program were built on an action agenda for change through education and information in the way AYA survivors perceive themselves and are perceived by their peers, providers, advocates, and communities. The agenda for change includes ongoing developments in the skills and knowledge base of community health care professionals, doctors, nurses, and administrators who treat and care for AYA cancer survivors.

This evaluation offers a contribution to the understanding of the AYA survivor community and to the health care professionals and advocates who aid them in their efforts to a new normal life and well-being in their survivorship. This evaluation highlights the need to continue to build the survivor and professional resources to address the unique impact of cancer on the quality of life and well-being of AYA cancer survivors. To adequately provide quality care for AYA survivors, health care organizations and providers must address both the health and the psychosocial needs of this population. To do so will require ongoing research in understanding AYA survivors as a highly heterogeneous population that requires management of cancer and treatment late effects including fertility, body image, and cognitive and most particularly psychosocial effects and care needs. These areas of research have been identified and expanded upon in the increasing body of knowledge regarding AYA cancer care and survivorship [21,25,26]. As part of this process, policy and programmatic improvements are needed to facilitate transition to AYA survivors into community and off treatment care through the provision of care plans and age-appropriate information and support service resources [26].

The development of survivorship research methods and measurable outcomes to support evidence-based educational materials and guidelines depends on the availability of funding opportunities at a time of increasingly limited resources and economic pressures in both academic and health care settings. The ability to develop quality research studies related to the AYA population is also dependent on the recruitment of sufficient numbers of survivors into these studies.

### Multimedia Appendix

**Multimedia Appendix 1.** Examples of After Cancer Care Ends, Survivorship Starts for Adolescent and Young Adults (ACCESS AYA) Prompt Evidence Assessment and Review of the Literature Service (PEARLS).

## Acknowledgments

The project was funded by CPRIT under grant PP110121 and operated by the Seton Healthcare Family, a hospital system in central Texas. This evaluation effort was funded through the grant to Seton Healthcare Family to the Texas A&M School of Public Health. Contributions by authors are as follows: Deborah Vollmer Dahlke, DrPH, is the primary author; Kayla Fair, DrPH, participated in the qualitative reviews; Y Alicia Hong, PhD, MS, provided guidance for the qualitative reviews; Deborah Kellstedt, MPH, and Marcia Ory, PhD, MPH, conducted the qualitative interviews; and Dr Ory provided overall guidance for the evaluation. Ramona Magid, CPRIT Senior Program Manager for Prevention reviewed the final document for the funding organization. The ACCESS AYA evaluation was conducted under protocol IRB2013-0498D approved by the Texas A&M University IRB.

## Conflicts of Interest

None declared.

## Multimedia Appendix 1

Examples of After Cancer Care Ends, Survivorship Starts for Adolescent and Young Adults (ACCESS AYA) Prompt Evidence Assessment and Review of the Literature Service (PEARLS).

[[PDF File \(Adobe PDF File\), 561KB - cancer\\_v3i1e3\\_app1.pdf](#)]

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## Abbreviations

**ACCESS AYA:** After Cancer Care Ends, Survivorship Starts for Adolescent and Young Adults

**AYA:** adolescent and young adult

**CDC:** Centers for Disease Control and Prevention

**CIPP:** context input process product

**CME:** continuing medical education

**CPRIT:** Cancer Prevention and Research Institute of Texas

**CTxCARES:** Communities of Texas Cancer Activity Resource Education Support

**DVD:** digital video disc

**IRB:** institutional review board

**NCI:** National Cancer Institute

**PEARLS:** Prompt Evidence Assessment and Review of the Literature Service

**QOL:** quality of life

*Edited by G Eysenbach; submitted 30.03.16; peer-reviewed by L Smith, G Seçkin, M Jefford; comments to author 08.06.16; revised version received 29.11.16; accepted 05.01.17; published 10.02.17.*

*Please cite as:*

Vollmer Dahlke D, Fair K, Hong YA, Kellstedt D, Ory MG

*Adolescent and Young Adult Cancer Survivorship Educational Programming: A Qualitative Evaluation*

*JMIR Cancer* 2017;3(1):e3

URL: <http://cancer.jmir.org/2017/1/e3/>

doi: [10.2196/cancer.5821](https://doi.org/10.2196/cancer.5821)

PMID: [28410172](https://pubmed.ncbi.nlm.nih.gov/28410172/)

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Original Paper

# Assessing the Comparability of Paper and Electronic Versions of the EORTC QOL Module for Head and Neck Cancer: A Qualitative Study

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## Abstract

**Background:** Patient-reported outcome (PRO) instruments are important tools for monitoring disease activity and response to treatment in clinical trials and clinical practice. In recent years, there have been movements away from traditional pen-and-paper PROs towards electronic administration. When using electronic PROs (ePROs), evidence that respondents complete ePROs in a similar way to their paper counterparts provides assurance that the two modes of administration are comparable or equivalent. The European Organisation for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire-Core 30 item (EORTC QLQ-C30) and associated disease-specific modules are among the most widely used PROs in oncology. Although studies have evaluated the comparability and equivalence of electronic and original paper versions of the EORTC QLQ-C30, no such studies have been conducted to date for the head and neck cancer specific module (EORTC QLQ-H&N35).

**Objective:** This study aimed to qualitatively assess the comparability of paper and electronic versions of the EORTC QLQ-H&N35.

**Methods:** Ten head and neck cancer patients in the United States underwent structured cognitive debriefing and usability interviews. An open randomized crossover design was used in which participants completed the two modes of administration allocated in a randomized order. Using a “think-aloud” process, participants were asked to speak their thoughts aloud while completing the EORTC QLQ-H&N35. They were thoroughly debriefed on their responses to determine consistency in interpretation and cognitive process when completing the instrument in both paper and electronic format.

**Results:** Participants reported that the EORTC QLQ-H&N35 demonstrated excellent qualitative comparability between modes of administration. The proportion of noncomparable responses (ie, where the thought process used by participants for selecting responses appeared to be different) observed in the study was low (11/350 response pairs [35 items x 10 participants]; 3.1%). Evidence of noncomparability was observed for 9 of the 35 items of the EORTC QLQ-H&N35 and in no more than 2 participants per item. In addition, there were no apparent differences in level of comparability between individual participants or between modes of administration.

**Conclusions:** Mode of administration does not affect participants’ response to, or interpretation of, items in the EORTC QLQ-H&N35. The findings from this study add to the existing evidence supporting the use of electronic versions of the EORTC instruments when migrated to electronic platforms according to best practice guidelines.

(*JMIR Cancer* 2017;3(1):e7) doi:[10.2196/cancer.7202](https://doi.org/10.2196/cancer.7202)

**KEYWORDS**

ePRO; comparability; EORTC QLQ-C30; head and neck cancer; quality of life questionnaire

## Introduction

Patient-reported outcomes (PROs) are used in clinical trials and clinical practice to assess symptoms, impacts, and health-related quality of life (HRQoL) from the patient perspective. Understanding patients' symptoms and physical functioning is important in oncology and other disease areas to assess disease activity and response to treatment, and this information best comes from the patients themselves [1]. The European Organisation for Research and Treatment of Cancer Quality of Life-Core 30 (EORTC QLQ-C30) is a self-reported 30-item questionnaire developed to assess HRQoL in cancer participants [2]. It was established in 1987 and has been used in over 3000 studies worldwide [3].

Tumor-specific questionnaire modules supplement the EORTC QLQ-C30, including the EORTC Quality of Life Head and Neck 35-item questionnaire (EORTC QLQ-H&N35). Head and neck cancer is the sixth most common cancer worldwide, with an incidence of over 600,000 newly diagnosed cases each year [4]. The disease and associated treatments can have a profound effect on patients' HRQoL [5]. Both the EORTC QLQ-C30 and EORTC QLQ-H&N35 were originally developed and validated for administration and completion via pen and paper. However, there are considerable advantages to the adaptation of PRO measures to electronic forms of data capture. This includes the potential for minimizing administrative burden, thereby increasing patient acceptance and adherence, avoiding secondary data entry errors, and ultimately producing more accurate and complete data [6-11]. However, in migrating pen-and-paper instruments to electronic platforms, some adaptations and modifications are necessary. Evidence that respondents complete electronic PROs (ePROs) in a similar way to their paper counterparts and that the two modes of administration may be considered comparable or equivalent is desirable and is a requirement if the electronic instrument is to be used to support regulatory labeling claims [12,13]. The concern with implementing an electronic mode of administration for a previously developed and validated instrument for paper-and-pen completion within a clinical trial is that measurement error could be introduced if the electronic version of the instrument PRO does not provide data comparable to the original paper version. This would reduce statistical power and interfere with the ability of the trial to detect real change (ie, treatment effect) in the PRO-based endpoint [12,14].

A number of meta-analyses and systematic reviews of studies evaluating measurement equivalence between ePROs and their validated paper-based equivalents in a number of disease areas have been conducted [15-17]. Findings are supportive of the comparability between paper and electronic modes of administration [15-17], and studies have reported a general preference among respondents for electronic administration [15]. Prior studies have evaluated the comparability of paper and electronic versions of the EORTC QLQ-C30 and have shown good levels of comparability [9,11,17,18]. However, no

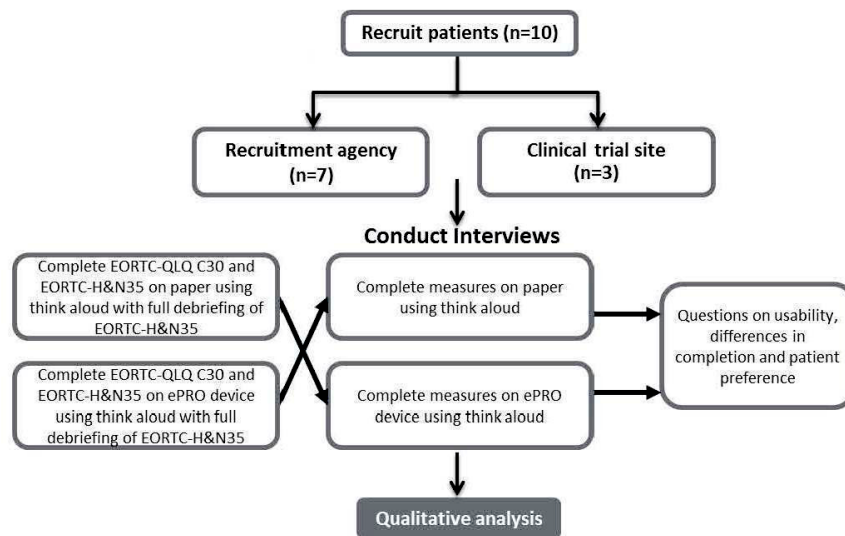
studies evaluating the comparability of paper and electronic versions of the EORTC QLQ-H&N35 (as a companion module to the EORTC QLQ-C30, for use with head and neck cancer participants) have been published.

This study aimed to provide evidence on the qualitative comparability of data collected from paper versus electronic (tablet-based) administration of the EORTC QLQ-H&N35. The primary objective was to explore whether there were any features of the electronic-version of the EORTC QLQ-H&N35 where participants' understanding and interpretation of instructions, items, and response options differed when compared to the original pen-and-paper version of the instrument. While the primary objective relates to the EORTC QLQ-H&N35, participants also completed the EORTC QLQ-C30 in line with developer guidelines. Feedback from participants regarding the usability of electronic device for completion of the instruments was also investigated.

## Methods

The level of evidence required to assess comparability across modes of administration depends on the extent to which the instrument has been modified from its original format in migration to the new format [12,13]. Moving from a pen-and-paper format to an electronic screen text format without significantly reducing font size, altering item content, recall period, or response options (including appreciation of the fact that ePRO versions may present fewer items on a screen than are typically presented on a page) may be considered a "minor modification" [12]. Evidence suggests that such modifications are unlikely to have a substantive effect on the performance of the measure. Nonetheless, evidence that respondents interpret instruments in the same manner as the original paper version and that electronic administration is suitable for the intended population is recommended by best practice guidelines [12]. Based on the minor nature of the changes to electronic format, comparability can be assessed through qualitative research methods (cognitive debriefing interviews and usability testing) with the focus on comparability of the "thought processes" used to respond to items, rather than a quantitative assessment of equivalence of instrument scores.

The EORTC QLQ-H&N35 is designed to be administered alongside the EORTC QLQ-C30. This study implemented an open randomized crossover design in which participants completed the two modes of administration for the EORTC QLQ-C30 and H&N35 (Group 1 [G1]: paper followed by electronic tablet; Group 2 [G2]: electronic tablet followed by paper) allocated in a randomized order (Figure 1). The design allowed the researchers to ensure the order of administration had no influence on the results. Participants completed each mode of administration one after another (ie, no break between completions). The interview process itself acted as a distraction task by incorporating interviewer questioning on each item as the participant completed the instruments to minimize potential learning effects.

**Figure 1.** Interview methodology.

## Ethics

This study was approved by Copernicus Group, a centralized Institutional Review Board in the United States (IRB #ADE1-15-702). The study was performed in accordance with the ethical standards in the 1964 Declaration of Helsinki and its later amendments.

## Recruitment

Ten people with head and neck cancer were recruited to participate into this study in the United States. This sample size is in accordance with recommendations from the International Society for Pharmacoeconomics and Outcomes Research ePRO Good Research Practices Task Force Report, which recommends 5-10 participants for studies involving cognitive debriefing and

usability testing where minor modifications have been made in migration to another mode of administration [12].

Participants were required to meet predefined inclusion and exclusion criteria (Table 1). Participants were recruited via a specialist oncology center and a patient advocacy group between May and September 2016. A demographically and clinically diverse sample of participants with head and neck cancer were recruited by monitoring predefined quotas for gender, age, ethnicity, highest education level, technical familiarity, disease severity, and Eastern Cooperative Oncology Group (ECOG) status. These quotas correspond to sample characteristics of previous EORTC QLQ-H&N35 validation studies [19-21] and were used to ensure that the recruited sample was representative of the broader target population.

**Table 1.** Study inclusion/exclusion criteria.

Study	Criteria
Inclusion	<p>Participant is at <math>\geq 18</math> years of age.</p> <p>Participant is willing and able to provide written informed consent and attend and participate in a 1-hour interview.</p> <p>Participant is literate in English and verbally fluent in English.</p> <p>Participant has confirmed H&amp;N cancer or has been in remission for up to 3 years<sup>a</sup>.</p> <p>The eligible primary tumor locations included pharynx (oropharynx, hypopharynx, epipharynx, parapharynx, nasopharynx), oral cavity, and larynx.<sup>b</sup></p> <p>Participant has a current ECOG performance status of grade 0-2.<sup>b</sup></p>
Exclusion	<p>Participant has brain metastases or intracranial extension of the tumor with cognitive impairment.</p> <p>Participant has significant difficulty hearing, reading, or speaking.</p> <p>Participant has an uncontrolled psychiatric condition or mental condition (eg, schizophrenia, bipolar disorder) or severe physical, neurological, or cognitive deficits rendering the participant unable to understand study scope or participate in a 1-hour interview.</p>

<sup>a</sup>Consistent with disease criterion defined in validation studies of the H&N module [19].

<sup>b</sup>Participants recruited via the patient advocacy group were asked to provide their tumor location using a descriptive diagram, and ECOG status was estimated based on participant self-report.

## ePRO Device

The electronic tablets used in this study (TrialMax Slate) were provided by a third party agency, CRF Health. The device used was an ACER ASPIRE SWITCH 10, with a 10.1-inch display. As the devices used were “dummy devices,” participant responses were not recorded on the devices themselves but participants were asked to read aloud their responses, with responses recorded by the interviewer and documented on the audio-recording of the interview. The device displayed approximately 6 items per screen. Of note, this format differs from the paper versions of the EORTC QLQ-H&N35, which displays approximately 18 items per page.

## Interview Procedure

All interviews were conducted by trained experienced interviewers using a semi-structured interview guide. In the absence of existing published evidence regarding the comparability of paper and electronic versions, the EORTC QLQ-H&N35 was the primary focus of discussions, although participants also provided feedback on the interpretation of individual items of the EORTC QLQ-C30.

Participants completed the questionnaires on the first mode of administration as part of a “think-aloud” exercise, whereby they were asked to speak aloud their thoughts as they read each instruction and complete each item. Interviewers used focused probes during this process to ensure that the EORTC QLQ-H&N35 was debriefed in full and that participant understanding/interpretation of items and reasons for selecting certain responses was fully understood. Participants then repeated the think-aloud exercise for the second mode of administration. Any apparent differences in interpretation of instrument instructions, items, and response options between modes of administration were explored.

Finally, participants were asked for their feedback on the usability of the electronic tablet, any perceived differences in their experience of completing the instruments across modalities, and their preference for either modality.

## Analysis

All interviews were audio-taped and transcribed verbatim to allow for qualitative analysis using ATLAS.ti software. All

transcripts were assigned a unique patient identification code, which was made up of the interview location number, participant number, participant gender, participant age, and group number (ie, G1 being paper followed by electronic version, and G2 being electronic followed by paper version). In accordance with the principles of thematic analysis, a coding scheme was developed in which excerpts from transcripts were assigned codes and grouped according to consistent themes. Coding was completed by one researcher.

A primary focus of the analysis was to determine the extent to which participant responses to PRO items in electronic and pen-and-paper formats could be considered comparable. In this context, responses were defined as comparable if it was clear from qualitative feedback that the participant had interpreted the item and selected their response using the same thought process for both modes of administration. Crucially, while in many cases participants may have selected identical responses to items for each respective administration, this was not necessary for the formats to be considered comparable. Similarly, even if respondents had selected identical responses, if it was clear from discussion and feedback that the thought process for selecting responses was different then this was highlighted as noncomparable. Where it was not clear whether the participant had interpreted the item differently between modalities, this was counted as not clear. Comparability of response was evaluated for each participant by 2 independent researchers and was checked by the project leader.

## Results

### Demographic and Clinical Characteristics

Table 2 contains the demographic and clinical characteristics of the participants who participated in this study. The majority of participants were under 65 (n=9), and an equal number of male (n=5) and female (n=5) participants were recruited. Participants had been diagnosed with head and neck cancer for various lengths of time ranging from less than 6 months (n=3) to more than 2 years (n=4). All disease stages were represented in the sample. The majority of participants (n=8) reported using a touchscreen device “all the time.” Only 2 participants reported not frequently using such type of devices: “sometimes” (n=1) or “rarely” (n=1).

**Table 2.** Demographic and clinical characteristics of participants.

Characteristic	Participants, n
<b>Age, mean (range)</b>	51.5 (34-80)
<65 years	9
>65 years	1
<b>Gender</b>	
Male	5
Female	5
<b>Living status</b>	
Live alone	2
Live with husband/wife/partner	4
Live with parents/family or friends	4
<b>Ethnicity</b>	
Hispanic or Latino	1
Not Hispanic or Latino	9
<b>Race</b>	
Caucasian	7
Multiracial	3
<b>Highest education level</b>	
High school diploma	4
Some years of college	1
University/college degree (2 or 4 year)	4
Graduate or professional degree	1
<b>Work status</b>	
Working full or part-time	6
Retired	2
Not working due to head and neck cancer	2
<b>Devices used on a regular basis</b>	
Desktop	9
Tablet	7
Mobile phone	8
<b>Touchscreen device use</b>	
All the time	8
Sometimes	1
Rarely	1
<b>Time since diagnosis</b>	
<6 months	3
6-12 months	1
1-2 years	2
2-3 years	2
3-5 years	2

Characteristic	Participants, n
<b>Location of primary tumor</b>	
Oropharynx	2
Hypopharynx	1
Epipharynx	1
Larynx	3
Oral cavity	3
<b>Current disease stage</b>	
Stage I	4
Stage II	2
Stage III	1
Stage IVa-b	1
Stage IVc	2
<b>Recurrent H&amp;N cancer</b>	
Yes	2
No	8
<b>In remission?</b>	
Yes	3
No	7
<b>ECOG performance status</b>	
0	6
1	1
2	3
<b>Current active treatment</b>	
Concurrent systemic therapy plus radiation	1
Radiation	1
Immunotherapy	1
None	6
Other <sup>a</sup>	1

<sup>a</sup>Participant due to start a trial in 2 weeks.

