Published in final edited form as:

Contemp Clin Trials. 2018 February ; 65: 61–68. doi:10.1016/j.cct.2017.11.018.

Study design and protocol for *My Guide*: An e-health intervention to improve patient-centered outcomes among Hispanic breast cancer survivors

Betina R. Yanez^{a,*}, Diana Buitrago^a, Joanna Buscemi^{b,c}, Francisco Iacobelli^d, Rachel F. Adler^d, Marya E. Corden^a, Alejandra Perez-Tamayo^e, Judy Guitelman^f, and Frank J. Penedo^a

^aNorthwestern University, Department of Medical Social Sciences, 633 N St. Clair St. 19th Floor, Chicago, IL 60611, United States

^bDePaul University, Department of Psychology, 2219 N Kenmore Ave., Chicago, IL 60614, United States

^cUniversity of Illinois at Chicago, Institute for Health Research and Policy, 1747 W Roosevelt Rd., Chicago, IL 60608, United States

^dNortheastern Illinois University, Department of Computer Science, 5500 N St. Louis Ave., Chicago, IL 60625, United States

^eUniversity of Illinois at Chicago, Department of Surgery, 1801 W Taylor St., Chicago, IL 60608, United States

^fALAS-WINGS, The Latina Association for Breast Cancer, 3023 N Clark St. Suite 613, Chicago, IL 60657, United States

Abstract

Breast cancer is the most commonly diagnosed non-skin cancer in women and the leading cause of death among Hispanic women living in the United States. Relative to non-Hispanic white women, Hispanic women report poorer health related quality of life (HRQoL) after treatment. Although eHealth interventions delivered via Smartphones are a viable approach to addressing supportive care accessibility issues while also integrating multidisciplinary approaches for improving HRQoL, few eHealth interventions have been developed that specifically target Hispanic breast cancer survivors (BCS). This manuscript describes the methodology of a multisite, randomized controlled behavioral trial investigating the feasibility and preliminary efficacy of a Smartphone application aimed at improving HRQoL and cancer-specific distress among Hispanic BCS. Participants will be randomized to receive the intervention application, *My Guide* (psychoeducation & self-management program), or the health education control condition application, *My Health* (health education), for six weeks. All participants will also receive weekly telecoaching to enhance adherence to both control and intervention conditions. We will measure the study's primary outcomes, general and disease-specific HRQoL and cancer-specific distress, at three time points: prior to, immediately after the intervention, and eight weeks after initial

*Corresponding author. betina.yanez@northwestern.edu (B.R. Yanez).

application use. *My Guide* may have the potential to improve HRQoL, and to address issues of limited access to supportive care among Hispanic women recovering from breast cancer treatment.

Keywords

Breast cancer; Hispanic; Health-related quality of life; Interventions; eHealth

1. Introduction

Among Hispanics, the largest and fastest growing ethnic minority group in the U.S., cancer is the leading cause of death [1]. Approximately 1 in 3 Hispanics will receive a diagnosis of cancer and among Hispanic women, breast cancer is the most commonly diagnosed type of cancer [1]. Relative to non-Hispanic Whites, Hispanics are under-represented in oncology clinical trials [2] and few interventions have been developed specifically to enhance access to supportive care for Hispanic women diagnosed with breast cancer [3].

Breast cancer survivors (BCS) often experience symptoms related to their diagnosis and treatment that result in poor health-related quality of life (HRQoL) outcomes both during and following treatment. Common side effects of breast cancer treatments may include fatigue, hot flashes, depressive symptoms, sleep changes, changes in sexual functioning, and hair loss. Relative to non-Hispanic White women, Hispanic women report poorer HRQoL after completing active treatment for breast cancer, even when adjusting for socioeconomic status [4,5]. Poorer HRQoL among Hispanic BCS may in part be due to an increased level of stressors and barriers to care such as language barriers, lack of information on survivorship, as well as culturally driven beliefs and attitudes such as *simpatia* and fatalism [4,6–8]. Additionally, poor HRQoL has been linked to lower adherence to follow-up care and anti-cancer medications. Therefore, culturally tailored, supportive oncology interventions to improve patient-centered outcomes are an important first step to improving follow-up care, and ultimately sustaining the long-term health of Hispanic women diagnosed with breast cancer [9–11].

The past decade has seen an increase in observational research focusing on the HRQoL of women diagnosed with breast cancer, including Hispanic women, [12–17] as well as a handful of studies documenting the efficacy of supportive interventions to improve HRQoL among Hispanic women diagnosed with cancer [13,16]. While preliminary findings suggest that increasing cancer knowledge, self-efficacy in communication, and self-management skills can improve HRQoL outcomes in this population [6,17–22], the extant literature is limited by in-person or phone-based treatment modalities. These approaches can be more costly, time intensive, and less scalable than interventions facilitated with Smartphones [23].

Over the past decade, there has been a proliferation of Smartphone-based applications that deliver evidence-based treatments for health management [23–26]. Although this method is innovative and has potential for widespread dissemination, no Smartphone-based intervention to date has been developed to improve patient-centered outcomes among Hispanic breast cancer survivors. Hispanics own Smartphones and seek health information online from mobile devices at similar or higher rates than other racial/ethnic groups in the

U.S. [27]. Therefore, Smartphone-based interventions offer an opportunity to overcome obstacles to accessing in-person supportive care and services that can be linguistically and culturally tailored and provide skills to improve HRQoL [27,28]. Studies have yet to determine the efficacy of a Smartphone-based intervention in improving outcomes among this understudied patient population.

