

PROTOCOL TITLE:

An e-Health Intervention to Improve Symptom Burden and Health-Related Quality of Life among Hispanic Women Completing Active Treatment for Breast Cancer

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1.0 Purpose of the Study:

This study aims to create and evaluate *Mi Guia* study aims, a culturally informed eHealth educational and psychosocial intervention for English or Spanish-speaking Hispanic women completing treatment for breast cancer. *Mi Guia* is grounded in evidence-based paradigms to improve our Primary Outcomes: Cancer-Related Symptom Burden and HRQOL and our Secondary Outcomes: cancer-specific distress, depressive symptoms, and markers of *Mi Guia* use. We propose a two-phase study to develop our Smartphone-based intervention that can be disseminated to survivors at a relatively low cost. We will use innovative methodology; MOST framework that will allow us to achieve both optimization and evaluation of *Mi Guia* by determining which single components or combination of components in *Mi Guia* affect our outcomes^{9,10}. Study components (one on breast cancer education, two psychosocial evidence-based components relevant to Hispanic women who have been diagnosed with breast cancer) will be paired with personal tele-coaching.

Aim 1 (Phase 1, Year 1): Create *Mi Guia*, an eHealth intervention designed to improve cancer-related symptom burden and HRQOL. Aim 1 is further broken down into four parts. Using a mixed-methods approach, we will 1a) collect qualitative data (n= 20) on the study content, 1b) conduct usability testing on the *Mi Guia* Smartphone application, and 1c) conduct feasibility testing (e.g., field trial) to refine the content in the components and the design of the Smartphone-delivered intervention for Hispanic women. Finally, we will add one more part to Aim 1, aim 1d) to conduct interviews with community stakeholders about the *Mi Guia/My Guide* application. These interviews with community stakeholders will not include any questions about participants. The interviews will only include questions about the application itself and their ideas on how to improve it.

Aim 2 (Phase 2, Years 2 & 3): Optimize components for *Mi Guia* through an 6-week randomized trial to evaluate the efficacy of *Mi Guia* relative to a smartphone application on health education (*Mi Salud*), our control condition. The health promotion application, *Mi Salud*, includes health education content on nutrition, and general advice on lifestyle choices and prevention. 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 early-stage women completing active treatment (n= 90) We hypothesize that Hispanic BCS will find the smartphone application, *Mi Guia*, an acceptable and feasible way of accessing post-treatment relevant information. Furthermore, we expect that, in comparison to the control condition, *My Guide* will have a measurable, positive impact on this population's HRQOL and cancer-specific distress.

2.0 Background / Literature Review / Rationale for the study:

Ethnic minority and underserved populations are disproportionately burdened by cancer.¹ Among Hispanics, the largest and fastest growing ethnic minority group in the U.S., cancer is the leading cause of death whereas cardiovascular disease is the leading cause of death for African Americans and non-Hispanic Whites (NHWs). Hispanics also experience substantially lower rates of 5-year cancer-specific survival relative to non-Hispanic Whites (NHWs). Relative to NHWs, Hispanics are more likely to be diagnosed with advanced stages of breast cancer.² Furthermore, the average age of breast cancer diagnosis for Hispanics is 50 years, which is a decade earlier than for NHW women. Barriers to accessing and effectively engaging in health care, limited cancer information, beliefs about cancer are some factors that may contribute to these disparities.¹⁻³

Hispanic cancer patients in the U.S. also report significantly worse cancer-related symptom burden and health-related quality of life (HRQOL) than NHWs, even after adjusting for socioeconomic factors.^{3,4} Despite this, very few randomized, intervention studies have specifically targeted cancer-related symptom burden and HRQOL outcomes among Hispanic women, especially during the period at the end of active treatment which is a critical period to intervene to provide skills and tools to assist with the transition to survivorship⁵. The few, existing studies were too small and underpowered to detect differences or yielded null findings^{6,7}. One study did report a positive effect, however which components or combination components of psychosocial interventions that may reduce symptom burden and improve HRQOL in Hispanic breast cancer survivors (BCS) remains unknown, thus creating a critical gap in the literature⁸. Hispanic women diagnosed with cancer may have difficulty gaining access to supportive and psychosocial services that can assist with symptom burden and HRQOL and face obstacles such as cost, lack of insurance coverage, time constraints to name a few^{1,11}. Therefore innovative approaches to providing interventions such as Smartphone technology are especially important for this patient population. Ubiquitous Smartphone use among ethnic minorities in the US provide a unique opportunity to implement a pragmatic technology- and evidence-based psychosocial intervention that overcomes some access to care barriers as well as time and logistical constraints¹². Given that Hispanics own Smartphones and seek health information online from a mobile device at similar or higher rates than other groups in the U.S., Smartphone interventions offer an opportunity to overcome obstacles to accessing resources and services that can be culturally informed and provide skills to improve symptom burden and HRQOL¹². We have previously shown that cancer-related knowledge, stress management, coping skills, and communication can negatively affect the post-treatment survivorship phase, underscoring the importance addressing these components in a psychosocial intervention^{3,13,14}.

3.0 Inclusion and exclusion criteria:

Eligibility Criteria will remain mostly the same for all the phases of the study. Inclusion criteria: 1) Female; 2) Diagnosis of BC, 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 BC (surgery, chemotherapy and/or radiation therapy, current hormonal treatment allowed); 4) No current evidence of disease; 5) Within 3 to 15 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 symptom burden and HRQOL; 10) Self-identified Hispanic/Latina ethnicity; 11) with the exception of nonmelanoma skin cancer, no previous diagnosis of cancer. Exclusion criteria: 1) Visual, hearing, voice, or motor impairment that would prevent completion of study procedures; 2) diagnosis of an unmanaged psychotic or psychiatric disorder (e.g., clinical depression, anxiety, or PTSD), bipolar disorder, dissociative disorder, or other diagnosis for which participation in this trial is either inappropriate or dangerous – this includes patients who have 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., chronic severe pain, fibromyalgia); 3) Illicit substance or alcohol dependence 4) Suicidal ideation, plan, intent; 5) Alzheimer's, dementia or history of stroke. 6) Scheduled reconstruction surgery within 1 month of any study procedures or involvement. Also women in presurgery preparations such as expanders that would affect quality of life and/or study outcomes. To minimize threats to internal validity, we evaluate intervention components among a relatively homogenous population with regard to cancer type, stage and treatment. Patients with metastatic disease have a

higher likelihood of dying of breast cancer, more extensive treatment, and may differ in levels of HRQOL and therefore will not be included. Previous observational studies indicate that Hispanic women are more likely to report symptom burden within 6 months of completing active treatment relative to NHWs.

Additionally during Aim 1c only, we will expand eligibility criteria to include women who are as far out as 36 months and who do not have an elevated score on the breast cancer symptom burden and HRQOL questionnaire. Our goal is to have at least half of the sample for Aim 1c (10 women) meet all eligibility criteria, but if need be use the expanded criteria just described. Since the field trial is mainly focused on addressing the functionality of the phone application, we have decided to expand the criteria since this is a phase in the project when we can be more lenient with eligibility. It is also very possible that women other than those with lower HRQOL or high symptom burden could benefit from being part of the project.

During Aim 2 only, we will expand eligibility criteria to include women who are as far out as 24 months after completing treatment, and women who have had cancer recurrences as they might also benefit from our intervention. We will include participants with cancer recurrences as long as they still fit the original breast cancer specific eligibility criteria listed above, and as long as the occurrence of a different cancer does not confound our ability to make direct inferences about the source of breast cancer related distress, and for whom our breast cancer intervention will be most relevant. We have created a flow chart and additional questions that we will use when deciding how to include women in the study who have had recurrences (see screening questionnaire).

Additionally, during Aim 2, we will exclude women who only received education until the 4th grade as we have observed difficulties among participants with limited education that could cause more challenges for the participant rather than benefiting them. We will also be excluding women who will be traveling or who have previous scheduled events that could hinder their commitment and availability for the study.

Finally, as we did during Aim 1c, in Aim 2 we will include women who do not meet our originally established score on the breast cancer symptom burden and HRQOL questionnaire. Based on preliminary observations of the data collected from Aim 1c, it appears that all participants can equally benefit from using My Guide. However we will ask participants during screening the abridged version of the FACT questionnaire (the FACT-G7-See screening questionnaire). Our goal is to have at least 25 women meet the elevated FACT-G7 score (-14).

Participants for Aim 1d will be community stakeholders who have worked with Latina/Hispanic breast cancer survivors who would like to view the application and provide feedback.

4.0 Procedures Involved:

Specific Aim 1.