## Qualitative Comparability

As the EORTC QLQ-H&N35 is designed to be administered following the EORTC QLQ-C30, numbering of EORTC QLQ-H&N35 items starts at 31. Overall, the EORTC QLQ-H&N35 demonstrated strong evidence of qualitative comparability between modes of administration. The majority of items showed comparability when completed on paper and electronically, with feedback from participants indicating that they had interpreted the item in the same way or used the same thought process when completing the item in both modalities (Figure 2). For example:

(01-03-F-50-G1): Item 31. Have you had pain in your mouth?

*Have you had pain in your mouth? I'm going to say a little only because I have dentures and I think, um, that all has a little bit to do with the, the radiation*

*and stuff. I had a hard time wearing them... I'm going to say I had a little bit of discomfort. [Paper]*

*Um, have you had pain in your mouth? I'm going to put a little. Again, that's just the denture thing. [ePRO]*

(03-03-F-48-G2): Item 51. Have you had trouble eating in front of other people?

*A little bit, yes. I feel a little self-conscious sometimes... I was a little more self-conscious about eating in front of others out in public... because of the partial paralysis I have at the corner of my mouth and it just sort of makes me feel a little awkward. [ePRO]*

*I would choose number two, a little bit. More of a self-conscious thing, uh, than it was mechanical.* [Paper]

In total, the proportion of noncomparable responses (ie, where the thought process used by participants for selecting responses appeared to be different) observed in the study was low (11/350 response pairs [35 items x 10 participants]; 3.1%). Evidence of noncomparability was observed for only 9 of the 35 items of the EORTC QLQ-H&N35. For these 9 items, noncomparable responses were typically observed only for a single participant (7/9 items) and never more than 2 individual participants (2/9 items). In instances where responses were noncomparable, participants seemed to use a different thought process to select a response (eg, responding to the question in a different context), although participants often selected the same or adjacent response options. Indeed, no instances where response options selected by participants differed by more than one response category between modes of administration were observed (examples provided below). For items 52 (“Have you had trouble enjoying your meals?”) and 54 (“Have you had trouble talking on the telephone?”), where 2 individual participants provided noncomparable responses, the different thought processes used may be attributed to participants’ understanding of item wording:

(03-03-F-48-G2): Item 40. Have you had problems opening your mouth wide?

*Have you had problems opening your mouth wide? Uh, quite a bit, number three. Um, biting into sandwiches and, you know, taking spoonfuls of food has been problematic this week.* [Paper]

*Have you had problems opening your mouth wide? I’m going to go with four, uh, very much ‘cause I’m always having problems opening my mouth wide... I think I kind of consider that similar to the have you had pain in your jaw. And, um, those two kind of are related. Uh, opening my jaw wide, opening my mouth wide is painful.* [ePRO]

(03-02-F-39-G1): Item 52. Have you had trouble enjoying your meals?

*Have you had trouble enjoying your meals? I just say a little, only because of the swallowing being little inconvenient, but other than that I really don’t have any problems.* [Paper]

*Have you had trouble enjoying your meals? No, not at all. I enjoy my meals.* [ePRO]

(01-01-M-59-G1): Item 55. Have you had trouble having social contact with your family?

*Have you had trouble having social contact with your family? Not at all. We get together for all the family functions, birthdays, and Christmas and Easter and all that good stuff.* [ePRO]

*Have I had trouble having social contact with my family? I don’t know if this pertains to your survey, but because I am living with my mother right now she is really hard of hearing. And between my voice and her ears I don’t talk very much... I’m going to put a little.* [Paper]

There were a small number of instances across 17 items where it was not possible to determine whether participant interpretation was comparable (ie, detailed as “not clear”). In the majority of cases, this was due to the brevity of information provided by participants during the think-aloud and subsequent discussion. For example:

(03-02-F-39-G1): Item 33. Have you had soreness in your mouth?

*Have you had soreness in your mouth? Uh, number two, a little... just an achy type pain, and I do have that achiness from time to time.* [Paper]

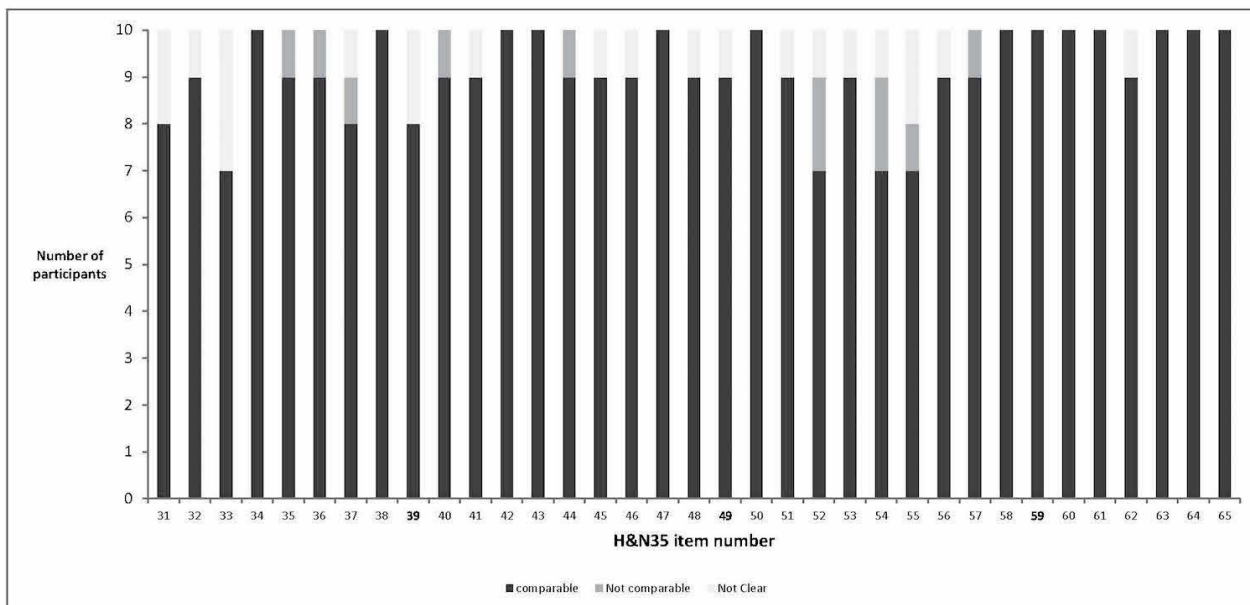
*Have you had soreness in your mouth? One, not at all.* [ePRO]

Exploring noncomparable responses in more detail revealed that that these came from 6/10 participants. Among these participants, no individual appeared to interpret items differently or use a different thought process to select a response on any more than two items (Figure 3). Discernable differences between those participants demonstrating some evidence of noncomparable responses and the remainder of the study sample, in terms of demographic and clinical characteristics, were not evident. Furthermore, there were no trends to indicate that order of administration (eg, paper followed by electronic and vice versa) had an impact on comparability and there did not appear to be any systematic bias. Of responses to the 35 items on each mode of administration (175 completion pairs for each group), participants completing on paper and then ePRO had 158 instances of equivalence (90%) while participants completing on ePRO and then paper had 160 instances of equivalence (91%).

When asked directly, most participants (n=8) reported that mode of administration (paper or electronic) made no difference in their understanding of the EORTC QLQ-H&N35 instructions and items or the way in which they selected responses to items. Two participants reported that the mode of administration did influence their ability to understand, interpret, and respond to EORTC QLQ-H&N35 items. One participant commented that the tablet version of the instrument was easier to understand: “where in the paper I may have gone through it quicker.” Another participant reported that it “feels differently looking at it on paper.” While no further information was provided by these participants, their responses were largely comparable across modes of administration (equivalent responses provided across 28/35 items, 80%; and equivalent responses provided across 33/35 items, 94%; respectively). While not the purpose of the current study, equivalence of scores on the EORTC QLQ-C30 was also observed.

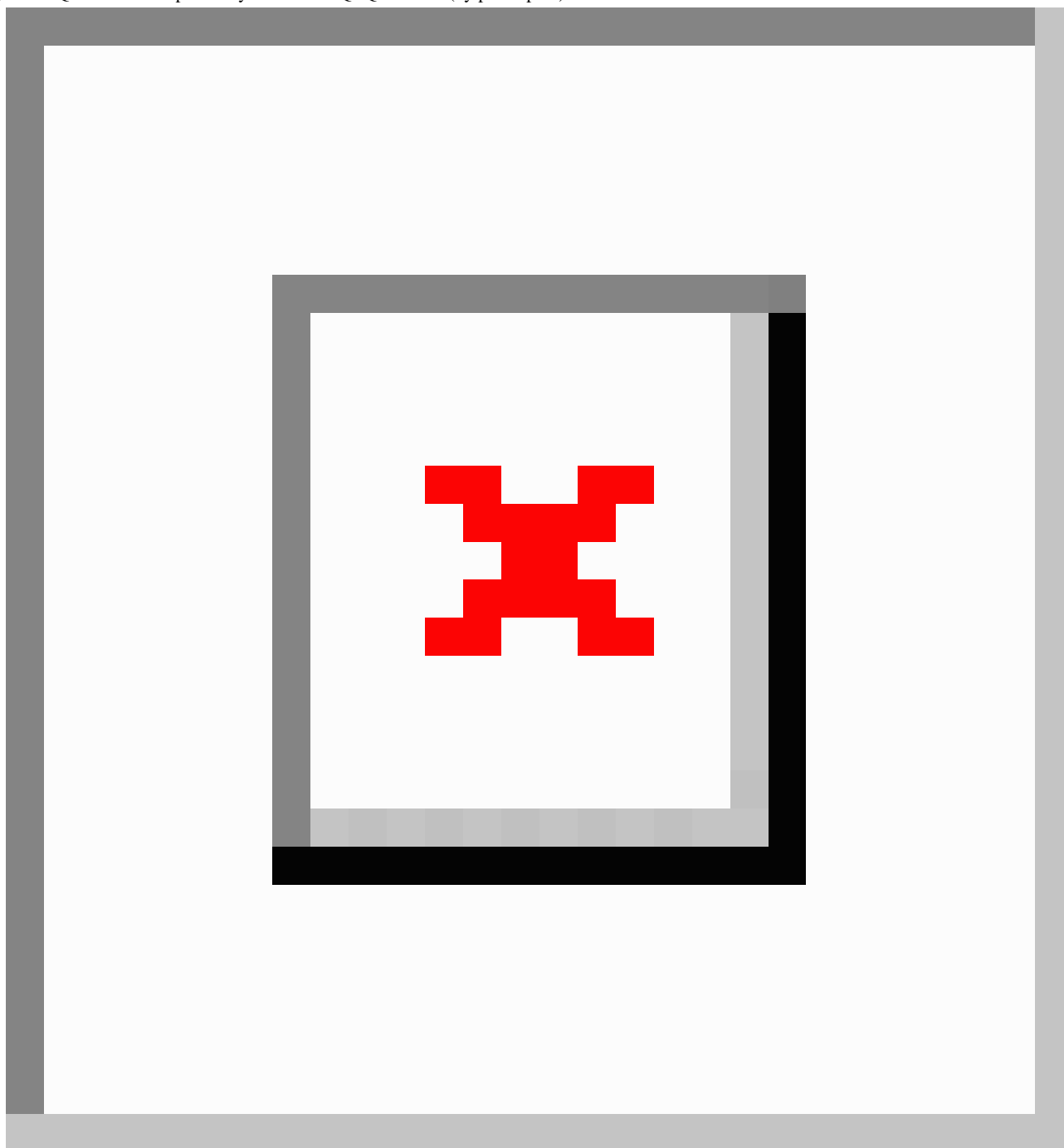


**Figure 2.** Qualitative comparability of EORTC QLQ-H&N35 (by item).



\*Note: EORTC-QLQ-C30 items are labelled #1-30 and EORTC-H&N35 items are labelled #31-65

**Figure 3.** Qualitative comparability of EORTC QLQ-H&N35 (by participant).



### Usability

All 10 participants reported that the tablet device was easy to use, with 7 participants spontaneously adding that it was easier than the paper version. No participants demonstrated any issues with selecting a response on the touchscreen or moving on to the next page of the questionnaire. Similarly, participants did not report any concerns about changing an answer, moving to a previous page, or saving responses. Some participants commented that completing the instrument on the electronic tablet was faster than on paper (n=3) or that there was no difference in completion time between paper and electronic tablet version (n=3).

When asked, most participants (n=7) said that they preferred completing the instrument on the electronic tablet than on pen and paper, as it was easier to use (n=3), had a better “flow” (n=2), would be more efficient in data transfer (n=2), and meant that pen and paper were not needed (n=1). Two participants preferred pen and paper, as it was familiar (n=1) and allowed the full questionnaire to be viewed at once (n=1). One participant did not have a preference.

### Discussion

This study used a standard qualitative methodology to assess comparability for the EORTC QLQ-H&N35, whereby comparability was judged to have been met if the participant

demonstrated that they had interpreted the item in the same way for both completions. There were only a very small number of instances (3.1%) where participants interpreted the item differently on paper and electronic tablet and used a different thought process to choose a response. Overall, these findings suggest that mode of administration does not affect the way that participants respond to and interpret items in the EORTC QLQ-H&N35. While not the main focus of the study, observations and agreement between scores suggest that paper and electronic versions of the EORTC QLQ-C30 were also comparable. These findings are in alignment with existing literature regarding the EORTC QLQ-C30 and other associated modules [9,11,17,18,22,23]. The methods used to assess comparability in this study are in line with industry-recognized, best practice recommendations on generating evidence for comparability or equivalence when minor changes have been made in migration of an instrument from paper to electronic format [12]. Specifically, where minor modifications are made, industry-accepted best practice standards recommend that small-scale (5-10 patients) cognitive debriefing and usability testing be conducted to establish that participants are responding to the items in the intended manner and that the ePRO software works sufficiently when used by the target population [12]. The qualitative methodology allowed for greater insight into the potential impact of mode of administration on participants' responses to individual items than would have been obtained from a quantitative study looking at score equivalence.

It is worth noting that there were some limitations to the study design. While there were a small number of instances where participants provided a different response across modes of administration, we acknowledge that this could easily be attributed to participant understanding of item wording or fallibility of human memory rather than the impact of the mode of administration. Furthermore, the interview procedure allowed participants a second opportunity to consider their response and question their original choice. Some participants were aware that they were changing their response between modes of administration. There were some participants who saw the

double completion as a memory test and aimed to try and remember their original response on the second mode of administration, rather than treating it as a new item. Finally, it was difficult to recruit participants who were not familiar with using electronic smart devices. This is reflective of the widespread use of smart devices, across all age groups, in the United States in 2016 [24].

Given the large amount of evidence for comparability of electronic and paper versions of the EORTC instruments and the lack of concerns identified, further comparability studies for EORTC modules that have undergone minor modifications to electronic administration are unlikely to lead to different conclusions and are probably not warranted. It is acknowledged that this study explored equivalence of paper versus PROs administered in an electronic (tablet) format, yet there exist other electronic formats (eg, mobile phone or app-based versions) that are commonly implemented. However, meta-analyses and systematic reviews by Gwaltney et al and Muehlhausen et al conclude that the majority of comparability and equivalency studies demonstrate that the paper PRO questionnaires evaluated are quantitatively comparable with measures administered on a variety of electronic devices, including tablets and mobile phones, when minor modifications have been made [16,17]. These findings suggest that electronic measures can generally be assumed to be comparable to pen-and-paper measures and the authors question whether equivalence studies are necessary when an instrument has been migrated to an electronic platform following best practice guidelines for minor modifications [14,16].

## Conclusion

This study provides evidence for comparability of the EORTC QLQ-H&N35 administered via an electronic device compared to administration via pen and paper. These findings add to the existing evidence supporting the use of electronic versions of the EORTC QLQ-C30 and associated EORTC modules to collect data in clinical trials when migrated according to best practice guidelines.

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## Acknowledgments

The authors would like to acknowledge Dr Andrew Bottomley for his review of this manuscript.

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## Authors' Contributions

JN, DC, and TM conceived the study. All authors participated in the study design and contributed scientific insight for the interviews and analysis. CT, CP, and AG developed study materials, oversaw interviews, and conducted data analysis. All authors contributed to the writing of this manuscript.

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## Conflicts of Interest

None declared.

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## Abbreviations

**ECOG:** Eastern Cooperative Oncology Group

**EORTC QLQ-C30:** European Organisation for Research and Treatment of Cancer Quality of Life-Core 30 item

**EORTC QLQ-H&N35:** EORTC Quality of Life Head and Neck 35 item

**ePROs:** electronic patient reported outcomes

**G1:** Group 1

**G2:** Group 2

**HRQoL:** health-related quality of life

**PROs:** patient reported outcomes

*Edited by G Eysenbach; submitted 21.12.16; peer-reviewed by P O'Donohoe, RL Mercieca-Bebber; comments to author 02.02.17; revised version received 16.03.17; accepted 31.03.17; published 12.05.17.*

*Please cite as:*

*Norquist J, Chirovsky D, Munshi T, Tolley C, Panter C, Gater A*

*Assessing the Comparability of Paper and Electronic Versions of the EORTC QOL Module for Head and Neck Cancer: A Qualitative Study*

*JMIR Cancer 2017;3(1):e7*

*URL: <http://cancer.jmir.org/2017/1/e7/>*

*doi: [10.2196/cancer.7202](https://doi.org/10.2196/cancer.7202)*

*PMID: [28500019](https://pubmed.ncbi.nlm.nih.gov/28500019/)*

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Original Paper

# Parent and Health Care Provider Perceptions for Development of a Web-Based Weight Management Program for Survivors of Pediatric Acute Lymphoblastic Leukemia: A Mixed Methods Study

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## Abstract

**Background:** Survivors of pediatric acute lymphoblastic leukemia (ALL) may experience unhealthy weight gain during treatment, which has been associated with higher risk for chronic health issues.

**Objective:** The purpose of this study was to obtain feedback on weight management in pediatric ALL survivors and on the content and implementation of a Web-based weight management program.

**Methods:** Study participants included 54 parent survey respondents and 19 pediatric oncology professionals in 4 focus groups. Survey questions included report of child weight status and interest in participating in weight management programming at various time points. Pediatric oncology professionals were asked about the preferred topics and timing, as well as their role. Focus group data were analyzed by a multidisciplinary research team for common themes.

**Results:** The mean age of survivors was 6.5 years. By parent report, 19% of children were overweight and 25% were obese. Preferred timing for weight management program participation was within 3 months of starting maintenance chemotherapy (23/53, 43%) or within 12 months after completion of all cancer treatments (18/53, 34%). Pediatric oncology professionals likewise considered the maintenance phase appropriate. They considered parenting to be an important topic to include and indicated that their most appropriate roles would be promotion and support.

**Conclusions:** Parents and pediatric oncology professionals are interested in and supportive of early weight management in pediatric ALL survivors. Future research needs to identify strategies to integrate this into pediatric cancer care and to evaluate the feasibility and efficacy of these strategies.