This paper describes the procedures and methodology of a multisite, randomized controlled behavioral trial investigating the preliminary feasibility and efficacy of a Smartphone-based intervention to reduce cancer-specific distress and improve HRQoL compared to a health education control condition among Hispanic BCS. The intervention will be administered over the course of six weeks to a sample of 80 English and Spanish-speaking Hispanic BCS.

2. Material and methods

2.1. Hypotheses

We hypothesize that Hispanic BCS will find the Smartphone application, *My Guide*, a feasible tool for accessing post-treatment relevant information, as well as for learning strategies to improve cancer-relevant self-efficacy, stress, communication and symptom management. Furthermore, we expect that, in comparison to the control condition, *My Guide* will have a measurable, positive improvement on Hispanic women's HRQoL and cancer-specific distress.

2.2. Study design

The study design was informed by the CONSORT eHealth guidelines for eHealth interventions [17] and previous interventions in cancer control and survivorship [25,29]. This study is a randomized control trial for Hispanic BCS designed to evaluate the efficacy of *My Guide* relative to a Smartphone application on overall health promotion (*My Health*), our control condition. Consistent with assessment timelines in previous psychosocial studies, our study is a six-week intervention with a baseline, a six-week, and an eight-week follow-up assessment measuring the study outcomes and intervention targets [30–32]. Participants will complete the same procedures regardless of randomization assignment to help minimize potential confounding factors during the intervention or control delivery.

Participants will be individually randomized, 1:1, to the control condition (*My Health*) or to the *My Guide* condition for a total of six weeks, they will be encouraged to use their respective application for 2 h each week, and will be assigned to weekly telecoaching calls based on their level of adherence to the recommended application use (see Fig. 1). We will use a stepped-care approach [33] to schedule telecoaching calls with participants in order to enhance adherence to both control and intervention conditions. Based on this approach, participants will stop receiving regular telecoaching calls if they continue to use the application for a minimum of 1.5 h per week. Adherent participants who continue to meet the goal will be sent positive reinforcement text messages in lieu of a call, unless they fall under the 1.5 h threshold, which triggers a telecoaching call.

Participants will complete a psychosocial baseline assessment along with a sociodemographics questionnaire before accessing the application, a six-week follow-up

assessment, and one final follow-up assessment after eight weeks. Baseline and follow-up assessments consist of questionnaires measuring our primary outcomes, HRQoL and cancer-specific distress, as well as our intervention targets which are breast cancer knowledge, cancer-relevant self-efficacy, stress and symptom management skills, and satisfaction with cancer-related needs. Immediately after the six-week intervention, participants will complete a questionnaire to assess the usability and usefulness of the control and intervention applications. Participants will be compensated \$100 for completing study procedures, and reimbursed for telephone data usage and transportation to appointments. All procedures and questionnaires have been approved by the Northwestern Institutional Review Board (IRB), the IRB of record for this multisite study.

2.3. Participants

Participants will be Hispanic BCS with a first time diagnosis of stage 0-IIIa breast cancer who have completed active treatment and present with low HRQoL [34]. We will enroll a total of 80 participants from the Robert H. Lurie Comprehensive Cancer Center at Northwestern Memorial Hospital, the University of Illinois Hospital and Health Sciences System, and various breast cancer support groups and community-based support groups for cancer survivors.

2.4. Eligibility

Participants will be initially identified through electronic medical record (EMR) screening, and the final determination for study eligibility will occur over the phone via completion of a self-report questionnaire. Our study inclusion and exclusion criteria are as follows:

Inclusion criteria: 1) Female; 2) Diagnosis of breast cancer, non-metastatic, stage 0-IIIa; for women diagnosed with stage 0, either radiation or chemotherapy is required as an additional treatment to surgery; 3) Completed active treatment for breast cancer (surgery, chemotherapy and/or radiation therapy, current hormonal treatment allowed); 4) No current evidence of disease; 5) Within 3 to 24 months post-active treatment [e.g., surgery, chemotherapy, radiation, or combination of the two or three]; 6) At least 21 years of age; 7) Able to speak and read English or Spanish; 8) Able to provide informed consent; 9) Elevated score on breast cancer symptom burden and HRQoL, measured by the Functional Assessment of Cancer Therapy-Breast using an established cut-off score for clinically meaningful, compromised HRQoL; [34] and 10) Self-identified Hispanic/Latina ethnicity. Exclusion criteria include: 1) Visual, hearing, voice, or motor impairment that would prevent completion of study procedures; 2) Diagnosis of an unmanaged psychotic disorder, bipolar disorder, dissociative disorder, or other diagnosis for which participation in this trial is either in-appropriate or dangerous – this includes patients who have a life-threatening illness (e.g., end-stage kidney disease) or diagnosis of a chronic disease that is associated with a major functional impairment (e.g., fibromyalgia); 3) Illicit substance or alcohol dependence; 4) Suicidal ideation, plan, or intent; 5) Alzheimer's, dementia or history of stroke; 6) Scheduled reconstruction surgery within 1 month of any study procedures or involvement.

