Research Protocol Paper

A pre-post study of using mental health apps in breast cancer patients and their caregivers in the USA: a pilot study protocol

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ABSTRACT

Background: Over a third of cancer patients experience clinically significant mental distress, and distress in caregivers can exceed that of the cancer patients for whom they care. There is an urgent need to identify scalable and cost-efficient ways of delivering mental health interventions to cancer patients and their loved ones.

Objective: This study describes the protocol to pilot a mobile app-based mental health intervention for breast cancer patients and caregivers.

Methods: The IntelliCare mental health apps are grounded in evidence-based research in psychology. They have not been examined in cancer populations. This pilot study will adopt a within subject, pre-post study design, to inform a potential phase III randomized-controlled trial. A target sample of 50 individuals (with roughly equal numbers of patients and caregivers) at least 18 years of age and fluent in English will be recruited at a U.S. NCI-designated Clinical Cancer Center. Consent will be obtained in writing and smartphones will be provided if needed. Self-report surveys assessing mental health outcomes will be administered at a baseline session and after 7 week intervention. Before using the apps, participants will receive a 30-minute coaching call to explain their purpose and function. A 10-minute coaching call 3 weeks later will check on user progress and address questions or barriers to use. Self-report and semi-structured interviews with participants at the end of the study period will focus on user experience and suggestions for improving the apps and coaching in future studies.

Results: This project is ongoing and data collection will be completed by the end of 2018.

Conclusions: Results from this study will inform how scalable smartphone-delivered programs can be used to support breast cancer patients and their loved ones.

Trial registration: ClinicalTrials.gov (Identifier: NCT03488745; Date Registered: April, 2018)

Keywords: cancer; caregivers; mental health; mHealth
INTRODUCTION

In the U.S., an estimated 266,120 new cases of invasive breast cancer are expected to be diagnosed in 2018 [1]. Breast cancer is the most common form of cancer in women and the second leading cause of cancer-related death in women. In the U.S., over 40% of newly diagnosed breast cancer patients report clinically significant distress [2]. Cancer affects not only patients, but also their caregivers, which can include a partner, relative, or friend. Responsibilities directly (e.g., coordinating care) and indirectly (e.g., providing emotional support) linked to their loved one’s care leaves caregivers at high risk for burnout [3]. This is alarming since a high level of caregiver distress predicts a lower level of patient well-being [4]. However, despite levels of psychological distress that can exceed those of the cancer patients for whom they care [4], caregivers of cancer patients remain an underserved, yet vulnerable, population. Thus, there is an urgent need to identify ways to provide supportive care to both cancer patients and their loved ones.

While distress screening has become standard practice for many cancer programs, distress intervention through mobile technology remains an important need. Community and healthcare organizations are important providers of support services for both cancer patients and their caregivers. Many of them are beginning to provide services through virtual means such as the phone and Internet. However, existing models of psychosocial intervention that are heavily reliant on human support are costly and not readily scalable to large populations. For example, on-demand phone helplines need to be constantly staffed by nurses or mental health professionals, and are limited in their ability to address the needs of a large and growing cancer population in the U.S. Given that over 77% of American adults own a smartphone [5], it is an ideal platform from which to deliver brief, empirically-supported interventions to anyone that needs them. Mental health apps are easily scalable and can provide tailored interventions when and where they are most needed.

Despite the promise of smartphone mental health apps, significant issues need to be addressed before making them widely available to cancer populations. Although researchers are increasingly examining the efficacy and effectiveness of mental health apps, few publicly available apps have any empirical evidence supporting them [6], and even fewer have been validated in cancer populations. Most health-related apps suffer from poor usability since they require lengthy engagement times that do not match user preferences. In reality, people use apps in short, frequent time bursts, and prefer apps that support a single or limited set of tasks [7]. Providing brief and targeted interventions is particularly important for cancer patients and caregivers since the demands of treatment often leave them with small pockets of time throughout the day. Importantly, pairing an app with light coaching can further increase motivation and adherence. In contrast to the majority of support apps that do not provide human assistance, light phone coaching can increase adherence by focusing on how apps can address people’s needs and by identifying obstacles to effective use [8].