1a. We will begin developing our intervention content by interviewing 20 English or Spanish-speaking Hispanic/Latina women (women will be stratified by language) who meet the study eligibility criteria. Individual interviews with the participants will be conducted by the bilingual PI and bicultural/bilingually trained research staff, using a semi-structured guide based on prior work from the PI. The translated final Spanish versions of all participant-facing materials for Aim 1a will be submitted prior to recruitment once the final English versions of the documents have been approved by

the IRB. This will help minimize back-and-forward resubmission of documents due to any changes requested prior to final approval.

Potential subjects at the Northwestern site will be identified by the electronic data warehouse (EDW) and EPIC (all oncologists specializing in breast cancer at NU will be informed of this project via email). Study staff will have IRB/HIPAA compliant approval to access electronic medical records (EMR) systems. EDW will release up to 100 viable participants for the purpose of recruitment, and the research staff will then review and identify participants to be recruited and then pre-screen those participants via their EMR in EPIC to determine potential eligibility using a Screening EMR Extraction form. For participants recruited through Judy Guitelman, no EMR extraction is feasible during screening, for these patients only the phone screening will be used to determine eligibility.

Once a patient is identified as potentially eligible based on the EMR screening, research staff will discuss the case with the attending physician and obtain physician approval prior to making contact with the patient to conduct a phone eligibility screening.

Participants for Aim 1a and 1b will be recruited from the Robert H. Lurie Comprehensive Cancer Center (RHLCCC). Once we receive IRB approval to add the University of Illinois as a recruitment site for Aim 1c and Aim 2, we will begin recruiting from UIC as well. An IAA will be submitted to the Northwestern IRB prior to recruitment at UIC. Patients will be identified either by physicians at Northwestern or UIC and at the Northwestern site participants will be screened in EMRs. Across all Aims, participants will also be recruited through Judy Guitelman, the associate director of the Latina Association of Breast Cancer, who is a study community consultant and breast cancer advocate. Once a patient is identified as potentially eligible based on the EMR screening or physician referral, and following physician approval to make contact with the patient, prospective participants will be contacted via a mailed pre-recruitment letter. Study staff will send the potential participant this letter, which introduces the study. One week later, unless the potential participant contacts the study staff to opt out of the study, the study staff will call the potentially eligible participant to provide additional information about the study. During this call, if the potential participant expresses interest, bilingual and bicultural study staff will proceed with a brief eligibility phone screening to determine further eligibility. Potential subjects recruited from the Latina Association of Breast Cancer will be identified by Judy Guitelman, the association director. Ms. Guitelman is informed of the study goals, procedures, and eligibility. Ms. Guitelman will briefly discuss the study goals and procedures with potentially interested women, and provide them with a study brochure. The study staff will call the women that express interest and agree to being contacted. During this call, research staff will provide the potentially eligible participant with additional information about the study, if the potential participant expresses interest, bilingual and bicultural study staff will proceed with a brief eligibility phone screening to determine further eligibility.

In order to minimize the possibility of coercion, the UIC PI, Dr. Perez-Tamayo, will be involved in identifying potentially eligible participants from her practice, but neither she nor her staff, Yvette Castro, will be involved in consenting participants. Any other member of the study staff will be involved in consenting patients recruited from UIC. This recruitment and consent structure will minimize possibility of coercion for participants recruited by Dr. Perez-Tamayo, the UIC site PI.

The phone screening is a short-answer and multiple choice questionnaire that is estimated to last about 10 minutes with each participant. The questions address all the items in the inclusion/exclusion criteria above (section 3.0) to determine participant eligibility for the study. Most of the phone screening questions regarding inclusion criteria items 1-8, 10 and 11 are short-answer questions and will serve to

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verify the data in the Screening EMR Extraction form, to address missing data or discrepancies if any. Certain items such as item 9 in the inclusion criteria, and items in the exclusion criteria are often not clearly defined in the EMR. To verify eligibility for item 9 in the inclusion criteria, we will include women who score higher than 30 points in the FACT-B questionnaire (version 4). For exclusion criteria items 1, 2, 5 and 6 we will ask yes/no questions to participants about the diagnosis or impairments mentioned above, and prove with a short-answer question to determine when the specific diagnosis or impairment would interfere with participation/eligibility in the study (because it is unmanaged, too severe and would make participation inappropriate, or because it would confound study outcomes). To further screen for item 2, we will exclude women who have been hospitalized for psychotic or psychiatric disorders in the past 12 months. To address item 3 on substance and alcohol abuse, we will ask the participant a series of short-answer questions to determine if any drug or alcohol use indicate dependence or abuse, in which case the participant would be excluded. Finally to address item 4, we will ask if the person has thoughts of harming themselves and determine the nature and imminence of the threat. Persons with suicidal ideation, plan or intent will be excluded from the study.

In the event that a participant expresses suicidal tendencies during the screening process (see question 3 on phone screening form), we will provide immediate assistance over the phone as appropriate and refer them for local treatment. Speaking privately with the participant, we will assess for suicidal ideation, plan of action, and likelihood of carrying out the plan. We will help the participant obtain immediate assistance in the home (e.g., ask if spouse/friend can be contacted) and will encourage her to seek medical attention if she is at high risk. Local resource referrals will be kept on file to be used in the event of such an emergency. Dr. Penedo, Northwestern site co-investigator, is a licensed clinical health psychologist, experienced in psychotherapy, and counseling of patients and families dealing with chronic and acute medical conditions, particularly cancer. Drs. Yanez and Penedo have doctorates in clinical psychology and have provided individual therapy for patients through the supportive oncology program at Northwestern.

The data collected in the EMR Extraction Screening form will not be retained as participant records. However, for eligible subjects that consent to participate in this study, the data collected during the eligibility phone screening will be used as study data across both aims. This will clearly be stated in the consent forms. Using the phone screening data as study data will allow us to minimize participant burden by not re-asking the same questions post-consent.

If a participant is eligible after verifying the data collected both in the EMR Extraction Screening form and during the phone screening, they will be notified right away on the phone that they are eligible, and be asked if they would like to participate in the study. For participants recruited through Judy Guitelman, no EMR extraction is feasible during screening, for these patients only the phone screening will be used to determine eligibility. If a participant is eligible and would like to participate, we will try to set up a time to meet in person to conduct the consent procedures and the study interview (see interview details below and 7.0 Consent Process). If the eligible participant does not want to participate in the study, study staff will not proceed with further screening. They will thank her for her time and will not contact her again. The completed screening documents of potential participants who are deemed ineligible will be destroyed after the completion of screening.

The purpose of the interview is to further understand Latina women's experiences with cancer and survivorship as well as symptom burden, quality of life and unmet needs during the cancer and survivorship experience and assess interest in a technology-assisted intervention. Participants who meet all study eligibility criteria and consent to participate will be scheduled for an in-person interview that will take approximately 60 minutes (see interview script) and take place at our laboratory space

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within the Department of Medical Social Sciences at the Feinberg School of Medicine or at a location convenient for the respondent (e.g., respondent's home, local library). Participants will also be asked to complete a technology survey to gather information on their general comfort with technology (e.g., cell phone, smartphones, computers). During the interview, participants will also be asked to complete a brief "Knowledge of Breast Cancer Questionnaire, and to review a breast cancer information packet from the National Cancer Institute (attached to the IRB application) and be asked to give the interviewer their opinion on the usefulness of this information. The demographics questionnaire, interview, Knowledge of Breast Cancer Questionnaire and technology survey are attached to the IRB application.

Upon completion of informed consent and HIPAA authorization participants will be asked to complete questions on their demographics (e.g., Hispanic ancestry, age, income, education) so that we may characterize the study sample. We are also requesting HIPAA authorization in order to obtain medical and treatment-related information from participants' medical records (e.g., stage of diagnosis, cancer treatments and dates of treatment, medical co-morbidities) as these data will be considered covariates in our data analyses and will be collected using the Post-Consent EMR Extraction form. We will also be obtaining genetic health information, specifically for BRCA susceptibility. Women who are aware of an increased risk of recurrence might experience more distress, and it is important to statistically control for this type of testing to understand the study results. For participants recruited through Judy Guitelman, the study staff will obtain the necessary information to request the patient's medical records by obtaining the required documentation from their doctor's office to release the records. Following completion of their demographics, women will complete the interview followed by the brief technology survey. All interviews will be audio recorded so that they may later be transcribed and coded for thematic content. The PI is experienced with qualitative methods and is PI on another grant with similar qualitative methods. Participants will be paid \$35 for their time and reimbursed for travel costs. A mix of inductive and deductive methods will be used to guide analyses for this phase of the study. Responses from the interviews will be transcribed and then examined using NVIVO software. Two independent raters will generate a list of themes and dimensions of major ideas expressed by participants. Findings from these interviews will be used to finalize the application content before proceeding to next phase (phase 1b) of our research. We anticipate completion of the interviews by June of 2016.

