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Cardiovascular Assessment Tool for Breast Cancer Survivors and Oncology Providers: Usability Study

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Abstract

Background: Cardiovascular health is of increasing concern to breast cancer survivors and their health care providers, as many survivors are more likely to die from cardiovascular disease than cancer. Implementing clinical decision support tools to address cardiovascular risk factor awareness in the oncology setting may enhance survivors’ attainment or maintenance of cardiovascular health.

Objective: We sought to evaluate survivors’ awareness of cardiovascular risk factors and examine the usability of a novel electronic health record enabled cardiovascular health tool from the perspective of both breast cancer survivors and oncology providers.

Methods: Breast cancer survivors (n=49) recruited from a survivorship clinic interacted with the cardiovascular health tool and completed pre and posttool assessments about cardiovascular health knowledge and perceptions of the tool. Oncologists, physician assistants, and nurse practitioners (n=20) who provide care to survivors also viewed the cardiovascular health tool and completed assessments of perceived usability and acceptability.

Results: Enrolled breast cancer survivors (84% White race, 4% Hispanic ethnicity) had been diagnosed 10.8 years ago (SD 6.0) with American Joint Committee on Cancer stage 0, I, or II (45/49, 92%). Prior to viewing the tool, 65% of survivors (32/49) reported not knowing their level for one or more cardiovascular health factors (range 0-4). On average, only 45% (range 0%-86%) of survivors’ known cardiovascular health factors were at an ideal level. More than 50% of survivors had ideal smoking status (45/48, 94%) or blood glucose level (29/45, 64%); meanwhile, less than 50% had ideal blood pressure (12/49, 24%), body mass index (12/49, 24%), cholesterol level (17/35, 49%), diet (7/49, 14%), and physical activity (10/49, 20%). More than 90% of survivors thought the tool was easy to understand (46/47, 98%), improved their understanding (43/47, 91%), and was helpful (45/47, 96%); overall, 94% (44/47 survivors) liked the tool. A majority of survivors (44/47, 94%) thought oncologists should discuss cardiovascular health during survivorship care. Most (12/20, 60%) oncology providers (female: 12/20, 60%; physicians:
14/20, 70%) had been practicing for more than 5 years. Most providers agreed the tool provided useful information (18/20, 90%), would help their effectiveness (18/20, 90%), was easy to use (20/20, 100%), and presented information in a useful format (19/20, 95%); and 85% of providers (17/20) reported they would use the tool most or all of the time when providing survivorship care.

**Conclusions:** These usability data demonstrate acceptability of a cardiovascular health clinical decision support tool in oncology practices. Oncology providers and breast cancer survivors would likely value the integration of such apps in survivorship care. By increasing awareness and communication regarding cardiovascular health, electronic health record–enabled tools may improve survivorship care delivery for breast cancer and ultimately patient outcomes.


**KEYWORDS**
electronic health records; clinical decision support; usability testing; cardiovascular diseases; cancer survivors; breast cancer

**Introduction**
Cardiovascular health is of increasing concern to breast cancer survivors and their health care providers [1,2], since older, postmenopausal survivors are more likely to die of cardiovascular disease rather than of cancer [3,4]. Breast cancer survivors are at greater risk of death due to cardiovascular disease, compared to age-matched women without a history of breast cancer [5]. Chemotherapy (eg, anthracyclines), monoclonal antibody treatment, hormonal treatments, and radiation all heighten cardiovascular disease risk among survivors [1,6], further increasing cardiovascular disease susceptibility among cancer survivors [5,7,8]. Addressing cardiovascular health is critical for all breast cancer survivors, especially those who receive cardiotoxic treatments [2,9,10].

According to 1582 long-term cancer survivors surveyed in California, 62% were overweight or obese, 55% were hypertensive, 21% were diabetic, 18% were physically inactive, and 5% were current smokers [11]. An analysis of these California cancer registry data highlighted the possible role of shared risk factors in the development of both cancer and cardiovascular disease, reporting that cancer survivors tend to have multiple cardiovascular disease risk factors and that survivorship care often does not address these risk factors [11,12]. Early recognition and treatment of cardiovascular risk factors may be important during survivorship, as this increased risk of cardiovascular death is evident approximately 7 years postdiagnosis [2,5].

Despite Institute of Medicine recommendations for adequate prevention efforts and care coordination for cancer survivors [13-15], cardiovascular risk continues to be undertreated in this population [16,17]. The majority of National Cancer Institute Community Oncology Research Program oncologists we interviewed (11 of 14) in a pilot study [18] reported cardiovascular health discussions to be “somewhat” or “very” important. Yet in general survivorship settings, few referrals for cardiovascular care are made by oncologists to primary care providers and cardiologists for guideline-driven follow-up care [11,16,19,20].

The American Heart Association’s (AHA) definition of cardiovascular health comprises modifiable risk factors, which are scored according to Table 1. Improvements in cardiovascular health can reduce cardiovascular disease and breast cancer recurrence risk [21-26], and increasing patient and provider awareness can enhance cardiovascular health [13]. Most cancer survivors do not meet AHA’s healthy standards in multiple cardiovascular health components such as body mass index (BMI), physical activity, diet, smoking, blood pressure, cholesterol level, and glucose level [2,11,21].
Table 1. American Heart Association simple 7 measures of cardiovascular health, adapted from [27].

<table>
<thead>
<tr>
<th>Measures</th>
<th>Poor health</th>
<th>Intermediate health</th>
<th>Ideal health</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Health behaviors</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smoking status</td>
<td>Current</td>
<td>Former ≤12 months</td>
<td>Never or quit &gt;12 months</td>
</tr>
<tr>
<td>BMI</td>
<td>≥30 kg/m²</td>
<td>25-29.9 kg/m²</td>
<td>&lt;25 kg/m²</td>
</tr>
<tr>
<td>Physical activity</td>
<td>None</td>
<td>1-149 minutes/week moderate or 1-74 minutes/week vigorous or 1-149 minutes/week moderate and vigorous</td>
<td>≥150 minutes/week moderate or ≥75 minutes/week vigorous or ≥150 minutes/week moderate and vigorous</td>
</tr>
<tr>
<td>Healthy diet score</td>
<td>0-1 components</td>
<td>2-3 components</td>
<td>4-5 components</td>
</tr>
<tr>
<td><strong>Health factors</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total cholesterol level</td>
<td>≥240 mg/dL</td>
<td>200-239 mg/dL or treated to goal</td>
<td>&lt;200 mg/dL</td>
</tr>
<tr>
<td>Blood pressure</td>
<td>Systolic ≥140 mm Hg or Diastolic ≥90 mm Hg</td>
<td>Systolic 120-139 mm Hg or Diastolic 80-89 mm Hg or treated to goal</td>
<td>Systolic ≤120 mm Hg Diastolic ≤80 mm Hg</td>
</tr>
<tr>
<td>Blood glucose level</td>
<td>≥126 mg/dL</td>
<td>100-125 mg/dL or treated to goal</td>
<td>&lt;100 mg/dL</td>
</tr>
<tr>
<td>Hemoglobin A₁c</td>
<td>≥6.5%</td>
<td>5.7%-6.4% or treated to goal</td>
<td>≤5.6%</td>
</tr>
</tbody>
</table>

Clinical decision support can provide relevant data to the point-of-care to prompt appropriate disease management and referrals [28]. Our team has previously developed, implemented, and evaluated a cardiovascular health assessment tool, Stroke Prevention in Health care Delivery Environments (SPHERE), in the primary care setting [29,30]. Use of SPHERE resulted in improved BMI and diabetes status in the interventional primary care clinic but not the control clinic [31]. We refined this tool based upon feedback received from qualitative interviews with oncologists [18] and added information about receipt of potentially cardiotoxic cancer treatments. For this study, we evaluated the acceptability of the new Automated Heart-Health Assessment tool (AH-HA, Figure 1) among oncology providers and the Vigor-Us mobile app (Figure 1) among breast cancer survivors. We hypothesized that the majority of survivors and oncology providers would express positive views about the tools and their use in the cancer survivorship setting.
The AH-HA tool was embedded within a simulated electronic health record environment and was intended to be used mainly with a cursor pointer (mouse). The Vigor-Us tool was a responsive web app suitable for both touch and click interactions, with larger interactivity components. AH-HA did not collect any data from the interface, whereas Vigor-Us collected all the information entered during the authenticated sessions (authenticated users, secure sockets layer–encrypted database).

Methods

Ethical Approval and Informed Consent

This study was approved by the Wake Forest Health Sciences Institutional Review Board. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or
comparable ethical standards. The Wake Forest Health Sciences Institutional Review Board approved the study with a waiver of written informed consent.

**Study Eligibility and Data Collection**

Eligible survivors included those who were at least 21 years of age, diagnosed with nonmetastatic breast cancer, and at least 3 months after potentially curative cancer treatment (i.e., surgery, chemotherapy, or radiation), excluding maintenance hormonal therapy. Additional inclusion criteria included no current evidence of disease or a history of cancer recurrence, a working email address, and ability to read medical information in English. Survivors were ineligible for the study if they had visual impairments that prohibited them from viewing material on a tablet device or if they were enrolled in hospice care or had a life expectancy less than 6 months. Survivors were identified through clinic appointment schedules and contacted by a research member prior to their appointment by telephone or immediately before their appointment in the waiting room.

Eligible providers included medical, radiation, gynecologic, and surgical oncologists; nurse practitioners, and physician assistants who provided survivorship care to posttreatment cancer survivors. A list of eligible oncologists, nurse practitioners, and physician assistants was procured from the oncology service line administrators, and providers were emailed an invitation to participate.

All participants provided informed consent prior to participation, and the study was approved by the Wake Forest Health Sciences Institutional Review Board (number 37786). Survivor participants completed a baseline survey, viewed the Vigor-Us tool (Figure 1) with their cardiovascular health information on a tablet computer with the study research coordinator, and then completed a brief postsurvey. The total research visit time was 15 to 20 minutes. Separate from the survivor assessment, provider participants were provided with a prototype of the enhanced AH-HA tool (Figure 1) on a tablet computer, introduced to the manipulation of slider bars and buttons, and asked to use the tool as they might with a cancer survivor. Providers also completed brief assessments before and after viewing the tool. Both survivor and provider participants received a US $10 gift card.

**Cardiovascular Health Assessment Tools**

The AH-HA tool (Figure 1) visualizes data regarding the AHA Simple 7 modifiable cardiovascular health factors—BMI, smoking status, blood pressure, total cholesterol level, and hemoglobin A1c level; self-reported factors included smoking, physical activity, and diet (Table 1). Survivor knowledge of cardiovascular health and perceived importance and appropriateness of heart health discussions during oncology care were evaluated with 6 questions assessing confidence in understanding risk of heart disease, understanding steps needed to improve heart health, perception that cancer (or heart disease) poses a risk to health, and desire to talk to a provider (oncologist or primary care provider) about heart health. Survivors were also asked about the numerical value of each heart health factor (with “I don’t know” as an option) and to rate each health factor as high (poor health), somewhat high (intermediate health), or low-risk (ideal health) according to Table 1. Following their use of the tool, survivors completed the same 6 preassessment questions along with 3 additional questions reflecting acceptability of heart health discussions with oncologists prior to, during, and after treatment completion. Survivor tool acceptability was assessed with 5 questions on a 5-point Likert scale (strongly agree to strongly disagree) regarding liking the tool, helpfulness, ease of understanding, picture/diagram improved understanding, and desire to use this tool with oncologist. Survivors also reported gender, race and ethnicity, years of education, internet and email usage, and health literacy [34].