The purpose of the present investigation is to conduct a pilot study that uses a set of brief, targeted app-delivered interventions that promote mental health. IntelliCare is a collection of apps that utilize an elemental, skills based approach to improving mental health [9].
Users can download up to 12 publicly available apps, each of which targets a specific aspect of mental health and well-being (e.g., identifying maladaptive thoughts, promoting sleep, and increasing relaxation skills). The apps are designed to be interactive and intuitive. Users can complete many exercises (e.g., identifying and challenging an unhelpful thought) in less than a minute. Exercises require few instructions to complete and are usually found on the first screen that is presented. Each IntelliCare app has a “Help” feature that contains educational and technical content regarding the specific app in question. See Table 1 for a description of IntelliCare apps and their objectives.

IntelliCare apps are available on both Android and iPhone stores. Those from the general public who download the apps are free to use the apps as desired [10]. In the current study, participants are instructed to systematically try 1-2 apps per week and retain the ones that are most helpful to them. The purpose of this strategy is to gradually expose participants to all of the apps in a systematic manner. This mirrors face-to-face cognitive behavioral therapy in which clients are encouraged to acquire skills through practice. In an 8-week study with light phone coaching, over 90% of users with elevated depression and anxiety symptoms used the apps an average of 195 times, for an average length of 1 minute [9]. In this initial study, IntelliCare app usage was notably higher than that of other intervention apps. It was also found that using the apps led to large and significant decreases in depression and anxiety symptoms⁹. However, the acceptability, usability, and potential impact of IntelliCare apps in cancer patients and caregivers is unknown. Cancer patients and caregivers are faced with the multiple physical and emotional sequelae of cancer treatment, making them potentially unique from other populations. In order to understand whether mental health apps can benefit cancer populations it is important to understand their preferences for using them.

Table 1.
Description of IntelliCare apps and their objectives.

<table>
<thead>
<tr>
<th>App Name</th>
<th>Objective</th>
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<tbody>
<tr>
<td>Aspire</td>
<td>Promote awareness of and striving toward personal goals and values. Helps users identify their values and keep track of their progress.</td>
</tr>
<tr>
<td>Day to Day</td>
<td>Promote knowledge about ways to bolster mood. Users receive a daily stream of knowledge tidbits and are prompted to build on a theme every day (e.g., cultivate gratitude, problem solve).</td>
</tr>
<tr>
<td>Daily Feats</td>
<td>Promotes goal setting and attainment. An in-app built calendar allows users to track their successes and identify new tasks to complete.</td>
</tr>
<tr>
<td>Worry Knot</td>
<td>Promotes knowledge about worry and provides an interactive exercise to decrease worry. The app also tracks the user’s progress and provides tailored feedback on ways to distract oneself from worrying thoughts.</td>
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Social Force Encourages users to identify supportive individuals in their life. The app prompts users to reach out to these people for encouragement.

My Mantra Increases self-efficacy and a positive perspective of oneself. The app prompts users to come up with personal mantras and to construct personalized photo albums that serve as reminders of these mantras.

Thought Challenger Increases the ability to identify and challenge negative thinking patterns. Guides users through a cognitive restructuring exercise and tracks the output of past exercises.

iCope Promotes coping and positive reinforcement by having users write and send themselves encouraging messages when they are most needed.

Purple Chill Increases relaxation skills by providing a library of mindfulness and guided meditation audio files.

MoveMe Promotes mood through physical activity. The app prompts users to schedule exercises throughout the day/week and provides instructional videos and lessons to increase motivation to exercise.

Slumber Time Promotes healthy sleeping by prompting users to keep an active sleep diary. The app also provides a checklist of things to do before bedtime to promote healthy sleep habits.

Boost Me Promotes positive mood by having users schedule positive activities throughout the day. A mood tracker allows users to see their progress and the impact of different activities on their mood.