3. Intervention and control components and delivery

3.1. Intervention content, development and final version

The content in the *My Guide* intervention was informed by the literature on eHealth interventions models of stress and coping, the extant literature on psychosocial adaptation during and after breast cancer, [25,35] and our preliminary findings suggest that cancer knowledge, stress awareness and management, social support, and enhanced communication and intimacy can improve symptom burden and HRQoL outcomes in this population [6,17–22]. The content in *My Guide* was further tested and refined through a mixed-methods study, which confirmed the importance of the above content for improving HRQoL through a Smartphone application, and assessed the preliminary feasibility of a *My Guide* prototype with a sample of 24 Hispanic BCS [36].

The finalized intervention content was organized in eight main modules (see Table 1 and Figs. 2–5 for additional information on *My Guide*). The final *My Guide* version incorporates elements in the published literature, previously mentioned preliminary research, as well as feedback from community stakeholders, human-computer interaction and Smartphone application design experts, and investigators with ample experience conducting research with Hispanic BCS.

My Guide is culturally informed so that it is aligned with Hispanic values and beliefs such as familism, fatalism, external locus of control, and culturally shaped gender roles (i.e., Machismo and Marianismo) [6–8]. All study content is in English and Spanish and was translated by IRB certified translators with ample experience translating medical content.

3.2. Health promotion content

The health promotion application, *My Health*, includes health education content on nutrition, and general advice on lifestyle choices and prevention (see Table 2 for an index of the specific topics covered). Our control content was based on similar content tested in a psychosocial intervention with cancer survivors [24].

3.3. Intervention and control delivery

Eligible patients who choose to participate will be randomized to receive either the intervention or control applications, *My Guide* or *My Health*, respectively. Although participants who are randomized to the control will have the opportunity to receive *My Guide* after they complete all study procedures, and vice versa, participants will only have access to one application at a time and access to the application will be granted by the study coordinator. The applications will be available in both English and Spanish and will be provided based on the participant's language preference. In order to minimize potential confounding factors during the intervention or control delivery, participants will complete the same procedures regardless of randomization assignment. Participants will complete an initial hour-long, in-person meeting where they will complete a demographics questionnaire, a baseline assessment, and will receive an orientation to their corresponding application. During the orientation, participants will be instructed to use their corresponding application for six weeks, for approximately 2 h per week.

After six weeks of active application use and monitoring in the intervention or control conditions, participants will complete a six-week and an eight-week follow-up appointment. During the first follow-up meeting, they will complete an assessment consisting of the same questions from the baseline questionnaire, as well as an application satisfaction questionnaire. The duration of the meeting is estimated to be 1 h. Two weeks later, we will contact participants for a final 30-minute long assessment consisting of the questions that measure our primary outcomes and intervention targets.

Telecoaching calls are designed to increase adherence to the recommended time of application use, and to resolve any issues that may present when accessing the application. We will use a stepped-care approach to schedule telecoaching calls with participants based on their level of application adherence (defined by the amount of time using the application) (see Fig. 1). Using this model, participants who continue to use the application for at least 1.5 h per week will stop receiving regular telecoaching calls, and will receive encouraging weekly reinforcement text messages instead. Participants who fall under the 1.5-hour weekly threshold will receive regular telecoaching calls with trained telecoaches. The telecoaching calls will be delivered following the principles of Motivational Interviewing [37]. During the first call, telecoaches will conduct a decisional balance exercise with participants to resolve potential ambivalence about using the application regularly. During the decisional balance exercise, participants will weigh the advantages and disadvantages of using the application regularly, and will set personalized weekly goals regarding their usage with their telecoaches. During subsequent calls, telecoaches will review participants' weekly usage and will give them personalized feedback regarding goal attainment. Barriers and facilitators to usage will be discussed, and telecoaches will problem solve with participants to set future usage goals.

A licensed clinical psychologist will conduct training for the telecoaches and will supervise the telecoaches on a weekly basis. Telecoaches will be trained in motivational interviewing, goal setting, and sensitivity to issues relevant for Hispanic BCS, including cultural beliefs that may influence coping and health behaviors. Coaches will have access to participants' application usage through a study administrative website. Telecoaching sessions will be audio-recorded to monitor intervention fidelity.

3.4. Application development

The Smartphone applications for both the control and intervention components were developed by the Center for Behavioral Intervention Technologies at the Northwestern University Feinberg School of Medicine (CBITs). CBITs uses up to date security measures that are consistent with those used by Electronic Medical Records and are HIPAA compliant. All data collected via the interventions and assessments are transmitted using Transport Layer Security (TLS) encryption to prevent tampering with information while it is in the transmission pipeline. Security measures to protect privacy threats associated with users' computers and devices include the following measures: users are automatically logged off of intervention and assessment tools after 20 min of no activity; any data stored locally is automatically encrypted based on the user authentication information and cannot be accessed without this information. All information collected by this application will be

immediately transmitted to CBITs as the application does not save any data to the phone's memory.

