FOX CHASE CANCER CENTER
TEMPLE HEALTH

Protocol Title

Enhancing Clinician Communication about Sexual Health in Breast Cancer

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N/A

Statistician:

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Funding Source:

1 R03 CA235238-01

Initial Version Date: 10/10/2018

Amendment #

7

Version date:

9/3/2020

IRB#: 18-1068MOD9 Approved: 9/4/2020 Expires: 8/16/2021

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1.0 Introduction

Over ninety percent of women with breast cancer survive 5 years beyond diagnosis,[1] making quality of life (QOL) concerns such as sexuality highly significant. Breast cancer negatively affects patients' sexuality and intimacy, leading to both physical (e.g., vaginal dryness) and motivational/emotional problems (e.g., body image distress).[2-7] Sexual problems such as these tend to persist over time even as other QOL concerns improve.[2,8,9] If unaddressed, sexual problems can lead to significant distress for breast cancer patients. In recognition of the seriousness of sexual problems for breast cancer patients and in light of the increasing availability of evidence-based interventions to address these problems,[10,11] recent clinical guidelines have uniformly called for breast cancer clinicians to discuss sexual health with their patients in their routine cancer care.[10,12,13] In the same vein, the vast majority of breast cancer patients want sexual health to be discussed with them during their cancer care.[14,15] Yet the evidence suggests that communication about sexual health is largely absent for breast cancer patients,[16,17] with only 30-40% of breast cancer patients reporting that their clinicians discussed sexual health with them.[15,16,18-20] A key factor underlying this lack of communication is the inadequate training that breast cancer clinicians receive in how to communicate with their patients about sexual health.[17-19,21] The absence of sexual health communication in the face of considerable patient distress thus constitutes a critical gap in the care of women with breast cancer. Evidence-based interventions are critically needed to target breast cancer clinicians' communication about sexual health.

2.0 Objectives

The objective of the proposed study is to adapt a previously tested brief intervention aimed at enhancing clinicians' communication about sexual health (iSHARE) to a mobile web-based platform showcasing a two-part podcast and to assess the feasibility, acceptability, and preliminary effects of the intervention in breast cancer clinicians.

Specific Aim 1. To assess the feasibility and acceptability of iSHARE in a mLearning format.

Hypothesis 1. iSHARE will be judged as feasible, determined through measures of rates of participant enrollment, retention, and study completion.

Hypothesis 2. iSHARE will be judged as acceptable, determined through post-intervention evaluations of intervention satisfaction, helpfulness, and relevance, and ease of participation.

Specific Aim 2. To assess the preliminary effects of iSHARE in a mLearning format.

Hypothesis 3. iSHARE will show positive effects on clinicians' knowledge, beliefs (self-efficacy, outcome expectancies), and communication with respect to sexual health from pre-to post-intervention.

3.0 Background/Rationale

A woman in the U.S. today has a 1-in-8 chance of being diagnosed with breast cancer.[22] Advances in detection and treatment improve survival for breast cancer, with a relative survival rate of 91% at 5 years post-diagnosis and 85% at 15 years post-diagnosis.[22] Yet these life-extending treatments come at the cost of substantial impact on quality of life (QOL) for many women. Sexual health problems are among the most distressing health problems women with breast cancer face due to their treatments.[23-25] Common sexual problems for breast cancer patients include both physical (e.g., vaginal dryness,

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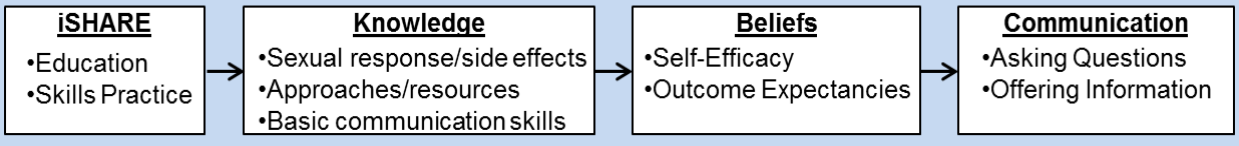
painful intercourse)[26-28] and motivational/emotional types of problems (e.g., loss of sexual interest, body image distress).[3,4] For breast cancer patients, surgical scarring can lead to body image distress, and hormonal therapy and chemotherapy can alter sex hormones, leading to distressing vaginal symptoms (e.g., dryness) and loss of sexual interest.[2,28] Sexual problems are distressing[4,29] and highly persistent for breast cancer patients improving at a much slower rate than other domains of health and function.[6,30-32] Addressing breast cancer-related sexual problems can improve women's mental health[33-35] and relationship quality;[34-37] reducing the distressing sexual side effects of hormonal therapies can improve treatment adherence.[38] Although sexual health is included in recent clinical cancer care guidelines alongside other health concerns (e.g., pain, fatigue),[12,13] it is overwhelmingly neglected clinically,[16,17] making this work significant and timely. Only 10-52% of breast cancer patients receive even basic information from their clinicians about sexual health effects of their treatments.[15,39-42] Research shows that most women with breast cancer want to preserve their sexual health and discuss these concerns with their clinicians.[14,43,44] All available data, however, suggest that patient-clinician communication about sexual health is inadequate for breast cancer patients.[16,19,45] Lack of appropriate training, knowledge, and basic skills for communicating about sexual health prevent clinicians from discussing sexual concerns with their patients.[16-19,21,46,47]