1b. Following completion of the interviews in **1a** and thematic coding of the interviews, participants (either those who previously participated who agree to be contacted for future similar studies in their consent or newly recruited participants) will participate in usability testing which is **1b**. Eligibility criteria is the same across all study aims. Recruitment procedures for new participants are the same as in Aim 1a. However, we anticipate that most is not all women participating in Aim 1b will be participants who previously participated in Aim 1a of the project. Upon completing consent and HIPAA authorization to collect protected health information, participants will be asked to complete demographic and clinical self-reported information. We are also requesting HIPAA authorization in order to obtain medical and treatment-related information from participants' medical records (e.g., stage of diagnosis, cancer treatments and dates of treatment, medical co-morbidities) as these data will be considered covariates in our data analyses and will be collected using the same Post-Consent EMR Extraction form used during Aim 1a. Participants who already completed demographics and information regarding their cancer treatment in Aim 1a will not be asked to complete demographic or clinical information again. Any participants who were not enrolled in Aim 1a but are now enrolled in Aim 1b as new study participants will be asked to complete their clinical and demographic information using the same forms as the IRB approved forms used in Aim 1a. Researchers Rachel Adler and Francisco Iacobelli from Northeastern Illinois University (NEIU) will collaborate with the

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Northwestern team in developing and conducting this phase of the project which will start shortly after completion of Aim 1a. The NEIU IRB approval letter is included in this IRB modification.

Patients involved in the qualitative interviews for Aim 1b will be asked to complete a 1 hour laboratory-based usability testing session on the Smartphone-based application that will take place within Dr. Yanez's laboratory space in the Department of Medical Social Sciences at Northwestern University. If a participant is unable to make it to Northwestern University of usability testing, the members of the study staff will conduct a field visit to the participant's house to conduct the usability testing.

We will employ a task-based usability approach, where participants will complete a series of tasks with mockups and prototypes of the application and performance measures related to usability will be captured on their ability to complete these tasks such as the USE questionnaire (see attached measures and questions that will be asked in Aim 1b). This test will focus on several aspects of usability: learnability, memorability, ease of use, and efficiency. Participants will complete the usability testing in a controlled laboratory environment while a member of the research team guides them through the process. A second member of the research team will observe, audio record the session, and take notes during the usability test as well as record the session. The usability observer will capture quantitative metrics related to usability performance such as time on task and errors accessing content on the application (e.g., unable to find the homescreen bottom or navigate through the application). The usability observer will also capture qualitative data from think aloud related to appeal, comprehension of words and graphs and appeal of the design of the application (e.g., are the colors appealing, is the font size to small or too big). Participants will also be prompted with questions addressing technical reliability on the application (e.g. problems with the technology) and functional reliability (e.g. problems with application use, integrating the system into daily life). Usability will also be assessed with the USE questionnaire to capture quantitative feedback on the prototype of the Smartphone-based application. Participants in the usability testing will be paid \$35 and reimbursed for travel. The translated final Spanish versions of the Aim 1b consent and the Aim 1b interview guide will be submitted prior to Aim 1b recruitment once the final English versions of these documents have been approved by the IRB. This will help minimize back-and-forward resubmission of documents due to changes requested prior to approval.

1c. Following completion of the interviews in **1a** and thematic coding of the interviews, as well as participating in usability testing for 1b, participants (either those who previously participated who agree to be contacted for future similar studies in their consent or newly recruited participants) will participate in a 4-week field trial, **1c**. We expect to recruit a total of 20 participants for this phase of the study. Eligibility criteria is mostly the same across all study aims. However during Aim 1c, we will expand eligibility criteria to also include women who are as far out as 36 months and who do not necessarily need to have an elevated score on breast cancer symptom burden and HRQOL questionnaire. Our goal is to have at least 10 women meet all original eligibility criteria, but if need be use the expanded criteria. Since the field trial is mainly focused on addressing the functionality of the phone application and study procedures, we have decided to expand the criteria. Additionally, it is possible that women other than those with lower HRQOL or high symptom burden could benefit from participation.

All interactions with participants will be conducted by the bilingual PI and bicultural/bilingually trained research staff. The translated final Spanish versions of all participant-facing materials for Aim 1c will be submitted prior to recruitment once the final English versions of the documents have been

approved by the IRB. This will help minimize back-and-forward resubmission of documents due to any changes requested prior to final approval.

Recruitment and screening procedures will be the same as in Aim 1a and Aim 1b. We will add the University of Illinois at Chicago as a recruitment site during Aim 1c and Aim 2 once we add the UIC signed IAA and UIC is approved by NU IRB as a study site.

Participants that completed Aim 1a or Aim 1b will be invited to participate in Aim 1c. If they are interested in being part of the field trial, we will explain all the procedures for Aim 1c, and if they choose to participate they will not have to redo any questionnaires, but will be asked instead to let us use already collected information in the previous study aims. This will be explained in the consent document as well. Additional details about recruitment and screening procedures are described under aim 1a above.

For participants that have not participated in previous phases, and all participants in Aim 2 if a participant is eligible after both verifying the data revised using the EMR Extraction Screening form (the first level of screening to exclude participants) and during the phone screening (the final level of eligibility screening to confirm unclear criteria in the EMR), they will be notified right away on the phone that they are eligible, and be asked if they would like to participate in the study. If a participant is eligible and would like to participate, we will try to set up a time to meet in person to conduct the consent procedures and the procedures for the first Aim 1c or Aim 2 in-person meeting (see below). If the eligible participant does not want to participate in the study, study staff will not proceed with further screening. They will thank her for her time and will not contact her again. The completed screening documents of potential participants who are deemed ineligible will be destroyed after the completion of screening.

University of Illinois Subject Enrollment: Dr. Perez-Tamayo will be involved in identifying potentially eligible participants from her clinic. In order to minimize the possibility of coercion, neither she nor her staff, Yvette Castro, will be involved in consenting participants. Both Dr. Tamayo and Yvette Castro will be added as research staff, however, other members of the study staff at Northwestern will be involved in consenting patients recruited from UIC. This recruitment and consent structure will minimize possibility of coercion for participants recruited from Dr. Perez-Tamayo's clinic. Dr. Perez Tamayo and Yvette Castro will introduce the study to potentially eligible patients using the study brochure and recruitment scrip, if patients agree to participate they will forward their name and phone number to the NU research staff via phone. The NU research staff will continue with the phone screening and setting up a time for their first meeting. At UIC, the EMR screening form will be used as a guideline only in order to guide the initial participant screening by Yvette Castro and Dr. Perez Tamayo. However, no information from the EMR will be recorded on this form by UIC personnel, only contact information necessary to call participants will be recorded in order to continue with recruitment and phone screening.

For both sites, when participants are eligible and agree to participate, we will ask them to set up a time for an in-person consenting process and for an initial meeting. There are 2 in-person meetings for aim 1c, these meetings will take place at our laboratory space within the Department of Medical Social Sciences at the Feinberg School of Medicine or at a location convenient for the respondent (e.g., respondent's home, local library). During the call when we set up a meeting for the initial interview, we will also ask participants whether they would like to borrow a study phone or use their own, and if they will need the study team to create a temporary email address to log into the phone application. These preparatory questions will help the research team have all study materials ready for the first

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meeting. At this point we will also ask participants if they would like to receive a text message to remind them of the appointment location and other general reminders for their first visit (see Study's Text Messages and Phone Screening documents). Text messages will be sent only from a secure Northwestern's Outlook account.

After completing the consent and HIPAA authorization, participants will be asked to complete a demographics questionnaire (unless otherwise completed in previous study phases). We are requesting HIPAA authorization in order to obtain medical and treatment-related information from participants' medical records (e.g., stage of diagnosis, cancer treatments and dates of treatment, medical comorbidities) as these data will be considered covariates in our data analyses. Only the information listed in the Post-Consent EMR Extraction form used in previous aims will be collected. Additionally as it was requested in previous aims, we will ask participants to let us use the information collected during the phone screening as part of the study records. This will be stated in the consent document. During the consent process, we will also ask participants if they would like to receive text message reminders for their weekly call and final appointment (see Study's Text Messages document). This is an optional element that is not required for participation.

Participants will then complete a multiple choice baseline assessment consisting of 6 validated questionnaires: the Impact of Event Scale (IES), Knowledge about Breast Cancer (already approved and used for previous aims), the Communication and Attitudinal Self-Efficacy scale for cancer (CASE-cancer), the Unmet Needs Scale, the Breast Cancer Prevention Trial symptom questionnaire, and the FACT-B (already used during the phone screening, but re-administered if more than 3 weeks pass between screening and baseline assessment). This baseline assessment is estimated to take 15 minutes to complete. In order to make it easier for participants to complete this questionnaire, we created a page with the response options to use when answering the questions in the assessment. This same document would also be used during their follow-up assessment on their last meeting, which consists of the same questions as the baseline assessment.