METHODS

Study Design

The purpose of this investigation is to conduct a pilot study to inform a potential phase III randomized-controlled trial. Consistent with prior definitions and reasons for conducting a pilot study (11, 12), the goals of the present study are to: a) assess the feasibility of various components (e.g., recruitment rates, retention rates, refusal rates) that need to take place in a larger study; b) understand and identify potential human and data optimization issues (e.g., issues of managing the study in a busy clinic, identifying challenges to recruitment from doctors and nurses, whether data show too much or too little variability); and c) examine whether participants respond to the intervention and to obtain estimates of the treatment effects and the variances of treatment effects. Importantly, a pilot study is not
only concerned with whether something can be done and how to proceed, but includes implementing something in a way intended in part of a future study [11]. This single-group, 7-week pre and post-test pilot study will provide IntelliCare apps to a sample of breast cancer patients and caregivers in the U.S. A mixed-methods approach utilizing self-report measures and qualitative interviews will be used to evaluate user satisfaction and potential for adoption in a larger and more diverse cancer population. Passively collected app usage data (i.e., app launches and app session duration) will inform our understanding of engagement with the apps among cancer patients and caregivers.

**Participants**

To limit barriers to entry, inclusion criteria are limited to the following: 1) breast cancer patient or informal caregiver (i.e., not receiving compensation for providing care); 2) at least 18 years of age; 3) proficient in English at a 6th-grade level; 4) has a smartphone or is willing to carry one around if provided. Participants are not required to have a minimum level of familiarity with mobile devices or technology. Participants will be eligible to receive a $50 gift card for providing user feedback at the end of the study.

A target sample size of 50 (25 patients, 25 caregivers) was chosen given the exploratory nature of this study. The primary objective of this study is to inform the feasibility of a larger RCT trial in a clinical setting. Data on usability and user experience from this sample will enable researchers to make iterative changes for future studies. A secondary objective of this study is to provide effect size estimates for a future trial. For reference, an effect size of $d=1.4$ for change in depression and anxiety symptoms was found in a prior non-cancer sample$^9$ at 80% power. However, it may not be appropriate to generalize an effect size from a symptomatic depressed sample to an unselected cancer population. The smallest effect size that can be detected with a sample size of 51, using paired $t$-tests with 80% power and alpha of .05, is $d=.40$. The smallest effect sizes that can be detected with sample sizes of 35 and 40, using paired $t$-tests with 80% power and alpha of .05, is $d=.49$ and $d=.45$, respectively.

**Materials**

Participants will use their own personal smartphone (Android or iPhone). Those who do not own a smartphone or have an incompatible device will be provided with a Samsung S7 Android phone with an unlimited data plan. Those who are provided a phone will be able to use it for non-study purposes. A concerted effort was made to include both Android and iPhone users into the study given differences between users of these platforms in some prior work [13]. All IntelliCare apps are currently available for Android users, and a subset of iPhone apps are available (as of March, 2018) although more are planned for release shortly.

**Recruitment Procedure**

Breast cancer patients and their caregivers will be recruited from a breast care clinic. Surgical oncologists will help to identify potential participants, who will be introduced to the study during a normal scheduled visit. Interested individuals will receive a flyer that contains information about the general purpose of the study and contact information of study personnel. Research staff will carefully guide eligible individuals through the
consenting process. Research staff will describe the aims of the study, introduce the IntelliCare apps, and review the study timeline. Infographics will serve as visual aids to improve understanding of the study components and timeline. Individuals who provide written consent will schedule a 30-minute coaching call to take place sometime within the next ten days. They will also be guided to download the apps but will be told not to open them until the coaching call. Downloading the apps at the end of the consenting process will allow coaching calls to be kept to within the allotted 30-minute timeframe. Participants will also have the option to download a separate app that passively collects location and movement data from their phone’s sensors. This app was developed by University of Virginia researchers [14] and has been used to collect location and movement data in college student samples [15]. Data collected from this app will be used in exploratory analyses to determine whether it is possible to identify behavioral markers of mood and well-being. Participants will be asked to spend 10-15 minutes to complete a measures that assess depression and anxiety symptoms, physical and social functioning, and subjective well-being. Measures will be completed online using Qualtrics through a desktop or laptop computer provided by research staff. Recruitment will cease if the target enrollment is met or funding expires at the end of 2018.