Research demonstrates that very brief communication training interventions (<5 hours) can significantly improve clinicians' knowledge, confidence, beliefs, and skills,[48-52] particularly when targeting specific communication tasks (e.g., sexual history-taking,[53] discussing cancer prognosis).[54] In a previous study, we developed and tested a novel, brief communication training intervention for breast cancer clinicians called improving patients' Sexual Health and Augmenting Relationships through Education (iSHARE). This intervention was grounded in social cognitive theory, which emphasizes individuals' beliefs (i.e., self-efficacy and outcome expectancies) as critical processes underlying successful behavioral interventions,[55-59] in current models of communication skills development,[59-61] and in the perspectives of cancer patients and clinicians from formative research.[62] We found promising effects of the intervention, but noted challenges in its administration. Given the promise that the iSHARE intervention showed in our pilot trial, the need for interventions that can be widely disseminated, and the growing evidence supporting incorporating mobile technologies into medical practice, the overall objective of the proposed study is to adapt the iSHARE intervention to a mobile technology (mLearning) format and pilot test it. Based on the results of our preliminary work, as shown in Figure 1, we expect that iSHARE will improve clinicians' (1) knowledge in key topic areas relevant to communication about sexual health, and (2) beliefs regarding their confidence for communicating about sexual concerns (self-efficacy) and that discussions will lead to a desired outcome such as successfully identifying patients with sexual concerns and addressing patients' concerns (outcome expectancies). Based on research suggesting that self-efficacy and outcome expectancy beliefs are strongly associated with the likelihood of engaging in a behavior,[63] we also expect that increasing clinicians' knowledge and beliefs in these domains will lead to increases in key clinician communication behaviors regarding sexual health (i.e., asking questions and offering information about sexual health), and this is supported by the effects we found in our pilot work.

Figure 1. Conceptual Schematic



Within the possible mLearning formats, a podcast was selected because recent research shows that podcast use is increasing rapidly in the general population, are most likely to be listened to in a mobile format (i.e., on a smartphone),[64,65] and have been shown to be well-received[66,67] and efficacious in increasing clinician knowledge, beliefs/attitudes, and communication skills both within and outside of cancer care.[66,68-70] If shown to be effective, the iSHARE intervention could ultimately be disseminated through existing channels offering continuing medical education (CME) or other medical education, such as the American Society for Clinical Oncology (ASCO), which have already incorporated podcasts into their web course offerings, and journals (e.g., JAMA). Finally, podcasts are consistent with many cancer clinicians' preferences for interventions that are brief, convenient, and flexible,[62] and would allow clinicians to insert the intervention into their daily routines (e.g., when commuting).

4.0 Study Design

4.1 Recruitment and Reimbursement

In all, about 43 breast cancer clinicians (oncologists, advanced practice clinicians) will participate (6-8 fellows in cognitive interviews; 30-35 oncologists or advanced practice clinicians in pilot trial). Due to attrition, we plan to recruit for the pilot trial until we reach 30 study completers. We estimate that we will need to consent 33 providers to the trial in order to reach 30 study completers, but may need to recruit a few more participants if attrition increases (i.e., due to COVID-related changes in clinician availability). We will recruit clinicians from Fox Chase Cancer Center, Temple University, and affiliate/community hospitals (e.g., MD Anderson Cooper, Einstein) using methods we successfully employed in our prior work, including during staff meetings, or through direct contact with the PI after identification through the FCCC Partners Program or through colleagues. Study collaborators may recruit their colleagues on behalf of the PI, using approved recruitment materials. Emails sent to study candidates will include the opportunity to click on a link to see the study information and be brought to the baseline survey directly, which may enhance feasibility. Candidates will be asked eligibility questions in REDCap to ensure that inclusion criteria are met before consent. Study candidates who enroll through this email link will be asked to provide contact information and will be asked their permission to receive occasional text messages about the study, such as survey reminders. Clinicians may forward the recruitment email to other clinicians to refer them to the study. We may also recruit through online websites or social media platforms such as the American Cancer Society TheoryLab, ASCO or similar organizations.