Provider self-reported demographic and practice data included gender, race/ethnicity, years in practice, and percentage of time spent in patient care. Provider usability was assessed using 6 questions utilized in our previous study of general internal medicine physicians [29] assessing useful information, promotion of effectiveness, ease in accessing needed information, information meets needs, easy to use, and useful format. These questions were rated on a 7-point Likert scale from strongly agree to strongly disagree. Three questions reflecting potential use of tool prior to, during, and after treatment completion were rated on a 4-point Likert scale (never, almost, always, almost always).

**Statistical Analyses**

For this pilot study, the sample size for the oncology provider survey (n=20) is driven primarily by feasibility concerns. For the survivor survey, we estimated power to test the hypothesis that responses to each Likert scale question are generally positive, which we defined as testing the alternative hypothesis that the mean score for each question is greater than 3.5 (where a score of 3 denotes a neutral response to the question). Assuming a sample of 50 survivors and a standard deviation of 1.0, we will have >80% power provided the true mean score for a particular question is 3.9 or greater (roughly corresponds to an average response of agree).
We conducted descriptive analyses and summarized oncology provider and survivor demographics and survey responses with counts and percentages. Providers’ responses were assessed on a 7-point Likert scale from strongly disagree to strongly agree; we categorized responses of 5-7 as agreeing. Survivors’ responses were assessed on a 5-point Likert scale from strongly agree to strongly disagree; responses of agree or strongly agree were categorized as agreeing. Wilcoxon signed rank tests were used to compare breast cancer survivors’ knowledge regarding their cardiovascular risk factors and perceived importance of cancer and heart disease before and after viewing the tool. Comparisons were made individually for each of the 6 questions included on the questionnaire about cardiovascular risk factor knowledge and perceived importance and appropriateness of heart health discussions during oncology care. Sidak correction for multiple testing were utilized due to the 6 questions; \( P \) values <.0085 were considered significant for these outcomes. We calculated the percent of survivors who reported “I don’t know” for each cardiovascular risk factor. Among those who did respond with a value for their risk factor, we calculated percent agreement between categorization of objective EHR data and the survivor’s subjective assessment. Finally, we present survivor and provider data on usability of the tools. Specifically, we calculated the percent of survivors and providers who agreed or strongly agreed with the usability questions, and we presented data on the preferred timing of the intervention according to survivors and providers.

Results

Sociodemographic and Health Characteristics of Breast Cancer Survivors

We enrolled 49 breast cancer survivors (Table 2). An additional 13 survivors were screened and not enrolled (4 did not have an email address, 6 were not interested, and 3 could not stay after an appointment). The majority of enrolled survivors (92%) had an early-stage cancer and were on 11 years postdiagnosis (mean 10.8 years, SD 6); all received surgical treatment, 55% (27/49) received chemotherapy, and 69% (34/49) received radiation. With regards to receipt of potentially cardiotoxic cancer treatments, one-third (17/49, 35%) had received treatment with an anthracycline; almost half received hormone therapy (24/49, 49%); 45% (22/49) received aromatase inhibitors, 6% (3/49) received monoclonal antibodies, 29% (14/49) received antimicrotubule agents, 43% (21/49) received alkylating agents, and 8% (4/49) received antimetabolites. Almost half of survivors (23/49, 47%) reported graduating from college, and 96% (47/49) reported adequate health literacy. Most had a cell phone (47/49, 96%), used the internet (43/49, 88%), and used email almost every day (34/49, 69%). Almost all, survivors (47/49, 96%) completed the postvisit assessment and provided cardiovascular health tool usability data.
Table 2. Characteristics of breast cancer survivor (n=49) and oncology provider (n=20) participants for usability testing of the AH-HA tool.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Breast cancer survivors (n=49)</th>
<th>Oncology providers (n=20)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;65</td>
<td>28 (57)</td>
<td>N/A&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>≥65</td>
<td>21 (43)</td>
<td>N/A</td>
</tr>
<tr>
<td>Sex, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>49 (100)</td>
<td>12 (60)</td>
</tr>
<tr>
<td>Male</td>
<td>0 (0)</td>
<td>8 (40)</td>
</tr>
<tr>
<td>Race, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>41 (84)</td>
<td>14 (70)</td>
</tr>
<tr>
<td>Black or African American</td>
<td>4 (8)</td>
<td>2 (10)</td>
</tr>
<tr>
<td>Asian</td>
<td>1 (2.0)</td>
<td>1 (5)</td>
</tr>
<tr>
<td>Southeast Asian</td>
<td>0 (0)</td>
<td>3 (15)</td>
</tr>
<tr>
<td>American Indian</td>
<td>0 (0)</td>
<td>1 (5)</td>
</tr>
<tr>
<td>More than one race</td>
<td>2 (4)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Unknown</td>
<td>1 (2)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Hispanic ethnicity, n (%)</td>
<td>2 (4)</td>
<td>2 (10)</td>
</tr>
<tr>
<td>Time since cancer diagnosis (years), mean (SD)</td>
<td>10.8 (6.0)</td>
<td>N/A</td>
</tr>
<tr>
<td>Cancer treatment received, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgery</td>
<td>49 (100)</td>
<td>N/A</td>
</tr>
<tr>
<td>Chemotherapy</td>
<td>27 (55)</td>
<td>N/A</td>
</tr>
<tr>
<td>Radiation</td>
<td>34 (69)</td>
<td>N/A</td>
</tr>
<tr>
<td>AJCC&lt;sup&gt;b&lt;/sup&gt; stage, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>4 (8)</td>
<td>N/A</td>
</tr>
<tr>
<td>I</td>
<td>23 (47)</td>
<td>N/A</td>
</tr>
<tr>
<td>II</td>
<td>18 (37)</td>
<td>N/A</td>
</tr>
<tr>
<td>III</td>
<td>4 (8)</td>
<td>N/A</td>
</tr>
<tr>
<td>Education level, n (%)</td>
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<td></td>
</tr>
<tr>
<td>≤High school</td>
<td>7 (14)</td>
<td>N/A</td>
</tr>
<tr>
<td>Some college</td>
<td>19 (40)</td>
<td>N/A</td>
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<tr>
<td>College graduate</td>
<td>23 (47)</td>
<td>N/A</td>
</tr>
<tr>
<td>Email use every day or almost every day, n (%)</td>
<td>34 (69)</td>
<td>N/A</td>
</tr>
<tr>
<td>Yes</td>
<td>15 (31)</td>
<td>N/A</td>
</tr>
<tr>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Internet use past 30 days, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>43 (88)</td>
<td>N/A</td>
</tr>
<tr>
<td>No</td>
<td>6 (12)</td>
<td>N/A</td>
</tr>
<tr>
<td>Adequate health literacy, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>47 (96)</td>
<td>N/A</td>
</tr>
<tr>
<td>No</td>
<td>2 (4)</td>
<td>N/A</td>
</tr>
<tr>
<td>Provider type, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physician (MD or DO)</td>
<td>N/A</td>
<td>14 (70)</td>
</tr>
<tr>
<td>Physician assistant/nurse practitioner</td>
<td>N/A</td>
<td>6 (30)</td>
</tr>
<tr>
<td>Characteristic</td>
<td>Breast cancer survivors (n=49)</td>
<td>Oncology providers (n=20)</td>
</tr>
<tr>
<td>--------------------------------------</td>
<td>-------------------------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td><strong>Years in practice, n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤5</td>
<td>N/A</td>
<td>8 (40)</td>
</tr>
<tr>
<td>6-10</td>
<td>N/A</td>
<td>4 (20)</td>
</tr>
<tr>
<td>≥11</td>
<td>N/A</td>
<td>8 (40)</td>
</tr>
<tr>
<td><strong>Oncology specialty, n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hematology</td>
<td>N/A</td>
<td>13 (65)</td>
</tr>
<tr>
<td>Radiation</td>
<td>N/A</td>
<td>1 (5)</td>
</tr>
<tr>
<td>Surgical</td>
<td>N/A</td>
<td>6 (30)</td>
</tr>
<tr>
<td><strong>Time spent in direct patient care, n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤50%</td>
<td>N/A</td>
<td>4 (20)</td>
</tr>
<tr>
<td>51-75%</td>
<td>N/A</td>
<td>7 (35)</td>
</tr>
<tr>
<td>&gt;75%</td>
<td>N/A</td>
<td>9 (45)</td>
</tr>
</tbody>
</table>

aN/A: not applicable.

bAJCC: American Joint Committee on Cancer.

Cardiovascular Health and Awareness of Breast Cancer Survivors

Prior to viewing the tool, 90% of survivors (44/49) agreed that cancer posed a risk to their health, and 84% (41/49) agreed that cardiovascular disease posed a risk to their health. On average, only 45% (range 0%-86%) of survivors’ known cardiovascular health factors were reported to be at an ideal level. More than 50% of survivors reported smoking status (45/49, 92%) and blood pressure (26/49, 53%) in the ideal category; less than one-third reported BMI, diet, and physical activity in the ideal range (Figure 2).
Prior to viewing the tool, 24% of survivors (12/49) expressed strong agreement that they understood their risk of cardiovascular disease; 58% (28/49) agreed. Yet 65% (32/49) reported not knowing the level for one or more cardiovascular health factors (range 0-4). Cardiovascular risk factors most likely to be self-reported as “not known” (Figure 2) included hemoglobin A1c (44/49, 90%), blood glucose level (32/49, 65%), cholesterol level (21/49, 43%), blood pressure (7/49, 14%), and BMI (1/49, 2%). When comparing concordance between the EHR and self-report for categorization of cardiovascular health factors as ideal vs nonideal among survivors who knew the categorization of their factor, 90% of survivors (44/49) were concordant for BMI, 47% (23/49) were concordant for blood pressure, 28% (14/49) were concordant for blood glucose level, and 34% (17/49) were concordant for cholesterol level (Figure 3).
Usability of the Tool Among Breast Cancer Survivors

Usage ratings of the tool by breast cancer survivors are shown in Figure 4. The majority of breast cancer survivors thought the tool was easy to understand (48/49, 98%), improved their understanding (45/49, 92%), and was helpful (45/49, 92%); 94% (46/49) liked the tool and agreed oncologists should discuss heart health during survivorship care. A majority (34/49, 69%) would like to use the tool with their oncologist at a future appointment. There were no differences in usability statistics by those 65 years and older versus those younger than 65 years.

We also assessed survivors’ perception of cardiovascular risk before and after viewing the tool (Figure 5). For all variables, survivors reported that they were in stronger agreement with the statements after viewing the tool (Figure 5). Significant changes were observed for understanding of cardiovascular risk ($S=-65$, $P=.009$), understanding steps to improve cardiovascular health ($S=-70.5$, $P<.001$), perception of health risk from cardiovascular disease ($S=-45$, $P=.007$), and desire to discuss cardiovascular risk with a primary care provider ($S=-121$, $P<.001$). There was no significant change in perception of health risk from cancer or desire to discuss cardiovascular risk with an oncologist.
Figure 5. Proportion of breast cancer survivors (n=47) whose cardiovascular health perceptions changed before and after viewing the assessment tool.