Phone Coaching

A coaching protocol was developed, based on the Efficiency Model of Behavioral Intervention Technology (BIT) Support* and supportive accountability [16]. A similar coaching protocol has been implemented in prior studies in the U.S. using IntelliCare apps [9]. The primary aims of coaching are to address usability issues, increase engagement with the apps, promote fit by assessing participants’ needs, promote knowledge acquisition of the skills found in the apps, and encourage implementation of the skills in participants’ lives. An initial 30-minute coaching call will focus on orienting participants to downloading and using the apps, setting expectations of the coach’s role, assessing how the apps may meet participants’ needs, and building rapport. Participants will also be told that they can contact coaches at any time with any app-related questions. Participants who contact coaches for crisis management will be connected with a nearby mental health service provider. Any participant inquiries will receive a response within 1 working day. Following the initial coaching call, participants will receive a text message (via Qualtrics Short Message Service tool) every week to remind them to download and try 1-2 new IntelliCare apps. Coaches have at least a bachelor’s degree and are trained and monitored by one of the authors with a background in mental health assessment (PC). Coaches received a detailed coaching manual and will attend weekly supervision meetings throughout the duration of the trial.

To encourage engagement with the apps, coaches will refrain from making explicit recommendations regarding which apps to use and how often to use them. Instead, following prior work [9], coaches will instruct participants to review the apps, remind them of their needs and goals, and ultimately allow participants to make their own decisions regarding which apps to use. If participants are resistant to making their own decision regarding which apps to use, coaches will be permitted to give recommendations. Precautions were made to help ensure that coaching calls focus on the app intervention program (i.e., providing a detailed and scripted coaching manual, intensive training on how
to direct conversation to focusing on app usage, fit, and adherence). Finally, a 10-minute phone call 3 weeks after the initial coaching call will serve as a check-in to make sure that participants have a clear understanding of the app program and to answer any lingering questions.

**Measures and Outcomes**

**Primary Objective and Measures**

Because a significant barrier to conducting this study is the enrollment of participants in a busy clinical setting, we will consider the study feasible if: a) we are able to recruit 1-2 participants per week from a single clinic, over 30 weeks; b) complete follow-up in at least 50% of all recruited subjects; and c) observe a median app launch rate of at least 3.0, as found in prior work [9]. Participants will be asked to provide feedback on the apps and coaching at the end of the study period. The USE [17]-short form will be used to examine usability of the IntelliCare apps. It is composed of 21 items that assess user experience (e.g., ‘I would recommend it to a friend’, ‘It is easy to learn to use it’, ‘It is simply to use’). Items are scored on a 7-point Likert scale (1=strong disagree, 7=strongly agree). The USE measure is a well-validated scale that is commonly used to evaluate user experience of digital interventions. Participants will be asked to describe the most positive and negative aspects of the apps, and which apps were most and least helpful and why. If participants stopped using the apps, they will be asked to comment on reasons why and barriers to using the apps.

Participants will also be asked to provide open-ended feedback. Research staff will conduct telephone interviews with participants which will cover the following topics related to using the apps: general impressions, design quality, technical needs, design suggestions to promote app implementation and usage. In addition, participants will be asked to provide feedback on the following aspects of phone coaching: general experience with coaches, usefulness of coaching, additional or unmet coaching needs, suggestions to improve the coaching experience. Thematic analysis will be used to analyze qualitative data gathered from interviews. Data yielded from this mixed methods approach will be used to make improvements to the apps and phone coaching in future work.