Number of subjects per year projected at FCCC	Total number of subjects at FCCC	Number of subjects nationally or internationally (if applicable	Number of subjects at collaborating institutions (if applicable)
Up to: 8	Up to: 8	33	2

Cognitive interview participants will be reimbursed $50; pilot trial participants will be reimbursed $50 for each of two surveys ($100 total). Compensation will be given in the form of gift cards.

4.2 Inclusion and Exclusion Criteria

Eligibility criteria are presented in **Table 1** below. We will exclude clinicians who previously participated in the pilot study of iSHARE, as this could confound findings. For cognitive interviews, we will include fellows who have been through their breast oncology rotation and have therefore had experience in treating breast cancer patients. We have recruited fellows for a similar purpose in our prior work.

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Table 1. Inclusion and Exclusion Criteria for Trial
Inclusion Criteria
• Is a medical oncologist or medical oncology advanced practice clinician (Nurse Practitioner, Physician Assistant) who treats breast cancer patients • Did not participate in the pilot study of iSHARE

4.3 Study Procedures

4.3.1 Cognitive Interviews

Prior to the cognitive interviews, the PI will draft a mock-up of iSHARE in its new mLearning format based on the following: iSHARE template, a review of evaluations from clinicians in our pilot study, expert team feedback, and a review of the literature.[71] The objective of the cognitive interviews (N=6-8; 60 min; led by PI or other trained staff member such as a post-doctoral fellow) will be to review the appropriateness and comprehensibility of the materials. Cognitive interviews will be completed with oncology fellows at FCCC in a private office or conference room and will be audio recorded. After signing a consent form and completing a brief demographic survey, the fellows will be asked to read through scripts of the podcasts and pause their reading to comment on aspects of the material that are especially (a) helpful/relevant, (b) unhelpful/irrelevant, or (c) unclear and a standard set of follow-up items will be administered to supplement this information. In addition, after the participants have completed the "off the cuff" part of the interview, the interviewer will ask a set of standard questions about the content and format of the program (see Cognitive Interview). Using methods we have found helpful previously, participants' responses will be summarized in a matrix to facilitate synthesis of their comments[72] according to type of comment (e.g., content, structure, wording/phrasing used) and by order of frequency of appearance (i.e., number of participants commenting on that issue).[73] Using this list, the PI will draft a list of modifications to be made, which will be reviewed by study team experts. Potential examples of changes that could be made using the cognitive interview data are: changing details of the case examples given, modifying wording or language, or adding clarification or emphasis. Although substantive changes will be made after the themes have been tallied across the interviews, modifications to the program scripts or other materials may also be made intermittently in between interviews in an iterative process when necessary. For instance, if a participant identifies an aspect of the script that is unhelpful or inappropriate, this should be changed prior to the upcoming interviews so that time is not spent in upcoming interviews on an obvious needed change. We may stop recruiting for the cognitive interviews after a minimum of 6, assuming that we have obtained adequate information that will be used to inform the intervention.

4.3.2 Intervention

All participants will receive the iSHARE podcast intervention. This will consist of a two-part podcast series with expert guests. **Part 1 (Education)** will include information on rates, types, and causes of breast cancer patients' problems related to sexual health, models of sexual response (function),[74] current evidence-based approaches for addressing sexual concerns (e.g., information from recent key randomized controlled trials),[75,76] and information about patient resources. **Part 2 (Skills)** will target basic clinician communication skills, with a major focus being teaching the stepped-care model of sexual health care known as PLISSIT[77] (see **Figure 2**), and an emphasis on the first two steps in the model, i.e., Permission and Limited Information. The major behavioral targets for