(*JMIR Cancer* 2017;3(1):e2) doi:[10.2196/cancer.6680](https://doi.org/10.2196/cancer.6680)

**KEYWORDS**

weight management; childhood cancer survivors; mixed methods

## Introduction

As survival rates among children diagnosed with cancer are rising, there is increased attention toward longer term health outcomes [1]. Childhood cancer survivors are at higher risk of morbidity and mortality from a number of conditions, including cardiovascular dysfunction [2], for which obesity is an established risk factor. There is a high prevalence of obesity among children diagnosed with acute lymphoblastic leukemia (ALL) [3], the most common cancer diagnosed in children. Unhealthy weight gain tends to begin during early treatment [4] and may be associated with chemotherapeutic agents, which can impact energy intake directly through complex pathways and indirectly by affecting physical activity levels through muscle strength impairment [5,6]. However, the proportion of cases of obesity associated with cancer treatment exposure in adult survivors of childhood cancer is only 42% [1]. In addition to the effects of chemotherapy, cancer treatment may initiate a trajectory that results in survivors adopting behaviors that contribute to weight gain, including poor dietary habits and very low levels of physical activity [7,8]. This suggests that the time during which children are receiving cancer treatment and just beyond is a sensitive window for addressing unhealthy weight gain. There are very few studies of weight management programming specifically for pediatric ALL survivors [9,10] and none found in the literature that focus on introducing weight management earlier in treatment. Programs that target early onset of obesity are a priority for improving long-term health outcomes in this high-risk population.

For young children, behavior change may be appropriate through parent-centered approaches, whereby parents influence habits in the household environment [11]. In the general population, research has shown that parent feeding practices directly impact children's lifelong dietary intake patterns and food relationships [12]. A previous qualitative study found that parents of pediatric cancer patients face unique stressors due to changes in appetite and weight during their child's treatment, which may lead them to form permissive feeding habits (ie, allowing children a high degree of choice regarding amount and type of food consumed) despite knowledge of the unhealthy nature of the food they offer [13].

The Healthy Eating and Active Living (HEAL) program, currently in its pilot phase, was adapted from existing childhood obesity interventions studies [9,10,14-16]. The program was developed to provide resources to parents of ALL survivors and to assist them in setting actionable plans to transition their families into healthier eating and physical activity habits. In designing this program, it was important to address issues specific to pediatric cancer survivors' experiences around unhealthy eating habits related to cancer treatment, such as food cravings [17] and changes in taste preference [18], as well as concerns such as the permissive feeding style that may develop. The program framework (Figure 1) and behavioral strategies are based on social cognitive theory [19]. A goal of this 12-week program was to provide the content missing from standard practice. It was designed to be Web-based and self-led and focused on the content areas of parenting, nutrition, and physical activity (see Textbox 1 for an outline of the curriculum).

**Textbox 1.** The 12-week curriculum of the Healthy Eating and Active Living program.

Session 1: Get to Know the Program, Get to Know YOU

- The Healthy Eating and Active Living (HEAL) program
- Program focus areas: Parenting, nutrition, and physical activity
- Session evaluation: How on-target was this session?

Session 2: Effective Parenting

- Practice good communication skills
- Use appropriate parenting styles
- Set Specific, Measurable, Attainable, Realistic/Relevant, and Time-Bound (SMART) Plan: Develop action plans for effective parenting
- Session evaluation: How on-target was this session?

Session 3: Food and Nutrition Basics

- What are nutrition-rich foods? MyPlate Plan
- Choose healthy food portion size and read nutrition labels
- Fun activity with your child: Spotting the Block
- Set SMART Plan: Priority and confidence assessment on nutrition
- Session evaluation: How on-target was this session?

Session 4: Food and Nutrition Environment

- Food and nutrition environment assessment
- Eating together as a family and mindful eating
- Fun activity with your child: Grocery store scavenger hunt
- Set SMART Plan for my child and family: Nutrition
- Session evaluation: How on-target was this session?

*HEAL Rewards: You Have Achieved BRONZE Status*

Session 5: Physical Activity Basics

- The importance of physical activity
- Is physical activity safe for my child?
- Resistance training and bone health
- Set SMART Plan: Priority & confidence assessment on physical activity
- Session evaluation: How on-target was this session?

Session 6: Physical Activity Environment

- Physical activity environment assessment
- How to get the whole family to move
- Set SMART Plans for my child and family: Physical activity
- Session evaluation: How on-target was this session?

Session 7: Counting Energy In and Out

- Energy balance: Counting energy in and out
- Calorie intake and food portion size
- Energy expenditure and types of physical activity
- Fun activity with your child: Fun and fast circuit course activity
- Session evaluation: How on-target was this session?

Session 8: Barriers for Healthy Eating and Active Living



- Overcoming active living barriers
- Overcoming healthy eating barriers
- Identify my barriers
- Program goal: Revise my SMART plans
- Session evaluation: How on-target was this session?

*HEAL Rewards: You Have Achieved SILVER Status*

Session 9: Body Image

- Body image basics and beyond
- Body image environment assessment
- Minimize media impact activity
- Session evaluation: How on-target was this session?

Session 10: Emotional Eating and Stress Management

- Emotional eating
- Stress management
- Session evaluation: How on-target was this session?

Session 11: Beyond the Basics

- Satiety and energy density
- Strategies to eat less but healthy and eat less without being hungry
- Session evaluation: How on-target was this session?

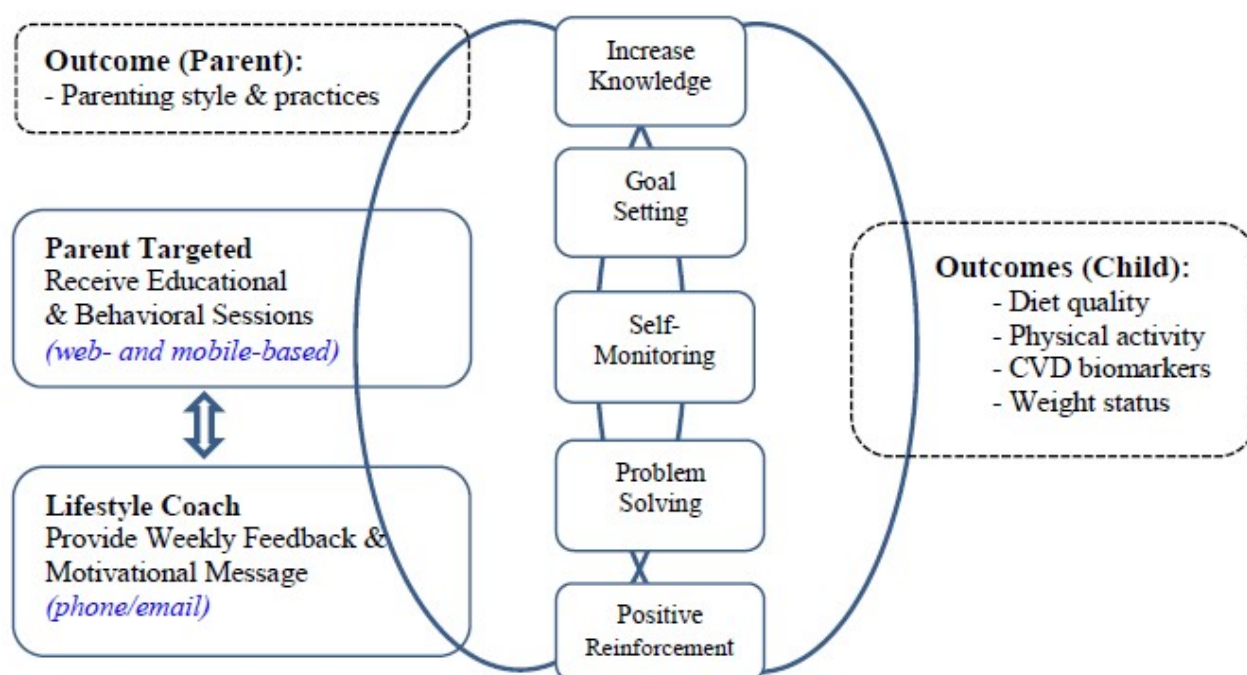
Session 12: Move Forward with Healthy Habits

- Moving forward with healthy habits
- Keeping up with SMART plans
- Session evaluation: How on-target was this session?
- HEAL program final participant evaluation

*HEAL Rewards: You Have Achieved GOLD Status*

The aim of this study was use qualitative and quantitative methods to gain information to help iteratively refine the HEAL program while it was in the pilot phase. We therefore sought to understand perceptions on weight management generally in the

pediatric ALL survivor population, to obtain feedback on the content of the HEAL program, and to gain insight on factors related to its implementation, such as the optimal timing and potential barriers.

**Figure 1.** Healthy Eating and Active Living Program framework.

## Methods

This study used a mixed methods approach, which involved both quantitative (survey) and qualitative (focus group) data collections methods. We describe the procedures for both methods below. A convergent mixed methods design [20] was used, whereby integration of findings occurred during the analysis phase.

### Survey With Parents for Weight Management in Pediatric ALL Survivors

Between September 1, 2014, and January 31, 2015, parents with children who attended the pediatric oncology clinics at 2 metropolitan medical centers in the United States, 1 in Texas and 1 in the Northeast region, were given a survey to complete anonymously. Parents were eligible if they had a child diagnosed with pediatric ALL who was between the ages of 3 to 11 years. To gain multiple perspectives on timing, the parent was eligible if the child was either receiving early treatment (chemotherapy prior to starting the maintenance phase), on maintenance therapy, or within 2 years of completion of all treatments. Surveys were distributed by the clinic receptionist or dietitian, who informed parents that participation was voluntary and would not affect clinical care. Participants placed the completed survey in an envelope and returned it to the receptionist, who then mailed them to the research team for data entry and analysis. The institutional review boards at both institutions approved this study.

The survey instrument included 13 items. Parents were asked about their child's age, sex, current weight and height, type of cancer diagnosed, year at diagnosis, treatment status (on versus off treatment), and time of last treatment for those who had completed treatment.

To gain perceptions about timing, parents were also asked to indicate interest in participating in a 12-week online weight management program to help facilitate healthy eating and active living among their children at time points related to typical treatment milestones: (1) within 3 months after child starts maintenance therapy, (2) 3 to 6 months after child starts maintenance therapy, (3) 6 to 12 months after child starts maintenance therapy, (4) at least 12 months after child starts maintenance therapy, (5) within a year after child completes all treatments, (6) 1 to 2 years after child completes all treatments, (7) at least 2 years after child completes all cancer treatments, and (8) none of these points—not interested. Parents were asked to indicate obstacles that could prevent them from participating in an online weight management program for their child: lack of time, lack of Internet access, and/or lack of interest. They were also prompted to list any other obstacles not included in the survey.

Summary statistics were calculated using SAS version 9.3.1 (SAS Institute, Inc). Additionally, body mass index (BMI) was calculated using the standard approach ( $\text{kg}/\text{m}^2$ ). BMI  $z$ -score and BMI percentile were then calculated using the 2000 US Centers for Disease Control and Prevention (CDC) growth charts for children [21]. Weight categorizations were defined based on the current recommendations of the CDC [22].

### Focus Groups With Pediatric Oncology Professionals

A total of 4 focus groups with pediatric oncology professionals were conducted. One group was with a pediatric oncology team from the clinic at a northeastern medical center to gain perspectives from a full team involved with treatment and survivorship care. Email invitations were sent to all members of the team requesting their participation in the in-person focus group, held in May 2015. The remaining 3 groups were comprised of pediatric oncology dietitians who were members

of the pediatric subunit of the Oncology Nutrition Dietetic Practice Group of the Academy of Nutrition and Dietetics, who were recruited between January 1, 2015, and May 30, 2015, via email. They represented 13 health care facilities in 9 states across the country. These groups were conducted via WebEx online conferencing.

All focus groups lasted approximately 1 hour and were moderated by the study principal investigator (FFZ), who was trained by another member (SCF) with expertise in qualitative methods. The focus group guide was developed by the principal investigator with input from the entire study team, including the qualitative methods expert. It was identical across all 4 groups, however the pediatric oncology dietitians received the HEAL curriculum for review prior to the groups while the pediatric oncology team was presented with the content during the focus group. Participants were asked about their experiences in working with pediatric ALL survivors around weight management, followed by questions on the content of the HEAL program and factors related to its implementation (format, delivery, timing, barriers, and their role). To help confirm that participant perceptions of key points were captured, just prior to concluding the moderator summarized main discussion points and asked for feedback on them. Participants received a \$50 gift card for their participation.

Recordings of the focus group sessions were transcribed verbatim. Thematic analysis was undertaken by 5 members of the study team, who independently reviewed and themed the data by examining the transcripts for recurring patterns, implicit meaning, and negative evidence [23]. They then met and obtained consensus on themes; any areas of disagreement were resolved based on review of the transcripts. Data were then coded by theme by 1 research team member using Microsoft Excel (qualitative analysis software was not necessary based on the small number of groups). As a final step, the principal investigator and qualitative expert reviewed the codes and confirmed the themes. Supporting quotes for each theme were identified for each focus group.

## Results

### Characteristics

Characteristics of the pediatric ALL survivors, based on survey report by parents, are presented in [Table 1](#). The average age of the children was 6.5 years, and 33 of the 54 children were male (61%). The mean reported age of diagnosis was 3.6 years, and mean time interval from diagnosis was 2.7 years. Children were in all 3 treatment stages. A slight majority of children were of normal weight, and the rest were overweight or obese per parent report of height and weight.

**Table 1.** Characteristics of pediatric acute lymphoblastic leukemia survivors in survey.

Characteristics	N=54 <sup>a</sup>
Age, years, mean (SD)	6.5 (2.1)
<b>Gender, n (%)</b>	
Male	33 (61)
Female	21 (39)
Age at diagnosis, years, mean (SD)	3.6 (2.2)
Interval from diagnosis, years, mean (SD)	2.7 (1.3)
<b>Treatment status, n (%)<sup>b</sup></b>	
Currently receiving active treatment for cancer	16 (30)
Completed active treatment and is now on maintenance chemotherapy	18 (34)
Completed all cancer treatments	19 (36)
Body mass index percentile, mean (SD)	78.3 (21.5)
<b>Weight status, n (%)<sup>c</sup></b>	
Normal weight	27 (56)
Overweight	9 (19)
Obese	12 (25)
<b>Parents' thoughts about child's weight status, n (%)</b>	
I would like to help my child gain weight	1 (2)
I would like to help my child continue to maintain a healthy weight for his/her age	42 (78)
I would like to help my child lose weight	8 (15)
I don't think about my child's weight	3 (6)
<b>Parents' interest in participating in weight management program at various time points during and after treatment, n (%)</b>	
Within 3 months after child starts maintenance therapy	23 (43)
At 3 to 6 months after child starts maintenance therapy	11 (21)
At 6 to 12 months after child starts maintenance therapy	15 (28)
At least 12 months after child starts maintenance therapy	15 (28)
Within a year after child completes all treatments	18 (34)
At 1 to 2 years after child completes all treatments	10 (19)
At least 2 years after child completes all treatments	8 (15)
None of these points—not interested	5 (9)

<sup>a</sup>Percentages were calculated based on the number of respondents who provided answers to specific questions.

<sup>b</sup>Active treatment refers to the period from the start of treatment until the start of maintenance chemotherapy.

<sup>c</sup>Weight status was defined based on BMI z-score or percentile using the 2000 Centers for Disease Control and Prevention growth charts for children. Normal weight was defined as BMI z-score = -1.645 to 1.035 (5th-84.9th percentile), overweight as BMI z-score = 1.036-1.644 (85th-94.9th percentile), and obese as BMI z-score  $\geq$  1.645 ( $\geq$  95th percentile).

The focus group with the pediatric oncology team was comprised of 3 pediatric oncologists, 3 nurses, 1 social worker, and 1 child life specialist. Participants in the 3 remaining groups were 13 oncology dietitians and 1 social worker, and group size ranged from 3 to 6 participants.

### Importance of Weight Programming

Both the quantitative (survey) and qualitative (focus group) results support a need for weight management programming for pediatric ALL survivors. On the surveys, the majority of parents (43/54, 78%) indicated that they would like to help their child continue to maintain a healthy weight for his/her age; 8/54 (15%) indicated that they would like to help their child lose

weight (Table 1). In the focus groups, dietitians and pediatric oncology team members reported observing significant weight gain in pediatric ALL patients. They described weight gain as tending to start during treatment, with behaviors that contributed to weight gain becoming habitual into survivorship (Table 2).

**Table 2.** Topic areas, major themes, and representative quotes from focus groups with pediatric oncology professionals.

Topic	Themes	Representative quotes
Program content	<p>There is a need for weight management programming overall.</p> <p>The parenting component of the program is critical.</p> <p>The nutrition information could be improved to be simpler, shorter, and more practical.</p>	<p>“... a lot of questions that I get even in the hospital really have to do a lot with the parenting and normal feeding struggles that families have. . . I really like that you start out with that because I think it helps parents gain some skills.” [Pediatric oncology dietitian]</p> <p>“I think it’s just, the parents always go back to ‘Well my kid has cancer so they’re going to do whatever they want.’ It’s just the permissive parenting that we see all the time. . .” [Pediatric oncology nurse]</p> <p>“A lot of my patients, even if they may read things online and have a lot of access to nutrition-related information, their understanding of nutrition is very basic and this is high-level nutrition information that’s being presented.” [Pediatric oncology dietitian]</p>
Program implementation: timing	<p>Starting programming during treatment would be ideal but is not feasible.</p> <p>The start of maintenance treatment is the most appropriate time to begin programming.</p> <p>Anticipatory guidance could be given at earlier stages of treatment.</p>	<p>“When you’re looking at a leukemia [patient] maybe maintenance therapy is a good time to intervene because they’re getting treated more like a healthy kid.” [Pediatric oncology dietitian]</p> <p>“I always try at least even in the initial stages of treatment to give a little anticipatory guidance. . . some information upfront so that they have it, but not really getting into any serious counseling until maintenance.” [Pediatric oncology dietitian]</p>
Program implementation: format	<p>The Web-based, self-directed format was considered useful and appropriate.</p> <p>More audio and/or video would break up the content and could improve accessibility.</p> <p>The program should not extend beyond 12 weeks.</p>	<p>“I personally really like the computer or Web-based delivery, because I think you have an opportunity to reach more people that have a different schedule or different families that are split apart. . . And also just the fact that they can do it at any time of day is going to make it able to be available to some people that wouldn’t, based on work schedule or travel.” [Pediatric oncology dietitian]</p>
Program implementation: barriers	<p>Time and Internet and computer accessibility could pose challenges for families.</p>	<p>“Just because as a parent, whether or not they even have a job, just having 20 minutes just to themselves, might be hard to find that.” [Pediatric oncology dietitian]</p>
Role of pediatric oncology professionals	<p>The most appropriate role for pediatric dietitians would be to provide an introduction and support.</p> <p>Information about program-related nutrition and physical activity goals could be incorporated into patients’ charts and records.</p>	<p>“... with maintenance, we generally only see our patients once a month. . . it’s outpatient per request. . . So I wouldn’t even be the person to see them and remind them.” [Pediatric oncology dietitian]</p> <p>“I could see it as just telling them to reach out to me when they have questions.” [Pediatric oncology dietitian]</p> <p>“And if [physicians are] really supporting the program, then we’ll probably find some way to incorporate it into maybe [electronic medical record system].” [Pediatric oncology dietitian]</p>

## Program Content

Findings from the focus groups included several themes regarding the content of the HEAL program. A major theme expressed in all groups was that the content on effective parenting is critical for successful weight management, especially since permissive feeding practices were a likely contributor to weight gain in the children. Another theme was that addressing parents’ fears about physical activity safety would be especially helpful for this population. Several themes emerged related to aspects of the program content that could be improved. Across the groups with dietitians, the nutrition information was perceived as too advanced for parents (eg, content on weight status and energy density). The clinical oncology team discussed the likely benefit of adding very

practical nutrition advice, such as tips for food shopping or kid-friendly recipes. There was also concern that too much information was presented overall, and it was suggested that the content could be condensed to make it more reader-friendly and easier to comprehend.