Once the baseline assessment is completed, participants will go through an orientation of the Mi Guia application. Participants will be given the option to either use their own phone to download the application, and be reimbursed \$40 for data usage at the end of the trial; or they can choose to borrow a study phone (an Android Nexus 5X) with the application already downloaded. Participants who would do not have their own headset, will be given a headset at no cost. Once the participant downloads the application or is provided with a new phone, we will create a unique account with the participant. Only an email address and password is required to register. If the participant does not have an email address, we will create a temporary email address using pseudonyms, which will be deleted at the end of the trial. During the registration we will go over all the features of the application with the respondent, and address any questions. At this point we would give participants a copy of the orientation document so that they can refer to the images and instructions in the document in the future if they have questions during their individual use.

The baseline assessment, and the protocol to be used during registration/orientation is attached to this IRB application. The total estimated time for completing the demographics questionnaire, baseline assessment and orientation process is 1 hour. After this initial meeting is completed, participants will receive \$35, out of a possible \$100. The remainder \$65 will be received during the second and final meeting of Aim 1c.

Participants will then be instructed to access the application for an average of 3-4 hours per week for the duration of the trial (4 weeks total). All the information contained in the application has been

submitted for review, and we will submit images of the final application design prior starting Aim 1c. During the 4 week trial, the application will prompt participants once a week to complete the FACT-B (the short, multiple choice questionnaire already used during screening and baseline). The weekly completion of the FACT-B questionnaire should take less than 5 minutes.

We will also schedule a weekly telecoaching 15-minute call to guide participants through application content they might not be aware of, and to see if there are any issues accessing the application. Coaching participants improves eHealth adherence and outcomes. Dr. Yanez will conduct training for the telecoaches and Dr. Yanez will supervise the telecoaches on a weekly basis. Training will include sensitivity to issues relevant for Hispanic BCS, including cultural beliefs that may influence coping and health behaviors. Telecoaching sessions will be audio-recorded to monitor intervention fidelity, and this has been included in the consent. The protocol/script for this weekly call is attached to the IRB application.

After the completion of the week field trial, we will schedule a final meeting with participants at a location of their choice. During this final meeting, they will complete a follow up assessment consisting of the exact same questions from the baseline, as well as an exit interview (see attached script). The duration of the final in-person meeting will be 1 hour, and this meeting will not be audio recorded. During this meeting we ask all participants if they would like to remove the application from their phones, and follow the described procedures to do so if they would like to have it removed; however, participants that would like to keep the phone application to access information will be allowed to keep it. Those participants will be instructed to not continue to answer weekly questionnaires, and will be told that if the application is moved to another server, they will not be able to access it any more. Participants will then receive \$65 for the completion of Aim 1c, and might be reimbursed \$40 if they used their personal phone during the trial.

Aim 1d. We will conduct 5-10 interviews with community stakeholders about the phone application My Guide. In the past we have worked with multiple support groups and organizations actively involved in the Latino/Hispanic community. We will reach out to our contacts at these organizations via phone call or email to see if they would like to provide feedback about My Guide. If these community stakeholders would like to participate, we will consent them verbally (see section on aim 1d consent below), and provide them with instructions on how to download My Guide to their phones. We will encourage these participants to explore My Guide on their own for 2-4 weeks, and to participate in 1 interview about the application that lasts about 1hr. We will use the Exit interview guide already approved for Aim 1c participants for this interview. We will not ask Aim 1d participants any questions about themselves, but only about how to improve My Guide.

Although the application My Guide has a questionnaire built into the application (the FACT-B/see above), we will ask community stakeholders to review the design/interphase of the questionnaire, but to not input any personal information in the app.

Aim 1d participants will be reimbursed \$100 for their participation.

Specific Aim 2.

Aim 2 (Phase 2): Optimize components for Mi Guia through a 6-week randomized trial to evaluate the efficacy of Mi Guia relative to a smartphone application on health education (My Health), our control condition. 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 early-stage women completing active treatment (n= 90), see eligibility criteria above. A

minimum of 25 participants will meet the compromised cancer-related symptom burden and HRQOL. We hypothesize that Hispanic BCS will find the smartphone application, My Guide, an acceptable and feasible way of accessing post-treatment relevant information. Furthermore, we expect that, in comparison to the control condition, My Guide will have a measurable, positive impact on this population's HRQOL and cancer-specific distress.

Participants will be individually randomized, 1:1, to the health promotion application (control condition) or to the My Guide application (intervention condition). A longitudinal mixed effects linear model will be fit with the outcome (the Functional Assessment of Cancer Therapy-Breast; FACT-B) score as the dependent variable. Type of treatment (e.g., surgery type, hormonal therapy), 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. Effect sizes will be calculated by dividing by the baseline standard deviation. The potential moderating effect will be examined by entering interaction terms into the model. Similar models will be fit to examine the subscales of the FACT-B. A total of 90 participants will be randomly assigned to one of 2 conditions (control or intervention), resulting in 45 participants per condition. The main effect of each intervention component will be evaluated by comparing the outcomes for participants who receive the intervention (n= 45) to those who did not receive the intervention (control; n=45), allowing a comparison of main effects. Participants will be compensated \$100 and reimbursed up to \$22 for travel and data usage.

Technology.

Both My Guide (Mi Guia) and My Health (Mi Salud) will be interactive study applications developed for use with a Nexus 6 Smartphone on the T-Mobile[©] network (see Appendix). Study content will be delivered by a combination of text, video, and audio. The health education application, Mi Salud, includes health education content on nutrition, and general advice on lifestyle choices and prevention (see submitted Mi Salud content under supporting documents in our IRB application). We selected Smartphones due to their smaller, more discrete size, and transportable nature that we believe will provide participants with greater accessibility to lessons and assessments. Moreover, Hispanics own Smartphones, go online from a mobile device and use social networking sites at similar or higher rates than do other groups in the US¹² and Hispanic women are more likely to use the Internet to access health care information than men.⁴⁹ Among participants already having a Smartphone with an Android platform (we anticipate 25% of the sample), we will evaluate compatibility to run each application to be installed by a member of the research team onto their Smartphone. Participants' scores on assessments and application usage (e.g., logins, time spent on application) will be captured and sent wirelessly to a secure server at CBITs. All participants will be trained to use the application.

Trial Design.

Recruitment and screening procedures will remain the same for Aim 2 as they were for earlier Aims in the study (see Aim 1c procedures above, and recruitment procedures below). We will have the same study sites, and the same procedures for identifying and contacting participants as before.

The screening was slightly modified to address the changes to the eligibility criteria mentioned above. Also, as we have done in previous Aims, the data collected in the EMR Extraction Screening form (applicable to NU participants only) will not be retained as participant records. However, for eligible subjects that consent to participate in this study, the data collected during the eligibility phone screening will be used as study data across both aims. This will clearly be stated in the consent

forms. Using the phone screening data as study data will allow us to minimize participant burden by not re-asking the same questions post-consent.

Eligible participants who want to participate will be randomized to the control (My Health/Mi Salud) or intervention conditions (My Guide/Mi Guia) for a total of six weeks. In order to minimize potential confounding factors during the intervention or control delivery, participants will complete the same procedures regardless of randomization assignment.

We will follow the same consenting and scheduling procedures we used for previous study aims. When participants are eligible and agree to participate, we will ask them to set up a time for an in-person consenting process (see consent section below) and for an initial meeting. As we did during Aim 1c, during the call when we set up a meeting for the initial interview, we will also ask participants whether they would like to borrow a study phone or use their own, and if they will need the study team to create a temporary email address to log into the phone application. These preparatory questions will help the research team have all study materials ready for the first meeting. At this point we will also tell participants they can receive a text message to remind them of the appointment location (see Study's Text Messages and Phone Screening documents). All text messages will be sent only from a secure Northwestern's Outlook account.

As it was done during Aim 1c, during the first meeting after the consent and HIPAA authorization, participants will be asked to complete a demographics questionnaire. We are requesting HIPAA authorization in order to obtain medical and treatment-related information from participants' medical records (e.g., stage of diagnosis, cancer treatments and dates of treatment) as these data will be considered covariates in our data analyses. Only the information listed in the Post-Consent EMR Extraction form used in previous aims will be collected. During the consent process, we will tell participants that they will receive text message reminders for their weekly call and final two appointments (see Study's Text Messages document).