4. Data collection and outcomes

4.1. Data collection

Data for our study will be collected during eligibility screening, immediately before, after and during the six-week intervention, and eight weeks after the baseline assessment. The screening questionnaire is administered over the phone to determine initial eligibility. Eligible participants are scheduled for an in-person meeting where they complete a sociodemographics questionnaire and a psychosocial baseline assessment. During the intervention participant application usage is collected, as well as responses to a weekly questionnaire. Immediately post-intervention, participants complete a follow-up assessment, and an interview on the perceived usefulness and usability of their application. Finally, two weeks later, participants will complete a final follow-up assessment, and we will conduct a medical record review in order to corroborate the self-reported medical and disease characteristics collected during the screening and initial questionnaires.

4.2. Measures

4.2.1. Sociodemographic, medical, and disease characteristics—Participants will self-report medical information such as time since diagnosis and treatment, stage of cancer, surgery type, adjuvant treatment information (as applicable), as well as information on prior or current psychiatric diagnoses. All medical and disease information will be verified via medical chart review. Medical comorbidities will be assessed with the Charlson Comorbidity Index [38]. We will also collect age, education, income racial background and Hispanic ancestry, employment, relationship status, years in the US, and subjective social status using the MacArthur scale [39].

4.3. Outcomes and intervention targets

Our baseline and follow-up assessments are comprised of six questionnaires measuring the study's primary outcomes, HRQoL and cancer-specific distress, as well as the study's intervention targets: breast cancer knowledge, cancer-relevant self-efficacy, stress and symptom management skills, and satisfaction with cancer-related needs. The six questionnaires are described next.

4.3.1. Functional Assessment of Cancer Therapy – Breast—The Functional Assessment of Cancer Therapy-Breast (FACT-B) has been used extensively to measure HRQoL, and has been translated to and validated in Spanish [40,41]. The FACT-B assesses participant's wellbeing in physical, emotional, social, functional, and breast cancer related concerns in the last seven days using a five-point response scale (see Supplementary Appendix for full scale).

Additionally, each week throughout the six-week intervention, participants will complete the *Rapid version of the Functional Assessment of Cancer Therapy-General* (FACT-G7). The FACT-G7 measures the most prominent HRQoL concerns among cancer survivors in a valid

and reliable manner [42]. Participants will be asked to self-administer the FACT-G7 via the Smartphone application.

4.3.2. Impact of event scale—The Impact of Event Scale (IES) measures cancer-specific distress. The IES is made up of two subscales measuring the frequency of intrusion and avoidance experiences after a stressful event (see Table 4 for full scale). The overall reliability of the scale is high ($r = 0.86$), and the internal consistency of the subscales (Cronbach's Alpha), is also high (intrusion = 0.78, avoidance = 0.82). The IES has been widely used among patients diagnosed with cancer and has been translated and validated with Spanish-speaking participants [43,44].

4.3.3. Knowledge about breast cancer questionnaire—Breast cancer related knowledge will be measured using the knowledge about breast cancer questionnaire, which was tested with a large sample of Spanish-speaking Hispanic BCS [45]. This questionnaire is made up of 16 true and false questions regarding general breast cancer knowledge from which we will calculate the average number of correct responses. In addition to the general questions about diagnosis and treatment in the original questionnaire, we included questions on endocrine therapy, as it is often prescribed to BCS and an important precursor of health related outcomes for this population. The added questions were forward and backward translated to Spanish and used in previous research with this population [36,46].

4.3.4. Communication and attitudinal self-efficacy scale—To measure participants' self-efficacy in communication, information seeking, and emotional resilience when facing cancer, we will use the communication and attitudinal self-efficacy scale for cancer (CASE-cancer). The questionnaire is made up of three subscales measuring the previously stated types of self-efficacy. Each question asks participants to use a four-point response scale to agree or disagree with statements regarding their level of confidence with different skills. This measure is a psychometrically validated measure previously used with Hispanic BCS [47,48].

4.3.5. Breast cancer prevention trial symptom questionnaire—The Breast Cancer Prevention Trial symptom questionnaire (BCPT) measures participants' symptom burden. The BCPT asks participants to report their level of discomfort with 25 breast cancer related symptoms during the past four weeks using a five-point response scale. The BCPT has been extensively tested with BCS, and consists of statements asking participants to rate their level of discomfort with common breast cancer post-treatment symptoms in the last four weeks [49].

4.3.6. Prominent factors in the supportive care needs survey—To measure prevalent unmet cancer-related needs in our sample, we used the top 10 needs as measured and reported in a study with a sample over 880 diverse cancer survivors using the supportive care needs survey (SCNS) [50]. The top ten most prevalent needs from the SCNS survey assess psychological, physical and daily living needs, as well as patient information and health system needs. All the items in this survey were forward and backward translated to Spanish, and piloted with a sample of 24 patients during the feasibility trial of *My Guide*[36].

4.3.7. Feasibility of smartphone intervention—Application feasibility will be assessed by the acceptability and demand of the applications [29].

To assess acceptability, all participants will be asked to complete a previously tested application satisfaction questionnaire on study usability and usefulness at six weeks post-baseline [24]. This questionnaire will measure the usefulness, satisfaction, learnability and usability of *My Guide* and *My Health*. Our application satisfaction questionnaire was synthesized from validated measures assessing eHealth intervention feasibility, and was adapted for our study to better fit our target population and our application design [51–54]. Above average scores on the questionnaire will be considered acceptable.

We will measure demand through study recruitment, retention, participant usage of the website (e.g., logins, time spent on the website, content accessed). Based on previous psychosocial and behavioral studies in oncology, an 80% recruitment rate, 80% retention rate, and an average of 10 h of use will be considered adequate measures of demand [24,55,56].

