

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

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## ARTICLE INFO

### Keywords:

Breast cancer  
Hispanic  
Health-related quality of life  
Interventions  
eHealth

## 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 multi-site, 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 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.

## 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

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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

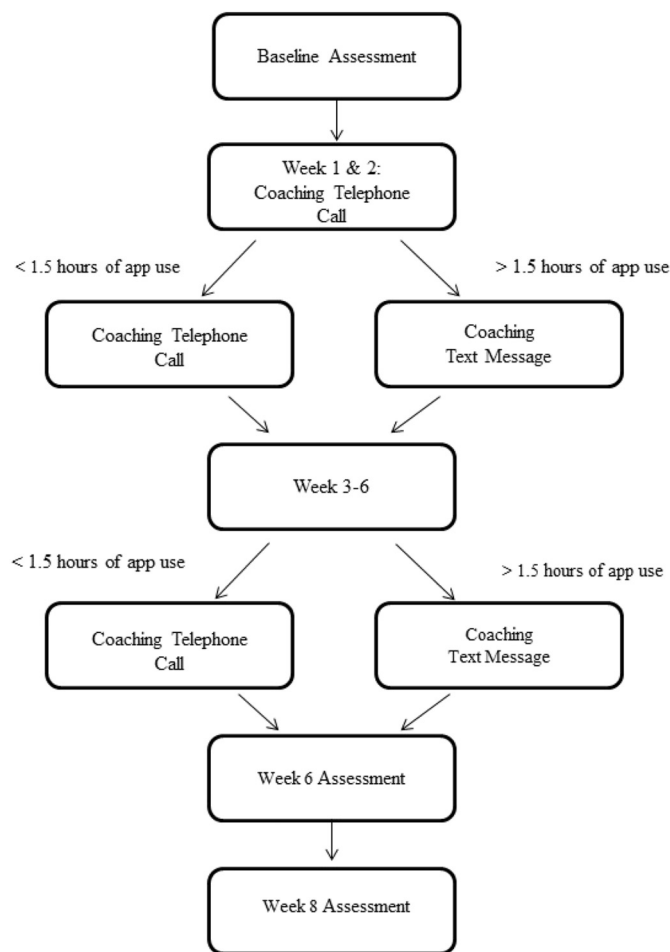


Fig. 1. Telecoaching stepped-care protocol.

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.

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