Participants will then complete a multiple choice baseline assessment consisting of 9 validated questionnaires: the Impact of Event Scale (IES), Knowledge about Breast Cancer, the Communication and Attitudinal Self-Efficacy scale for cancer (CASE-cancer), the COPE, the Social Provisions Scale, the Nutrition Questionnaire, the International Physical Activity Questionnaire, and the FACT-B. This baseline assessment is estimated to take 15 minutes to complete. In order to make it easier for participants to complete this questionnaire, we created a page with the response options to use when answering the questions in the assessment. This same document would also be used during their follow-ups assessments, which consist of the same questions as the baseline assessment.

Once the baseline assessment is completed, participants will go through an orientation of their corresponding application.

Participants will be given the option to either use their own phone to download the application, and be reimbursed \$15 for data usage at the end of the trial; or they can choose to borrow a study phone (an Android Nexus 5X) with the application already downloaded. Once the participant downloads the application or is provided with a new phone, we will create a unique account with the participant. Only an email address and password is required to register. If the participant does not have an email address, we will create a temporary email address using pseudonyms. During the registration we will go over all the features of the application with the respondent, and address any questions. At this point we would give participants a copy of the orientation document so that they can refer to the images and instructions in the document in the future if they have questions during their individual use.

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Additionally during the orientation, participants will be given a packet of documents to take home that will include responses to all of the questionnaires for the second and third meetings (in case they would like to complete the 2 follow up questionnaires over the phone), as well as a calendar to help them track their study progress. Participants who borrowed a study phone will also receive a mailing packet with instructions on how to mail our study phone. All participants will have the option of receiving a headset to interact with the application, it will be provided free of charge. During the first meeting, participants will receive the first portion of the study incentive \$30, and be reimbursed for up to \$7 for transportation expenses.

The baseline assessment, and the protocols to be used during registration/orientation is attached to this IRB application. The total estimated time for completing the demographics questionnaire, baseline assessment and orientation process is 1 hour.

During the first six weeks, participants will be encouraged to use their respective application for two hours each week, and will be assigned weekly telecoaching calls based on their level of adherence to the recommended application use (see Figure 1). We will use a stepped-care approach to schedule telecoaching calls with participants in order to enhance adherence during the first six weeks of active application use for 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 hours per week. Adherent participants who continue to meet the goal will receive encouraging text messages in lieu of a call (see Study's Text Messages document), unless they fall under the 1.5 hour threshold, and trigger a telecoaching call. All participants are also asked to complete a 7 question FACT-G7 questionnaire every week for the first six weeks of the study.

After six weeks of active application use and telecoaching in the intervention or control conditions, participants will complete two follow-up appointments. At the end of week six, they will complete their first follow-up meeting, they will complete an assessment consisting of the same questions from the baseline questionnaire, as well as an exit interview (the baseline questionnaire, and exit interviews were previously used in Aim 1c of this study). The duration of the meeting is estimated to be under one hour. This meeting can be completed over the phone, or in person at Northwestern depending on the participant's request.

Two weeks later, we will contact participants for a final 30-minute long assessment consisting of the same questions from the baseline which measure our primary outcomes and intervention targets. Participants will **not** be expected to use the phone application, and will not receive telecoaching calls during the 1st follow-up and the 2nd follow-up period.

Participants also have the option of coming to our office at Northwestern for our last meeting. If they choose to come to Northwestern for the final meeting, they can have their compensation in cash rather than receiving the amount in a gift card via mail.

We will first submit all English versions of our Aim 2 documents and application content to the IRB. Once the English versions of the documents are approved, we will submit final clean versions of the Spanish documents. This will help minimize back-and-forward resubmission of documents due to any changes requested prior to final approval.

After the 8 weeks, participants will have the opportunity to receive the application they did not have

access to during the trial. We would like to make sure that even participants that were not assigned the intervention application (My Guide) have the opportunity to learn from it if they want to. Similarly, it is possible that the My Health application will be useful for My Guide participants. Participants will be promised access to the other application for 8 weeks.

We cannot promise indefinite access to either of the study applications since we are not sure of the cost to host the applications long-term. However, if a participant wants to continue to use either application, we will allow them to keep it, but we will inform them that they could lose access to the application at any time after the initial 8 weeks.

Cultural Awareness.

Mi Guia will be culturally informed so that it is aligned with Hispanic values and beliefs such as familism, fatalism and external locus of control, and gender roles.^{27,43,60} All study content will be available in English and Spanish. Much of our study content has already been translated into Spanish¹³ and content that requires translation will be translated by an in-house team of IRB-approved translators at Northwestern and reviewed by all bilingual investigators and staff for approval. Bilingual telecoaches will receive additional intensive training based on models of multicultural awareness. In instances where beliefs, spirituality and mental health stigma are discussed, the telecoach will strive to balance tradition with medical practice, respect spiritual beliefs and destigmatize mental health care. Dr. Penedo and Dr. Yanez have successfully implemented these models in psychosocial interventions in Hispanic cancer survivors.

More on Weekly Telephone Coaching.

Telecoaching calls are designed to increase adherence to the recommended time of use during the first six weeks of the study, and to resolve any issues when accessing the application if any. We will use a stepped-care approach to schedule telecoaching calls with participants in order to enhance adherence during the first six weeks of active application use for both control and intervention conditions. We will use a stepped-care approach to schedule telecoaching calls with participants based on their level of adherence to the recommended application use (see Figure 1). Using this model, participants who continue to use the application for at least 1.5 hours per week will stop receiving regular telecoaching calls, and will receive encouraging weekly 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 in a Motivational Interviewing style.¹⁹ During the first call, telecoaches will conduct a decisional balance exercise with participants to resolve potential ambivalence around 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. All telecoaches will complete training on Therapist Training Manual comprised of intensive in-class training in psychosocial interventions such as motivational interviewing (see Telecoaching Guide attached to application). Coaches will have access to participants' activities through the study website interface. The PI and Co-Investigators have prior experience from CBITs trials. Dr. Buscemi will conduct training for the telecoaches and Dr. Buscemi will supervise the telecoaches on a weekly basis. Training will include sensitivity to issues relevant for Hispanic BCS, including cultural beliefs that may influence coping and health behaviors. Telecoaching sessions will be audio-recorded per CBITs procedures to monitor fidelity. More specifics about the

recruitment procedures, consent process and other aspects of the study for Aim 2, as well as all the corresponding documents will be submitted at a later modification upon completion of Aim 1. Telecoaching sessions will be audio-recorded to monitor intervention fidelity.

5.0 Multiple sites:

Participants will be recruited from Northwestern during all study aims, and Northwestern will be the lead site throughout the duration of the study. Participants for Aims 1c and 2 will be also recruited from the University of Illinois at Chicago (UIC). Researchers at UIC will be engaged in research procedures, and will also have access to PHI. The NU IRB will be the IRB of record, we will upload documentation to corroborate this agreement, and we will add UIC researchers engaged in research to the NU IRB. We will for the most part use the same documents for UIC and NU participants. However, since recruitment and consenting documents differed significantly prior to the IAA, we will keep a unique UIC brochure and consent document. We will also submit a recruitment script with a different introduction for UIC participants who are recruited in a different way from NU participants (see Recruitment procedures).

Northeastern Illinois University investigators Rachel Addler and Francisco Iacobelly will collaborate with the Northwestern team in developing and conducting Aim 1b of the project only. The NEIU IRB has also agreed to make Northwestern the IRB of record (see attached agreement between the 3 institutions), and we will add NEIU researchers to the NU IRB. However please note that NEIU researchers will only access participant PHI during Aim 1b. Starting the field trial, NEIU will assist with the development of materials, but they will not access PHI, or be engaged with researching participants directly.

DePaul University investigator Joanna Buscemi will collaborate with the Northwestern team during Aim 1c and Aim 2. Dr. Buscemi will guide tele-coaching calls during Aim 1c and Aim 2, and she will be accessing PHI during these two phases of the study. Northwestern will request an IRB Authorization Agreement from DePaul University prior to Dr. Buscemi's engagement in the research, and upload the signed IAA form to the supporting documents page once approved. We will also upload her CITI training to the supporting documents page.

6.0 Recruitment:

Participants for Aims 1a, 1b, 1c and 2 will be recruited from the Robert H. Lurie Comprehensive Cancer Center (RHLCCC). During Aim 1c and 2, the University of Illinois at Chicago Cancer Center will be added as a recruitment site. Across all Aims, participants will also be recruited through Judy Guitelman, the associate director of the Latina Association of Breast Cancer.

During Aim 2, we will also begin recruiting from ELLAS, a breast cancer support group organized through The Resurrection Project Chicago. Araceli Lucio, the organizer of ELLAS has agreed to let us distribute brochures through her organization. However, since she works closely with, and holds meetings at various community organizations and clinics in Chicago, she recommended a more general brochure that highlights our collaboration with ELLAS and the community. As we continue to make more relationships with community stakeholders, we hope to be able to distribute this brochure across different groups that are willing to share it with the community.