Sociodemographic and Practice Characteristics of Providers

We enrolled 14 physicians, 2 physician assistants, and 4 nurse practitioners; 60% (12/20) were female, 70% (14/20) were White, 10% (2/20) were Black, and 10% (2/20) identified as Hispanic or Latino (Table 2). Hematology oncology was defined as the practice specialty for 65% of providers (13/20), 60% (12/20) had been practicing as an attending for more than 5 years, and 80% (16/20) spent more than 50% of their time in direct patient care. Only 50% (10/20) reported usually or always talking to their posttreatment patients about cardiovascular health, and 35% (7/20) usually or always initiated discussion about cardiovascular health with posttreatment patients. However, 95% (19/20) reported it was somewhat or very important to discuss cardiovascular health with posttreatment patients. About half of providers (9/20, 45%) reported a high level of comfort with cardiovascular health discussions.

Usability of the Tool Among Oncology Providers

Usability ratings of the tool by providers are shown in Figure 4. Most providers agreed the tool provided useful information (18/20, 90%), would help their effectiveness (18/20, 90%), was easy to use (20/20, 100%), and presented information in a useful format (19/20, 95%); and 85% of providers (17/20) reported they would use the tool most or all of the time when providing survivorship care, with 50% (10/20) reporting the same for initial treatment planning and 45% (9/20) during active treatment.

Discussion

Principal Results

Overall, our results suggest both the need for and suitability of a tailored cardiovascular health assessment tool to heighten awareness of cardiovascular health among oncology providers and breast cancer survivors. We present the first usability data from breast cancer survivors and oncology providers on the usability of EHR-integrated cardiovascular health assessment tools. On average, only 45% of breast cancer survivors’ known cardiovascular health factors were at an ideal level, most survivors did not know the value or categorization of at least one of their cardiovascular health factors, and 94% of survivors (46/49) thought oncologists should discuss heart health during survivorship care. Nearly all providers indicated that it was either somewhat important or very important to discuss cardiovascular health with posttreatment patients. However, less than half of providers reported a high level of comfort with cardiovascular health discussions, and only half reported usually or always talking to their posttreatment patients about cardiovascular health. Usability data from providers and survivors demonstrate positive perceptions of the cardiovascular health apps; 85% of providers (17/20) reported they would use the tool most or all of the time when providing survivorship care. Thus, we conclude that clinical decision support tools such as AH-HA have potential to provide relevant data to providers at the point of care to initiate discussions and prompt appropriate referrals to primary care and cardiology—settings in which cardiovascular health can be managed effectively.

The use of the AH-HA and Vigor-Us tools are one strategy for improving risk assessment and personalized cardiovascular disease prevention in cancer survivorship programs, a research priority identified by the AHA [2]. A majority of breast cancer survivors did not know one or more of their cardiovascular health risk factors, despite a majority expressing agreement before viewing the tool that they understood their risk of heart disease. In particular, knowledge gaps exist among survivors with respect to their hemoglobin A1c and cholesterol values, which are strong independent predictors of cardiovascular disease [35]. Self-reported understanding of cardiovascular risk increased among survivors with use of the tool, and survivors increased their interest in discussing their heart health with primary care providers following the use of the tool. This increased awareness and interest may facilitate linking survivors back into primary care so these risks can be addressed.

Comparison With Prior Work

Our results are consistent with our previous evaluation of general cardiovascular health clinical decision support in the primary care setting. In our previous study [29], providers indicated that the content and the accuracy of the tool met their needs always...
or most of the time. Primary care providers felt the tool was clear and presented data in a useful format, was easy to use and user-friendly, and provided up-to-date information in a timely manner [29].

Limitations

Limitations of this study include the smaller sample size, nonrandomized usability assessment, single-institution setting, and the absence of data regarding the impact of the tool on cardiovascular health and health care utilization. Although we focused on breast cancer survivors in this usability study, the tool may also be appropriate for other survivor populations who have significant competing risk from cardiovascular disease. Future testing of this tool should take place in more diverse multi-institutional settings.

Conclusions

The AH-HA point-of-care EHR-based visualization tool brings together personalized cardiovascular health and contextual cancer treatment data to address potential gaps in breast cancer survivorship care. Our previous SPHERE study [29] suggested that cardiovascular health clinical decision support tools are well-received in the primary care setting. Findings from the current study suggest that oncology providers and breast cancer survivors would benefit from and value the integration of cardiovascular health clinical decision support apps in survivorship care. A newly initiated study will test the effectiveness and implementation of the AH-HA app in a clinic-randomized trial in community oncology practices.

Acknowledgments

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Conflicts of Interest

None declared.

References


Abbreviations

AHA: American Heart Association

AH-HA: Automated Heart-Health Assessment

EHR: electronic health record

SPHERE: Stroke Prevention in Healthcare Delivery Environments

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Physical Activity, Mental Health, and Technology Preferences to Support Cancer Survivors During the COVID-19 Pandemic: Cross-sectional Study

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Abstract

Background: COVID-19 has had significant health-related and behavioral impacts worldwide. Cancer survivors (hereafter referred to as “survivors”) are particularly prone to behavioral changes and are encouraged to be more vigilant and observe stricter social distancing measures.

Objective: We explored (1) changes in physical activity and sedentary behaviors since the onset of COVID-19, along with changes in mental health status, and (2) alternative strategies to support survivors’ physical activity and social health during and after COVID-19, along with the role of digital health in such strategies.

Methods: A questionnaire was distributed among survivors participating (currently or previously) in the community-based physical activity program LIVESTRONG at the Young Men’s Christian Association (YMCA), from 3 sites outside an urban area in Massachusetts. Questions addressed pre–COVID-19 vs current changes in physical activity and sedentary behavior. Anxiety and depression were assessed using the 2-item Generalized Anxiety Disorder scale (GAD-2) and 2-item Patient Health Questionnaire (PHQ-2), and scores ≥3 indicated a clinical diagnosis of anxiety or depression, respectively. Digital health preferences were assessed through closed-ended questions. Open-ended responses addressing other preferences for physical activity programs and social support were analyzed, coded, and categorized into themes.

Results: Among 61 participants (mean age 62 [SD 10.4] years; females: 51/61 [83.6%]), 67.2% (n=41) reported decreased physical activity and 67.2% (n=41) reported prolonged sitting times since the onset of COVID-19. Further, 24.6% (n=15) and 26.2% (n=16) met the GAD-2 and PHQ-2 criteria for clinical anxiety and depression, respectively. All participants owned a cellphone; 90% (n=54) owned a smartphone. Preferences for physical activity programs (n=28) included three themes: (1) use of digital or remote platforms (Zoom, other online platforms, and video platforms), (2) specific activities and locations (eg, outdoor activities, walking, gardening, biking, and physical activities at the YMCA and at senior centers), and (3) importance of social support regardless of activity type (eg, time spent with family, friends, peers, or coaches). The survey revealed a mean score of 71.8 (SD 21.4; scale 0-100) for the importance of social support during physical activity programs. Social support
preferences (n=15) revealed three themes: (1) support through remote platforms (eg, texting, Zoom, phone calls, emails, and Facebook), (2) tangible in-person support (YMCA and senior centers), and (3) social support with no specific platform (eg, small gatherings and family or friend visits).

**Conclusions:** Physical activity and mental health are critical factors for the quality of life of survivors, and interventions tailored to their activity preferences are necessary. Digital or remote physical activity programs with added social support may help address the ongoing needs of survivors during and after the pandemic.

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**KEYWORDS**
cancer; COVID-19; digital; physical activity; support; technology

**Introduction**

COVID-19 first emerged in December 2019 [1]. COVID-19 and social distancing have had deleterious effects on physical activity and mental health in the general population, resulting in decreased activity levels and increased anxiety, depression, and stress levels [2,3]. Current cancer survivors (hereafter referred to as “survivors”) and those previously undergoing treatment may have been affected in particular. Survivors have unique emotional needs owing to anxiety, depression, and familial and financial strains, along with many long-lasting preexisting health conditions [4-7]. However, few studies have addressed these concerns and explored means to provide additional support to survivors. Owing to their preexisting conditions and immunocompromised state, survivors are at an increased risk of disease and admission to the intensive care unit, increased ventilator use, and an increased risk of death due to COVID-19 [8,9]. Hence, survivors are encouraged to observe strict social distancing guidelines [10]. Further, many in-person survivorship resources, such as physical activity and mental health support, have been reduced [11].

We explored the effects of COVID-19 on a group of survivors who were current or previous participants in the community-based physical activity program, LIVESTRONG at the Young Men’s Christian Association (YMCA) [12]. This 12-week program involves physical activity (ie, aerobic, muscle strengthening, and flexibility exercises) and social support (ie, group support sessions) delivered in person by trained staff, twice a week, free of cost to survivors at participating YMCA sites nationwide. The program has effectively improved survivors’ physical activity, fitness, and quality of life [13]. In this study, we examined (1) changes in physical activity or sedentary behaviors since the onset of COVID-19, along with changes in their mental health status, and (2) alternative strategies to support survivors’ physical activity and social health during and after COVID-19, including the role of digital health in these strategies. Although the role of digital health in promoting physical activity and mental health has been understudied among survivors [14], some trials [15] have reported the feasibility, adherence, and effectiveness of digital health [15]. Because the lasting effects of COVID-19 are unknown, this formative study may contribute to the development of digital community-based physical activity and social support programs.

**Methods**

**Study Design**

This cross-sectional study included individuals participating in the 12-week LIVESTRONG at the YMCA program, which delivers support for physical activities and social health free of cost for those who (1) have or have had a cancer diagnosis, (2) are over 18 years of age, and (3) were medically cleared by a physician to perform physical activity. We coordinated with the program director at one LIVESTRONG site, who contacted program directors at two additional local sites outside an urban area in Massachusetts, to describe the study and deliver an online questionnaire survey to current and past program participants. From among these three sites, we estimated that these listservs had >300 eligible participants, but we could not estimate the total number of emails sent. Participants were provided a US $10 gift card upon completion of the questionnaire. The Institutional Review Board at UMass Medical School approved this trial (IRB docket number H00020448).

**Measures**

**Physical Activity and Sedentary Time**

We assessed subjective changes in physical activity by asking the question, “Since COVID-19, has your physical activity (a) decreased, (b) increased, or (c) stayed the same?” We assessed changes in sedentary behaviors by asking the question, “Since COVID-19, has your time spent sitting (a) decreased, (b) increased, or (c) stayed the same?”

**Mental Health**

Anxiety and depression were assessed using the 2-item Generalized Anxiety Disorder scale (GAD-2) [16] and the 2-item Patient Health Questionnaire (PHQ-2) [17], respectively. Both these tools have acceptable sensitivity and specificity [18].