## Program Implementation

### Timing

Data on optimal timing of the program were obtained from both the surveys and the focus groups. The points parents selected on the survey to be most of interest for weight management programming were within 3 months of starting maintenance therapy (23/54, 43%) and within a year of completing all treatments (18/54, 34%). Parents’ selection of preferred timing did not differ by current treatment status of their child (data not

shown). In the focus groups with pediatric dietitians, a theme was that information about healthy eating and physical activity would ideally be delivered during treatment, before negative habits could form. However, this was unlikely to be feasible since, in their perception, parents would be less receptive to information not directly related to treatment, and unhealthy eating might be tolerated in an effort to maintain the child's weight. There was therefore consensus across the groups that the most appropriate time to start the actual weight management programming would be around the start of maintenance, as the children are transitioning back into their regular lifestyles. However, in both types of focus groups, it was mentioned that providing anticipatory guidance around nutrition and physical activity education at earlier treatment stages may be helpful for parents.

### **Format**

In terms of format, pediatric oncology dietitians felt that the Web-based, self-directed delivery of the HEAL program would be useful for parents since it allows for flexibility with time and pace of completion. They indicated that they also preferred this format to an in-person or telephone-based counseling method of delivery since as dietitians they are limited in their ability to deliver information, due to infrequent contact with patients and general time constraints. In each of the groups, there was at least 1 suggestion to convert the program from its text-heavy format to include more audio and/or video presentations, for example, as a narrated slideshow. In 1 of the groups, it was suggested that audio features may improve the accessibility of the content for families in which there may be low literacy. As for the length of the program, there was agreement among the dietitians that the program should not extend longer than 12 weeks and that sessions should be kept brief (around 20 minutes), otherwise parents would likely lose interest.

### **Barriers**

Both quantitative and qualitative methods provided information on barriers to participation in the program. Among the 41 participants who answered the question about barriers on the survey, 29 (71%) of parents selected lack of time and 6 (15%) of parents selected lack of Internet access as obstacles that could prevent them from participating. In the focus groups, in response to an open-ended question about barriers, pediatric oncology dietitians also mentioned both time and Internet and computer accessibility as potential challenges for families. However, in 2 groups it was suggested that accessibility on portable devices (such as smartphones and tablets) would mitigate this since most parents have access to these devices. Some pediatric oncology dietitians also mentioned that eventual translation of the program into Spanish would be important to widening the reach of the program.

### **Role of Pediatric Oncology Professionals**

In the focus groups, several themes emerged related to the role of the pediatric oncology professionals in weight management programming. Across groups, all were supportive of the HEAL program. The dietitians indicated that appropriate roles would be to introduce it to patients and to support it by scheduling an in-person or phone meeting with parents when they had specific

questions. Pediatric oncology professionals suggested the possibility of incorporating information about nutrition and physical activity goals and behaviors that parents inputted as part of the program into patients' charts and records, to be reviewed during hospital visits. In 1 focus group, the dietitians suggested that this type of integration may make parents feel more accountable for their progress in the program and boost adherence.

## **Discussion**

### **Principal Findings**

In this mixed methods study, data were obtained from both parents and health care providers who work closely with pediatric ALL patients in addressing behaviors and issues related to weight management. Taken together, the data from these sources confirm a need and desire for weight management programming for pediatric ALL survivors. Health care professionals indicated the importance of the content on effective parenting for successful weight management. They suggested that the nutrition content should be simple and include practical tips. Results indicate that the most appropriate and feasible time to start the weight management programming is around the start of maintenance therapy, as the children are transitioning back into their regular lifestyles. The Web-based, self-directed delivery of the program was viewed favorably since it allows for flexibility with time and pace of completion, but health professionals suggested that there may be barriers related to health literacy and access to technology. They indicated that their appropriate role would be to introduce the program and to support its use.

Most parents indicated that that they would like to help their children maintain a healthy weight or lose weight. Consistent with the literature [4], pediatric oncology professionals, both the team and the dietitians, have observed weight gain in this population, which they perceived as related to behaviors within families that become habitual during treatment and therefore continue into survivorship. Permissive parenting related to food that develops during treatment was raised as a major contributing factor and suggested a need for guidance on reexamining parenting practices as children transition into survivorship. The HEAL program content on effective parenting was therefore viewed as essential.

Several of these findings are similar to 1 other mixed methods study designed to inform an obesity intervention for pediatric cancer survivors [10]. In that study, pediatric oncology professionals likewise noted behaviors that develop during treatment that then become habitual and difficult to reverse during the transition from treatment. Parents noted the changes in habits that occurred during treatment and, as in this study, expressed interest in weight management programming.

Despite this interest, results from the parent surveys suggest a disconnect between perceived and actual weight status of the children, with a significant number indicating that their children are at a healthy weight for age despite BMI z-scores that place children in overweight and obese categories. This mirrors inaccurate perceptions that exist in the general population [24]

and suggests that clinicians may have an important role to play in reviewing growth charts and discussing weight.

In focus groups, the Web-based format was perceived favorably since it would be convenient for parents and have a wide reach. It may also be more feasible than in-person counseling due to time constraints among parents, who indicated that time would be a major barrier to participation. Pediatric oncology professionals suggested prioritizing succinctness over comprehensiveness to improve adherence to the program. The program content has since been shortened based on this feedback. Pediatric oncology professionals indicated that their role would entail aiding in the promotion and introduction of the HEAL program and possibly also discussing aspects of it, such as behavioral goals, during clinical visits.

Oncology professionals suggested that a Web-based program should use interactive features and multimedia to engage readers. They also suggested presenting information in smaller sections. Based on this feedback, a narrated slideshow was added to each session of the curriculum for the pilot program as an alternative way to access content. It was further suggested that audio may be beneficial for reaching low-literacy audiences. However, while providing audio may help in making the content more accessible to parents with limited reading ability, inherent complexity of the underlying concepts could still serve as a major barrier to parents' ability to comprehend, evaluate, and use the information [25]. This issue merits additional attention as the program continues to be developed.

### Strengths and Limitations

This study had several strengths and limitations. Parents whose children are in treatment for cancer are challenging to reach since families are essentially in crisis. By using mixed methods, salient data were feasibly obtained quantitatively from parents

and validated and extended with qualitative data from professionals who interact most with parents on these issues. Surveys were conducted with a relatively small number of parents from 2 pediatric cancer clinics and may not generalize. Focus groups were likewise conducted with convenience samples: the pediatric oncology team was geographically located at the researchers' home institution, and the dietitians were accepted as they responded to recruitment. However, the dietitians were part of a professional practice group and represent pediatric oncology clinics across the United States. The survey was conducted anonymously in the clinics, and the response rate is unknown. An additional limitation of the anonymous survey is that parent reports of children's heights and weights were not corroborated by clinical data. However, the BMI distribution observed in this sample is consistent with measured values from a previous study conducted by the authors with a similar cohort [26]. To keep the survey to 2 pages, parents were not asked about ethnicity or socioeconomic status. However, the clinics where the surveys occurred treat a diverse range of families. Finally, parents were not asked about the delivery format or content of the program in this formative stage. Instead, detailed feedback is being obtained as parents complete a pilot version of the program.

### Conclusion

This study found that parents and pediatric oncology professionals were interested in and supportive of weight management programming for pediatric ALL survivors. They provided valuable input on the content and implementation of this type of program. Future studies will involve testing the HEAL program for feasibility and effectiveness. Clinicians are likely to play an important role by offering anticipatory guidance and promoting and supporting such programming.

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### Acknowledgments

All phases of this study were supported by a Tufts Collaborates Grant, Tufts University Office of the Provost. The funding source had no role in the design, conduct, or analysis of this study or the decision to submit the manuscript for publication.

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### Conflicts of Interest

None declared.

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## Abbreviations

**ALL:** acute lymphoblastic leukemia

**BMI:** body mass index

**CDC:** Centers for Disease Control and Prevention

**SMART:** Specific, Measurable, Attainable, Realistic/Relevant, and Time-Bound



*Edited by D Vollmer Dahlke; submitted 22.09.16; peer-reviewed by A Ahmadvand, G Juarez, J des Bordes; comments to author 01.11.16; revised version received 22.12.16; accepted 28.12.16; published 09.02.17.*

*Please cite as:*

*Folta S, Chang W, Hill R, Kelly M, Meagher S, Bowman WP, Zhang FF*

*Parent and Health Care Provider Perceptions for Development of a Web-Based Weight Management Program for Survivors of Pediatric Acute Lymphoblastic Leukemia: A Mixed Methods Study*

*JMIR Cancer 2017;3(1):e2*

*URL: <http://cancer.jmir.org/2017/1/e2/>*

*doi: [10.2196/cancer.6680](https://doi.org/10.2196/cancer.6680)*

*PMID: [28410182](https://pubmed.ncbi.nlm.nih.gov/28410182/)*

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Original Paper

# An eHealth Intervention to Increase Physical Activity and Healthy Eating in Older Adult Cancer Survivors: Summative Evaluation Results

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## Abstract

**Background:** A healthy lifestyle is associated with improved quality of life among cancer survivors, yet adherence to health behavior recommendations is low.

**Objective:** This pilot trial developed and tested the feasibility of a tailored eHealth program to increase fruit and vegetable consumption and physical activity among older, long-term cancer survivors.

**Methods:** American Cancer Society (ACS) guidelines for cancer survivors were translated into an interactive, tailored health behavior program on the basis of Social Cognitive Theory. Patients (N=86) with a history of breast (n=83) or prostate cancer (n=3) and less than 5 years from active treatment were randomized 1:1 to receive either provider advice, brief counseling, and the eHealth program (intervention) or advice and counseling alone (control). Primary outcomes were self-reported fruit and vegetable intake and physical activity.

**Results:** About half (52.7%, 86/163) of the eligible patients consented to participate. The most common refusal reasons were lack of perceived time for the study (32/163) and lack of interest in changing health behaviors (29/163). Furthermore, 72% (23/32) of the intervention group reported using the program and most would recommend it to others (56%, 14/25). Qualitative results indicated that the intervention was highly acceptable for survivors. For behavioral outcomes, the intervention group reported increased fruit and vegetable consumption. Self-reported physical activity declined in both groups.

**Conclusions:** The brief intervention showed promising results for increasing fruit and vegetable intake. Results and participant feedback suggest that providing the intervention in a mobile format with greater frequency of contact and more indepth information would strengthen treatment effects.

(*JMIR Cancer* 2017;3(1):e4) doi:[10.2196/cancer.6435](https://doi.org/10.2196/cancer.6435)

**KEYWORDS**

survivors; diet; food and nutrition; breast neoplasms; prostatic neoplasms; eHealth

## Introduction

More than 13.7 million persons in the United States have a history of cancer, a number that has been steadily increasing due to progress in detection and treatment and the overall aging of the population [1]. Most cancer survivors are aged above 55 years and are at increased risk for comorbid conditions, such as cardiovascular disease and diabetes. Many also experience long-term negative effects of treatment such as fatigue, cognitive impairment, pain, and reduced health-related quality of life (HRQoL) [2-4].

Adopting healthy lifestyle behaviors such as physical activity and eating a diet high in fruits and vegetables can improve HRQoL [5,6]. The American Cancer Society (ACS) and an expert panel of the American College of Sports Medicine (ACSM) suggest that survivors should aim to exercise at least 150 min per week and engage in muscle-strengthening activities at least 2 days per week [7]. In addition, the ACS recommends a dietary pattern that is high in vegetables, fruits, and whole grains [8]. Nonadherence to these behaviors also leads to being overweight or obese, which may independently increase the risk of recurrence for colon, prostate, and breast cancers [9-11].

Although survivors indicate interest in dietary and physical activity improvements, several studies have found that a diagnosis of cancer does not necessarily result in increased adherence to healthy lifestyles. Despite the potential benefits of being physically active, 75% of cancer survivors report not engaging in the recommended 150 weekly min of at least moderate physical activity [12] and more than 80% of cancer survivors are not meeting daily fruit and vegetable intake recommendations [6].

Findings from a national population survey of cancer survivors have suggested a need to intervene on more than one behavior to improve HRQoL among survivors [6]. Optimizing health behaviors, however, remains a challenge in the health care setting. The majority (70-80%) of survivors report that health care providers have not discussed physical activity or healthy eating with them [13,14] even though survivors prefer to receive such counseling within the health care setting [15,16]. Although several health behavior change interventions have been created and found to be efficacious for fruit and vegetable consumption and exercise [17], most of them have relied on in-person and telephone-based counseling modalities [17-20] creating challenges for widespread adoption by health care settings on a long-term basis [21]. eHealth behavior change interventions can reduce many implementation barriers [22,23] and thereby reach a greater number of survivors. Thus, our team worked with clinicians (nurse practitioners in a designated Survivorship Clinic) to develop and pilot a multibehavior change intervention for adult cancer survivors that would be easily disseminable and sustainable. A digital video disc (DVD) format was chosen, similar to other interventions for older adults, [24,25] as mobile phone and Internet access remains lower among older populations and was particularly so at the time (only 58% of our target population had access to either) [26,27]. The goal of the project was to provide information on feasibility and modifications needed for a larger trial. This paper reports

recruitment data and summative evaluation outcomes of the intervention collected at the final assessment.

## Methods

### Participants and Procedures

Patients at Memorial Sloan Kettering Cancer Center (MSKCC) who had completed their primary treatment for either breast or prostate cancer no more than 5 years previously and had an intake scheduled at the Survivorship Clinic were identified via the clinical database and sent an invitational letter signed by the director of the clinic describing the study and procedures. Two weeks later they were contacted by telephone. Once contacted, they were screened for additional eligibility criteria: the presence of at least one behavioral risk factor (engaging in <150 min of physical activity per week or eating less than 5 fruits or vegetables per day), English-speaking, and able to provide informed consent. During this call, the research assistant answered any questions about the study and scheduled a time to meet the patient immediately before their first Survivorship Clinic appointment to complete informed consent, the baseline survey, and randomization. Patients completed the survey on their own. The research assistant was present to clarify any questions when needed. Following the survey completion, the research assistant contacted the research office who provided the group assignment using the permuted block method stratified by the disease type (breast or prostate). If randomized to the intervention arm, the research assistant gave the participant the DVD and explained how to view it. One month following the clinic appointment, patients in the intervention arm were mailed a reminder letter to use it. Three months following the clinic appointment, all patients were mailed follow-up surveys and given the option to complete the surveys by phone or mail. At the completion of the study, patients in the control arm were offered the intervention components. The study was approved by the MSKCC and New York University Medical Center Institutional Review Boards. As a pilot, it was not a registered trial.

### Experimental Conditions

#### Intervention

On the basis of formative evaluation data with patients and providers, the intervention was provided on DVD as this modality, compared with mobile phones or Internet access, was most available to the older adult population at the time [26,28]. The intervention was guided by Social Cognitive Theory [29] and contained components of prior evidence-based interventions developed for cancer survivors [30]. This included focus on enhancing knowledge about the behaviors, developing positive expectancies, reducing barriers, supporting self-efficacy, and stories from cancer survivors. The program provided specific dietary and physical activity recommendations which were drawn from the ACS guidelines for cancer survivors [8]. These focused on eating at least five or more servings of fruits and vegetables a day, choosing high-fiber breads and cereals, lean protein, and low-sugar unprocessed products. For activity, the recommendation was to get at least 30 min of moderate to vigorous activity a day, and at the very least focus on reducing

sedentary time. Suggestions were provided for how to change behaviors. For instance, for dietary behaviors the DVD had them choose a healthy eating goal for the next week and provided general tips such as “focus more on benefits than losses,” “keep track of progress,” “set small goals,” and “get family or friends involved” along with a detailed voiceover narration about how to carry out each of these. A focus group of 9 clinicians with expertise in cancer survivorship (nurse practitioners, medical oncologists, clinical nutritionist, and health psychologists) reviewed a draft of the intervention and made suggestions for optimizing structure and content. The intervention made use of branching menus (accessed using a computer or DVD player remote control), which were used to tailor information and feedback on the following variables: level of activity and dietary adherence, readiness to change, barriers, benefits, knowledge, and goal setting ([Multimedia Appendix 1](#)). For instance, users could choose which barriers to healthy eating they wanted to hear more about (eg, getting family to eat vegetables, reducing food waste with fresh food, or feeling full), which was then followed by a description from a clinical nutritionist of options for overcoming each barrier. In addition, clips of interviews with 6 survivors were interspersed throughout the program to emphasize particular themes and provide opportunity for identification and modeling. Each topic (healthy eating and physical activity) was divided into 4 chapters each (for a total of 8 sections): (1) importance of the healthy behavior for survivors, (2) self-assessment, (3) behavior change strategies, and (4) links to additional information. The total DVD including healthy eating and physical activity took about 60 min to complete but could range from 45 to 90 min, depending on the participant’s choice of branching menus. Instructions were provided by the research assistant and the DVD jacket also contained technical instructions for how to play it as well as how to make use of it noting they could “choose whatever sections you are interested in and go back and review them as much as you want.”

### **Control**

The control group received standard care at the MSKCC Survivorship Clinic, which consists of routine health behavior assessment and advice and brief counseling regarding health maintenance provided by a nurse practitioner with expertise in cancer survivorship.

### **Measures**

#### ***Fruit and Vegetable Intake***

Fruit and vegetable intake was measured by the Thompson Food Frequency Questionnaire [31], which assesses quantity of food consumption by meal and computes a score on the basis of the total consumption of each food category. The measure defined servings of each food according to standards published by the US Department of Agriculture [32]. For fruit consumption, daily servings can range from 0 to 4.5. For vegetable consumption, servings can range from 0 to 6.75. To compute combined fruit and vegetable consumption scores, the 2 scores were summed together with a total score ranging from 0 to 11.25. The measure has been used in numerous studies and has found to be correlated with intake for older women (.53) and men (.67) [32].

#### ***Physical Activity***

The Godin Leisure-Time Exercise Questionnaire [33] was used to assess physical activity. The questionnaire asks participants to report their weekly performance of minutes spent engaged in mild, moderate, and strenuous exercise. The reported frequency of the various types of exercise is then converted into Metabolic Equivalent of Task units (METs). METs were computed by multiplying each reported instance of mild physical activity by 3, moderate activity by 5, and strenuous activity by 9 [33]. The measure has been found to have similar validity to other self-report measures and found to be correlated with accelerometer data in breast cancer survivors (.53) [34].

#### ***Demographics***

Participants reported their age, sex, race, marital status, highest education, occupation, and income. Primary cancer diagnosis was extracted from the medical record.

#### ***Qualitative Patient Feedback***

All intervention group participants completed use and evaluation items at the 3-month follow up [35]. Qualitative interviews (n=12) were also conducted with a random sample of intervention group participants who used the intervention. These were used to further investigate the acceptability and feasibility of the intervention and to inform improvements to future iterations of the program. The interviews were conducted over the phone by a qualitative methods specialist (Ms Shuk) and were limited to 45 min. Audio recordings were transcribed by an independent transcription company (RA Fisher, Inc).

#### ***Analytic Plan***

The primary goal of this pilot study was to examine patient interest in and feasibility of the intervention in order to guide the development of a larger trial. We therefore detail screening, exclusion, and refusal reasons. For each primary outcome, we report means and standard deviations at baseline and 3-month follow up along with effect sizes (Cohen d). This was calculated as difference in the change scores for intervention versus control divided by the pooled standard deviation. For dietary intake, we reported the number of fruit servings, vegetable servings, and combined fruit and vegetable servings. Between-group differences were not analyzed as the pilot was not powered to detect statistically significant differences. All analyses were conducted in SAS version 9.3 (SAS Institute, Inc).

The qualitative data were reviewed using inductive thematic text analysis, an iterative process of transcript review, interpretation, and consensus discussions [36-38]. An initial set of 3 interview transcripts were coded by 2 independent reviewers (Ms Shuk and Ms Williams), in which each reviewer read the same transcript, highlighting important content and recording reflections on the transcript in a process known as margin coding [39], prior to completing a written analysis template with supporting participant quotations. The reviewers subsequently met to generate collective findings for the transcript. Once key thematic findings had been identified for the first 3 transcripts, the reviewers subsequently read and coded the remaining transcripts through the same process, both exploring the themes that had been established and identifying additional salient findings. As per standard procedures, the final analytic phase

entailed generating higher-order descriptive and interpretive themes that represented the most frequent concepts observed across all interviews.