Finally, the PI has previously conducted studies with the same patient population where participants have been asked if they would like to hear about similar studies. Whenever possible, participants that have consented to be contacted for similar studies who are eligible will be asked if they would be interested in participating.

For participants recruited from the cancer center at Northwestern, once a patient is identified as potentially eligible based on the EMR screening, and following physician approval to make contact with the patient, prospective participants will be contacted via a mailed pre-recruitment letter. Study staff will send the potential participant this letter, which introduces the study. One week later, unless the potential participant contacts the study staff to opt out of the study, the study staff will call the potentially eligible participant to provide additional information about the study. During this call, if the potential participant expresses interest, bilingual and bicultural study staff will proceed with a brief eligibility phone screening to determine further eligibility.

For participants recruited at the University of Illinois, Dr. Perez-Tamayo and Yvette Castro will be involved in identifying potentially eligible participants from her clinic. In order to minimize the possibility of coercion, neither she nor her staff, Yvette Castro, will be involved in consenting participants. Both Dr. Tamayo and Yvette Castro will be added as research staff, however, other members of the study staff at Northwestern will be involved in consenting patients recruited from UIC. This recruitment and consent structure will minimize possibility of coercion for participants recruited from Dr. Perez-Tamayo's clinic. Dr. Perez Tamayo and Yvette Castro will introduce the study to potentially eligible patients using the study brochure and recruitment scrip, if patients agree to participate they will forward their name and phone number to the NU research staff to continue with the phone screening and setting up a time of their first meeting. At UIC, the EMR screening form will be used as a guideline only in order to guide the initial participant screening by Yvette Castro and Dr. Perez Tamayo. However, no information from the EMR will be recorded on this form by UIC personnel, only contact information necessary to call participants will be recorded in order to continue with recruitment and phone screening.

Potential subjects recruited from the Latina Association of Breast Cancer will be identified by Judy Guitelman, the association director. Ms. Guitelman is informed of the study goals, procedures, and eligibility. Ms. Guitelman will briefly discuss the study goals and procedures with potentially interested women, and provide them with a study brochure. The study staff will call the women that express interest and agree to being contacted. During this call, research staff will provide the potentially eligible participant with additional information about the study, if the potential participant expresses interest, bilingual and bicultural study staff will proceed with a brief eligibility phone screening to determine further eligibility.

7.0 Consent Process.

Upon meeting study eligibility, participants will be scheduled for an in-person visit at our laboratory space in the Department of Medical Social Sciences, or at a location of their choice if travel to the university is not feasible, where they will be provided additional information on the study (e.g., risks, benefits, procedures). We will assure that participants have a full understanding of the written informed consent by asking them several questions to ascertain comprehension (e.g., what is your understanding of the purpose of the study? Can you briefly explain to us what is expected of you? Can you please tell us what are the risks involved? The benefits involved?). We have used this approach in the past and it has helped us ascertain that our participants fully understand all procedures, and

provides us with an opportunity to clarify or answer any questions. In order to minimize the possibility of coercion or undue influence, all study staff who are involved in the consent process will repeatedly remind potential participants that their participation is voluntary and that participation or lack of participation in the study is not related to the receipt of their medical care.

Written consent will be obtained for each aim of the study. Women participating in the longitudinal aspects of the study (i.e., Aims 1c and 2) will only be asked to complete consent one time. Only the PI, CO-Is, and trained members of the study staff will be able to consent participants. We anticipate that the consent process will take between 15-20 minutes for Aims 1a and 1b and 20-25 minutes for Aims 1c and 2 as these aims will require additional explanation regarding the longitudinal intervention.

All participants will have the choice to complete the consent form in English or Spanish. Participants who request to complete the consent in Spanish will be consented by a fully bilingual members of the research team. Consent will be translated into Spanish by Diana Buitrago. Ms. Buitrago is a native Spanish speaker and is IRB-certified to translate documented from English into Spanish.

Community stakeholder participants for Aim 1d will be read a verbal consent to inform them about the study. There are no risks associated with this aim of the study, and many of the initial interactions with stakeholders will be via phone call or email. It would not be feasible to attain written consent prior to their use of My Guide. Additionally, the questions to these participants will not be about them, but about the application (see exit interview already being used with Aim 1c participants).

8.0 Process to Document Consent:

As stated above, participant consent will be obtained by bicultural and bilingual study staff using site appropriate IRB approved informed consent documents. These forms will be reviewed, discussed as needed, and then signed and dated by the participants on the date of their interview for Aims 1a, and 1b, and on the first meeting for the longitudinal portion of the study (Aims 1c and 2). The translated final Spanish versions of all participant-facing materials for Aim 1c will be submitted prior to recruitment once the final English versions of the documents have been approved by the IRB. This will help minimize back-and-forward resubmission of documents due to any changes requested prior to final approval.

Community stakeholder participants for Aim 1d will be read a verbal consent to inform them about the study. There are no risks associated with this aim of the study, and many of the initial interactions with stakeholders will be via phone call or email. It would not be feasible to attain written consent prior to their use of My Guide. Additionally, the questions to these participants will not be about them, but about the application (see exit interview already being used with Aim 1c participants).

9.0 Risks to Participants:

It is possible that participation in the study interviews may cause minimal psychological discomfort among women for some women. In our past research on breast cancer survivors, a few participants have at times become tearful when being interviewed about their experiences with cancer treatments. However, this psychological discomfort has always been brief, lasting a few minutes, and appropriate regarding the nature of the discussion. If women become psychologically uncomfortable during our

interviews, we will offer the participants the opportunity to take a break, remind the participant that her participation is voluntary and that she has the right to not answer any questions.

We have not encountered serious psychiatric disturbance (e.g., suicidal ideation) in our previous psychosocial research in cancer. However, in the event we encounter participants in acute crisis during the interviews, we will provide immediate assistance in-person as appropriate and refer them for local treatment. Speaking privately with the participant, we will assess for suicidal ideation, plan of action, and likelihood of carrying out the plan. We will help the participant obtain immediate assistance in the home (e.g., ask if spouse/friend can be contacted) and will encourage her to seek medical attention if she is at high risk. Local resource referrals will be kept on file to be used in the event of such an emergency. Dr. Penedo is a licensed clinical health psychologist, experienced in psychotherapy, and counseling of patients and families dealing with chronic and acute medical conditions, particularly cancer. Drs. Yanez and Penedo are have doctorates in clinical psychology and have provided individual therapy for patients through the supportive oncology program at the RHLCCC.

Specifically regarding the individual (unsupervised) use of the application, we do not foresee that the use of the application will cause distress. This application is meant to increase self-efficacy in communication and coping with emotions, as well as increase knowledge about breast cancer. It contains information only from legitimate sources, and it has been vetted by multiple clinical psychologists and doctors at Northwestern and UIC. Still, we have included disclaimers in the Aim 1c consent, the application and the scripts, reminding participants that the use of the application does not replace standard care provided by a doctor, and they are encouraged to tell their physical before about any changes to their health regimen. They are also instructed to call 911 if they have an urgent medical or mental health issue.

Additionally, women will be able to contact us if they have less pressing questions regarding the phone application, and they will also receive a weekly call, during which we will ask about any issues or concerns they have experienced. It is important to note that we included an additional disclaimer, letting them know that if they attempt to contact us, it might take up to 72 hours for us to respond. Once again, if they are having any urgent medical or mental health issues they are instructed to call 911, or their nearest emergency department.

There is a slight risk of loss of confidentiality. While any information transmitted through the application is protected (see data security section), there is some possibility that others may see participants open the application on the smartphones. We have included language in the consent reminding participants of this potential risk. Although the application does not collect any identifiable information except for the email address during login, if they have privacy concerns, they are instructed to use the application in private.

One final foreseen risk is that patients occasionally try to access the smartphone or participate in assessments while walking or driving. Risks associated with cell phone use and walking or driving will be managed by informing the participants that they are not permitted to use the phones while driving or walking.

We do not anticipate the need to withdraw participants from any of the study aims without their consent. All study data that is already collected, including screening data, will be considered usable data in the event that a participants voluntarily withdraws from the study.

There are no risks associated with participation in Aim 1d for community stakeholder participants.

10.0 Potential Benefits to Participants:

Participants in Aims 1a and 1b will not receive any direct benefit from study participation. However, we have found in our previous work that participants have often expressed gratitude for the opportunity to share their cancer-related experiences and to have the opportunity to contribute to research that may benefit other patients with cancer.

Participants in Aim 1c and Aim 2 will most likely benefit from the intervention content that is designed to improve health-related quality of life and reduced symptom burden. The magnitude of this potential benefit is expected to be moderate to high with a potential duration of several years.