**Physical Activity During or After COVID-19 and Digital Health Preferences**

Participants were asked to report all their preferred physical activities during and after COVID-19 from among the following: (1) indoor or outdoor activities with family or friends, (2) indoor or outdoor activities by themselves, (3) physical activity delivered through online platforms, and (4) physical activity delivered through video calls with family, friends, or fitness professionals. They were then asked to respond to an optional open-ended question regarding other preferred means of receiving physical activity programs.
Social Support and Digital Health Preferences

Participants ranked the importance of social support in a physical activity program (scale 0-100). They reported their most preferred means of receiving social support from among the following: (1) in person, (2) video calls, (3) social media, and (4) texting. They then responded to open-ended questions regarding their preferred means of receiving social support.

Statistical Analysis

We analyzed descriptive statistics for quantitative variables, using STATA (version 15, StataCorp). For the GAD-2 and PHQ-2, we summed the two questions and applied a cut-off ≥3 to generate a dichotomous variable. Scores ≥3 were classified as “clinically diagnosable” independently for anxiety and depression [16,17]. Responses to open-ended questions were open-coded verbatim to identify relevant themes and corroborated with two additional investigators.

Results

Participants (N=61) had a mean age of 62 (SD 10.4) years, were mainly female (n=51, 83.6%), and had pursued higher education (college diploma: n=18, 29.5%; bachelor’s degree: n=15, 24.6%; advanced college degree: n=24, 39.3%). All of them owned a cell phone, and the vast majority (n=54, 90%) owned smartphones that can access the internet (Table 1).

Table 1. Demographic characteristics and technology usage among the study participants (N=61).

<table>
<thead>
<tr>
<th>Variable</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>10 (16.4)</td>
</tr>
<tr>
<td>Female</td>
<td>51 (83.6)</td>
</tr>
<tr>
<td><strong>Age (years), mean (SD)</strong></td>
<td>62.0 (10.4)</td>
</tr>
<tr>
<td><strong>Marital status, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>38 (62.3)</td>
</tr>
<tr>
<td>Divorced/separated</td>
<td>10 (16.4)</td>
</tr>
<tr>
<td>Widowed</td>
<td>5 (8.2)</td>
</tr>
<tr>
<td>Single/unmarried</td>
<td>8 (13.1)</td>
</tr>
<tr>
<td><strong>Education level, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Finished high school or GED(^a)</td>
<td>4 (6.6)</td>
</tr>
<tr>
<td>College diploma</td>
<td>18 (29.5)</td>
</tr>
<tr>
<td>Bachelor’s degree</td>
<td>15 (24.6)</td>
</tr>
<tr>
<td>Advanced college degree</td>
<td>24 (39.3)</td>
</tr>
<tr>
<td>Uses the internet, n (%)</td>
<td>55 (90.2)</td>
</tr>
<tr>
<td><strong>How do you use the internet?, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Read information on websites</td>
<td>55 (90.2)</td>
</tr>
<tr>
<td>Send or receive emails</td>
<td>35 (57.4)</td>
</tr>
<tr>
<td>Watch videos/listen to audio clips</td>
<td>21 (34.4)</td>
</tr>
<tr>
<td>Use online social network sites</td>
<td>40 (65.6)</td>
</tr>
<tr>
<td>Owns a cell phone, n (%)</td>
<td>61 (100)</td>
</tr>
<tr>
<td>Owns a smartphone, n (%)</td>
<td>54 (90)</td>
</tr>
<tr>
<td><strong>How do you use your cell phone?, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Send or receive emails</td>
<td>39 (63.9)</td>
</tr>
<tr>
<td>Send or receive text messages</td>
<td>45 (73.8)</td>
</tr>
<tr>
<td>Access the internet</td>
<td>42 (68.9)</td>
</tr>
<tr>
<td>Look for health/medical information online</td>
<td>36 (61)</td>
</tr>
<tr>
<td>Take photographs</td>
<td>46 (78)</td>
</tr>
</tbody>
</table>

\(^a\)GED: General Education Diploma.
Physical Activity, Sedentary Time, and Mental Health

Most participants reported decreased physical activity (n=41, 67.2%) and a prolonged sitting time (n=41, 67.2%) since the onset of COVID-19 (Table 2). On mental health evaluation, 26.2% (n=16) and 24.6% (n=15) of participants had scores greater than the clinical cut-off for depression and anxiety, respectively.

Table 2. Changes in physical activity and sedentary time, mental health evaluation, and preferences for physical activity and social support among the study participants (N=61).

<table>
<thead>
<tr>
<th>Variable</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Change in physical activity</strong>, n (%)</td>
<td></td>
</tr>
<tr>
<td>More physically active</td>
<td>13 (21.3)</td>
</tr>
<tr>
<td>No change in physical activity</td>
<td>7 (11.5)</td>
</tr>
<tr>
<td>Less physically active</td>
<td>41 (67.2)</td>
</tr>
<tr>
<td><strong>Change in sedentary time</strong>, n (%)</td>
<td></td>
</tr>
<tr>
<td>Sitting more</td>
<td>41 (67.2)</td>
</tr>
<tr>
<td>No change in sitting time</td>
<td>16 (26.2)</td>
</tr>
<tr>
<td>Sitting less</td>
<td>4 (6.6)</td>
</tr>
<tr>
<td><strong>PHQ-2</strong>^b score, mean (SD)</td>
<td>1.35 (1.4)</td>
</tr>
<tr>
<td>&lt;3, n (%)</td>
<td>45 (73.8)</td>
</tr>
<tr>
<td>≥3 (clinical cut-off), n (%)</td>
<td>16 (26.2)</td>
</tr>
<tr>
<td><strong>GAD-2</strong>^c, mean (SD)</td>
<td>1.84 (1.53)</td>
</tr>
<tr>
<td>&lt;3, n (%)</td>
<td>46 (75.4)</td>
</tr>
<tr>
<td>≥3 (clinical cut-off), n (%)</td>
<td>15 (24.6)</td>
</tr>
<tr>
<td><strong>Physical activity preference during COVID-19</strong>^d, n (%)</td>
<td></td>
</tr>
<tr>
<td>Online programs</td>
<td>17 (27.9)</td>
</tr>
<tr>
<td>Indoor or outdoor activities with family or friends</td>
<td>26 (42.6)</td>
</tr>
<tr>
<td>Indoor or outdoor activities by themselves</td>
<td>40 (65.6)</td>
</tr>
<tr>
<td>Video calls (with family, friends, or fitness professionals)</td>
<td>25 (42.6)</td>
</tr>
<tr>
<td><strong>Physical activity preference after COVID-19</strong>^d, n (%)</td>
<td></td>
</tr>
<tr>
<td>Online programs</td>
<td>31 (50.8)</td>
</tr>
<tr>
<td>Indoor or outdoor activities with family or friends</td>
<td>24 (39.3)</td>
</tr>
<tr>
<td>Indoor or outdoor activities by self</td>
<td>24 (39.3)</td>
</tr>
<tr>
<td>Video calls (with family, friends, or fitness professionals)</td>
<td>14 (23)</td>
</tr>
<tr>
<td><strong>Importance of social support for physical activity programs (scale 0-100), mean (SD)</strong></td>
<td>71.8 (21.4)</td>
</tr>
<tr>
<td><strong>Social support preference, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>In-person</td>
<td>42 (68.9)</td>
</tr>
<tr>
<td>Video calls</td>
<td>13 (21.3)</td>
</tr>
<tr>
<td>Social media groups</td>
<td>3 (4.9)</td>
</tr>
<tr>
<td>Texting</td>
<td>3 (4.9)</td>
</tr>
</tbody>
</table>

^aQuestions addressing variables for comparison with pre–COVID-19 values.
^bPHQ-2: 2-item Patient Health Questionnaire.
^cGAD-2: 2-item Generalized Anxiety Disorder.
^dParticipants were asked to check all applicable responses.
Physical Activity During or After COVID-19 and Digital Health Preferences

Table 2 highlights the preferred physical activities during and after COVID-19. During COVID-19, survivors most preferred indoor activities by themselves (n=40, 65.6%) in person; after COVID-19, online programs (n=31, 50.8%). Three main themes were identified from the open-ended responses (n=28) regarding the survivors’ preferences for other physical activity programs. The present themes and sample responses are provided below.

Digital and Remote Programs

One participant who was enrolled in the LIVESTRONG program stated the following when the program was moved to an online platform: “I like the Zoom program better than anything I have ever done.” Three others (10.7%) reported the following regarding remote activities and the use of technology: “Challenges on Fitbit,” “online,” and “videos or DVDs.”

Specific Activities or Specific Locations for Activities

In total, 4 (14.3%) survivors preferred “walking, light hiking,” “walking trails,” and “swimming” at no specified location; 6 (25%) others preferred additional outdoor activities including “outdoor activities - walking, biking,” “bike riding, fishing, gardening,” “yard work,” and “anything outdoors,” and 4 (16.7%) participants preferred indoors “gym,” “senior center,” “LIVESTRONG,” and “market walking.”

Importance of Social Support Regardless of Activity Type

In total, 6 (25%) participants preferred social support in addition to their preferred physical activity, such as “phone call with a friend while walking ‘together’” and “walking with friends, family, or other people,” “gym with cancer patients,” and “I need a partner to hold me accountable.”

Preferences for Alternative Means of Social Support

Table 2 highlights the participant preferences for social support and digital health. Three main themes were identified from the questions on open-ended preferences (n=15) for other forms of social support.

Using Digital Platforms for Support

In total, 5 (33.3%) participants preferred social support to be delivered through a remote or digital platform, such as “phone calls, emails, Zoom, Google, Nest, WhatsApp, and Facebook.” Others (n=2, 13.3%) indicated the involvement of specific individuals, such as “text messages with peers or coaches,” and “video conferencing or phone calls with friends or family.”

Tangible In-Person Support

In total, 3 (20%) participants preferred in-person support (“I would like to have support in person, but [the Y] is just too far away from my house…” and “to attend senior center,” “Gym or fitness center”).

Social Support With no Specified Platform

In total, 5 (33.3%) participants preferred social support but did not specify whether they preferred in-person or remote support (“an advocate to help with the things I struggle with,” “visits with friends or family,” and “small groups”).

Discussion

Principal Findings

Survivors self-reported decreased physical activity levels and greater anxiety and depression levels, similar to those of the general population [2]. In both our quantitative and qualitative analyses, survivors reported their preferences for digital health. Other reported preferences highlighted the importance of social support.

Reductions in the survivors’ physical activity and increases in sedentary behaviors are concerning, as physical activity is critical for their physical and mental health [19-21]. The proportions of our participants who met the diagnostic criteria for depression and anxiety (n=16 [26.2%] and n=15 [24.6%], respectively) were higher than those previously reported for prostate cancer survivors (9.4% and 7.9%, respectively) but lower than those of breast cancer survivors (32.2% and 38.2%, respectively) [22,23]. Overall proportions of survivors are much higher than those of the general US population (3.1% of the general US population adults >18 years have been diagnosed with generalized anxiety disorder and 7.1% with major depressive disorder) [24]. It is critical to develop methods to support the mental health needs of survivors, and our study suggests that the pandemic and social isolation may increase the need for such support.