## Results

### Participants

A total of 466 individuals were screened for eligibility. Of those, 259 could not be contacted via phone and 25 had no risk factors. Additionally, 10 individuals reported inability to operate a DVD, 8 were non-English speaking, and 1 was still under treatment. Of the 163 eligible individuals, 86 consented to participate for a 52.7% participation rate. The main reasons for refusal were

time constraints (n=32) and lack of interest in making health behavior changes (n=29). At the 3-month follow up, the retention rate was 73% (32/44) and 86% (36/42) for the intervention and control groups, respectively (Figure 1). Recruitment and data collection were conducted from August 2013 to March 2014.

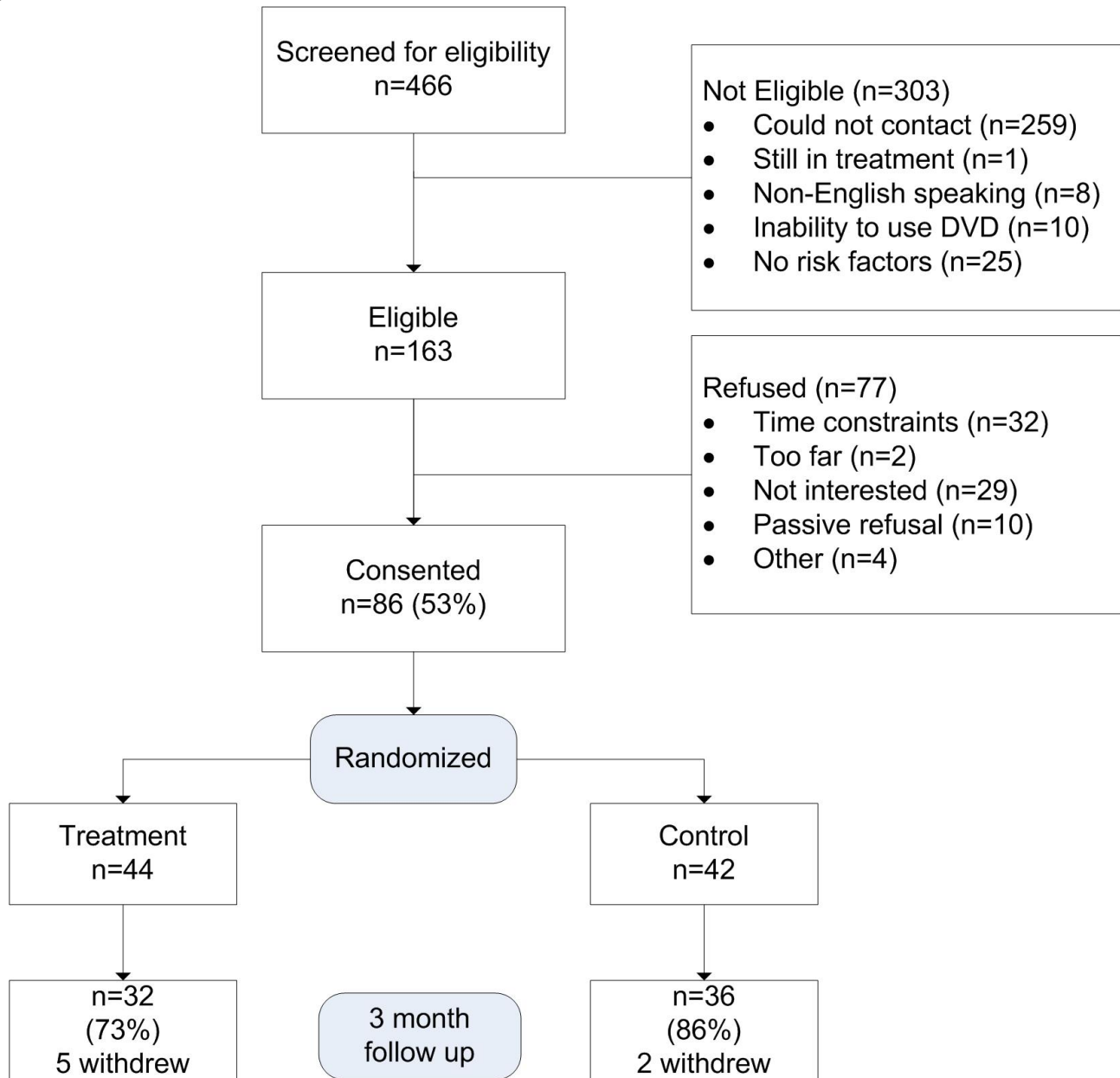
Demographic characteristics of the sample are shown in Table 1. Participants were predominantly non-Hispanic white (81%, 69/86), and female (96%, 82/86), with a mean age of 59.8 (standard deviation, SD 11.4). Recruitment of prostate cancer survivors was limited due to clinic scheduling and change in staffing during the study period.

**Table 1.** Demographic Characteristics (n=86).

Demographic characteristics <sup>a</sup>	n (%)
<b>Age in years, (mean 59.8, SD 11.4)</b>	
35-54	29 (34)
55-64	25 (30)
65-74	20 (23)
75+	11 (13)
<b>Sex</b>	
Female	82 (96)
<b>Primary cancer diagnosis</b>	
Breast	83 (97)
Prostate	3 (3)
<b>Relationship status</b>	
Married or partnered	59 (69)
<b>Race or ethnicity</b>	
Non-Hispanic white	69 (81)
Non-Hispanic black	5 (6)
Non-Hispanic Asian	2 (2)
Non-Hispanic other	2 (2.4)
Multiracial	2 (2)
Hispanic	5 (6)
<b>Employment status</b>	
Employed	41 (48)
Homemaker	7 (8)
Retired or disabled	35 (38)
Unemployed	2 (2)
<b>Education</b>	
≤High school	7 (8)
Some college	21 (25)
College graduate	18 (21)
Graduate degree	39 (46)
<b>Income (K)</b>	
10-29	4 (5)
30-49	7 (8)
50-69	12 (14)
70-89	14 (17)
90k+	47 (56)

<sup>a</sup>One person consented but did not choose to complete demographic data. Two people did not complete income data.

Figure 1. Patient Flow.



## Primary Outcomes

### *Fruit and Vegetable Consumption*

As shown in Table 2, the intervention group increased its intake by 0.18 servings whereas the control group decreased their intake by 0.10 ( $d=0.25$ ). Fruit and vegetable intakes were also analyzed separately. The mean fruit score at follow up increased by 0.09 for the intervention group and decreased 0.08 for the

control group ( $d=0.33$ ). The vegetable score increased to 0.08 for the intervention group and decreased to 0.02 for the control group ( $d=0.12$ ).

### *Physical Activity*

Both groups decreased their physical activity during the intervention period. Intervention group participants had a mean decline of 3.36 total weekly METS from the baseline; the control group had a smaller mean decline of 1.03 ( $d=-0.11$ ).

**Table 2.** Means and SDs for dietary and physical activity outcomes.

Variables	Time point	Intervention (n=32), mean (SD)	Control (n=36), mean (SD)	Effect size d (95% CI)
Fruit servings	Baseline	0.75 (0.76)	0.96 (0.70)	
	Follow up	0.84 (0.79)	0.88 (0.68)	
	Change	0.09 (0.46)	-0.08 (0.57)	0.33 (0.21 to 0.45)
Vegetable servings	Baseline	1.30 (0.99)	1.18 (1.06)	
	Follow up	1.38 (1.08)	1.16 (0.95)	
	Change	0.08 (0.91)	-0.02 (0.79)	0.12 (-0.08 to 0.32)
Combined fruits and vegetable servings	Baseline	2.04 (1.50)	2.14 (1.57)	
	Follow up	2.22 (1.70)	2.04 (1.43)	
	Change	0.18 (1.11)	-0.10 (1.14)	0.25 (-0.01 to 0.52)
Weekly total METs <sup>a</sup>	Baseline	24.55 (21.01)	29.81 (25.14)	
	Follow up	21.19 (21.64)	28.78 (21.04)	
	Change	-3.36 (21.70)	-1.03 (21.01)	-0.11 (-5.12 to 4.89)

<sup>a</sup>METs: Metabolic Equivalent of Task units.

### Patient Evaluation Feedback

At the 3-month assessment, all intervention group participants (n=32) completed survey items to provide feedback on their experiences with the intervention. Results are summarized in [Table 3](#). Among the intervention group, 72% (23/32) viewed the DVD, with 50% (16/32) completing the entire DVD. Of those who used it, 60% did so more than once. More than half (14/23) rated it as easy to use, whereas a third (35%, 8/23) found it neither easy nor difficult. Most reported that it kept their

attention at least somewhat (87%, 20/23), and looked professional (96%, 22/23). All the participants (100%, 23/23) stated it did a good job of presenting health information, found nothing offensive in the material, and was culturally appropriate, with only 1 person stating it made her feel uncomfortable. Users found it relevant for them as cancer survivors (91%, 21/23). Overall, they felt it was the right length (83%, 19/23), were satisfied (30%, 7/23), or extremely satisfied with it (61%, 14/23), and would recommend the intervention to others (91%, 21/23).



**Table 3.** Patient evaluation feedback for the intervention group.

Evaluation item	n (%)
<b>How much time did you spend using the program? (n=32)</b>	
None	9 (28)
5-10 mins	2 (6)
10-20	5 (16)
All of it	16 (50)
<b>What part did you watch? (n=23)</b>	
Intro	22 (96)
Physical activity	19 (83)
Healthy eating	22 (96)
<b>How many unique times did you use the program? (n=20)</b>	
Unsure	1 (5)
1	7 (35)
2-3	7 (35)
4-5	3 (15)
More than 5	2 (10)
missing	3
<b>How easy or difficult was it to use? (n=23)</b>	
Very easy or easy	14 (61)
In between	8 (35)
Very difficult or difficult	1 (4)
<b>How easy was it to see the on-screen text? (n=23)</b>	
Very easy	14 (61)
Easy	8 (35)
Neither easy or difficult	1 (4)
<b>To what extent did the program keep your attention? (n=23)</b>	
Very much	15 (65)
Somewhat	5 (22)
In between, so-so	3 (13)
<b>How would you rate the professionalism or production value of the program? (n=23)</b>	
Very good (like something I'd see on TV)	14 (61)
Somewhat good	8 (35)
Very poor (looks unprofessional)	1 (4)
Did a good job at presenting health information	23 (100)
Speaks to you as a cancer survivor	21 (91)
Was nothing offensive or problematic	23 (100)
The program made me feel uncomfortable	1 (4)
The suggestions and content were appropriate for someone from your culture and background	23 (100)
<b>Overall experience with program (n=23)</b>	
Extremely satisfied	14 (61)
Satisfied	7 (30)
In between	2 (9)

Evaluation item		n (%)
<b>Would you recommend the program to others? (n=23)</b>	Dissatisfied	0 (0)
	Definitely	14 (61)
	Probably	7 (30)
	Maybe	2 (9)
<b>How would you rate the length of the program? (n=23)</b>	Too short	1 (4)
	About right	19 (83)
	Too long	3 (13)

Qualitative interviews were also conducted with 12 of the intervention group participants who reported using the intervention. Three key themes emerged from the qualitative analysis of transcripts regarding engagement, content, and usability. Key themes and select quotes are presented below:

**Theme 1:** The program engaged patients' interest as cancer survivors. Patients liked that it came from a reputable information source, found it to be engaging and interesting, liked the positive, encouraging tone, and found the survivor stories to be inspiring. Participants suggested greater racial, ethnic, and socioeconomic diversity of the survivors who were interviewed, and 1 user did not like that a survivor interview mentioned cancer as a "blessing in disguise."

*Because when you start watching what's on the DVD, you know, you get very interested. It's informative. You know, so whatever you watch and memorize, it motivates you.*

*I think the whole DVD is a very positive, you know, approach, and it had a nice balance of survivors and then professionals.*

**Theme 2:** Patients made suggestions for adding specific physical activity and healthy eating content. Nutrition and physical activity information was perceived to have been presented with an appropriate level of detail, and participants appreciated the focus on setting small goals and how to incorporate changes into their daily routines. They found it to be motivational and a good reminder of what their goals should be. In terms of preferences not included, patients requested more information on how fruits and vegetables and activity help the body physiologically, specific recipes, more exercises to perform, and how to tailor exercise to various needs such as living in urban areas or for older persons.

*It's very good for survivors, you know? It—it helps us to learn how to control our eating habits, especially, you know, when you're not used to eating that healthy. I liked how the CD was set up, how—if I remember correctly, showing pictures, and not just somebody lecturing you, but they showed you, it was more interactive, showing you pictures of things and—that was helpful.*

*Take it to the next level. That was my biggest complaint about it, that I wanted more.*

**Theme 3:** Patients liked the interactive structure and suggested usability improvements. Patients reported that the self-assessments were engaging and helped determine their current eating and activity habits. Patients generally found the menu structure easy to use on screen, but wanted it to be easier to go back and review sections. Patients also found it difficult to access the additional resources listed as they had to write them down. Patients noted they would want to have a follow up with greater detail and more specifics, with some noting they would like to have it available in a mobile app version they could access more readily on a mobile phone or tablet.

*I was curious to see, you know, with the questions they were asking me, of where that—to go on to find out where I stood.*

*They didn't seem in depth enough for me to—you know, again, I think the disconnect I have is you sit, you watch it, and then you're left to your own devices. So, if there was something that I could—you know, again, that I could take with me to refer to during the day, I think that would impress me more, you know, impress upon my life more.*

## Discussion

### Principal Findings

This pilot study examined the potential of a theory-based, eHealth intervention designed to assist adult cancer survivors make improvements in healthy diet and physical activity. Results indicate that recruitment and retention was feasible for this older adult survivorship population and that they had high interest in the intervention. Results on behavior change outcomes should be interpreted with caution as the study was not powered to detect reliable differences. Observed power for the effect sizes ranged from .06 to .21. Findings indicate small effects on dietary outcomes, primarily fruit intake, and suggest that additional modifications would be necessary to increase efficacy of the physical activity component.

Results should be interpreted with regard to feasibility of pursuing a larger powered trial. The following criteria were assessed as indicators of whether to pursue follow-up work: recruitment of the target sample size in the allotted timeframe, acceptance rate of at least 50% [40], retention of at least 80% [40], at least small effect sizes ( $d=0.2$ ) on primary outcomes, minimal adverse events, and patient report of interest in and acceptability of the

intervention. In light of these criteria, recruitment goals were met within the allotted time frame of 7 months. The study intended to recruit equal numbers of prostate and breast cancer survivors, but a loss of clinic staff resulted in no new survivorship visits for men during the recruitment period. Thus, unfortunately, we do not know how men would respond to the intervention. Consent rates among those eligible were good (53%) and consistent with or higher than diet and activity studies among cancer survivors [41]. Response bias is always a possibility, but given our inclusion criteria, the identified and final sample was likely to differ little by demographics or treatment characteristics. Follow-up rates in the control group met the criteria (86%), but could slightly be improved in the intervention group (73%). No adverse effects were reported by the participants. The majority of the intervention group (72%, 23/32) used the DVD and rated it highly in terms of engagement and usability. Interviews with participants indicated that they found it to be helpful.

For fruit and vegetable intake, a small effect was observed for increased consumption for the intervention as compared with the control group at 3-month follow up, primarily attributable to increased fruit intake ( $d=.33$ ) versus vegetables ( $d=0.12$ ). The mean difference between intervention and control in combined fruit and vegetable score would be comparable with about 0.28 standard servings per day. Intensive, multisession telephone-counseling studies conducted with survivors have generally observed increases of 0.5-0.9 servings a day at the 3-month follow up [17,18]. Thus, the results here make sense for a low-contact intervention. Nevertheless, effects on fruit and vegetable intake would meet the criteria for pursuing a larger trial, albeit with greater attention to intervention intensity to further improve results.

The results did not meet the criteria for physical activity. Surprisingly, declines in METs were observed in both intervention and control groups with a slightly greater decline in the intervention group compared with the control. We investigated additional analyses to provide further insight into this finding. As participants only had to have at least one risk factor (meaning some were already active) we analyzed results by baseline activity and found an interesting trend—those who were already physically active and who used the intervention had less of a decline in activity compared with those who did not use the intervention; participants who did not meet the physical activity criteria at baseline showed a trend for greater increase in activity compared with those who did not use the intervention (Multimedia Appendix 1). These follow-up findings were similar to the findings of Pinto et al [42], who found that those who were more active at the baseline regressing to the mean at follow up. It should also be noted that in this study, the control group reported more physical activity at the baseline than the intervention group. Other studies have also observed over-reporting of physical activity at the baseline [43], which increases the difficulty of observing changes at follow up. It is noteworthy that study follow-ups were conducted solely during the winter months in the Northeastern United States, such that seasonality may potentially explain the overall mean decreases in activity for an older survivorship population. The intervention's focus on low-impact activities such as walking

could also have led participants to decrease their activity during the winter months.

In terms of informing a larger trial, the recruitment plan and follow up generally went well, a small effect was observed on fruit and vegetable intake, and patients liked the program. Nevertheless, results for physical activity were disappointing. A number of improvements would be indicated prior to pursuing further work. In terms of recruitment, contacting patients via telephone appeared a difficulty given that few people now answer their phones. Although a more time-intensive method, it may be necessary to meet patients first in person to offer study enrollment versus on telephone or through email. Nowadays, we employ an “on-call” research assistant who can quickly come to the clinic when a provider identifies an interested patient. Follow up should be extended to 6 months or a year as time and funding limited the period of study here. In terms of measurement, while standard measures of diet and activity were used, these rely on self-report and recall. Using multiple 24-hour recalls (ie, ASA24) would also improve assessment of dietary practices, and which are now available on the Internet through the National Cancer Institute (NCI) [44]. Measurement of physical activity, in particular, would benefit from use of accelerometers and mobile heart rate monitors now available that can more accurately capture additional activities such as strength training. In addition, depending on location, physical activity studies should account for seasonality by conducting the intervention period over a longer time frame and by stratifying by season of recruitment.

## Conclusions

In terms of behavioral endpoints, promoting lifestyle changes among cancer survivors remains a challenge. Studies of fruit and vegetable consumption indicate that it has tended to be an easier behavior to improve than physical activity, likely due to a number of factors; it does not require much additional time or scheduling changes, offers immediate reward, has few if any contraindications due to comorbidities, does not result in physical discomfort, and does not require large increases in knowledge or skills [21]. Physical activity, on the other hand, has been a particularly difficult intervention endpoint in cancer survivorship. A comprehensive review of physical activity interventions in cancer populations found that no studies reported 75% or greater adherence to the 150 min per week guideline, even when they used multisession counseling and supervised training sessions [21]. The most common barriers survivors report are being “too busy” and lack of “willpower,” factors which predict level of activity [45]. As survivors are also concerned about safety and comorbid medical conditions, combining introductory in-person demonstrations [46] along with an interactive self-guided program would better address barriers related to self-efficacy, motivation, and time. Achieving and sustaining robust behavior change will likely require further contacts and specific goal setting and monitoring, enhancements that have been linked to increased behavioral adherence [21,47]. Interviews with participants indicated interest in having the resource available via a mobile platform that would enable additional features such as tracking and goal setting. Indeed, a mobile phone app modality to present information, combined with automated tailored text messaging, to provide ongoing

intervention components may be one strategy to integrate these features into an updated intervention. Recent reviews have called for interventions that can be more readily disseminated to a more diverse range of survivors beyond those who can attend

in-person sessions at major cancer centers [21]. This study provided important insights that can be integrated into a more intensive mobile-based intervention, which is planned in a future trial.