**Secondary Objectives and Measures**

Several measures will be administered at part of the study, at baseline and 7 weeks later. Demographic and background variables (e.g., age, gender, race/ethnicity) will be collected at the baseline session. Disease variables (e.g., cancer site, stage, treatments) will also be collected from the patient’s electronic medical record. Measures will be administered and completed online via a secure data collection website (Qualtrics). Data are stored in a secure database that is only accessible to study personnel to ensure confidentiality.

Depression symptoms will be assessed with the 4-item scale from the Patient-Report Outcomes Measurement Information System (PROMIS; 18) 29 item profile version 2.0 (PROMIS-29 Profile v2.0). PROMIS, a U.S. National Institutes of Health (NIH) Roadmap program, provides sensitive and reliable measures of patient-reported outcomes. A goal of
PROMIS is to allow for organized and effective assessment of patient-reported outcomes across a range of chronic diseases. Participants are asked to report (1=never; 5=always) the degree to which they experienced various depressed states (e.g., ‘I felt worthless’, ‘I felt hopeless’) over the past 7 days. Continuous anxiety symptoms will be assessed with the 4-item scale from the PROMIS-29 Profile v2.0. Participants are asked to report (1=never; 5=always) how much they have experienced different anxious states (e.g., ‘My worries overwhelmed me’, ‘I felt fearful’) over the past 7 days.

The Patient Health Questionnaire-4 (PHQ-4; 19) will be administered to examine whether using mental health apps leads to a clinically significant decrease in mood symptoms. The PHQ-4 will be used to classify individuals based on the severity of their mood symptoms at baseline and post-assessment. The PHQ-4 is a 4-item scale that is well-validated in both general and clinical samples [19, 20]. Individuals are asked to rate (0=not at all; 3=nearly every day) the degree to which they have experienced different states (e.g., ‘Little interest or please in doing things’) over the past 2 weeks. Scores range from 0-12. A score of 6-8 indicates moderate mood symptoms whereas a score of 9 and higher indicates severe mood symptoms.

Several measures will be administered to both patients and caregivers. Life meaning will be assessed with the 4-item PROMIS [18] Life Meaning/Purpose scale. Participants are asked to report (1=not at all; 5=very much) the degree to which they agree with 4 statements (e.g., ‘my life has meaning’, ‘I have a clear sense of direction in life’). Sleep quality will be assessed with the 4-item PROMIS [18] Sleep Disturbance scale from the PROMIS-29 Profile v2.0. Participants are asked to report (1=very poor; 5=very good) on their sleep quality over the last 7 days. They are also asked to report (1=not at all; 5=very much) the degree to which they experienced sleep difficulties (e.g., ‘I had difficulty falling asleep’) over the past 7 days. Patients and caregivers will also complete a measure of healthcare utilization. Patients will be asked whether they visited the emergency department over the past two months, whether any of these visits were related to side effects from cancer treatment, whether they missed a scheduled appointment for cancer treatment, and whether they have used cancer support services in the past 2 months. Caregivers will be asked whether they visited the emergency department over the past two months, how many times they visited a primary care doctor for anything other than routine care, and whether they have used cancer support services in the past 2 months.

Several additional scales will be administered to patients. Physical functioning will be assessed with the 4-item PROMIS [18] Physical Health scale from the PROMIS-29 Profile v2.0. Participants are asked to report (1=unable to do; 5=without any difficulty) the degree to which they are able to perform 4 activities (e.g., ‘Are you able to go for a walk of at least 15 minutes?’, ‘Are you able to run errands and shop?’). Engagement in social activities will be assessed with the 4-item PROMIS [18] Ability to Participate in Social Roles and Activities scale from the PROMIS-29 Profile v2.0. Participants are asked to report (1=never; 5=always) the degree to which they agree with 4 statements (e.g., ‘I have trouble doing all of my regular leisure activities with others’, ‘I have trouble doing all of the family activities that I want to’). Fatigue will be assessed with the 4-item PROMIS [18] Fatigue scale from the PROMIS-29 Profile v2.0. Participants are asked to report (1=not at all; 5=very much) the
degree to which they agree with 4 statements and questions (e.g., ‘I feel fatigued; ’how run-
down did you feel on average?’) as it pertains to the prior 7 days. Finally, pain interference
will be assessed with the 4-item PROMIS [18] Pain Interference scale from the PROMIS-29
Profile v2.0. Participants are asked to respond (1=not at all; 5=very much) to questions
assessing pain interference in daily life (e.g., ‘How much did pain interfere with your day to
day activities?’; ‘how much did pain interfere with your household chores?’) as it pertains to
the prior 7 days. Finally, participants will respond to a single item assessing pain level over
the past 7 days, on a 0 (no pain) to 10 (worst pain imaginable) scale.