4.3.8. Analytic plan—Descriptive statistics will be used to characterize the overall sample and each condition. We will explore whether data are distributed normally or non-normally using Levene's test and the Shapiro-Wilk test. We will use *t*-tests, Chi-square, Fisher's exact tests, and non-parametric Mann-Whitney *U* test for non-normal data, as appropriate, to preliminarily examine differences in feasibility between the study conditions. Non-normal data will be examined with Levene's test and a sample size of 40 participants per condition will yield 80% power to detect a change in 0.63 standard deviations for our main outcomes. Power is based on the effect size defined as the group difference in the mean change divided by the pooled standard deviation of the change. With 40 participants per arm, there is 80% power to detect an effect size of 0.63 assuming a two-tailed test and a Type I error rate of 5%. All power calculations were run using PROC POWER in SAS v9.4.

Our expected effect size of 0.63 is based on previous e-health interventions in oncology [24] and validation data on FACT-G [57]. For all outcomes, change from baseline will be calculated and the mean changes within study condition will be converted to effect sizes. Follow-up scores on the outcomes, as well as all intervention targets, will be compared between study conditions, after adjusting for baseline score, using repeated measures analysis of covariance (ANCOVA). We will also reference established cutoffs for clinically meaningful differences for scores on the FACT, and FACT subscales, to identify ranges and patterns of change scores in HRQoL across the study conditions from study baseline to the follow-up assessments. Mixed effects models will be used to model the study outcome scores over time for each group, with fixed effects for baseline score, study group, and time and random effects for patient. Type of treatment, time since completion of active treatment, stage of diagnosis, education, marital status, language, comorbidities and age at diagnosis will be examined for their associations with study outcomes for potential entry as covariates in the statistical model.

4.3.9. Data management—All research data will be organized and managed using Research Electronic Data Capture (REDCap) hosted at Northwestern University. REDCap is

a research management tool which enables a secure study website accessible to all IRB approved research team members regardless of study site [58]. REDCap will be used to administer the screening, sociodemographics, baseline and follow-up questionnaires, and to organize medical record review data. *My Guide* and *My Health* usage data and weekly questionnaires will be captured via the *My Guide* and *My Health* administrative interface and uploaded to REDCap to centralize all research information. Once collected, all research data will be imported into SPSS for cleaning and analysis.

5. Discussion

The goal of this study is to improve the health-related quality of life of Hispanic BCS. In light of the increasing number of Hispanics accessing the Internet mostly through Smartphones, we selected this technology-based platform to deliver our intervention. Smartphone-based interventions have the benefit of increasing access to hard-to-reach patient populations such as minorities, are scalable, and can be accessed by the patient at any time and location. However, there is limited evidence on the efficacy of Smartphones to improve the quality of life of Hispanic BCS.

A few limitations of the study protocol warrant discussion. First, because the focus of this study is on cancer survivors, women in active treatment will not be enrolled in the current study. Future studies should test the efficacy of using technology-based platforms to reduce the symptom burden and improve the quality of life of Hispanic women undergoing cancer treatment through frequent assessment of treatment-related side effects and concerns, embedding patient-reported outcomes into clinical care in real time to facilitate management of side effects and concerns. Although the *My Guide* application does not provide a forum to directly communicate with other BCS, as done in cancer support groups, participants are able to access cancer survivor stories and receive information on local cancer support groups in English and Spanish. Finally, given the relatively small sample size of the study, mediation analyses to determine which if any mediators explain the effect of the *My Guide* intervention on improving outcomes is not possible. Future research with larger sample sizes should assess explanatory mechanisms of *My Guide*, which would enable us to discern whether changes in mediator variables precede improvement in health-related quality of life and symptom burden.

An interdisciplinary team of investigators, as well as Hispanic BCS and breast cancer advocates assisted in the development of the current protocol and the *My Guide* application. Our protocol addresses several potential threats to low participant enrollment and retention by offering monetary incentives, weekly reinforcement text messages, as well as the opportunity for study completers to receive the study application to which they were not randomized. Additionally, *My Guide*'s unique features such as availability in English and Spanish and audio accessible text may facilitate enrollment and retention to historically underserved patients and hard-to-reach study participants, and thus increase the generalizability of our study findings to a broader number of Hispanic BCS living in the U.S. Finally, our stepped care approach to telecoaching has the potential to enhance study retention and adherence to the application through weekly engagement for study participants who have low levels of application use. Incorporating a stepped-care approach also

conserves study resources as only women who have a low use of the application will continue to receive a phone call from a member of the study staff.

In conclusion, findings from this study are expected to contribute to the literature by establishing whether Smartphones are potential options for delivering supportive oncology interventions for hard-to-reach patient populations. If our study demonstrates preliminary efficacy, dissemination of our application may be able to occur quickly, increasing the public health impact among Hispanic BCS.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

Support for this project was provided by National Cancer Institute of the National Institutes of Health under Award Number NCI U54 CA203000. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.cct.2017.11.018>.