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## Acknowledgments

We extend our appreciation to the staff at the MSKCC Survivorship Clinics for their support and help with this research, Sarah Borderud for her help in project management, and Sam Palmucci and Susan Weil-Kazzaz at the MSKCC Media Services Department for their expertise and assistance in creating the DVD. We thank Dr. Wendy Demark-Wahnefried as well for advice and assistance in conceptualizing the study. This project was funded by National Cancer Institute Grant # R03CA142042 (Krebs).

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## Conflicts of Interest

None declared.

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## Multimedia Appendix 1

Follow up analysis and example of tailoring algorithm.

[[PDF File \(Adobe PDF File\), 115KB - cancer\\_v3i1e4\\_app1.pdf](#)]

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## Abbreviations

**DVD:** digital video disk

**HRQoL:** health-related quality of life (HRQoL)

**METs:** Metabolic Equivalent of Task units

*Edited by K Eddens; submitted 02.08.16; peer-reviewed by MY Chih, D Reinwand, T Baranowski; comments to author 17.08.16; revised version received 06.01.17; accepted 21.01.17; published 01.03.17.*

*Please cite as:*

*Krebs P, Shtaynberger J, McCabe M, Iocolano M, Williams K, Shuk E, Ostroff JS*

*An eHealth Intervention to Increase Physical Activity and Healthy Eating in Older Adult Cancer Survivors: Summative Evaluation Results*

*JMIR Cancer* 2017;3(1):e4

URL: <http://cancer.jmir.org/2017/1/e4/>

doi: [10.2196/cancer.6435](https://doi.org/10.2196/cancer.6435)

PMID: [28410171](https://pubmed.ncbi.nlm.nih.gov/28410171/)

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Original Paper

# The Fitbit One Physical Activity Tracker in Men With Prostate Cancer: Validation Study

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## Abstract

**Background:** Physical activity after cancer diagnosis improves quality of life and may lengthen survival. However, objective data in cancer survivors are limited and no physical activity tracker has been validated for use in this population.

**Objective:** The aim of this study was to validate the Fitbit One's measures of physical activity over 7 days in free-living men with localized prostate cancer.

**Methods:** We validated the Fitbit One against the gold-standard ActiGraph GT3X+ accelerometer in 22 prostate cancer survivors under free-living conditions for 7 days. We also compared these devices with the HJ-322U Tri-axis USB Omron pedometer and a physical activity diary. We used descriptive statistics (eg, mean, standard deviation, median, interquartile range) and boxplots to examine the distribution of average daily light, moderate, and vigorous physical activity and steps measured by each device and the diary. We used Pearson and Spearman rank correlation coefficients to compare measures of physical activity and steps between the devices and the diary.

**Results:** On average, the men wore the devices for 5.8 days. The mean (SD) moderate-to-vigorous physical activity (MVPA; minutes/day) measured was 100 (48) via Fitbit, 51 (29) via ActiGraph, and 110 (78) via diary. The mean (SD) steps/day was 8724 (3535) via Fitbit, 8024 (3231) via ActiGraph, and 6399 (3476) via pedometer. Activity measures were well correlated between the Fitbit and ActiGraph: 0.85 for MPVA and 0.94 for steps (all  $P < .001$ ). The Fitbit's step measurements were well correlated with the pedometer (0.67,  $P = .001$ ), and the Fitbit's measure of MVPA was well correlated with self-reported activity in the diary (0.84;  $P < .001$ ).

**Conclusions:** Among prostate cancer survivors, the Fitbit One's activity and step measurements were well correlated with the ActiGraph GT3X+ and Omron pedometer. However, the Fitbit One measured two times more MVPA on average compared with the ActiGraph.

(*JMIR Cancer* 2017;3(1):e5) doi:[10.2196/cancer.6935](https://doi.org/10.2196/cancer.6935)

**KEYWORDS**

prostatic neoplasms; exercise

## Introduction

Prostate cancer is the most commonly diagnosed invasive cancer and the second leading cause of cancer death among men in the United States. Emerging evidence suggests that postdiagnosis physical activity may improve clinical outcomes in prostate cancer survivors [1-3]. Our group was the first to observe that men who reported brisk walking and vigorous activity after diagnosis of localized prostate cancer had lower risk of cancer progression and mortality [2,3]. Like most cohort analyses of cancer survivors, however, these studies relied on self-reported physical activity. Self-report assessments are subject to limitations including poor ability to measure low-intensity or unstructured activities and lack of precision for quantifying activity intensity or duration [4]. Therefore, objective measures of physical activity are needed to better inform guidelines for prostate cancer survivors. No physical activity tracker has been validated for use in cancer survivors.

Whereas research-grade accelerometers (eg, the ActiGraph) are used in some cancer survivorship studies, they are costlier than consumer-based physical activity trackers and are generally not acceptable to wear over periods longer than 1 week. Leveraging commercial wearable devices may enable more research teams to capitalize on the advantages of objective measurement. These devices are appropriate for long-term measurement of behavior and may be useful tools as part of a physical activity intervention [5-7].

A growing number of consumer-level, wearable physical activity trackers may be well-suited for both objectively measuring physical activity and promoting vigorous-intensity activity in men with prostate cancer. These devices have many advantages for health research, including low participant burden, lack of reliance on accurate recall, and the ability to upload individual-level physical activity data to a cloud-based database, allowing both users and researchers to view data in real time. Previous studies have reported that modern physical activity trackers provide a valid measure of physical activity in controlled laboratory settings, but few studies have evaluated such trackers in free-living conditions [8]. This is important because the type and intensity of physical activity (eg, gait speed) for chronic disease populations may differ from the types of activity typically assessed in a lab-based validation study. Moreover, there is a lack of data on the validity of physical activity trackers in older populations and cancer survivors, who engage in different types of activities compared with younger adults.

Although several manufacturers make consumer-based physical activity trackers, Fitbit is the dominant brand used by health behavior researchers. Fitbit makes several models of physical activity trackers. We selected the Fitbit One for this study because it was one of the most advanced Fitbit models available in 2013; it remains a widely available and popular tracker in 2017. The Fitbit One is a 3-axis, accelerometer-based, physical activity tracker that measures steps, floors climbed, distance traveled, calories burned, physical activity, and sleep. The device is small (0.76"×0.38"×1.89") and can be clipped to a belt, tight-fitting clothing, or a pocket.

In this study, we validated the Fitbit One's measures of physical activity over 7 days in free-living men with localized prostate cancer against the ActiGraph GT3X+ accelerometer (gold standard) and a physical activity diary. We also compared the devices' measures of steps with the HJ-322U Tri-axis USB Omron pedometer. We hypothesized that the Fitbit One would provide a valid measure of physical activity in men with prostate cancer.

## Methods

### Study Population

This study was conducted among 25 men with prostate cancer. Participants were recruited in the University of California, San Francisco (UCSF) Department of Urology between 2013 and 2015. To be eligible, the men must have been diagnosed with adenocarcinoma of the prostate and be on active surveillance. We excluded 2 men with missing ActiGraph GT3X+ accelerometer data (our gold standard) and 1 man missing Fitbit data, leaving 22 men available for analysis. All participants provided written informed consent, and this study was approved by the UCSF Institutional Review Board.

### Physical Activity Assessments

Participants were asked to wear 3 physical activity trackers—ActiGraph GT3X+ (ActiGraph Inc, United States), Fitbit One (Fitbit Inc, United States), and HJ-322 Tri-axis Omron pedometer (Omron Healthcare, The Netherlands)—on a belt around their waist and keep a physical activity diary for 7 consecutive days.

The ActiGraph GT3X+ is considered the gold standard for activity tracking; it has been validated in numerous populations and is widely used in research settings [9,10]. The Omron pedometer is also widely used in research and has also been validated in healthy populations [11]. The trackers were positioned next to one another on a belt over the right hip. Participants were instructed to wear the belt during all waking hours and to remove the belt when sleeping, bathing, or swimming. All setup, charging, and syncing of the devices was done by the research staff. Participants were not provided with the Fitbit One charging cable or wireless sync dongle and were instructed not to change the devices' setup. Therefore, the only feedback that the participants may have received while wearing the devices was their daily steps on the pedometer and the Fitbit One. Fitbit Inc donated the Fitbit One devices used in this study but had no role in the design, conduct, or analysis of the study.

The physical activity diary has been previously described [4]. Participants were provided with seven 24-hour charts that included one row for each hour of the day and were asked to report how many minutes they spent in each of the following activities during each hour: lying down or sleeping; walking outdoors (eg, for exercise, transport); mixed standing and walking at home; mixed standing and walking away from home (eg, work, shopping); sitting at home; sitting at work or in a car or train; sports or other activities. For sports or other activities, the participants were asked to specify the type of activity (eg, tennis, swimming, yoga, gardening) and the intensity of the activity (eg, low, medium, high). If they participated in weight



lifting, they were asked to indicate the muscle group worked (eg, arms, legs, back).

### Data Processing

The accelerometer data were processed using ActiLife version 6.13.3 (ActiGraph, LLC). The data were downloaded in 5-second epochs. Nonwear was defined as an interval of consecutive 0 counts lasting 60 minutes or longer. A valid day was defined as a minimum of 10 hours of wear; we required at least three valid days. A total of 2 men were missing their ActiGraph GT3X+ accelerometer data: 1 man did not wear the belt on the instructed days, and the data for the other man did not download correctly. For the remaining men, we used the ActiGraph GT3X+ data to identify valid calendar days for all devices and the diary. We used the Troiano cut-points to estimate duration of light, moderate, and vigorous physical activity from the accelerometer data: light activity was defined as 100-2019 counts per minute, moderate activity was defined as 2020-5998 counts per minute, and vigorous activity was defined as 5999 or more counts per minute [12].

The Fitbit One devices were synced by the research staff to the manufacturer's website and the available data were downloaded using the "export your data" function under settings for analysis

[13]. The data available for each participant included daily total steps, minutes lightly active, minutes fairly active, and minutes very active, as well as other variables not examined (eg, estimated calories burned, distance, floors). On the basis of the information from the Fitbit website [14] and data reported in a recent validation study of the Fitbit Flex [15], Fitbit trackers calculate active minutes using metabolic task equivalents (METs). For example, "fairly active" minutes correspond to minutes engaged in activities requiring 3-5.9 METs. Therefore, we assumed that "light," "fairly active," and "very active" physical activity categories in the Fitbit data corresponded to standard definitions of light (<3 METs), moderate (3-5.9 METs), and vigorous ( $\geq 6$  METs) physical activity, respectively [16].

The Omron pedometer devices were synced to the manufacturer's website by the research staff and the available step data were downloaded for analysis [17].

For the diary data, we used the compendium of physical activities to assign specific MET values to each of the activities reported by the participants. Activities were then categorized as vigorous ( $\geq 6$  METs), moderate (3-5.9 METs), or light (<3 METs; see Table 1) [16]. We summed the duration of time in each of the activity categories to obtain estimates of time spent in light, moderate, and vigorous physical activity.

**Table 1.** Physical activities reported in a 7-day physical activity diary by 20 men with localized prostate cancer.

Activity	n <sup>a</sup> (%)	Mean (SD), minutes per day <sup>b</sup>	MET <sup>c</sup> value [16]
<b>Moderate-intensity activities (MET 3-5.9)</b>			
Walking	19 (95)	29 (23)	3.5
Golf	6 (30)	87 (55)	3.5
Heavy outdoor work	3 (15)	65 (92)	5.5
Other aerobic activities	5 (25)	15 (12)	4.3
Gardening	6 (30)	11 (12)	3.5
Weight lifting	5 (25)	10 (6)	3.5
Housework	4 (20)	13 (11)	3.3
Rowing	1 (5)	13 (-) <sup>d</sup>	4.8
Elliptical	2 (10)	9 (2)	5.0
Hiking	1 (5)	32 (-) <sup>d</sup>	5.3
Yoga	3 (15)	8 (5)	3.3
<b>Vigorous-intensity activities (MET <math>\geq 6</math>)</b>			
Bicycling	7 (35)	36 (39)	6.8
Tennis	3 (15)	90 (130)	7.3
Jogging	3 (15)	9 (7)	7.0
Running	3 (15)	11 (7)	9.8

<sup>a</sup>Two of the 22 men in this study did not complete a physical activity diary.

<sup>b</sup>Average minutes per day spent engaged in that activity among men who ever reported that particular activity.

<sup>c</sup>MET: metabolic task equivalent.

<sup>d</sup>Only one man reported rowing or hiking, so we did not calculate a standard deviation.

## Statistical Analysis

In order to calculate average daily minutes of light, moderate, and vigorous physical activity for each device, we summed the total number of minutes per day across days with valid data and divided it by the number of valid days. We then used descriptive statistics (eg, mean, standard deviation, median, interquartile range [IQR]) and boxplots to examine the distribution of average daily light, moderate, and vigorous physical activity and steps measured by each device and the diary. Average daily light and moderate physical activity and steps were normally distributed; average daily vigorous activity was skewed right. Therefore, we used Pearson correlation coefficients to compare measures of light and moderate physical activity and steps, and Spearman rank correlation coefficients to compare measures of vigorous activity between devices and the diary. All statistical analyses were performed using SAS v9.4 (SAS Institute, Inc) and two-sided *P* values <.05 were considered statistically significant.

## Results

On average, the men had 5.8 days of valid wear time available for analysis. The activities reported by men with prostate cancer in our study are presented in Table 1. Consistent with the prior publications reporting activity in men with localized prostate cancer [2,3], walking was the most common form of exercise, reported by 19 out of the 20 men with diary data (95%). Cycling was the next most popular activity, reported by 7 out of 20 men (35%).

Sociodemographic and clinical characteristics of the study participants are presented in Table 2. The median age was 66 years (IQR 56-83 years) and median body mass index (BMI) was 26.7 kg/m<sup>2</sup> (IQR 20.1-34.4 kg/m<sup>2</sup>). Of the 22 men, 15 were white (68%), 6 (27%) reported "other race," and 1 man (5%) was Asian or Pacific Islander. The median time from diagnosis to enrollment was 1.6 years (IQR 0.7-3.5).

**Table 2.** Characteristics of the 22 men with localized prostate cancer, who wore a Fitbit One, ActiGraph GT3X+, and Omron Pedometer, and kept a physical activity diary for 7 days.

Characteristics	Median (IQR) or n (%)
Age (years), median (IQR)	66 (56-83)
Body mass index (kg/m <sup>2</sup> ), median (IQR)	26.7 (20.1-34.4)
<b>Race, n (%)</b>	
White	15 (68)
African American	0 (0)
Asian or Pacific Islander	1 (5)
Other	6 (27)
Years since diagnosis, median (IQR)	1.6 (0.7-3.5)
Prostate-specific antigen at diagnosis (ng/ml), median (IQR)	5.6 (0.7-17.0)
<b>Gleason score, n (%)</b>	
6	19 (86)
3+4	3 (14)
<b>Clinical T-stage, n (%)</b>	
T1c	17 (77)
T2a	5 (23)

The physical activity trackers and diary detected different absolute levels of light, moderate, and vigorous physical activity (Table 3). The mean (SD) daily vigorous physical activity measured by each device and diary was: 19 (20) minutes/day according to the Fitbit One, 4 (6) minutes/day according to the ActiGraph GT3X+, and 29 (59) minutes/day according to the diary. For moderate activity, the values were: 81 (37) minutes/day according to the Fitbit One, 47 (26) minutes/day according to the ActiGraph GT3X+, and 80 (62) minutes/day according to the diary. Combined, the Fitbit One measured an

average of 49 more minutes of MVPA per day than the ActiGraph GT3X+. However, this difference varied substantially within individuals, ranging from -5 minutes (ie, the Fitbit measured 5 minutes less MVPA than the ActiGraph GT3X+) up to 109 minutes. Finally, the Fitbit One recorded 190 (50) minutes/day and the ActiGraph GT3X+ recorded 125 (32) minutes/day on average of light activity. The average daily step counts were: 8724 (3535) according to the Fitbit One, 8024 (3231) according to the ActiGraph GT3X+, and 6399 (3476) according to the Omron pedometer.

**Table 3.** Average duration of daily physical activity and steps measured by the Fitbit One, ActiGraph GT3X+, Omron pedometer, and a physical activity diary over 7 days among 22 men with localized prostate cancer.

Measuring device	Fitbit One		ActiGraph GT3X+		Diary <sup>a</sup>		Omron pedometer <sup>a</sup>	
	Mean (SD)	Median (range)	Mean (SD)	Median (range)	Mean (SD)	Median (range)	Mean (SD)	Median (range)
No. of men	22		22		20 <sup>b</sup>		21 <sup>b</sup>	
Activity category								
Vigorous <sup>c</sup> (minutes/day)	19 (20)	11 (1-63)	4 (6)	1 (0-27)	29 (59)	9 (0-240)	-	-
Moderate <sup>d</sup> (minutes /day)	81 (37)	76 (13-173)	47 (26)	39 (14-113)	80 (62)	64 (9-195)	-	-
MVPA <sup>e</sup> (minutes/ day)	100 (48)	92 (17-184)	51 (29)	42 (15-116)	110 (78)	77 (16-266)	-	-
Light <sup>ef</sup> (minutes /day)	190 (50)	185 (92-283)	125 (32)	121 (72-185)	-	-	-	-
Steps	8724 (3535)	8032 (2729-15,843)	8024 (3231)	7031 (4207-15,251)	-	-	6399 (3476)	5051 (1362-12,532)

<sup>a</sup>The diary and pedometer did not measure all activity categories of interest. The diary did not measure light activity or steps. The pedometer does not measure light, moderate, or vigorous physical activity.

<sup>b</sup>Two men did not complete a physical activity diary and there were no data on one of the pedometers after it was returned by the participant.

<sup>c</sup>Vigorous activity included 6+ metabolic task equivalent (MET) activities (cycling, jogging, running, tennis).

<sup>d</sup>Moderate activity included 3-5.9 MET activities (heavy outdoor work, elliptical, gardening, hiking, housework, weight lifting, other aerobic activities, rowing at a moderate pace, walking, and yoga).

<sup>e</sup>MVPA: moderate-to-vigorous physical activity.

<sup>f</sup>Light activity included activities with <3 MET values (eg, easy walking).

Despite differences in the absolute levels of activity and steps recorded, average daily vigorous, moderate, and light activity and steps were highly correlated between the trackers (Table 4). Comparing the Fitbit One and ActiGraph GT3X+, the correlation coefficients were: .65 for vigorous activity, .70 for

moderate activity, .72 for light activity, and .94 for steps (all  $P < .001$ ). The Fitbit One and the ActiGraph both recorded step measurements that were relatively well correlated with the pedometer (.67 and .72, respectively;  $P < .001$ ).

**Table 4.** Correlation coefficients comparing average daily vigorous, moderate, moderate-to-vigorous, and light physical activity and steps measured by the Fitbit One, ActiGraph GT3X+, Omron pedometer, and a physical activity diary among 23 men with localized prostate cancer.

Measuring device <sup>a,b</sup>	Fitbit One versus ActiGraph GT3X+		Fitbit One versus Diary <sup>c</sup>		Fitbit One versus Omron pedometer		ActiGraph GT3X+ versus Diary		ActiGraph GT3X+ versus Omron pedometer	
	<i>r</i>	<i>P</i> value	<i>r</i>	<i>P</i> value	<i>r</i>	<i>P</i> value	<i>r</i>	<i>P</i> value	<i>r</i>	<i>P</i> value
No. of men	22		20		21		20		21	
Activity Category	<i>r</i>	<i>P</i> value	<i>r</i>	<i>P</i> value	<i>r</i>	<i>P</i> value	<i>r</i>	<i>P</i> value	<i>r</i>	<i>P</i> value
MVPA	.85	<.001	.84	<.001	-	-	.68	.001	-	-
Vigorous activity	.65	.001	.47	.04	-	-	.66	.001	-	-
Moderate activity	.70	<.001	.38	.10	-	-	.57	.009	-	-
Light activity	.72	<.001	-	-	-	-	-	-	-	-
Steps	.94	<.001	-	-	.67	.001	-	-	.72	<.001

<sup>a</sup>Pearson correlations were used for measures that were normally distributed: steps, light activity, and moderate activity. Spearman correlations were used for skewed measures: vigorous activity.