Survivors expressed their interest in support from digital health platforms for physical activities after COVID-19. While more survivors (n=40, 65.6%) reported their preferences for indoor or outdoor activities by themselves during COVID-19, they may possibly not have had the opportunity to receive support from digital health programs thus far. During and after COVID-19, digital health platforms may serve as a substitute for in-person support for survivors, and they can be tailored to augment the benefits of in-person support, potentially providing long-term support to survivors. COVID-19 has forced practitioners and survivors to embrace digital technology to promote and maintain health care provision and deliver physical activity programs [25]. Some oncological trials assessing physical activity have shifted to digital platforms [26]; however, community-based programs may provide less support and resources to convert in-person programs to virtual ones. A worldwide survey of fitness trends in 2021 reported that online programs ranked 1st in 2021 as opposed to 26th in 2020 [27], indicating that COVID-19 has brought about a paradigm shift in the fitness industry, and practitioners will need to adjust to this trend.

Furthermore, survivors acknowledged the importance of social support, and some expressed preferences for peer support. Telephonically delivered support by trained peer coaches coupled with remote activity monitoring has led to an increase in physical activity in a randomized trial with breast cancer survivors [28]. Although, in this study, 69% (n=42) of survivors preferred in-person social support, peer support for survivors delivered digitally is ideal for those who are unable to attend in-person programs and need additional support [29]. A digital health intervention that includes social support (ie, from family or friends, peer coaches, or other survivors) may address the preferences of survivors for remote programs and their

http://cancer.jmir.org/2021/1/e25317/
accountability, while potentially improving their physical activity and mental health [30]. However, larger trials are required to examine the causal effects of different types of social support among survivors [31].

**Limitations**

This exploratory study had a small cohort size; therefore, the statistical power was not high enough to enable hypothesis testing to assess relationships among variables. Survivors having already participated in the LIVESTRONG at the YMCA program might have been more motivated than those not enrolled in this program; thus, reductions in physical activity reported here may underestimate the prevalence of this issue in the general survivor population. Although this study lacks data on cancer types, previous studies have reported data from a higher proportion of breast cancer survivors [13]. These studies and our study show the homogeneity of the characteristics of participants in the LIVESTRONG to the YMCA program [13], and future trials will need to examine more diverse populations. Program directors had access to email listservs through the YMCA but did not have access to the number of participants registered on them; hence, we could not determine neither the final number of emails sent to eligible participants nor the valid response rate. All responses are self-reported and were obtained in a cross-sectional manner, warranting future assessments of baseline measures to assess longitudinal changes objectively, for example, using activity monitors.

**Conclusions**

In conclusion, during and after COVID-19, survivors may benefit from support to sustain their physical activity levels and mental health. The survivors in our study voiced various preferences for physical activity and social support, some preferring indoor physical activity by themselves during COVID-19 and others preferring online or remote programs along with social support, including support from family or friends and peer coaches, after COVID-19. Community-based physical activity programs can successfully engage survivors if they provide programs tailored to individual preferences during and after the COVID-19 pandemic.

**Acknowledgments**

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**Conflicts of Interest**

None declared.

**References**


Abbreviations

GAD-2: 2-item Generalized Anxiety Disorder
PHQ-2: Patient Health Questionnaire
YMCA: Young Men’s Christian Association

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Effects and Implementation of a Mindfulness and Relaxation App for Patients With Cancer: Mixed Methods Feasibility Study

Abstract

Background: Cancer diagnosis and cancer treatment can cause high levels of distress, which is often not sufficiently addressed in standard medical care. Therefore, a variety of supportive nonpharmacological treatments have been suggested to reduce distress in patients with cancer. However, not all patients use these interventions because of limited access or lack of awareness. To overcome these barriers, mobile health may be a promising way to deliver the respective supportive treatments.

Objective: The aim of this study is to evaluate the effects and implementation of a mindfulness and relaxation app intervention for patients with cancer as well as patients’ adherence to such an intervention.

Methods: In this observational feasibility study with a mixed methods approach, patients with cancer were recruited through the web and through hospitals in Switzerland. All enrolled patients received access to a mindfulness and relaxation app. Patients completed self-reported outcomes (general health, health-related quality of life, anxiety, depression, distress, mindfulness, and fear of progression) at baseline and at weeks 4, 10, and 20. The frequency of app exercise usage was gathered directly through the app to assess the adherence of patients. In addition, we conducted interviews with 5 health professionals for their thoughts on the implementation of the app intervention in standard medical care. We analyzed patients’ self-reported outcomes using linear mixed models (LMMs) and qualitative data with content analysis.

Results: A total of 100 patients with cancer (74 female) with a mean age of 53.2 years (SD 11.6) participated in the study, of which 25 patients used the app regularly until week 20. LMM analyses revealed improvements in anxiety ($P=.04$), distress ($P<.001$), fatigue ($P=.01$), sleep disturbance ($P=.02$), quality of life ($P=.03$), and mindfulness ($P<.001$) over the course of 20 weeks. Further LMM analyses revealed a larger improvement in distress ($P<.001$), a moderate improvement in anxiety ($P=.001$), and a larger improvement in depression ($P=.03$) in patients with high levels of symptoms at baseline in the respective domains. The interviews revealed that the health professionals perceived the app as a helpful addition to standard care. They also made suggestions for improvements, which could facilitate the implementation of and adherence to such an app.

Conclusions: This study indicates that a mindfulness and relaxation app for patients with cancer can be a feasible and effective way to deliver a self-care intervention, especially for highly distressed patients. Future studies should investigate if the appeal of the app can be increased with more content, and the effectiveness of such an intervention needs to be tested in a randomized controlled trial.

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KEYWORDS

mobile app; mobile phone; mindfulness; relaxation; cancer; qualitative research; implementation science; mHealth; evaluation study; patient compliance; patient participation; patient preference
Introduction

Background
Cancer diagnosis and subsequent medical treatments can cause high levels of distress [1-4]. However, adequate psychological support for patients with cancer is often lacking in standard medical care [5,6]. Therefore, a variety of supportive treatments have been suggested to reduce distress in patients with cancer, such as mind-body medicine (MBM) [7]. MBM combines various effective treatments such as mindfulness meditation, relaxation, yoga, and tai chi [7,8]. Such MBM treatments can have beneficial effects on cancer-related symptoms, such as pain, fatigue, and sleep disturbance [9-11]. Furthermore, MBM treatments can have beneficial effects on the quality of life of patients with cancer [12-14]. These treatments can be provided through guided MBM programs for patients with cancer, where the patients learn various exercises (eg, physical exercises, relaxation, and stress reduction) and are encouraged to practice these newly learned exercises at home [15,16].

However, the uptake of supportive treatments in distressed patients with cancer is moderate [17]. Barriers for the uptake of such treatments include stigmatization, unawareness of such interventions, or limited access [18,19]. This is problematic because untreated, elevated levels of distress can lead to additional negative effects, such as reduced quality of life, daily functioning, and lower adherence to medical treatment [20,21]. Access can be restricted, for instance, because of geographical distance, lack of treatment providers or knowledge thereof, and financial constraints [22-24]. To overcome these limitations in access, eHealth and mobile health (mHealth) interventions have been proposed. eHealth is defined more broadly as the delivery of health services or information through the internet and related technologies [25], whereas mHealth uses mobile technologies such as smartphones for the delivery of health services [26]. So far, research indicates that eHealth interventions with mindfulness or relaxation components can have beneficial effects on health outcomes in various patient populations [27-29]. However, eHealth studies focusing on patients with cancer have shown inconsistent results [30,31]. Nonetheless, eHealth interventions seem promising because they can have positive effects on the well-being of patients with cancer [31].

Although mHealth interventions have some advantages over web-based eHealth interventions (eg, more flexible access because of mobility, the possibility of reaching a large number of patients because of the large popularity of smartphones), little is known about the best practices for the implementation of mHealth interventions [32,33]. In addition, mHealth research so far indicates that the adoption of mHealth interventions by health professionals and patients can be inhibited by various factors, such as perceived usefulness and ease of use [34,35]. Furthermore, there is a lack of mHealth studies with mindfulness or relaxation-based interventions [27]. Therefore, we developed a research app to conduct a feasibility study of a mindfulness- and relaxation-based mHealth intervention for patients with cancer [36]. The app included 3 exercises, namely, mindfulness meditation, guided imagery, and progressive muscle relaxation.

Objectives
The aim of this study is to assess the feasibility of this mHealth intervention using the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) evaluation framework, which was developed for the evaluation of public health interventions [37]. Although the results for the reach of the dimensions, adoption over the course of 10 weeks, and maintenance were published elsewhere [36], the present analyses focus on the 3 dimensions of effectiveness, adoption, and implementation over the course of 20 weeks to assess the pre-post effects of the app on a variety of health outcomes and adherence to the app intervention. In doing so, we investigate whether such an app may be a beneficial, supportive care tool for patients with cancer.

Methods

Study Design
For this feasibility study, we used a mixed methods approach. For quantitative data, we assessed 4 paper-and-pencil questionnaires that were sent to patients with cancer at baseline and at weeks 4, 10, and 20. Demographics and patient characteristics were assessed at baseline, and health outcomes (physical, mental, and social health, health-related quality of life, anxiety, depression, distress, mindfulness, and fear of progression) were assessed over the 4 time points. Qualitative data consisted of semistructured interviews with 5 health professionals. In those interviews, we inquired about health professionals’ perspectives on a mindfulness- and relaxation-based mHealth intervention for patients with cancer and its implementation in standard medical care. To receive feedback from different health professionals, we conducted 2 face-to-face group interviews (1 interview with 2 nursing experts and the second interview with 2 psychologists providing MBM treatment for patients with cancer) and 1 individual interview with an oncologist. All interviewees received access to the app before the interview and could test the app. The interviewer also demonstrated the app and its content to the interviewees before the interview started.

To assess the feasibility of our mHealth intervention, we used the RE-AIM implementation science framework [37]. Ethical approval for the study was granted in April 2016 by the cantonal ethics committee Zurich (BASEC-Nr. 2016-00258), and we registered the study in the German Clinical Trials Register (DRKS00010481).

Participants
Patients were eligible if they (1) had any cancer diagnosis at any stage of cancer, (2) were aged 18 years or older, and (3) owned either an iPhone (Apple Inc.) or an Android-based smartphone with at least a weekly connection to the internet. Patients were excluded if they had suicidal ideation or insufficient German language skills, if they intended to move to another country, or if they had insufficient knowledge on how to use a smartphone. The patient recruitment process is described in detail elsewhere [36]. For the interviews with health professionals, we invited experts (an oncologist, nursing experts,
and psychologists) from the University Hospital Zurich, who provide health care for patients with cancer.

### App Intervention

All enrolled patients received the mindfulness and relaxation app, which was specifically developed for this study and only available for patients participating in the study. The app could be downloaded in the Apple iTunes store and Google Play Store for Android devices and accessed with a code, which was provided to the patients after study inclusion. The app offered 3 exercises: mindfulness meditation, guided imagery, and progressive muscle relaxation. The exercises were included in the app as audio files with a duration of approximately 15 minutes each, and the patients could choose between a female or male narrator. Patients were free to choose which exercises they wanted to use and how often they wanted to practice. However, we recommended to the patients to use an exercise of their choice on a daily basis, ideally 5 times per week. To help patients practice regularly, the app included an optional notification feature that patients could set up to receive a daily push notification on the mobile device, reminding them to practice at an individually set time. Information about the use of exercises (exercise type, date, and start and end times) was saved in the backend and was only accessible to the researchers as an XML log file. More information about the app is presented in a previously published paper [36].