References

1. American Cancer Society. Cancer Facts & Figures for Hispanics/Latinos 2015-2017 2015 <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/cancer-facts-and-figures-for-hispanics-and-latinos/cancer-facts-and-figures-for-hispanics-and-latinos-2015-2017.pdf> Accessed July 14, 2017
2. Langford AT, Resnicow K, Dimond EP, et al. Racial/ethnic differences in clinical trial enrollment, refusal rates, ineligibility, and reasons for decline among patients at sites in the National Cancer Institute's Community Cancer Centers Program. *Cancer*. 2014; 120(6):877–884. [PubMed: 24327389]
3. Chen MS, Lara PN, Dang JHT, Paterniti DA, Kelly K. Twenty years post-NIH Revitalization Act: enhancing minority participation in clinical trials (EMPaCT): laying the groundwork for improving minority clinical trial accrual. *Cancer*. 2014; 120:1091–1096. [PubMed: 24643646]
4. Yanez B, Thompson EH, Stanton AL. Quality of life among Latina breast cancer patients: a systematic review of the literature. *J Cancer Surviv*. 2011; 5(2):191–207. [PubMed: 21274649]
5. Lockett T, Goldstein D, Butow PN, et al. Psychological morbidity and quality of life of ethnic minority patients with cancer: a systematic review and meta-analysis. *Lancet Oncol*. 2011; 12(13): 1240–1248. [PubMed: 21996168]
6. Nápoles-Springer A, Ortíz C, O'Brien H, Díaz-Méndez M. Developing a culturally competent peer support intervention for Spanish-speaking Latinas with breast cancer. *J Immigr Minor Health*. 2009; 11(4):268–280. [PubMed: 18340533]
7. Gallo LC, Penedo FJ, Espinosa de los Monteros K, Arguelles W. Resiliency in the face of disadvantage: do Hispanic cultural characteristics protect health outcomes? *J Pers*. 2009; 77(6): 1707–1746. [PubMed: 19796063]
8. Interian A, Díaz-Martínez AM. Considerations for culturally competent cognitive-behavioral therapy for depression with Hispanic patients. *Cogn Behav Pract*. 2007; 14(1):84–97.

9. Andersen BL, Yang HC, Farrar WB, et al. Psychologic intervention improves survival for breast cancer patients: a randomized clinical trial. *Cancer*. 2008; 113(12):3450–3458. [PubMed: 19016270]
10. Andersen BL, Thornton LM, Shapiro CL, et al. Biobehavioral, immune, and health benefits following recurrence for psychological intervention participants. *Clin Cancer Res*. 2010; 16(12): 3270–3278. [PubMed: 20530702]
11. McGregor BA, Antoni MH. Psychological intervention and health outcomes among women treated for breast cancer: a review of stress pathways and biological mediators. *Brain Behav Immun*. 2009; 23(2):159–166. [PubMed: 18778768]
12. Molina Y, Thompson B, Espinoza N, Ceballos R. Breast cancer interventions serving US-based Latinas: current approaches and directions. *Women's Health (Lond Engl)*. 2013; 9(4):335–348. (quiz 349-350). [PubMed: 23826775]
13. Ashing K, Rosales MA. Telephonic-based trial to reduce depressive symptoms among Latina breast cancer survivors. *Psychooncology*. 2014; 23(5):507–515. [PubMed: 24217994]
14. Rush CL, Darling M, Elliott MG, et al. Engaging Latina cancer survivors, their caregivers, and community partners in a randomized controlled trial: Nueva Vida intervention. *Qual Life Res*. 2015; 24(5):1107–1118. [PubMed: 25377349]
15. Ramirez A, Perez-Stable E, Penedo F, et al. Reducing time-to-treatment in underserved Latinas with breast cancer: the six cities study. *Cancer*. 2014; 120(5):752–760. [PubMed: 24222098]
16. Napoles AM, Ortiz C, Santoyo-Olsson J, et al. Nuevo amanecer: results of a randomized controlled trial of a community-based, peer-delivered stress management intervention to improve quality of life in latinas with breast cancer. *Am J Public Health*. 2015; 105(Suppl. 3):e55–63.
17. Yanez B, Maggard Gibbons M, Moreno PI, Jorge A, Stanton AL. Predictors of psychological outcomes in a longitudinal study of Latina breast cancer survivors. *Psychol Health*. 2016; 31(11): 1359–1374. [PubMed: 27373454]
18. Ashing-Giwa KT, Tejero JS, Kim J, Padilla GV, Hellemann G. Examining predictive models of HRQOL in a population-based, multiethnic sample of women with breast carcinoma. *Qual Life Res*. 2007; 16(3):413–428. [PubMed: 17279444]
19. Ashing-Giwa K. The contextual model of HRQoL: a paradigm for expanding the HRQoL framework. *Qual Life Res*. 2005; 14(2):297–307. [PubMed: 15892421]
20. Ashing-Giwa KT, Padilla GV, Bohorquez DE, Tejero JS, Garcia M. Understanding the breast cancer experience of Latina women. *J Psychosoc Oncol*. 2006; 24(3):19–52. [PubMed: 17088240]
21. Graves K, Jensen R, Cañar J, et al. Through the lens of culture: quality of life among Latina breast cancer survivors. *Breast Cancer Res Treat*. 2012; 136(2):603–613. [PubMed: 23085764]
22. Ganz PA, Kwan L, Stanton AL, Bower JE, Belin TR. Physical and psychosocial recovery in the year after primary treatment of breast cancer. *J Clin Oncol*. 2011; 29(9):1101–1109. [PubMed: 21300931]
23. Leykin Y, Thekdi SM, Shumay DM, Muñoz RF, Riba M, Dunn LB. Internet interventions for improving psychological well-being in psycho-oncology: review and recommendations. *Psychooncology*. 2012; 21(9):1016–1025. [PubMed: 21608075]
24. Yanez B, McGinty HL, Mohr DC, et al. Feasibility, acceptability, and preliminary efficacy of a technology-assisted psychosocial intervention for racially diverse men with advanced prostate cancer. *Cancer*. 2015; 121(24):4407–4415. [PubMed: 26348661]
25. Eysenbach G, Group C-E. Consort-Ehealth: improving and standardizing evaluation reports of web-based and mobile health interventions. *J Med Internet Res*. 2011; 13(4):e126. [PubMed: 22209829]
26. Mohr DC, Schueller SM, Montague E, Burns MN, Rashidi P. The behavioral intervention technology model: an integrated conceptual and technological framework for eHealth and mHealth interventions. *J Med Internet Res*. 2014; 16(6):e146. [PubMed: 24905070]
27. Lopez MH, , Gonzalez-Barrera A, , Patten E. Closing the Digital Divide: Latinos and Technology Adoption 2013 <http://www.pewhispanic.org/2013/03/07/closing-the-digital-divide-latinos-and-technology-adoption/> Accessed October 1, 2014