Caregivers will be administered the 21-item Caregiver Self-Efficacy Scale (CaSES; 21), which
was developed to measure self-efficacy in informal cancer caregivers. The CaSES was found
to have good validity and reliability in a large sample of caregivers [21]. Items assess
caregivers’ perceptions of their duties and capabilities (e.g., ‘I can be positive when I need
to be’, ‘I can continue to provide care when I feel scared’, ‘I have the ability to talk openly
with the person I care for’), and are scored on a four-point scale (0=not at all confident;
4=very confident).

Finally, app use data will be collected passively. Specifically, engagement will be ascertained
from the number of app launches, defined as a user-initiated event after at least 5 minutes
of no activity [9]. The duration of individual app use sessions will also be used to reflect
engagement, and is defined as the length between an app launch at the last event in that
session.

To understand the preliminary impact of IntelliCare on daily mood, social functioning, and
health behavior during the study, patients and caregivers will respond to a short online
survey every week throughout the study period. Surveys will be delivered using the
Qualtrics SMS tool. Participants will receive a text message on their phone at 8pm. An
embedded link within the text message will automatically connect participants to a secure
Qualtrics web page containing survey items. Weekly surveys are each expected to take 1-2
minutes to complete.

All participants will be asked to report (1=very negative; 5=very positive) how they have
felt over the past week, and how they expect to feel the following week. They will also be
asked about the following behaviors/activities over the past week: how well they have
managed negative feelings, how much they have used alcohol or tobacco to cope with
negative feelings, amount of physical pain experienced, how connected they felt to family
and friends, how much support they received from loved ones, how much support they
were able to provide to loved ones, how much anxiety they experienced, how much
interest/pleasure they had in doing things, and amount of physical activity. At the end of
the survey, participants are reminded to focus on trying out new IntelliCare apps for the
upcoming week. They will be asked to note which specific apps they intend to use during
the upcoming week.

Data Analysis
All data will be stored in a secured Qualtrics server for highly sensitive data. Data will be
cleaned and analyzed in statistical software packages (i.e., SPSS, SAS, R). Protocol non-
adherence will be defined as individuals who fail to complete the baseline and post-intervention surveys. Because this pilot study is only being conducted at a single site, a data monitoring committee was not utilized.

Quantitative data on user experience will be analyzed descriptively, to be compared with user data in existing literature. Qualitative data on user experience will be evaluated for content and emerging themes. The investigators will compile user feedback data and, combined with passively collected app use data, decide what changes need to be made in future studies.

Because of the within-subject pre-post design, changes in outcome measures in both cancer patients and caregivers will primarily be analyzed using paired t-tests. Descriptive statistics will primarily be used to examine whether IntelliCare use is associated with changes in process variables (i.e., mood, social functioning, and health behavior) during the study period. A separate set of analyses will examine associations between changes in cancer patient and caregiver outcomes. Specifically, zero-order correlations will be computed to examine whether improvement in caregiver depression/anxiety symptoms is positively associated with improvement in patient depression/anxiety symptoms. Correlations will also be computed to examine whether improvement in caregiver self-efficacy is positively associated with improvement in patient mood symptoms. The purpose of these analyses is to obtain estimates of effect size that can be used to inform future trials. Additional discussions with cancer clinicians will be used to obtain additional information on possibility effect size and variance estimates [22].