### Outcomes

#### Effects

As we conducted a single-arm study without a control group, we were not able to assess the effectiveness of the app intervention. Therefore, for the RE-AIM dimension effectiveness, we looked into pre-post effects in a variety of health outcomes relevant to patients with cancer. We assessed physical, mental, and social health using the Patient-Reported Outcomes Measurement Information System (PROMIS 29) [38], PROMIS 29 is a 29-item scale assessing 7 health domains: physical function (Cronbach α=.81), fatigue (Cronbach α=.94), pain interference (Cronbach α=.96), depressive symptoms (Cronbach α=.85), anxiety (Cronbach α=.81), ability to participate in social roles and activities (Cronbach α=.88), and sleep disturbance (Cronbach α=.86) with 4 items, each on a 5-point scale, and pain intensity with a single item on a 10-point numeric rating scale.

For the assessment of health-related quality of life for patients with cancer, we administered the Functional Assessment of Cancer Therapy—General (FACT-G) [39,40]. The FACT-G consists of 4 subscales: physical well-being (Cronbach α=.85), social well-being (Cronbach α=.76), emotional well-being (Cronbach α=.70), and functional well-being (Cronbach α=.79), measured with 27 items on a 5-point scale. A higher score indicates a better quality of life.

For the assessment of distress, we administered the Distress Thermometer [41]. The Distress Thermometer is a numeric rating scale, ranging from 0 to 10. A score of 5 or higher is considered to indicate clinically relevant distress [42].

For the assessment of mindfulness, we administered the short version of the Freiburg Mindfulness Inventory (FMI) [43]. The FMI (Cronbach α=.87) assesses mindfulness with 14 items on a 4-point scale, with a higher score indicating higher mindfulness.

We measured anxiety and depression using the Hospital Anxiety and Depression Scale (HADS). The HADS assesses 7 items for the subscales anxiety (Cronbach α=.79) and depression (Cronbach α=.67) on a 4-point scale, with a maximum score of 21 for each subscale. A score of up to 7 is considered normal, a score between 8 and 11 is considered borderline, and a score above 11 is considered caseness [44].

For the assessment of fear of progression, we administered the Fear of Progression Questionnaire-Short Form (FoP-Q-SF) [45]. The FoP-Q-SF (Cronbach α=.81) consists of 12 items with a 5-point scale. A higher score indicates a greater fear of progression.

We assessed PROMIS 29, FACT-G, and FMI at baseline and at weeks 4, 10, and 20 and HADS, FoP-Q-SF, and Distress Thermometer at baseline and at weeks 10 and 20. We defined a continuous app user as a patient who regularly used the app exercises (at least one exercise per week). We counted an exercise as completed if the patient played the exercise audio file for at least 10 minutes of the total time of 15 minutes. We defined an intervention dropout as a patient who stopped using the exercises for 4 consecutive weeks because regular practice might be a prerequisite for a beneficial intervention. We defined the first week when the patient stopped using the exercises as a dropout week. A patient who never used an app exercise was counted as a week 1 intervention dropout.

#### Adoption

For the RE-AIM dimension adoption, we looked at the number of completed app exercises over 20 weeks and app exercise preferences. We reported the median of completed app exercises by all enrolled patients per week as well as the median of completed app exercises by continuous app users. For exercise preferences, we reported frequencies of used exercises for all enrolled patients, stratified by gender of the patient and the narrator.

#### Implementation

For the RE-AIM dimension implementation, we reported results from interviews with health professionals regarding their opinion on the implementation of the app intervention in addition to standard medical care. In the interviews, we inquired about the general impression regarding the app, implementation of the app as an addition to standard medical care, and suggestions for improvements.

#### Sample Size

One aspect evaluated in our feasibility study was the characteristics and number of patients with cancer who participated in the study (evaluation dimension reach), which was reported previously [36]. Therefore, we did not perform an a priori analysis to determine the required sample size for adequate power. However, we aimed to recruit at least 100 patients, which is sufficient to achieve 80% power for a
two-tailed \( t \) test with an \( \alpha \) level set at .05 and a small effect size of Cohen \( d \) of 0.28.

**Data Analysis**

**Quantitative Data**

All printed case report forms were entered by trained researchers into the electronic database REDCap (Research Electronic Data Capture), which was hosted at the University Hospital Zurich. All analyses were carried out in SPSS version 25.0 (IBM Corp).

For baseline characteristics of patients, we used descriptive statistics (frequencies and percentages for categorical variables and mean and SD for continuous variables). For the analyses of pre-post effects, we used linear mixed models (LMMs) to analyze changes over time (baseline, week 4, week 10, and week 20) in health outcomes as well as differences between continuous app users and intervention dropouts in health outcomes. All patients who provided baseline data were included in the analyses, and because we used LMMs, patients with missing data in weeks 4, 10, and 20 questionnaires were included. The dependent variables were the 7 PROMIS 29 domains, FACT-G, HADS subscales anxiety and depression, Distress Thermometer, FMI, and FoP-Q-SF. Furthermore, we looked at the changes in the respective health outcomes for subsamples with high distress (Distress Thermometer score ≥5), high anxiety (HADS anxiety score of ≥8), and high depression (HADS depression score of ≥8). As a covariance type, we used an autoregressive covariance structure (AR1). Time was included as a fixed effect. For group analyses, (continuous app users vs intervention dropouts), we added group and time-by-group as fixed effects. Hedge g effect sizes were calculated as mean differences (baseline and week 20) divided by pooled SDs for each health outcome of interest.

**Qualitative Data**

For the dimension implementation, we recorded the interviews and transcribed the interviews verbatim. We used thematic coding for structuring the interviews using MAXQDA 11 (VERBI Software), and we used content analysis according to Mayring [46].

**Results**

**Patient Characteristics**

Between June 2016 and December 2018, we were able to recruit 100 patients with cancer, all of whom provided baseline information. At week 20, 72 (72%) patients completed questionnaire 4 (Figure 1). Baseline characteristics of all enrolled patients (N=100) as well as subsamples of patients with high distress (62/100, 62%), high anxiety (35/100, 26%), and high depression (20/100, 20%) are summarized in Table 1. Most patients (74/100, 74%) were female. The mean age of all patients was 53.24 (SD 11.55) years, ranging from 23 to 84 years. Patients predominantly owned an iPhone smartphone (67/100, 67%), whereas 30 patients (30/100, 30%) owned an Android smartphone, and a few (3/100, 3%) owned both.

![Figure 1. Flowchart.](https://cancer.jmir.org/2021/1/e16785)
Table 1. Demographics for the total sample and high distress, high depression, and high anxiety subsamples.

<table>
<thead>
<tr>
<th>Patient demographics</th>
<th>Total sample (N=100)</th>
<th>High distress(^a) subsample (n=62)</th>
<th>High anxiety(^b) subsample (n=35)</th>
<th>High depression(^c) subsample (n=20)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>74 (74)</td>
<td>48 (77)</td>
<td>26 (74)</td>
<td>15 (75)</td>
</tr>
<tr>
<td>Male</td>
<td>26 (26)</td>
<td>14 (23)</td>
<td>9 (26)</td>
<td>5 (25)</td>
</tr>
<tr>
<td>Age (years), mean (SD)</td>
<td>53.24 (11.55)</td>
<td>52.74 (10.67)</td>
<td>51.22 (10.67)</td>
<td>51.74 (11.63)</td>
</tr>
<tr>
<td>Type of cancer, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Breast cancer</td>
<td>39 (39)</td>
<td>27 (44)</td>
<td>18 (51)</td>
<td>8 (40)</td>
</tr>
<tr>
<td>Colon cancer</td>
<td>9 (9)</td>
<td>7 (11)</td>
<td>2 (6)</td>
<td>3 (15)</td>
</tr>
<tr>
<td>Ovarian or cervical cancer</td>
<td>6 (6)</td>
<td>3 (5)</td>
<td>2 (6)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Lung cancer</td>
<td>6 (6)</td>
<td>3 (5)</td>
<td>0 (0)</td>
<td>1 (5)</td>
</tr>
<tr>
<td>Others</td>
<td>40 (40)</td>
<td>22 (35)</td>
<td>13 (37)</td>
<td>8 (40)</td>
</tr>
<tr>
<td>Status of cancer treatment, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total removal</td>
<td>46 (46)</td>
<td>33 (53)</td>
<td>24 (69)</td>
<td>11 (55)</td>
</tr>
<tr>
<td>Recurrence or incomplete removal</td>
<td>25 (25)</td>
<td>15 (24)</td>
<td>6 (17)</td>
<td>5 (25)</td>
</tr>
<tr>
<td>Uncertain</td>
<td>3 (3)</td>
<td>1 (2)</td>
<td>1 (3)</td>
<td>2 (10)</td>
</tr>
<tr>
<td>Other</td>
<td>26 (26)</td>
<td>13 (21)</td>
<td>4 (11)</td>
<td>4 (20)</td>
</tr>
<tr>
<td>Highest education, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary school</td>
<td>3 (3)</td>
<td>2 (3)</td>
<td>2 (6)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Apprenticeship</td>
<td>22 (22)</td>
<td>16 (26)</td>
<td>5 (14)</td>
<td>5 (25)</td>
</tr>
<tr>
<td>Secondary education</td>
<td>41 (41)</td>
<td>21 (34)</td>
<td>14 (40)</td>
<td>7 (35)</td>
</tr>
<tr>
<td>University degree</td>
<td>33 (33)</td>
<td>22 (35)</td>
<td>14 (40)</td>
<td>7 (35)</td>
</tr>
<tr>
<td>Unknown</td>
<td>1 (1)</td>
<td>1 (2)</td>
<td>0 (0)</td>
<td>1 (5)</td>
</tr>
</tbody>
</table>

\(^a\)Distress Thermometer score ≥5.
\(^b\)Hospital Anxiety and Depression Scale anxiety score ≥8.
\(^c\)Hospital Anxiety and Depression Scale depression score ≥8.

**Effects**

The health outcome values at baseline and at week 20 as well as effect sizes for the total sample and the high distress, high anxiety, and high depression subsamples are presented in Table 2. Baseline distress was 5.29 (SD 2.31); therefore, patients were on average above an assumed clinically relevant threshold of 5, with 62% of patients (62/100) reporting a distress level of 5 or higher. At week 20, distress decreased to an average of 4.1 (SD 2.12; Hedge g=0.53). The mean HADS anxiety score at baseline was 6.88 (SD 3.50) and dropped to 6.31 (SD 3.78; Hedge g=0.16) at week 20. Overall, 35% (35/100) of patients reported an elevated HADS anxiety score (≥8) at baseline (mean 10.71, SD 1.95), which dropped to 8.85 (SD 3.50; Hedge g=0.68) at week 20. For HADS depression, the mean score at baseline was 4.96 (SD 2.78) and dropped to 4.55 (SD 3.31; Hedge g=0.14) at week 20. Overall, 20% (20/100) of patients reported an elevated HADS depression score (≥8) at baseline (mean 9.00, SD 1.12), which dropped to 8.85 (SD 3.50; Hedge g=0.61) at week 20. For the remaining measures without a proposed threshold (PROMIS, FACT-G, FMI, and FoP-Q-SF), changes from baseline to week 20 were small, with Hedges g effect sizes ranging from 0.04 to 0.33.
Table 2. Mean values of health outcomes at baseline and week 20, response rate (n), and effect sizes (N=100).