Participants randomized to health control in Aim 2 will benefit from learning more about breast cancer and healthy living (e.g., diet, exercise, nutrition). In our previous research, we have found that former cancer patients have reported medium to high satisfaction with learning about healthy living and have reported that they have been able to incorporate the information on healthy living into their everyday routines.

There are no benefits associated with participation in Aim 1d for community stakeholder participants.

11.0 Financial Compensation:

Participants will receive \$35 dollars, in cash, for their participation in Aims 1a and 1b. Participants will be compensated even if they withdraw from the study before finishing. Participants will be compensated \$100 for participation in Aim 1c, the field trial. Participants will be compensated \$35 at the start of the trial, and will receive the remaining \$65 upon completion of the trial. Participants who withdraw from the trial before finishing will not receive their remaining \$65. Participants will be paid in cash. We do not foresee any costs to participants because we will cover transportation costs to our laboratory space within the Department of Medical Social Sciences (e.g., reimbursement for parking, CTA travel).

In Aim 2 participants will receive a total of \$100 at the end of the study. \$30 will be given at the end of the first in-person meeting. At the end of the third meeting after completion of eight weeks, they will receive \$70 through a gift card if they complete the appointment over the phone, or cash if they complete the final appointment in person. In addition those who did not receive a study phone will receive \$15 to help cover the cost of data. In addition, there is an option for participants to receive transportation reimbursement for the first in-person meeting of a maximum of \$7. Additionally, all participants who completed all three study appointments will be entered into 3 raffles to win an additional \$50 gift card received via mail. The raffle will occur no later than 3 months after completion of the study and participants will be notified the day of the raffle via text. Only one win per participant will be available.

Aim 1d participants will receive \$100 dollars for reviewing the application Mi Guia and for participating in the 1-time, 1hr interview.

12.0 Provisions to Protect the Privacy Interests of Participants:

For all aims, we will ensure privacy by interviewing or assessing participants in a private room in the Department of Medical Social Sciences or a location selected by the participant. Only the study PIs,

the Co-Investigators, and trained members of the research staff will have access to any sources of information about the participants. Access to the computer data files will be by password codes. The list matching participant number to identifying information will be maintained in a locked drawer located at Northwestern University in the office of Dr. Betina Yanez, Northwestern PI for the study. Additionally, in order to be able to track participants, we will keep a separate record of each participant's address, telephone number and contact person information. This record will indicate whether or not a participant has completed the study but will not include information concerning their assessment or intervention performance. Participants will be made explicitly aware at the time of the informed consent of the nature of the two separate records that will be kept.

13.0 Confidentiality and Data Management:

All participants' files including the signed, dated informed consent documents will be stored in a secure, locked cabinet. Participants' identities will be protected by removing all identifying information from interview and additional demographic and medical/treatment data. Participant names and phone numbers, which are obtained for the purpose of recruitment and scheduling, will be stored on a password protected FSM server and destroyed at the end of data collection. All names and contact information will be stored securely and separately from the completed consent forms and electronic data collected from the medical record. Confidentiality will be maintained by keeping all research paper-based records (e.g., study data, consent forms) in locked file cabinets located at Northwestern University in the office of Dr. Betina Yanez, Northwestern PI for the study and for electronic data access to the computer database will be restricted to key study personnel and will be stored on the password protected FSMserver. No information will be stored directly on desktops/individual computers, but only on the server. Audio-recordings will be destroyed following data analyses by being deleted from the FSM server, the only location where they are stored. All personnel involved in this project will be trained with regard to the importance of maintaining patient confidentiality.

For Aim 2, all research data will be organized and managed using REDCap electronic data capture tools hosted at Northwestern University. REDCap (Research Electronic Data Capture) is a research management tool which enables a secure study website accessible to all IRB approved research team members regardless of study site. The REDCap website will be used to administer the screening, sociodemographics, baseline and follow-up questionnaires, and to organize medical record review data. My Guide usage data and weekly questionnaires will be captured via the CBITs My Guide interface and uploaded to REDCap to centralize all research information. Once collected, all research data will be imported into SPSS for cleaning and analysis. (The REDCap platform provides automated export procedures for seamless data downloads to common statistical packages.)

All data collected from participants will be kept strictly confidential, except as mandated by law. All research files, including study data, are kept on secure, password protected departmental and medical school servers. All electronic data will be stored on secure servers behind firewalls meeting all security requirements of the medical school.

For Aim 1c and Aim 2, all procedures regarding self-reported and EMR recorded data remain the same as were described above. Regarding confidentiality of information collected and transmitted via the smartphone application in Aim 1c and Aim 2 of the study, all data collected will be transmitted using Transport Layer Security (TLS) encryption to prevent eavesdropping and tampering of information and data while they are in the transmission pipeline. To prevent unauthorized access to the Smartphone, all phones will be set up to be password protected (password selected by the participant at

the time of phone training). All electronic data will be stored on secure servers behind firewalls at the Center for Behavioral Intervention Technologies at the Northwestern University Feinberg School of Medicine. Internet interventions and mobile assessments will be conducted through *Purple Development Environment*, which is a development and deployment platform created and maintained by the Northwestern University Center for Behavioral Intervention Technologies (CBITs). This platform 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 eavesdropping and tampering information while it is in the transmission pipeline. In addition, all data stored within the intervention is de-identified with a unique key. 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 5 minutes of no activity; any data stored locally is automatically encrypted using 128-bit Blowfish encryption based on the user authentication information and cannot be accessed without this information. (After five failed attempts to access, this information is deleted and must be restored from remote backup). All information collected by this application will be immediately transmitted to CBITs, this application does not save any data to the phone's memory.

During Aim 1c and Aim 2, each participant will login to the application with a unique password using an email address. Besides the email required for login, no other PHI will be collected by this application, or stored/requested by the application at any point. The FACT-G7, already administered to patients during the phone eligibility screening, will be re-administered weekly by the application, however note that the FACT-G7, a multiple choice questionnaire, does not collect any PHI. Application usage (e.g., number of logins to the application) will also be collected by the application.

Participants will be given the option to either use their own phone to download the application, or they can choose to borrow a study phone (an Android Nexus 5X) with the application already downloaded. Once the participant downloads the application or is provided with a study phone, we will create a unique account with the participant. Only an email address and password is required to register, if the participant does not have an email address, we will create a temporary email address using pseudonyms, which will be deleted at the end of the trial.

At the end of participation, the application will be deleted from the participant's phone, and no other information will be collected, unless the participant explicitly requests to continue using the application. Participants that elect to continue using the phone, will be instructed to not complete a weekly questionnaire. For participants that borrowed a study phone, the application will also be deleted from the phone, and the phone will be reset to the factory setting.

The master key with unique identifiers used to track the data collected during the application (the list with the unique application identifier and the email address) will be stored on a password protected server at Northwestern Feinberg School of Medicine and destroyed at the end of data collection by deleting it from the server. Only IRB approved members of the research staff will have access to the master key. The Northwestern site PI and a trained, bilingual research assistant will conduct the interviews in Aim 1a. The interviews for Aim 1a will be audio-recorded and transcribed resulting in a more complete data set than if only notes were taken of the responses. Audio recording for Aim 1a interviews is mandatory for the study as all recordings will be transcribed and analyzed for thematic content. Participants will not have the opportunity to edit the recordings or the transcripts. The audio tapes from Aim 1a will be reviewed by the Northwestern PI. In order to facilitate confidentiality, the patient's name will not be mentioned during the interview. The interviews will

be transcribed by GMR Transcription (a company used by many departments at Northwestern that already has an NU business associate agreement in place to work with study data). Five to 10% of the taped interviews will be chosen at random and their transcriptions checked for accuracy by the Northwestern PI or a trained research assistant working with the Northwestern PI. A code book will be developed to categorize the responses to the open-ended questions from the interviews.

Planned Analyses Aim 1: Grounded theory methods will be used to guide analyses for Specific Aim 1a. Grounded theory is appropriate when the study of social experiences aims to explain a process. Recordings from the interviews will be transcribed verbatim. All data will be coded using NVivo software. Responses from the interviews will be examined systematically. Based on the principles of grounded theory, two independent raters will generate a list of themes expressed by participants. Members of the study team will participate in an iterative group process to develop a coding manual used to identify themes from the interviews. We will reduce subjectivity by using two coders and a calculated agreement between coders (Kappa). The codes will then be compiled in frequency tables. For qualitative data analysis, an analogue to statistical power is “data saturation,” or the point at which successive information serves only to replicate previous content themes and no new information is obtained. Based upon recommended methods for determining saturation, we will consider a concept as “saturated” when it has been mentioned by at least 70% of the sample. Past research reveals that saturation often occurs within the first ten to twelve interviews and basic elements for themes are sometimes present as early as six interviews. We therefore expect to achieve data saturation with our proposed sample of 20 women. Analyses from Aim 1b include descriptive statistics on the USE Questionnaire and qualitative summaries of participants’ comments regarding the usability of the Smartphone-based application. Information obtained from participants in Aim 1b will be reviewed by the PI and Co-Investigator and based on these data they will make decisions to modify the Smartphone-based application, Mi Guia. Analyses for Aim 1c include descriptive statistics on the Smartphone-based application, Mi Guia (e.g., number of logins to the application, mean time spent on the application). These descriptive statistics will provide valuable information to the investigators as to how often participants are engaging with the mobile application and therefore using the intervention.