Results
This project will run for 8 months, and recruitment will be completed by the end of 2018. The study was approved by the local university Institutional Review Board. Research staff has been hired and trained, and set up has been completed to store all data on secure university servers. Recruitment commenced in March, 2018. As of the end of June 2018, 17 breast cancer patients and 7 cancer caregivers have been consented. We will monitor participant progress and continue to recruit participants over the next 4 months or until we successfully hit our target enrollment.

Discussion

Principal Findings
A cancer diagnosis impacts both patients and their loved ones. Over a third of U.S. cancer patients experience clinically significant mental distress [23]. Studies also show a high level of distress in cancer caregivers in the U.S., with over 25% screening positive for depression and 35% screening positive for anxiety [24]. Unfortunately, face-to-face models of mental health care are not sufficient to meet the growing demand for mental health resources in cancer populations. Mental health and support apps may therefore address a critical healthcare gap, though few studies have evaluated the impact of mental health apps in cancer populations. Findings from this study will help to address this weakness in clinical care, by providing preliminary data to estimate the effect of a suite of smartphone
apps on mental health outcomes in breast cancer patients and caregivers. In addition, while some studies have found unique benefits of interventions target patient-caregiver dyads [25], this study will be among the first to examine the preliminary effects of providing mental health apps to patients-caregiver dyads.

Findings from systematic reviews indicate that despite a plethora of mental health apps available in online stores, only a few are empirically supported [6, 26] and even fewer target cancer populations. IntelliCare apps are publicly available through both Android and iPhone stores and have been tested in individuals with clinical mood symptoms [9]. These factors create an ideal situation to conduct a pilot study in cancer patients and caregivers. Findings from this study will extend existing work on how mobile technology can be used to address mental health needs in cancer populations.

Limitations
This study should be interpreted in light of several limitations. Because the focus on this investigation is to conduct a pilot study of a potential phase III trial, the sample size will be relatively small and there will be no comparison condition. Thus, it is impossible to rule out the possibility that improvement in psychosocial outcomes is due to IntelliCare apps or outside factors. Recruiting a larger sample size, combined with a randomized control trial design, is an appropriate next step to understand whether using the IntelliCare apps leads to improvement compared to standard treatment. Further, because this study will be recruiting individuals directly from the clinic, in order to achieve the targeted sample size there are few exclusion criteria which may lead to potential confounders (e.g., psychiatric diagnosis). In addition, this study is conducted in a U.S. NCI-designated Clinical Cancer Center, and therefore findings may have limited generalizability to settings that do not possess as many resources. Thus, we hope that data from this pilot study will inform future work that attempts to administer IntelliCare apps from those recruited from a range of clinical settings.

It should be noted that some individuals may not possess a personal smartphone or have a data plan that allows them to participate in this study. We will therefore provide a Samsung S7 Android phone with an unlimited data plan to ensure equal access to the mHealth intervention. However, what remains unknown, and what this pilot study will address, is an estimate of the approximate percentage of individuals who require a smartphone in future trials. Finally, to address low literacy of using technology and mobile devices, phone coaching will provide participants with any needed instructions of how to download, use, and manage the IntelliCare apps. Coaches will also be available to provide technical support as needed.

Conclusions
Very little work has examined the potential effectiveness of mental health apps in cancer patients and their informal caregivers. This pilot study will provide preliminary data regarding the usability and acceptability of a suite of mental health apps in a sample of cancer patients and caregivers in the U.S. The mixed-methods approach to gathering user feedback will provide a rich data set that will guide improvements to the apps and coaching procedure in future studies.
ACKNOWLEDGEMENTS
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CONFLICTS OF INTEREST
DM has equity ownership in Actualize Therapy, a company developing and making available mobile technology products related to the research reported in this manuscript. DM will not have direct access to the final raw dataset.
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