28. Valero-Aguilera B, Bermudez-Tamayo C, Garcia-Gutierrez JF, et al. Factors related to use of the internet as a source of health information by urological cancer patients. *Support Care Cancer*. 2012; 20(12):3087–3094. [PubMed: 22415609]
29. Bowen DJ, Kreuter M, Spring B, et al. How we design feasibility studies. *Am J Prev Med*. 2009; 36(5):452–457. [PubMed: 19362699]
30. Antoni MH, Lechner SC, Kazi A, et al. How stress management improves quality of life after treatment for breast cancer. *J Consult Clin Psychol*. 2006; 74(6):1143–1152. [PubMed: 17154743]
31. Herschbach P, Book K, Dinkel A, et al. Evaluation of two group therapies to reduce fear of progression in cancer patients. *Support Care Cancer*. 2010; 18(4):471–479.
32. Penedo F, Molton I, Dahn J, et al. A randomized clinical trial of group-based cognitive-behavioral stress management in localized prostate cancer: development of stress management skills improves quality of life and benefit finding. *Ann Behav Med*. 2006; 31(3):261–270. [PubMed: 16700640]
33. van't Veer-Tazelaar PJ, van Marwijk HJ, van Oppen P, et al. Stepped-care prevention of anxiety and depression in late life: a randomized controlled trial. *Arch Gen Psychiatry*. 2009; 66(3):297–304. [PubMed: 19255379]
34. Pearman T, Yanez B, Peipert J, Wortman K, Beaumont J, Cella D. Ambulatory cancer and US general population reference values and cutoff scores for the functional assessment of cancer therapy. *Cancer*. 2014; 120(18):2902–2909. [PubMed: 24853866]
35. Stanton AL, Snider PR. Coping with a breast cancer diagnosis: a prospective study. *Health Psychol*. 1993; 12(1):16–23. [PubMed: 8462494]
36. Buitrago D, , Maciel C, , Shivaprakash N. , et al. Development of a Patient-Centered Smartphone Application for Hispanic Breast Cancer Survivors; Paper Presented at: The 14th International Conference of the Society for Integrative Oncology; Chicago, IL. 2017
37. Miller WR, , Rollnick S. *Motivational Interviewing: Helping People Change* Guilford press; 2012
38. Charlson M, Slatkowski TP, Peterson J, Gold J. Validation of a combined comorbidity index. *J Clin Epidemiol*. 1994; 47(11):1245–1251. [PubMed: 7722560]
39. Adler NE, Epel ES, Castellazzo G, Ickovics JR. Relationship of subjective and objective social status with psychological and physiological functioning: preliminary data in healthy, White women. *Health Psychol*. 2000; 19(6):586–592. [PubMed: 11129362]
40. Brady MJ, Cella DF, Mo F, et al. Reliability and validity of the Functional Assessment of Cancer Therapy-Breast quality-of-life instrument. *J Clin Oncol*. 1997; 15(3):974–986. [PubMed: 9060536]
41. Cella D, Hernandez L, Bonomi AE, et al. Spanish language translation and initial validation of the functional assessment of cancer therapy quality-of-life instrument. *Med Care*. 1998; 36(9):1407–1418. [PubMed: 9749663]
42. Yanez B, Pearman T, Lis CG, Beaumont JL, Cella D. The FACT-G7: a rapid version of the functional assessment of cancer therapy-general (FACT-G) for monitoring symptoms and concerns in oncology practice and research. *Ann Oncol*. 2013; 24(4):1073–1078. [PubMed: 23136235]
43. Horowitz M, Wilner N, Alvarez W. Impact of event scale: a measure of subjective stress. *Psychosom Med*. 1979; 41(3):209–218. [PubMed: 472086]
44. Báguena MJ, Villarroja E, Beleña A, Díaz A, Roldán C, Reig R. Propiedades psicométricas de la versión española de la Escala Revisada de Impacto del Estrés (EIE-R). *Análisis Modificación Conducta*. 2001; 27:581–604.
45. Chen JY, Diamant AL, Thind A, Maly RC. Determinants of breast cancer knowledge among newly diagnosed, low-income, medically underserved women with breast cancer. *Cancer*. 2008; 112(5):1153–1161. [PubMed: 18189306]
46. Yanez B, , Buitrago D, , Carrio M, , Salas K, , Reyes K, , Penedo FJ. Adherence to endocrine therapies among Hispanic breast cancer survivors: a qualitative analysis; Paper Presented at: Society for Behavioral Medicine; Washington DC. 2016
47. Wolf MS, Chang CH, Davis T, Makoul G. Development and validation of the communication and attitudinal self-efficacy scale for cancer (CASE-cancer). *Patient Educ Couns*. 2005; 57(3):333–341. [PubMed: 15893217]