<sup>b</sup>Correlation coefficients were not calculated if one of the devices did not measure the activity category of interest. The diary did not measure light activity or steps. The pedometer does not measure light, moderate, or vigorous physical activity.

<sup>b</sup>One individual reported high levels of tennis, which was classified as a vigorous activity in the diary data based on the standard MET value for tennis (7.3 METs) but was classified as a moderate activity for this individual by the Fitbit. The correlations for vigorous and moderate physical activity as assessed by the Fitbit One and diary excluding this individual were  $r=.61$ ,  $P=.006$  and  $r=.61$ ,  $P=.005$ , respectively. We also reclassified tennis as a moderate activity in the diary data, and the correlations between the Fitbit One and the diary for vigorous and moderate activity were similarly improved ( $r=.58$ ,  $P=.008$  and  $r=.73$ ,  $P<.001$ ).

In contrast to the ActiGraph GT3X+, the Fitbit One's measures of average moderate and vigorous physical activity were not well correlated with the physical activity diary ( $r=.47$ ,  $P=.04$  and  $r=.38$ ,  $P=.10$ ). Upon examining scatterplots, we identified one participant who had a low measure of vigorous activity (5 minutes/day) and a high measure of moderate activity (173 minutes/day) according to the Fitbit One, but high measure of vigorous activity (240 minutes/day) and a low measure of moderate activity (26 minutes/per day) according to the diary. This discrepancy appeared to be due to a difference in the classification of the intensity of tennis between the Fitbit and diary data. The individual reported an average of 240 minutes per day of tennis and 26 minutes per day of walking. Based on the compendium of MET values [16], tennis requires 7.3 METs and was thus classified as a vigorous activity in the diary data. We ran two sensitivity analyses to evaluate the impact of this individual on the estimated correlation coefficients. First, we calculated correlations between vigorous and moderate physical activity as assessed by the Fitbit One and diary excluding this individual ( $r=.61$ ,  $P=.006$  and  $r=.61$ ,  $P=.005$ , respectively), and classifying tennis as a moderate activity in the diary data ( $r=.58$ ,  $P=.008$  and  $r=.73$ ,  $P<.001$ ).

## Discussion

### Principal Findings

In this study, we validated the Fitbit One's measure of physical activity and steps against the ActiGraph GT3X+, Omron pedometer, and a 7-day physical activity diary in free-living conditions among 22 men with localized prostate cancer. The Fitbit One's measure of vigorous, moderate, and light physical activity and steps were well correlated with the ActiGraph GT3X+ accelerometer, Omron pedometer, and physical activity diary. Furthermore, the mean time spent engaged in moderate

and vigorous activity was comparable between the Fitbit One and physical activity diary, but substantially more than the estimated amount of time in these activities recorded by the ActiGraph GT3X+.

Six studies have demonstrated the validity of the Fitbit One in laboratory settings, but only one prior study has validated the Fitbit One's measure of physical activity in free-living conditions [8,18]. In that study, 21 healthy Australian adults (mean age: 33 years) wore 7 consumer-level activity monitors, including the Fitbit One, and two research-grade monitors, the ActiGraph GT3X+, and BodyMedia SenseWear Model MF (BodyMedia Inc, United States) for 48 hours. Consistent with our study protocol, the Fitbit One and ActiGraph GT3X+ were both worn on the right side of the waist on an elastic belt. In that study, the correlation between the Fitbit One and ActiGraph GT3X+ measures of MVPA was .91. The ActiGraph GT3X+ measured a median of 58.5 minutes of MVPA and the median absolute difference between the Fitbit One and ActiGraph GT3X+ measures of MVPA was 58.6 minutes. Our findings among older men with prostate cancer were remarkably consistent with those reported by Ferguson et al [18]. The median absolute difference between the Fitbit One and the ActiGraph GT3X+ measures of MVPA was 47 minutes in our study population. Overall, it appears that the Fitbit One's measure of MVPA is well correlated with the ActiGraph GT3X+, a widely accepted gold standard research-grade accelerometer. However, the Fitbit One may overestimate MPVA in free-living young and older adult populations.

A novel aspect of our study was the inclusion of a physical activity diary. Interestingly, the Fitbit One's measures of average daily moderate and vigorous physical activity were very similar to the time engaged in these activities reported in the participants' diaries. On average, the Fitbit One and diary

measured 100 and 110 minutes/day of MVPA, respectively. In contrast, the ActiGraph GT3X+ measured an average of 51 minutes of MVPA per day. Proportionally, there was a larger discrepancy in vigorous than moderate activity. The ActiGraph GT3X+ measured an average of 4 minutes per day, the Fitbit One measured an average of 19 minutes per day, and the diary reported an average of 29 minutes per day of vigorous activity.

### Limitations

On the basis of the diary data, we observed that walking and cycling were the most popular physical activities among men with localized prostate cancer, followed by golf and outdoor work or gardening. The distribution of time spent in various activities among the men in our study was consistent with data reported from two large cohort studies of men with prostate cancer in the United States [2,3]. Of note, none of the participants in our study swam for exercise; Fitbit, Inc instructs users not to swim with Fitbit One trackers. Newer models of activity trackers have waterproof features as well as include algorithms to determine what type of activity is being done, and future research is needed to assess the accuracy and utility of such data.

In addition, a limitation of self-reported physical activity data is the lack of objective assessment of activity intensity. Our data clearly demonstrated this point when comparing the Fitbit One and diary measures of moderate and vigorous physical activity. One participant reported a high duration of tennis, which we classified as vigorous activity based on the compendium of MET values. However, based on the Fitbit One's data, it appeared that tennis was better classified as a moderate intensity activity for this individual. It is also possible that, when worn on the hip, the Fitbit One and ActiGraph GT3X+ are not very good at detecting the intensity of a sport that requires a lot of arm motion. Future studies should combine objective and self-reported physical activity data in order to best assess the participants' usual duration, intensity, and mode of physical activity.

This study had a number of strengths, including: (1) comparing the Fitbit One to the ActiGraph GT3X+ and a physical activity diary, which are widely accepted gold standard measures; (2) having participants wear the monitors and keep a diary in free-living conditions for 7 consecutive days; and (3) being the first study to examine the validity of the Fitbit One in cancer survivors. Lack of generalizability to populations with different racial or ethnic, sex, and disease status, or physical activity patterns is a potential limitation of our study, although our results were markedly similar to the prior validation study conducted in healthy young adult men and women.

### Future Work

New physical activity trackers, as well as updated products and software, are constantly being released. At the time this study was initiated in early 2013, the Fitbit One was the most advanced Fitbit model available. Since that time, several new models have been released, including wrist-based trackers. Further studies are needed to determine whether wrist-based trackers have accuracy similar to the Fitbit One, as well as evaluate patient preferences between a clip-on versus wrist-based device. Overall, rigorously evaluating and reporting results in peer-reviewed journals on up-to-date and relevant devices is a particular challenge for researchers in this field due to the fast growth of the activity tracker industry. Nonetheless, validation studies are crucial for the design and interpretation of clinical studies utilizing wearable physical activity trackers.

### Conclusions

In conclusion, the Fitbit One's measure of physical activity and steps are well correlated with the ActiGraph GT3X+, Omron pedometer, and a physical activity diary. The Fitbit One's estimate of time spent in MVPA was consistent with that reported in the physical activity diary, but approximately twice the duration, on average, measured by the ActiGraph GT3X+. Therefore, the absolute duration of moderate and vigorous activity measured by the Fitbit One and self-reported methods should be interpreted cautiously.

### Acknowledgments

We thank Fitbit Inc for donating the Fitbit One devices used in this study; Fitbit Inc had no role in planning or executing this study, analyzing the results, or writing the manuscript. Research reported in this publication was supported by the following grants from the National Institutes of Health: RO1CA181802, KL2TR000143, K07CA197077, and K07CA178870.

### Conflicts of Interest

None declared.

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## Abbreviations

**BMI:** body mass index  
**IQR:** interquartile range  
**MET:** metabolic task equivalents  
**MVPA:** moderate-to-vigorous physical activity  
**PSA:** prostate-specific antigen  
**SD:** standard deviation  
**UCSF:** University of California, San Francisco

*Edited by H Wu; submitted 01.11.16; peer-reviewed by B He, J Schragar; comments to author 26.11.16; revised version received 30.01.17; accepted 21.02.17; published 18.04.17.*

### *Please cite as:*

Van Blarigan EL, Kenfield SA, Tatum L, Cadmus-Bertram LA, Carroll PR, Chan JM  
*The Fitbit One Physical Activity Tracker in Men With Prostate Cancer: Validation Study*  
*JMIR Cancer* 2017;3(1):e5  
URL: <http://cancer.jmir.org/2017/1/e5/>  
doi: [10.2196/cancer.6935](#)  
PMID: [28420602](#)

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Original Paper

# Rotterdam Prostate Cancer Risk Calculator: Development and Usability Testing of the Mobile Phone App

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## Abstract

**Background:** The use of prostate cancer screening tools that take into account relevant prebiopsy information (ie, risk calculators) is recommended as a way of determining the risk of cancer and the subsequent need for a prostate biopsy. This has the potential to limit prostate cancer overdiagnosis and subsequent overtreatment. mHealth apps are gaining traction in urological practice and are used by both practitioners and patients for a variety of purposes.

**Objective:** The impetus of the study was to design, develop, and assess a smartphone app for prostate cancer screening, based on the Rotterdam Prostate Cancer Risk Calculator (RPCRC).

**Methods:** The results of the Rotterdam arm of the European Randomized Study of Screening for Prostate Cancer (ERSPC) study were used to elaborate several algorithms that allowed the risk of prostate cancer to be estimated. A step-by-step workflow was established to ensure that depending on the available clinical information the most complete risk model of the RPCRC was used. The user interface was designed and then the app was developed as a native app for iOS. The usability of the app was assessed using the Post-Study System Usability Questionnaire (PSSUQ) developed by IBM, in a group of 92 participants comprising urologists, general practitioners, and medical students.

**Results:** A total of 11 questions were built into the app, and, depending on the answers, one of the different algorithms of the RPCRC could be used to predict the risk of prostate cancer and of clinically significant prostate cancer (Gleason score  $\geq 7$  and clinical stage  $>T2b$ ). The system usefulness, information quality, and interface quality scores were high—92% (27.7/30), 87% (26.2/30), and 89% (13.4/15), respectively. No usability problems were identified.

**Conclusions:** The RPCRC app is helpful in predicting the risk of prostate cancer and, even more importantly, clinically significant prostate cancer. Its algorithms have been externally validated before and the usability score shows the app's interface is well designed. Further usability testing is required in different populations to verify these results and ensure that it is easy to use, to warrant a broad appeal, and to provide better patient care.

(*JMIR Cancer* 2017;3(1):e1) doi:[10.2196/cancer.6750](https://doi.org/10.2196/cancer.6750)

**KEYWORDS**

mHealth; prostate cancer; nomogram

## Introduction

Prostate cancer is a serious health issue, accounting for 14% of all new cancers and 6% of total cancer deaths in men worldwide

[1]. With the expected increase in life expectancy, the disease's burden is projected to increase substantially [2]. However, neither the optimal balance between screening intensity and the risk of overdiagnosis (ie, detecting indolent disease) nor the



ideal prostate cancer screening test or combination of tests have been determined [3].

To address these issues, screening trials were initiated. Recently, the third analysis of the European Randomized Study of Screening for Prostate Cancer (ERSPC), the world's largest prostate cancer screening study, has been published. Currently, with more than 13 years of follow-up, the updated results show a stable relative benefit of screening (relative risk=0.79, ie, a 21% prostate cancer mortality reduction in favor of screening) but a still increasing absolute benefit [3]. The recently published findings show that to avoid one prostate cancer death, 781 men would need to be invited to screening and 27 additional prostate cancer cases will be diagnosed compared with no screening, both decreasing as compared with previous reports with shorter follow-up [3]. In summary, the number needed to screen and to treat to avoid one death from prostate cancer is decreasing and is now lower than the reported number needed to screen in trials for breast cancer [4].

Currently, the decision to perform a prostate biopsy is mostly based on the outcome of the serum prostate-specific antigen (PSA) test. However, the serum PSA level can increase in many situations, including benign (eg, benign prostatic hyperplasia) and inflammatory conditions (eg, acute prostatitis). Moreover, the optimal cutoff value has not yet been established [5].

Leveraging the decision of performing prostate biopsy solely on the PSA value, using a PSA value greater than 3.0 ng/mL as indication for Bx, resulted in 76% negative biopsy results [6]. Conversely, using a higher PSA threshold can neglect prostate cancer cases [7]. To address this lack of specificity, it is recommended that the PSA value should be combined with other relevant patient characteristics, using so-called risk calculators [2]. Even though many are available, currently it is not possible to provide a clear recommendation about which one to use in which situation (eg, first prostate biopsy, repeated prostate biopsy, patient with small prostate) because there are no direct head-to-head comparisons [8]. One scientifically sound and extensively validated risk calculator is the Rotterdam Prostate Cancer Risk Calculator (RPCRC), based on the ERSPC Rotterdam data [9].

The RPCRC predicts the risk of a biopsy-detectable prostate cancer and also of potentially high-risk prostate cancer, defined as Gleason score  $\geq 7$  and clinical stage  $>T2b$ . This has important clinical implications as a way of decreasing overdiagnosis and overtreatment [3]. The different RPCRC algorithms provide an increasingly accurate risk estimation (ie, adding variables to

the model increases its area under the curve, AUC). The algorithm uses information on PSA level, previous negative prostate biopsy, digital rectal examination (DRE) findings, prostate volume measurement, and transrectal ultrasonography (TRUS) findings. Additionally, the Prostate Health Index ( $\phi$ ), which aggregates the results from the Hybritech PSA, free PSA, and p2PSA (the [-2] form of proPSA), can also be used to further stratify prostate cancer risk [10]. All these different prediction models are available on the website of the Prostate Cancer Research Foundation (Figure 1) [11].

At present, mobile health (mHealth), the delivery of health care services via mobile communication devices, is a growing trend with more than 160,000 medical apps available, and the number is expected to grow even further, expedited by the ubiquitous presence of mobile phones and the continuous improvements in hardware and software [12,13]. To increase its usability and accessibility, the originally Web-based RPCRC [11] has been redesigned as an app, which has several benefits for the user.

Even though the app uses the same algorithms as the available Web-based risk calculators [11], the app's proprietary step-by-step workflow ensures that, depending on the available information, the most complete algorithm is always used. In contrast, the website user has to initially choose a specific RPCRC, which may not be the most comprehensive available and inadvertently dismiss known clinical data.

Another strength of the app is that the calculations are performed in the user's mobile phone (ie, it works offline), which ensures a safe user experience, bypassing issues with website blocking (eg, some facilities constrain Internet access) and with infrastructure and Internet service providers (eg, slow intranet or low-speed Internet access).

Several studies have shown that mHealth was well received by users, including health care professionals and patients, in both urban and rural settings. Some examples include the use of mobile phone-based guidance for rural health providers in Tamil Nadu, India [14], and the use of a gestational diabetes app by pregnant women in Oxford, United Kingdom [15]. Moreover, it has been documented not only in young adults [16], but also in older adults—both had a high degree of acceptance of apps that promoted physical activity [17].

The aim of this study was to design and develop a mobile phone app for prostate cancer screening, based on the RPCRC algorithms. Moreover, we sought to evaluate the usability of the developed app using IBM's Post-Study System Usability Questionnaire (PSSUQ) [18].

**Figure 1.** Screenshot of the Prostate Cancer Research Foundation website showing the prostate cancer risk calculators.

The screenshot shows the website for the Prostate Cancer Research Foundation, Rotterdam. The header features the SWOP logo and the text 'Prostate Cancer Research Foundation, Rotterdam'. Below this, it states 'In partnership with the European Randomized Study of Screening for Prostate Cancer'. The navigation menu includes 'Home', 'Patient Info', 'Your Risk Calculator', 'Health Professionals', 'About us', and 'Contact'. A search bar is located on the right side of the header.

The main content area is titled 'The Prostate Cancer Risk Calculators – including the ‘future risk’ calculator'. It lists four calculators:

- Risk Calculator 1 – the general health calculator** is a starting point, looking at family history, age and any medical problems with urination.
- Risk Calculator 2 – the PSA risk calculator** looks at the levels of prostate specific antigen (PSA) in patient’s blood to help predict whether further investigation is required.
- Risk calculator 3** predicts the chance of a positive sextant biopsy in a man who has never been screened; and also assesses the degree of aggressiveness.
- Risk calculator 3 + DRE assessment** predicts more accurately the chance of a positive sextant biopsy, compared to only assessing a patient’s PSA value (RC 2), but without the necessity of a TRUS. An additional feature is the prediction of a high grade or advanced prostate cancer.
- Risk calculator 4** is used for men who have previously had PSA screening, but have either had no biopsy or one that was negative. It predicts the chance of a positive sextant biopsy and its degree of aggressiveness.
- Risk calculator 4 + DRE** provides additional information, without the necessity of a TRUS, for assessing men who have previously been screened, whether they have had a prior biopsy or not. It also predicts the chance of a positive outcome and whether that would be high grade or advanced.

On the right side, there are two boxes: 'Contact Information' and 'Your Feedback'. The 'Contact Information' box lists Monique Roobol, Risk Calculator Administrator, with the email info@prostatecancer-riskcalculator.com. The 'Your Feedback' box asks users to provide feedback on the risk calculators and their experience.

## Methods

This study was structured according to the standard life cycle of system development: analysis, design, implementation, and evaluation, as shown in [Figure 2](#).

### System Analysis

Knowledge and functional requirements for system implementation were assessed.

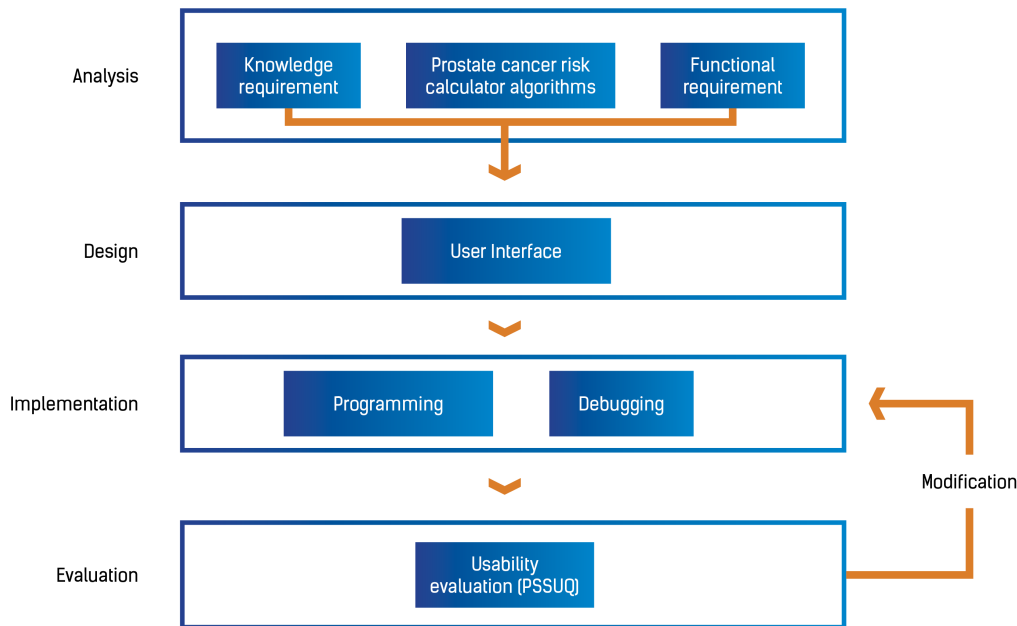
### Knowledge Requirements

All risk calculator algorithms used in the app were developed based on the Rotterdam arm of the ERSPC, using the clinical data and prostate biopsy outcome from 3624 previously unscreened men and 2896 men with previous negative prostate

biopsy. The following 4 models were built, with cumulative clinical information:

- Model 1—PSA alone;
- Model 2—PSA and DRE (normal/abnormal);
- Model 3—PSA, DRE (normal/abnormal) and DRE-assessed volume;
- Model 4—PSA, DRE (normal/abnormal), TRUS (normal/abnormal), and TRUS-assessed volume.