<table>
<thead>
<tr>
<th>Sample and outcome</th>
<th>Baseline</th>
<th>Week 20</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (SD)</td>
<td>n</td>
</tr>
<tr>
<td><strong>Total sample</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HADS(a) anxiety</td>
<td>6.88 (3.50)</td>
<td>99</td>
</tr>
<tr>
<td>HADS depression</td>
<td>4.96 (2.78)</td>
<td>100</td>
</tr>
<tr>
<td>Distress</td>
<td>5.29 (2.31)</td>
<td>99</td>
</tr>
<tr>
<td>PROMIS physfunc(b)</td>
<td>46.55 (6.54)</td>
<td>99</td>
</tr>
<tr>
<td>PROMIS anxiety(c)</td>
<td>55.97 (6.46)</td>
<td>99</td>
</tr>
<tr>
<td>PROMIS depression(d)</td>
<td>55.20 (6.81)</td>
<td>100</td>
</tr>
<tr>
<td>PROMIS fatigue(e)</td>
<td>56.11 (9.23)</td>
<td>99</td>
</tr>
<tr>
<td>PROMIS sleep(f)</td>
<td>51.44 (8.85)</td>
<td>100</td>
</tr>
<tr>
<td>PROMIS social(g)</td>
<td>48.42 (7.64)</td>
<td>99</td>
</tr>
<tr>
<td>PROMIS pain(h)</td>
<td>52.88 (9.10)</td>
<td>97</td>
</tr>
<tr>
<td>FACT-G(i)</td>
<td>75.54 (13.85)</td>
<td>99</td>
</tr>
<tr>
<td>FMI(j)</td>
<td>38.46 (6.62)</td>
<td>96</td>
</tr>
<tr>
<td>FoP(k)</td>
<td>31.33 (7.83)</td>
<td>93</td>
</tr>
<tr>
<td><strong>High distress(l)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distress</td>
<td>6.79 (1.36)</td>
<td>62</td>
</tr>
<tr>
<td><strong>High anxiety(m)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HADS anxiety</td>
<td>10.71 (1.95)</td>
<td>35</td>
</tr>
<tr>
<td><strong>High depression(n)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HADS depression</td>
<td>9.00 (1.12)</td>
<td>20</td>
</tr>
</tbody>
</table>

\(a\)HADS: Hospital Anxiety Depression Scale; negative effect=improvement.
\(b\)PROMIS physfunc: Patient-Reported Outcomes Measurement Information System Physical Function; positive effect=improvement.
\(c\)PROMIS anxiety: Patient-Reported Outcomes Measurement Information System Anxiety; negative effect=improvement.
\(d\)PROMIS depression: Patient-Reported Outcomes Measurement Information System Depression; negative effect=improvement.
\(e\)PROMIS fatigue: Patient-Reported Outcomes Measurement Information System Fatigue; negative effect=improvement.
\(f\)PROMIS sleep: Patient-Reported Outcomes Measurement Information System Sleep Disturbance; negative effect=improvement.
\(g\)PROMIS social: Patient-Reported Outcomes Measurement Information System Ability to Participate in Social Roles and Activities; positive effect=improvement.
\(h\)PROMIS pain: Patient-Reported Outcomes Measurement Information System Pain Interference; negative effect=improvement.
\(i\)FACT-G: Functional Assessment of Cancer Therapy—General; positive effect=improvement.
\(j\)FMI: Freiburg Mindfulness Inventory; positive effect=improvement.
\(k\)FoP: Fear of Progression; negative effect=improvement.
\(l\)Distress Thermometer score ≥5; negative effect=improvement; n=62.
\(m\)HADS anxiety score ≥8; negative effect=improvement; n=35.
\(n\)HADS depression score ≥8; negative effect=improvement; n=20.

The results for effects over time are presented in Table 3. LMM analyses revealed that there was a significant decrease over time in distress (\(P<.001\)), fatigue (\(P=.01\)), sleep disturbance (\(P=.02\)), and anxiety (\(P=.04\)) measured with the HADS. Furthermore, there was a significant increase in quality of life (\(P=.03\)) and mindfulness (\(P<.001\)). No significant effects were found for physical functioning, anxiety measured with PROMIS, depression, ability to participate in social roles and activities, and fear of progression. LMM analyses for the subsamples revealed that distress decreased significantly in the high distress subsample (\(P<.001\)), anxiety decreased significantly in the high anxiety subsample (\(P=.001\)), and depression decreased significantly in the high depression subsample (\(P=.03\)). Dose-response analyses using LMMs with group-by-time revealed no significant results.
Table 3. Linear mixed models: estimates of fixed effect of time on health outcomes from baseline to week 20.

<table>
<thead>
<tr>
<th>Sample and dependent variable</th>
<th>Estimates of fixed effects (time)</th>
<th>t test (df)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Estimate (95% CI)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total sample (N=100)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HADS anxiety</td>
<td>−0.40 (−0.79 to −0.01)</td>
<td>−2.04 (201.95)</td>
<td>.04</td>
</tr>
<tr>
<td>Distress depression</td>
<td>−0.29 (−0.62 to 0.04)</td>
<td>−1.71 (206.42)</td>
<td>.09</td>
</tr>
<tr>
<td>Distress</td>
<td>−0.41 (−0.62 to −0.21)</td>
<td>−3.96 (325.86)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>PROMIS physfuncb</td>
<td>−0.13 (−0.68 to 0.43)</td>
<td>−0.45 (318.35)</td>
<td>.66</td>
</tr>
<tr>
<td>PROMIS anxietyc</td>
<td>−0.46 (−1.09 to 0.18)</td>
<td>−1.42 (325.74)</td>
<td>.16</td>
</tr>
<tr>
<td>PROMIS depressiond</td>
<td>−0.52 (−1.11 to 0.07)</td>
<td>−1.72 (324.81)</td>
<td>.09</td>
</tr>
<tr>
<td>PROMIS fatigued</td>
<td>−1.15 (−2.02 to −0.28)</td>
<td>−2.61 (324.73)</td>
<td>.01</td>
</tr>
<tr>
<td>PROMIS sleepf</td>
<td>−0.85 (−1.55 to −0.15)</td>
<td>−2.39 (322.65)</td>
<td>.02</td>
</tr>
<tr>
<td>PROMIS socialg</td>
<td>0.43 (−0.15 to 1.01)</td>
<td>1.45 (314.63)</td>
<td>.15</td>
</tr>
<tr>
<td>PROMIS painh</td>
<td>−0.14 (−0.94 to 0.66)</td>
<td>−0.34 (322.51)</td>
<td>.74</td>
</tr>
<tr>
<td>FACT-Gi</td>
<td>1.13 (0.10 to 2.15)</td>
<td>2.16 (307.58)</td>
<td>.03</td>
</tr>
<tr>
<td>FMIj</td>
<td>1.11 (0.62 to 1.59)</td>
<td>4.46 (300.46)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>FoPk</td>
<td>−0.68 (−1.56 to .20)</td>
<td>−1.52 (180.05)</td>
<td>.13</td>
</tr>
<tr>
<td><strong>High distressl (n=62)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distress</td>
<td>−0.81 (−1.05 to −0.57)</td>
<td>−6.64 (200.45)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td><strong>High anxietym (n=35)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HADS anxiety</td>
<td>−1.13 (−1.77 to −0.48)</td>
<td>−3.47 (81.69)</td>
<td>.001</td>
</tr>
<tr>
<td><strong>High depressionn (n=20)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HADS depression</td>
<td>−0.87 (−1.65 to −0.09)</td>
<td>−2.23 (47.99)</td>
<td>.03</td>
</tr>
</tbody>
</table>

**a**HADS: Hospital Anxiety Depression Scale.
**b**PROMIS physfunc: Patient-Reported Outcomes Measurement Information System Physical Function.
**c**PROMIS anxiety: Patient-Reported Outcomes Measurement Information System Anxiety.
**d**PROMIS depression: Patient-Reported Outcomes Measurement Information System Depression.
**e**PROMIS fatigue: Patient-Reported Outcomes Measurement Information System Fatigue.
**f**PROMIS sleep: Patient-Reported Outcomes Measurement Information System Sleep Disturbance.
**g**PROMIS social: Patient-Reported Outcomes Measurement Information System Ability to Participate in Social Roles and Activities.
**h**PROMIS pain: Patient-Reported Outcomes Measurement Information System Pain Interference.
**i**FACT-G: Functional Assessment of Cancer Therapy—General.
**j**FMI: Freiburg Mindfulness Inventory.
**k**FoP: Fear of Progression.
**l**Distress Thermometer score ≥5.
**m**HADS anxiety score ≥8.
**n**HADS depression score ≥8.

**Adoption**

According to our definition, 25% (25/100) of all enrolled patients used the app continuously (ie, at least one completed exercise per week) at week 20 of the intervention. The average number (median) of completed exercises during the 20-week intervention for all patients as well as continuous app users is presented in Figure 2. Across all patients, the median of completed exercises was 2 during the first week and dropped to 0 at week 9. For continuous app users, who completed an app exercise at least once per week until week 20, the median of completed exercises at week 1 was 6. For the subsequent weeks up to week 20, the median of completed exercises varied between a median of 3 and 5 for the continuous app users.

The percentage of completed exercises is presented in Figure 3. All patients together completed 3526 exercises. Mindfulness meditation was used most often, with a total of 1633 completed.
exercises (46.31%), followed by guided imagery with 1077 completed exercises (30.55%). Progressive muscle relaxation was used least frequently, with 816 completed exercises (23.14%). In both mindfulness meditation and guided imagery, the female narrator voice was preferred.

Furthermore, female patients showed a preference for exercises with a female narrator (1935 completed exercises with a female narrator vs 1031 completed exercises with a male narrator). However, male patients preferred exercises with a male narrator (389 completed exercises with a male narrator vs 171 completed exercises with a female narrator). The probability of choosing the same sex in audio files is therefore increased for women by 87% and for men by 127%, which corresponds to a 2-fold higher preference for the same sex as the narrator.

Figure 2. Completed app exercises by all enrolled patients (N=100) and by continuous app users (n=25) per week (median).

Figure 3. Completed exercises (3526) of all patients (N=100) over 20 weeks by type (mindfulness meditation, guided imagery, and progressive muscle relaxation), gender of patient (male and female), and sex of narrator (male and female). Percentages refer to the total number of exercises per gender.
Implementation

A total of 5 health professionals took part in an interview: 2 female nursing experts (one from an inpatient unit and the other from an outpatient oncology unit), 2 female MBM psychologists, and 1 male oncologist. Interviews were conducted between January and March 2018 and lasted for an average of 45 minutes (SD 9.54). The qualitative analysis of the interviews yielded 4 themes: (1) general impression of the app, (2) suggestions for improvement, (3) implementation in standard care, and (4) experience with recommending the app to patients.

Overall, the general impression of the app was positive. For instance, the oncologist summarized his impression of the app as follows:

"I think [the app] is a very helpful thing because it is relatively easy [to use]. You can test it. You can try it and if you like it, you can integrate it relatively easy into everyday life. I think it is very practical. It is a practical thing and if patients are interested, I also see that they take it up willingly."