Planned Analyses Aim 2: Descriptive statistics will be used to characterize the overall sample and each condition. We will use Chi-square, Fisher’s exact tests, and Mann-Whitney U test for nonnormal data, as appropriate, to preliminarily examine differences in feasibility between the study conditions. While the sample sizes of 40 per condition will have 80% power to detect 0.63 standard deviations for our main outcomes. For all outcomes, change from baseline will be calculated and the mean changes within study condition will be converted to effect sizes. Effect sizes will be defined as the difference in means or proportions between the study conditions divided by the standard deviation of the outcome. Follow-up scores on the outcomes, HRQoL and cancer-specific distress, as well as all intervention targets, will be compared between study conditions, adjusted for baseline score, using 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, and all intervention targets, over time for each group. 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.

14.0 Data Monitoring Plan to Ensure the Safety of Participants:

For Aim 1a and 1b the informed consents, all assessment measures and intervention modules will be reviewed and subject to approval by the Institutional Review Board at NU. As detailed in the Human Subjects section of the protocol and in the informed consent document, this study involves minimal risk to study participants. Regarding participant safety, any occurrence of a serious adverse event (e.g., hospitalization, injury, death) will be discussed at the weekly project meeting. Adverse events will be documented, logged, and submitted to the IRB within the mandated time frame. The PI will review the data safety quarterly, and a cumulative report will be submitted to the IRB on an annual basis as required for continuing review and/or final report. Interim analyses for the purposes of discontinuing the study will only be conducted if during a review of adverse events it seems that risks or complications appear to be greater than those originally stated. For Aims 1c and 2, if the PI or IRB suspects that an unusual number of adverse events are occurring, the PI will determine if the adverse events occur significantly more frequently in any one condition. In the unlikely event of such analyses, the IRB will be informed of these results in a timely manner. Moreover, the IRB will be informed within one working day of any temporary or permanent suspension of the protocol.

15.0 Data and if applicable, Specimen Banking:

All data is kept in encrypted and password protected files on a locked Northwestern University network. Participant names and all other identifying information are kept in a separate, locked and protected location. Data will be stored for a period of five years after the study results have been published. At this point any paper-based data will be shredded and electronic data will be deleted. Data will not be stored for future use nor will data be stored outside of Northwestern. Data may be released to a third party if required by law (e.g., court order). All data will be kept in encrypted and password protected files on a locked Northwestern University network. Participant names and all other identifying information are kept in separate, locked and protected locations to ensure participant identity cannot be linked to their study data.

16.0 Qualifications to Conduct Research and Resources Available:

Dr. Betina Yanez will serve as the Northwestern site PI and Dr. Frank Penedo will serve as the study Co-Investigator.

Since her faculty appointment in 2013, Dr. Yanez has received funding from the NCI and American Cancer Society to conduct research in cancer control and survivorship and health disparities in cancer outcomes. Dr. Penedo is the leader of the Cancer Control and Survivorship Program and the director of the Cancer Survivorship Institute at the RHLCCC. He has received numerous grants to investigate cancer survivorship outcomes and disparities in patient-reported outcomes and culturally tailored interventions in oncology. Both Dr. Yanez and Dr. Penedo have numerous peer-reviewed publications in the area of cancer control and survivorship and ethnic minority health.

The research will be conducted within Dr. Yanez's laboratory space in the Department of Medical Social Sciences. Dr. Yanez and her staff have computers, audio recorders for recording the interviews, and software for analyzing interviews (NVivo). Dr. Yanez's office and laboratory space also has locked filing cabinets for storing paper-based data.

We have not encountered serious psychiatric disturbance (e.g., suicidal ideation) in our previous psychosocial research in cancer. However, in the event we encounter participants in acute crisis during the interviews, we will provide immediate assistance in-person as appropriate and refer them for local treatment. Speaking privately with the participant, we will assess for suicidal

ideation, plan of action, and likelihood of carrying out the plan. We will help the participant obtain immediate assistance in the home (e.g., ask if spouse/friend can be contacted) and will encourage her to seek medical attention if she is at high risk. Local resource referrals will be kept on file to be used in the event of such an emergency. Dr. Penedo is a licensed clinical health psychologist, experienced in psychotherapy, and counseling of patients and families dealing with chronic and acute medical conditions, particularly cancer. Drs. Yanez and Penedo have doctorates in clinical psychology and have provided individual therapy for patients through the supportive oncology program at the RHLCCC.

All research staff will be trained on the research protocol by the PI, Dr. Yanez. Diana Buitrago, the study research assistant, is bilingual and has ample experience in research, including consenting participants in Spanish and conducting qualitative interviews. Additional research staff will receive training on all aspects of human subjects ranging from screening participants to consenting and storing study data to ensure confidentiality. Study staff will also receive training on cultural sensitivity and awareness by the PI or by the Co-I Dr. Penedo and all study staff will receive training on delivering the study intervention Aims 1c and Aim 2 (e.g., conducting assessments, telecoaching calls, participant payments). This training will occur prior to implementing Aims 1c 2.

Figures

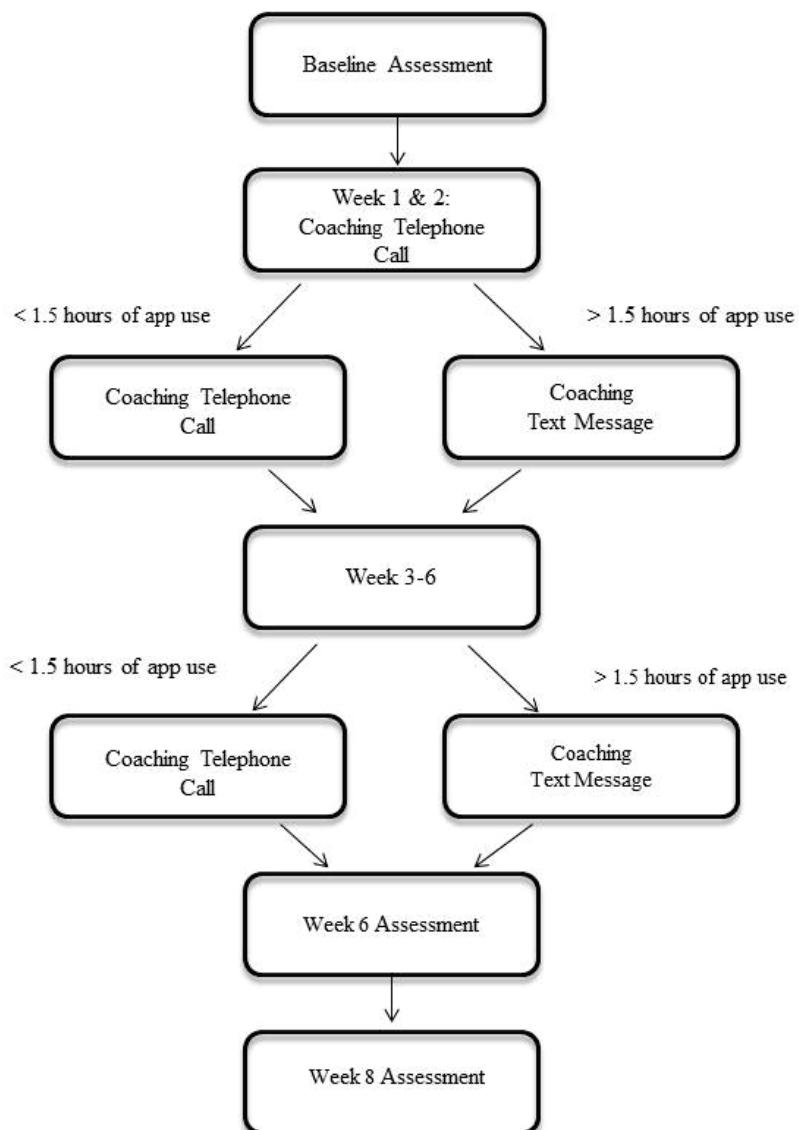


Figure 1 Illustration of the Step-care Protocol for telecoach sessions.

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