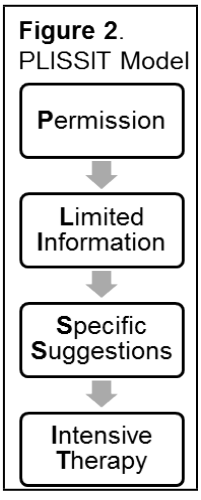

Figure 2. PLISSIT Model

communication skills training that will be emphasized are initiating a conversation about sexual health, asking effective questions to patients about sexual health or concerns, offering information about the impact of breast cancer treatment(s) on patients' sexual health, and initiating a referral for a patient, when appropriate. Key topics within patients' sexual health that will be discussed could include vaginal dryness and discomfort during sexual activity, sexual desire or interest, safety of sexual activity during treatments, and body image or appearance. Information from the most updated NCCN Survivorship Guidelines, which provide guidelines for assessing and managing sexual function for cancer survivors, may also be included such as suggested wording for initial questions for clinicians to ask patients. Content could also include recognition of common patient and clinician barriers to effective communication about sexual health,[62,78-81] patient preferences for communication about this topic,[62,82] and discussion of contextual/socio-cultural factors, such as the partner's presence in the room, a gender mismatch between the patient and clinician, patient sexual minority status, or ethnic or religious differences.[62,78,83] Other relevant information may also be added during the refinement phase.

4.3.3 Measures and Self-Report Data Collection

Clinicians who participate in the cognitive interviews will be asked to complete a brief demographic survey (6 items) prior to listening to the podcast draft, either in person or online. Clinicians who participate in the pilot trial will be asked to complete an online consent form and baseline survey. **Table 2** shows the self-report measures that will be administered to pilot trial participants. Paper copies of consents and surveys will be provided for participants who prefer to complete hard copies of these forms. Web consents and surveys will be sent to participants using a REDCap link. REDCap is a secure, web-based application that is flexible enough to be used for a wide variety of research studies, offers intuitive interfaces for data entry and real time data validation, and supports easy data manipulation with audit trails and reporting capabilities, including automated export to common statistical packages. REDCap for electronic data collection is preferred over paper and pencil administration for this study because: (1) it can be completed in less time and is therefore potentially less burdensome for participants; (2) it is less burdensome to the investigators in terms of both collection and data entry – essentially eliminating the need for by-hand data entry of self-report measures; (3) it leads to fewer human errors because it obviates the need for by-hand data entry. Participants will be asked to complete two additional surveys throughout the study: one after podcast episode 1, which includes knowledge quiz items and the episode 1 program evaluation (acceptability items), and another one after podcast episode 1, which contains the knowledge items, the acceptability items, and the outcome measures (e.g., communication, beliefs).

Table 2. Pilot Self-Report Measures

Measure	# Items	Minutes to Complete	Baseline	Post-Episode 1	Post-Episode 2
Demographics	6	3	X	-	-
Knowledge	T1: 10 Post Ep 1: 5 T2: 5	3	X	X	X
Self-efficacy (Beliefs)[84]	3	1	X	-	X
Outcome Expectancies (Beliefs)[59]	7	3	X	-	X
Communication Behaviors	10	5	X	-	X
COVID-19 Clinic Assessment	13	5	X	-	-
Program Evaluation	12	5	-	X	X

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Totals						
-	Baseline (T1)	49	20			
-	Post-Episode 1	17	8			
-	Post-Training (T2)	37	17			

4.3.3.1 Outcome Measures

Aim 1. (1) Feasibility will be measured through measures of participant enrollment defined as the percent of eligible candidates approached who enroll, retention to study completion, defined as completion of all study surveys, and rates of intervention completion, defined by self-report responses on the program evaluation. We are also collecting self-report information on the amount of each of the two podcast episodes that participants listened to. If possible, we will also collect data on intervention usage through tracking whether each participating clinician clicked on the REDCap links sent to them and submitted online forms documenting completion of the intervention. If these data appear reliable, we may use these for the intervention completion data either alongside or instead of the self-report data. (2) Acceptability will be measured primarily through self-report surveys assessing clinicians' perceptions of each podcast episode, and specifically: satisfaction, informativeness, relevance, ease of listening, likelihood of recommending to colleagues, and likelihood of impacting practice. Additional items assess distracting or interruptions during the podcast, mind-wandering during the podcast, problems or difficulties occurring in listening, one takeaway message clinicians had from the podcast, and thoughts on how the podcast could be improved. Most of these items were successfully administered in the initial pilot study.