48. Jean-Pierre P, Fiscella K, Freund KM, et al. Structural and reliability analysis of a patient satisfaction with cancer-related care measure. *Cancer*. 2011; 117(4):854–861. [PubMed: 20922802]
49. Stanton AL, Bernaards CA, Ganz PA. The BCPT symptom scales: a measure of physical symptoms for women diagnosed with or at risk for breast cancer. *J Natl Cancer Inst*. 2005; 97(6): 448–456. [PubMed: 15770009]
50. Sanson-Fisher R, Girgis A, Boyes A, et al. The unmet supportive care needs of patients with cancer. *Cancer*. 2000; 88(1):226–237. [PubMed: 10618627]
51. Venkatesh V, Davis FDA. Theoretical extension of the technology acceptance model: four longitudinal field studies. *Manag Sci*. 2000; 46(2):186–204.
52. Lewis JR. Psychometric evaluation of the post-study system usability questionnaire: the PSSUQ. *Proceedings of the Human Factors and Ergonomics Society Annual Meeting*. 1992; 36(16):1259–1260.
53. Brooke J. SUS-A quick and dirty usability scale. *Usability Evaluation in Industry*. 1996; 189(194): 4–7.
54. Lund AM. Measuring usability with the USE Questionnaire12. *Usability Interf*. 2001; 8(2):3–6.
55. Campbell LC, Keefe FJ, Scipio C, et al. Facilitating research participation and improving quality of life for African American prostate cancer survivors and their intimate partners. *Cancer*. 2007; 109(S2):414–424. [PubMed: 17173280]
56. Kissane DW, Grabsch B, Clarke DM, et al. Supportive-expressive group therapy for women with metastatic breast cancer: survival and psychosocial outcome from a randomized controlled trial. *Psychooncology*. 2007; 16(4):277–286. [PubMed: 17385190]
57. Brucker PS, Yost K, Cashy J, Webster K, Cella D. General population and cancer patient norms for the functional assessment of cancer therapy-general (FACT-G). *Eval Health Prof*. 2005; 28(2): 192–211. [PubMed: 15851773]
58. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform*. 2009; 42(2):377–381. [PubMed: 18929686]

Fig. 1.
Telecoaching stepped-care protocol.

Fig. 2.
Managing My Health page screenshot.

Fig. 3.
Friends & Family page screenshot.

Fig. 4.
Friends & Family page screenshot.

Fig. 5.
Community & Everyday Support page screenshot.

Table 1

My Guide main components.

<i>My Guide</i> components	Description
Managing My Symptoms	This section highlights the physical and psychological symptoms commonly experienced after cancer treatment, and provides methods to manage them.
Managing My Health	This section provides general information on breast cancer, adjuvant treatments and related side effects, and strategies to manage side effects.
Friends & Family	This section discusses ways in which relationships with family, friends, and other acquaintances might change after a cancer diagnosis, and presents strategies to address these changes.
Managing My Emotions	This section discusses the emotions most commonly experienced after cancer treatment, and provides stress management and relaxation techniques.
Breast Cancer Medications	This section presents important information specifically for survivors on different types of hormone therapies and related side effects.
Community & Everyday Support	This section provides a comprehensive list of external resources and community organizations for breast cancer survivors, including health-related and financial support.
Videos, Audio programs	Video and audio recordings are integrated throughout the sections to supplement information provided in the text. Videos provide expert explanations of side effects and breast health, while audio recordings walk participants through relaxation exercises.
Bookmarks	An added feature allows participants to mark their preferred sections for easy reference.

Table 2

My Health main components.

<i>My Health components</i>	Description
Food & Nutrition	This section discusses the importance of good nutrition for breast cancer survivors, and provides guidance on which foods to eat and which to limit.
Eating Well	This section instructs participants on how to maintain a balanced diet, including techniques on portion control, tips for eating out, and healthy recipes.
Preventing Diabetes & heart disease	Participants, who are largely older and post-menopausal, are at greater risk for developing diabetes and heart disease. This section presents information on diabetes and heart disease prevention, as well as a quiz component to dispel myths about both.
Exercise	This section discusses the benefits of exercise and provides non-traditional, culturally appropriate approaches to increasing activity levels and raising heart rates.
Lifestyle	This section presents important information on healthy lifestyle habits, including sun safety and smoking cessation.
Doctor's recommendations	This section provides guidance on medication adherence and tips for interacting with a doctor.