The predictive capability of the models within the RPCRC app were assessed in terms of discrimination (C statistic) for predicting the probability of both prostate cancer on biopsy and serious prostate cancer (defined as >T2b and Gleason score  $\geq 7$ ) [19]. Further details about the construction and the validation of the RPCRC algorithms have been previously published [19].

**Figure 2.** Study outline and research procedure. PSSUQ: Post-Study System Usability Questionnaire.

### Functional Requirements

The system's functional requirements were based on the available risk calculator algorithms that were developed by the Rotterdam ERSPC. To improve the RPCRC app usability, a unique decision tree was devised, with a multistep approach, to gather available clinical information: previous negative prostate biopsy, PSA value, DRE evaluation, TRUS evaluation, and phi value.

### System Design

The app's user interface was designed to ensure the best possible experience, according to Apple's design guidelines. The interface was based on the RPCRC decision tree, taking into account the clarity and ease of use, and was designed using the GNU Image Manipulation Program (GIMP).

### System Implementation

To ensure the best performance, a native iOS version was developed using Apple's Xcode (Apple Inc), an integrated development environment that comprises a suite of software development tools, including debugging functions.

### System Usability Evaluation

Usability is defined as the measure of the ease with which a system can be learned and used, including its safety, effectiveness, and efficiency [20]. Usability is also a measure of the effectiveness of the interaction between humans and computer systems (ie, how do users perform tasks in the system) [21]. The usability of the RPCRC app was evaluated using IBM's PSSUQ, which is currently in its third revision and consists of 3 domains: system usefulness, information quality, and interface quality [18]. These 3 domains cover 16 questions, rated on a Likert scale from 1 (I strongly disagree) to 5 (I strongly agree; Table 1). In addition, users also had the option to write their own comments. The PSSUQ was chosen because it is a popular usability testing instrument that was validated and showed discriminative validity, discerning applications

with recognizably different quality [22]. Moreover, it has been used in several other mHealth studies [16,23-25].

Urologists, medical students, and general practitioners (GPs) were selected as end users; GPs were included because they are the first gatekeepers for prostate cancer screening, making the decision of whether or not to refer the patient to a urologist. Medical students' evaluation is pertinent because they will be the urologists and GPs of tomorrow. An invitation to participate in the study was sent via email.

For the quantitative measurements (baseline characteristics, PSSUQ), means and standard deviations were calculated using software package IBM SPSS v20 (IBM Corporation).

## Results

### System Analysis

#### Knowledge Requirements

All risk calculator algorithms used in the app were developed based on the Rotterdam arm of the ERSPC, using the clinical data and prostate biopsy outcome from 3624 previously unscreened men and 2896 men with previous negative prostate biopsy [19].

In the original previously unscreened men, applying model 1 to model 4 resulted in AUCs from 0.69 to 0.79, respectively, for predicting prostate cancer and from 0.74 to 0.86, respectively, for predicting serious prostate cancer. In the previously screened group (men with at least one previous negative prostate biopsy), applying the same models, AUCs ranged from 0.62 to 0.69 for predicting prostate cancer and from 0.72 to 0.81 for predicting serious prostate cancer [19].

Several related papers that validate the algorithm of the RPCRC in different cohorts and compare the RPCRC with other calculators have been previously published, with good performance in the various settings [26-33].

### Functional Requirements

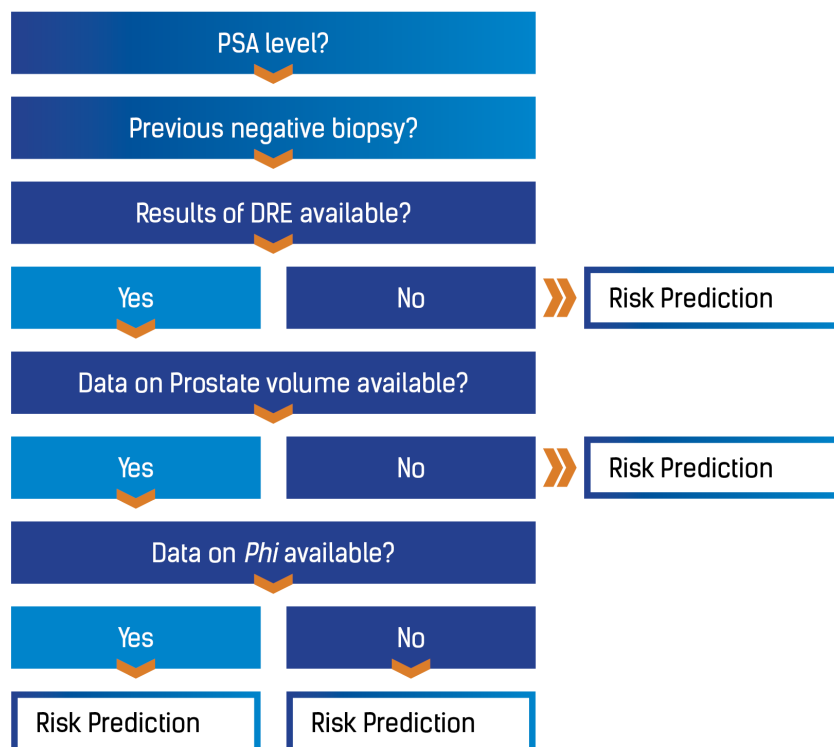
A unique decision tree was designed to ensure the app would always use the most powerful risk calculator model, depending on the available information (Figure 3). This ensures that the most significant available data is used in the most complete algorithm to compute with greater reliability the probability of a positive prostate biopsy and the risk of aggressive prostate cancer.

### System Design

The app design can be divided into 6 interface categories: disclaimer, question, explanation, language, results, and about

(Figure 4). The disclaimer must be accepted by the user before using the app. A total of 11 questions were built into the app, and, depending on the answers, one of the different algorithms could be used to predict the risk of prostate cancer and of significant prostate cancer. All question interfaces are designed in a similar way. For every question, there is an interface with an explanation of the question. The results (ie, risk of prostate cancer and risk of aggressive prostate cancer) are shown in numerical (percentage) and graphic forms. The “about” screen details the scientific background of the risk calculators and lists all contributions. The user also has the option to choose the default language: Chinese, Dutch, English, German, Portuguese, and Spanish.

**Figure 3.** The Rotterdam Prostate Cancer Risk Calculator decision tree. PSA: prostate-specific antigen; DRE: digital rectal examination; phi: Prostate Health Index.



### System Implementation

The debugging of the app was performed within the Apple Xcode environment. All code errors were identified in a step-by-step approach, through the use of the intrinsic debugging tools, and were corrected according to Apple’s guidelines.

The functionalities of the app were assessed in various devices, namely, mobile phones and tablets, in the usability evaluation stage. Care was taken to ensure a consistent user experience across all devices.

### System Usability Evaluation

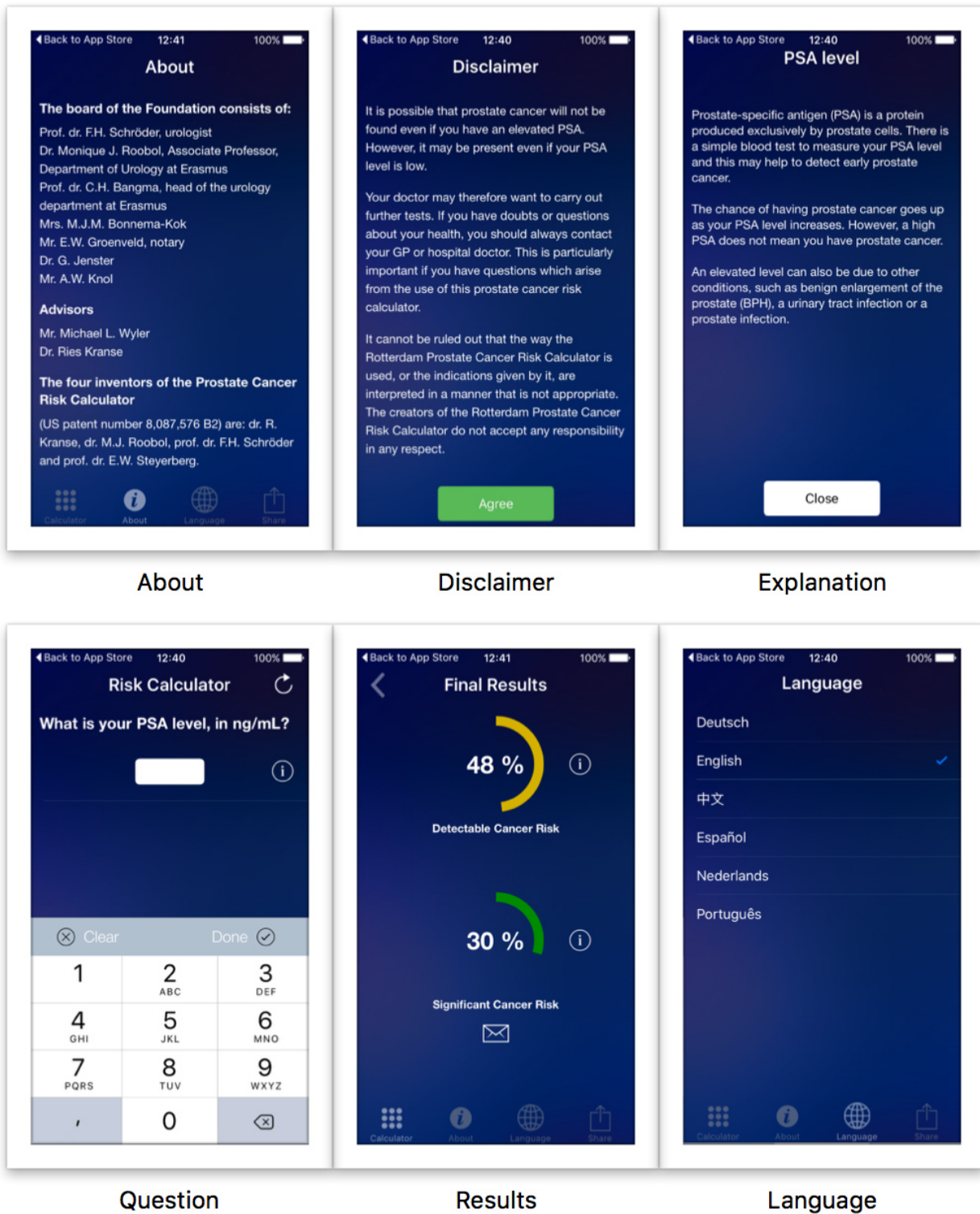
A total of 92 participants evaluated the usability of the app (response rate = 11%), among whom 28 (30%) were urologists, 29 (32%) were medical students, and 35 (38%) were GPs. The mean age of participants was 31 years and 62% were female.

The calculated mean and standard deviation of the PSSUQ 16 questions are presented in Table 1. “It was simple to use this application” and “It was easy to learn to use this application” had the highest rating among the 16 items, with 4.80 out of 5 possible points.

The final scores of the 3 domains evaluated (ie, system usefulness, information quality, and interface quality) are presented in Table 2. The highest score (92%) was reported for system usefulness, and information quality got the lowest score (87%). These results show that the participants were, overall, satisfied with the usability of the app.

Figure 5 shows the percentage of actual scores given by urologists, GPs, and medical students for system usefulness, information quality, and interface quality. The highest score was given for the system usefulness category by urologists.

**Figure 4.** Screenshots of the Rotterdam Prostate Cancer Risk Calculator app, showing “About,” “Disclaimer,” “Explanation,” “Question,” “Results,” and “Language” screens.



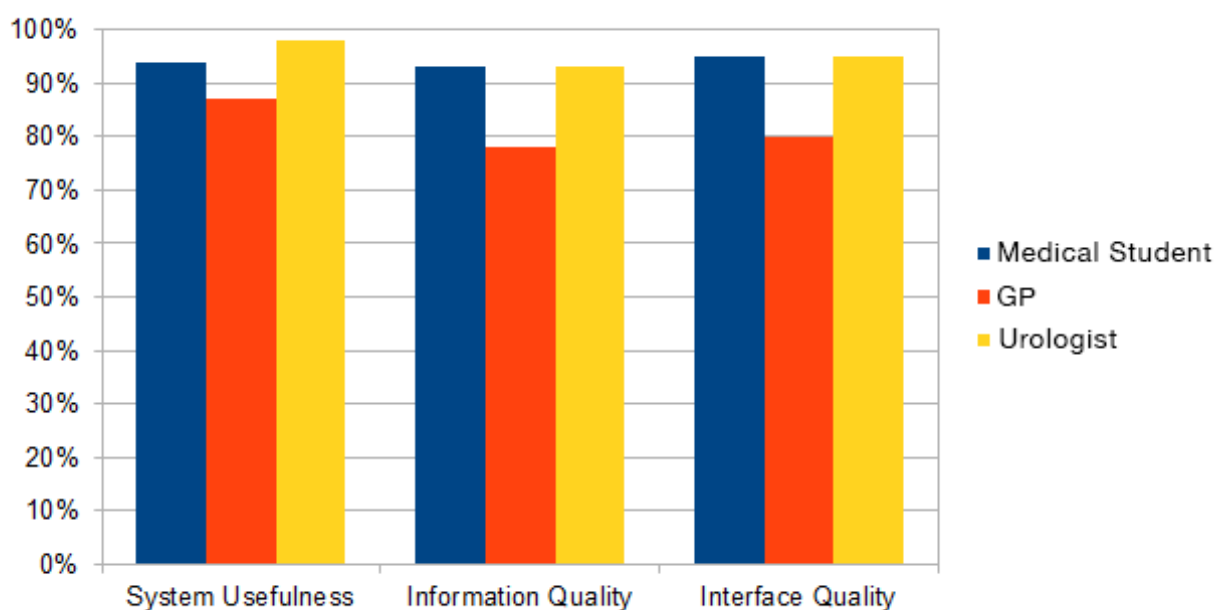
**Table 1.** Means and standard deviations of the Post-Study System Usability Questionnaire result.

Category	No.	Item	Mean	SD
System usefulness	1	Overall, I am satisfied with how easy it is to use this application	4.67	0.557
	2	It was simple to use this application	4.80	0.399
	3	I was able to complete the tasks and scenarios quickly using this application	4.53	0.601
	4	I felt comfortable using this application	4.55	0.747
	5	It was easy to learn to use this application	4.80	0.426
	6	I believe I could become productive quickly using this application	4.34	0.905
Information quality	7	The application gave error messages that clearly told me how to fix problems	3.85	1.398
	8	Whenever I made a mistake using the application, I could recover easily and quickly	4.16	1.067
	9	The information (such as on-line help, on-screen messages and other documentation) provided with this application was clear	4.43	0.701
	10	It was easy to find the information I needed	4.47	0.654
	11	The information was effective in helping me complete the tasks and scenarios	4.52	0.673
	12	The organization of information on the application screens was clear	4.76	0.477
Interface quality	13	The interface of this application was pleasant	4.57	0.789
	14	I liked using the interface of this application	4.51	0.819
	15	This application has all the functions and capabilities I expected it to have	4.29	1.064
Overall	16	Overall, I am satisfied with this application	4.42	0.880
Total			4.48	0.832

**Table 2.** Scores per evaluation category of the Post-Study System Usability Questionnaire.

Item category	Actual score	Possible score	% Actual score
System usefulness	27.7	30	92
Information quality	26.2	30	87
Interface quality	13.4	15	89

**Figure 5.** Percentage of actual score per item category and occupation of participants. GP: general practitioner.



## Discussion

### Principal Findings

Risk calculators are increasingly being used to stratify men at risk of prostate cancer. The RPCRC, previously only available digitally on the website [11], was based on the Rotterdam arm of the ERSPC, which started in 1993 in Europe to study the feasibility of population-based screening for prostate cancer and its effect on mortality [34]. This new app is publicly available on the Apple App Store [35].

To facilitate its use in clinical practice, we decided to create an mHealth version using the RPCRC algorithms. However, to simplify its use, a unique decision tree was created that offers a streamlined user experience, while incorporating additional information at every step. The app was well received by urologists and won the BJUI award for Best Urology App in 2015, presented at the American Urological Association Annual Meeting.

Starting with the total PSA value, a more complete assessment is built based on supplementary information regarding a previous negative prostate biopsy, DRE and TRUS findings, as well as phi value. Multiple external validations and comparisons of the RPCRC have shown that including more relevant information increases predictive capability [9].

This app builds on the ubiquitous presence of mobile phones to provide doctors and patients with a new way of using the RPCRC. Moreover, it maintains the ERSPC's original goal to optimize prostate cancer screening, reducing unnecessary prostate biopsies and preventing the overtreatment of indolent prostate cancer while avoiding underdiagnosis. mHealth offers the opportunity to change the paradigm of health services, and prostate cancer, the second most common cancer worldwide, must be included in that effort [1].

In addition, it was designed and developed from day 1 by a multidisciplinary team, which included not only urologists but also other health care professionals, which has been shown to influence significantly the number of app downloads [36].

The strength of the RPCRC app is its development based on high-quality health information extracted from various published studies that validate the outcome of ERSPC risk calculator in multiple cohorts.

The IBM Computer Usability Satisfaction Questionnaire allowed the authors to obtain quantitative information regarding the app usability, which offered strong measures of usability. Moreover, taking into consideration that tests with only 5 participants are able to uncover 85% of usability issues, we believe most usability issues would be identified in this study, which included 92 users [37].

### Limitations

In this study, we only discuss the development of the iOS app, but further studies are under way to replicate this for other mobile platforms. Only medical students and health care professionals took part in the usability testing, which may represent a selection bias. In the near future, a similar evaluation will be done for patients.

### Conclusions

We created a scientifically valid and convenient mobile app for the RPCRC. The RPCRC has been designed to help patients and to assist health care professionals in the decision-making process. The app was found to be easy to use and, therefore, can be useful in the daily management of patients. The RPCRC app can be used in a clinical setting to better stratify the risk of prostate cancer, avoiding unnecessary biopsies and, consequently, reducing overdiagnosis and overtreatment.

## Conflicts of Interest

None declared.

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## Abbreviations

**AUC:** area under the curve

**DRE:** digital rectal examination

**ERSPC:** European Randomized Study of Screening for Prostate Cancer

**GP:** general practitioner

**p2PSA:** (-2) form of proPSA

**phi:** Prostate Health Index

**PSA:** prostate-specific antigen

**PSSUQ:** Post-Study System Usability Questionnaire  
**RPCRC:** Rotterdam Prostate Cancer Risk Calculator  
**TRUS:** transrectal ultrasonography

*Edited by H Wu; submitted 06.10.16; peer-reviewed by S Loeb, W Xie, B He; comments to author 26.10.16; revised version received 22.11.16; accepted 19.12.16; published 06.01.17.*

*Please cite as:*

*Pereira-Azevedo N, Osório L, Fraga A, Roobol MJ*

*Rotterdam Prostate Cancer Risk Calculator: Development and Usability Testing of the Mobile Phone App*

*JMIR Cancer 2017;3(1):e1*

*URL: <http://cancer.jmir.org/2017/1/e1/>*

*doi: [10.2196/cancer.6750](https://doi.org/10.2196/cancer.6750)*

*PMID: [28410180](https://pubmed.ncbi.nlm.nih.gov/28410180/)*

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Publisher:  
JMIR Publications  
130 Queens Quay East.  
Toronto, ON, M5A 3Y5  
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