All health professionals perceived the app as appealing, clearly structured, and as a helpful supportive tool. In addition, the MBM psychologists liked the app as an addition to the 10-week face-to-face MBM course and appreciated the app as a good self-help tool complementing the course. The oncologist also stated that many patients with cancer look for something they can use to add to standard care and an app can provide a low threshold aid. As a negative aspect, a nursing expert stated that a smartphone is required and not every patient possesses such a device.

All health experts made various suggestions for improving the app. A shared opinion was that the content of the app (ie, number and variety of exercises) could be increased, as over an extended period, patients might get bored with a choice limited to 3 exercises. A nursing expert suggested that a new exercise could, for instance, be unlocked after completing the same exercise several times. An MBM psychologist suggested that every week, a different selection of exercises could be activated with alternating topics such as meditation, relaxation, self-compassion, or body exercises. In addition, the inclusion of exercises with different degrees of complexity was suggested. An MBM psychologist stated that exercises for beginners (eg, more detailed instructions, fewer moments of silence) as well as exercises for patients experienced in mindfulness and relaxation could be added. MBM psychologists and nursing experts also recommended that some exercises should be accompanied by soothing background music because longer periods of silence might be uncomfortable for some patients. They also recommended exercises with various lengths of time so that patients had more flexibility if they were facing time constraints or if they were too impatient for longer exercises.

The oncologist mentioned that adding exercises specifically for sleep disorders might be a good addition to the app, especially for inpatients, because poor sleep in hospitals is very common. As an additional topic that could be added, he mentioned body exercises such as yoga. An MBM psychologist mentioned that an app mirroring the MBM course more closely would be great:

"If I could make a wish, then I would say, it would be totally cool to have an accompanying Mind Body Medicine app. That is to say that a lot of exercises—not all of them—but a lot of exercises we do [could be added to the app]. Possibly also guided body exercises. That would be totally cool."

The interviewees mentioned several factors that could influence the implementation of a mindfulness- and relaxation-based app into standard care. Both nursing experts and one of the MBM psychologists stated that the time point when the information of the app is delivered to the patient might be important. These health professionals mentioned that the patients were bombarded with information during the first consultation or during the first day when a patient enters the hospital and additional information about the app might overwhelm some patients. The outpatient nursing expert also mentioned that they are often limited because of time constraints during consultation hours:

"On the one hand there are the concerns of the patients, which you have to discuss. But you also have a little bit of pressure, [to tell them] all relevant information. [...] And sometimes it’s already two minutes before the end [of the consultation]. [...] And you can’t just hand out the flyer. You also need to say a few words [about the app] and that’s why I sometimes forgot [to mention the app]. Due to shortage of time."

The nursing experts also mentioned that the nurses oftentimes forgot about the app because it is not part of standard care. Therefore, the nursing experts stated that it might be helpful to better inform the nurses about the app and setting up standards regarding the communication about the app, for example, when to inform the patients and how. In addition, the nursing experts stated that it might be helpful if they had a demonstration device at the oncology unit so that they could better explain the app to the patients. All interviewed health professionals further mentioned that patients with cancer are very diverse and that although some patients are very eager to try out various treatments, others are not. One MBM therapist also stated that not all patients perceive relaxation as important and that those patients might need some additional information which indicates why relaxation is good for them. All health professionals also stated that implementing such an app does not result in a lot of additional work for them and they appreciate the app, which they could recommend to suitable patients.

Regarding their experience with recommending the app to patients, health professionals shared the opinion that female patients are more drawn to mindfulness and relaxation exercises. Furthermore, the MBM therapists stated that patients who already practiced some form of relaxation or meditation often did not participate in the study. The MBM therapists also noticed that the composition of the MBM group had an influence on how many patients were willing to try out the app. For instance, if one patient was very motivated and expressed interest in the app, hesitant patients sometimes followed suit and were willing to try the app as well. One MBM therapist also noticed that many older people were willing to use the app:
I was surprised that so many older patients had the app on their phone and also used the app regularly. [...] I had the impression, that it appeals to the young. [...] But oftentimes, the older people have more time, because they don’t work anymore.

Discussion

Principal Findings

In this study, we explored the feasibility of a mindfulness- and relaxation-based self-help app for patients with cancer. To evaluate the feasibility, we used the RE-AIM framework [37], and in this analysis, we focused on the framework dimensions effectiveness, adoption, and implementation. Our findings support the feasibility of this mHealth intervention. The results indicate that the intervention might have beneficial effects on patients’ distress and quality of life. Furthermore, the mHealth intervention is accepted by the target population as well as by health professionals.

For the dimension effectiveness, we looked into pre-post effects. Our results suggest that the app might have the potential to reduce distress, fatigue, sleep disturbance, and anxiety as well as improve health-related quality of life and mindfulness. This is in line with a recent pilot study [47], in which a mobile mindfulness-based stress reduction program improved, among others, stress, anxiety, depression, sleep quality, quality of life, and mindfulness in patients with breast cancer with small to large effects. Furthermore, a recent randomized controlled trial conducted by Kubo et al [48] assessed the feasibility of a commercially available mindfulness program in which they targeted patients with cancer and their caregivers. This program leads to an increase in quality of life in patients with cancer with a medium effect size [48]. Similar to these findings, Rosen et al [49] reported that the quality of life of patients with breast cancer improved with a small effect size using a commercially available mindfulness course when compared with a control group.

As depressive symptoms and anxiety were not significantly reduced in the total sample in our study, we also looked at subsamples with higher HADS scores. In the high anxiety and high depression subsamples, anxiety and depression, respectively, decreased significantly over time. This might indicate that a mindfulness and relaxation mHealth intervention is especially beneficial for patients with cancer with higher emotional distress. This is also in line with a study by Barth et al [50], where highly distressed patients benefited most from psycho-oncological interventions. However, we did not find any group effects when comparing continuous app users with intervention dropouts. This might indicate that our definition of users and dropouts is not precise enough or that another variable than time spent practicing is responsible for changes in outcomes.

For adoption, our results showed that at week 20 of the intervention, 25 of 100 patients were using the app continuously. With 54 of 100 continuous app users at week 10 [36], this leads to a dropout rate of approximately 50% every 10 weeks. The 25 continuous app users practiced on average 3 to 5 times per week (median), which comes close to our initially stated recommendation of 5 exercises per week. We consider this a good adoption of the mHealth intervention because the intervention was set up as a self-care intervention without the involvement of a therapist or health professional. Mindfulness was the preferred exercise, followed by guided imagery and progressive muscle relaxation. However, mindfulness meditation exercises were also presented as the first choice in the app, whereas guided imagery was placed at the second position, and progressive muscle relaxation was placed at the third position. Therefore, the preference for mindfulness meditation could also be caused by the placement of the exercises in the app. These results regarding adoption are comparable with those of a study conducted by Kubo et al [48], in which patients with cancer received access to the commercially available mindfulness app Headspace (TM). In this study, 40 of 54 patients with cancer allocated to the intervention group completed the 8-week study, and 20 patients with cancer used the app on at least 50% of the days [48].

The results from the interviews with health professionals provide some insights into the implementation of a mindfulness and relaxation mHealth intervention into standard care. In general, all interviewed health professionals perceived the app as a helpful addition to standard care. The health professionals also suggested some improvements, which might increase the acceptance and long-term use of such mHealth interventions by patients. A suggested improvement shared by all health professionals is the increase in the content of the app, such as additional exercises or variations of the exercises. A statement about the implementation of the mHealth intervention given by several health professionals was the adequate provision of information. One of the interviewed MBM psychologists as well as the nursing experts stated that patients with cancer are, on the other hand, flooded with information, especially when they start their treatment. However, the provision of some information to the patients about a mHealth intervention is necessary, at least to let the patients get informed about the existing intervention. On the other hand, nursing experts also mentioned that nurses often forgot about the intervention, although they approve this kind of intervention. Therefore, a standardized procedure for informing patients about the mHealth intervention might facilitate the implementation of the intervention. In addition, health professionals such as nurses might have to be informed regularly about such interventions because it is not part of their standard treatment; therefore, they might forget about it, as seen in this study. Regarding the recruitment process, the health professionals made the observation that female patients were more interested in this mHealth intervention as compared to men. Therefore, the preference for mindfulness meditation could also be caused by the placement of the exercises in the app. These results regarding adoption are comparable with those of a study conducted by Kubo et al [48], in which patients with cancer allocated to the intervention group completed the 8-week study, and 20 patients with cancer used the app on at least 50% of the days [48].

Strengths, Limitations, and Future Directions

This study has several strengths and limitations. A strength of the study is the collection of objective data in the form of subjective responses and self-reports.

https://cancer.jmir.org/2021/1/e16785
logging the exercise use for each patient over the course of 20 weeks. Therefore, data on using the app exercises were not biased through self-report. Another advantage of this study was the use of a mixed methods approach, which is recommended for the development of digital interventions [54].

A limitation of the study is that we did not have a control group. Therefore, the effectiveness of the app cannot be determined in this study because regression to the mean could have an impact on the improvement of well-being. Furthermore, we used paper-and-pencil questionnaires, which might have led to more missing data compared with web-based questionnaires [55]. However, this was compensated by using LMM analyses, which take into account all patients who provided baseline data.

Another limitation is that we did not assess whether patients were practicing mindfulness and relaxation exercises without the app, which could have an effect on the assessed outcomes.

Therefore, future studies should investigate this topic with a randomized controlled trial to determine the effectiveness of a mindfulness and relaxation mHealth intervention. Our study provides some insights regarding the effects that might be expected in a similar study, which will be helpful to power future studies sufficiently. We also looked at aspects of implementing an mHealth intervention. All interviewed health professionals perceived such an mHealth intervention as a helpful addition to standard care, but as described earlier, they also stated barriers to the implementation of such an intervention, which should be investigated in future studies. Future studies could also investigate an mHealth intervention with more content than in this study app, as suggested during the interviews by health professionals. For instance, audio files with background music or exercises with variations in their duration could be added. In addition to mindfulness and relaxation exercises, physical exercise programs could be added. Physical exercise can have beneficial effects on symptoms of patients with cancer [56], and physical exercise has already been implemented in mHealth apps for patients with cancer [57].

Conclusions

The results of this observational feasibility study indicate that a mindfulness and relaxation app can be a feasible and an effective way to deliver a self-care intervention for patients with cancer. Our results indicate that such an intervention might be especially beneficial for highly distressed patients with cancer. The appeal of such an app could be increased with more diverse content, which might also positively affect the adherence of patients to such an intervention. The effectiveness and further aspects regarding the implementation of such an mHealth intervention should be investigated in a future randomized controlled trial.

Acknowledgments

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Conflicts of Interest

None declared.

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Abbreviations

FACT-G: Functional Assessment of Cancer Therapy–General
FMI: Freiburg Mindfulness Inventory
FoP-Q-SF: Fear of Progression Questionnaire-Short Form
HADS: Hospital Anxiety and Depression Scale
LMM: linear mixed model
MBM: mind-body medicine
mHealth: mobile health
PROMIS-29: 29-item Patient-Reported Outcomes Measurement Information System
RE-AIM: Reach, Effectiveness, Adoption, Implementation, and Maintenance

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