Aim 2. Preliminary effects of the iSHARE intervention will be assessed using self-report surveys at three time points (Pre-intervention, Post-episode 1, and Post-episode 2) and will assess clinicians' knowledge, beliefs (self-efficacy, outcome expectancies), and communication about sexual health (See Table 2). In accordance with current recommendations to include specific communication behaviors as outcomes in communication training trials[85] and with findings of recent reviews on outcomes with proven sensitivity to communication interventions[86,87] including our own iSHARE pilot project, the *key outcomes* will be clinicians' self-reported (1) **knowledge** across three major areas (sexual response/breast cancer-related sexual side effects, common approaches and resources for these problems, and basic communication skills pertaining to sexual health), assessed through 10 true/false or multiple-choice items developed for this study that were adapted from items used in similar research by the study team and found to be sensitive to communication interventions,[87-89] (2) two aspects of clinicians' **beliefs**, assessed using items developed for the initial iSHARE study based on social cognitive theory,[55,84] that showed sensitivity in the pilot project and are rated on a 0-10 point scale where 0=not at all confident or do not agree at all and 10=extremely confident or very strongly agree, namely (a) self-efficacy for communicating with breast cancer patients about sexual health (3 items; Cronbach's alpha in pilot =.77), and (b) outcome expectancies for communicating with breast cancer patients about sexual concerns (7 items; Cronbach's alpha in pilot =.90), and (3) **communication behaviors**, assessed using two sets of items, (a) clinicians' perceived comfort in engaging in key communication tasks (e.g., asking the patient if she has any sexual concerns, discussing the patient's loss of sexual interest or desire; 7 items), and (b) items adapted from those published in a similar trial[90] and captures the frequency of engaging in three key types of communication about sexual health with breast cancer patients (e.g., initiating a conversation about sexual health, offering information about the impact of breast cancer treatment(s) on sexual health; 3 items), rated on a 1 to 5 scale where 1=never/almost never and 5=always/almost always.

4.3.3.2 Additional Measures

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COVID-19 Clinic Assessment. Due to the current coronavirus pandemic, we anticipate that clinicians are experiencing changes to the format and volume of their clinics. Thus, we have added 13 items to the baseline survey assessing these changes including format (e.g., use of telehealth and availability of support staff), volume, and length of visits, and whether any of these changes may have had an impact on clinicians' ability or priority level regarding discussing sexual health with their patients. These items were drafted with the input of the multidisciplinary study team. Because these items were drafted after several clinicians had completed the study, these clinicians will be re-consented with a modified, abbreviated informed consent form and asked to complete only the COVID items.

5.0 Risks to Participants

This study involves participation in qualitative interviews, or participation in a behavioral intervention study with minimally invasive assessments (i.e., self-report). The major risks for study subjects are (1) discomfort at answering study questions or during discussions with clinicians, (2) loss of privacy or confidentiality. Due to the protections we will have in place, we believe these risks to be minimal. There are no procedures that will be conducted as part of the study.

6.0 Potential Benefits to Participants

There may be no direct benefit to the study participants. It is possible that the provider intervention will be effective at improving their knowledge, beliefs, and communication skills with respect to sexual health, and therefore have a beneficial effect on patient care or on patient-provider relationships, but this cannot be guaranteed. The research may inform future research to improve the quality of care given to patients with breast cancer. The minimal risks to subjects are reasonable in relation to potential benefit in improving clinicians' communication and clinical care of patients.

7.0 Provisions to Maintain the Confidentiality of Data

In order to minimize the risks associated with discomfort in answering questions, participants will be told that they do not have to answer any research questions and that, if they change their mind about participating, they can stop at any time. All information collected for this study will be kept confidential. Subjects will be told that all information will be kept in strict confidence. All data will be stored on computer files or in locked filing cabinets to which only select members of the research staff will have access. All discussions about the study and training sessions will occur in private areas or over the telephone. In order to minimize the risks associated with loss of confidentiality, all will be kept confidential and secure, will be de-identified for analytic purposes, and none of the participants' information will be released to their employer or any other third party without the clinician's permission, except as required by law.

8.0 Costs to Participants

There are no costs to participants for their participation in the study.

9.0 Consent Process

Consent from participants will be obtained at the following time points: For the cognitive interviews, in-person immediately before the interview, in the location where the qualitative interview will be held, by the PI or other consent designee (clinicians may also consent online via REDCap link in advance of their interview); for the pilot study, electronic consent will be obtained through REDCap or, for clinicians who prefer paper and pencil consents, written consent will be obtained in person or through US Mail. Only Participants will be given time to ask questions privately before they sign consent forms. Only English speaking clinicians will be enrolled.

10.0 Off-Study Criteria

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Any participant may leave the study at any time due to distress or other reasons. We do not have a priori reasons for letting participants off the study.

11.0 Drugs and Devices

N/A

12.0 Multi-Site Research Study

N/A

13.0 Statistical Analysis

We plan to enroll 30-35 providers to the pilot study, in order to collect complete data from 30 study completers; this sample size will be adequate to achieve the study objectives of testing the feasibility, acceptability, and preliminary effects of the iSHARE intervention. Descriptive analyses (e.g., frequencies, measures of central tendency) will determine the feasibility and acceptability of the intervention. The operating characteristics of the feasibility/acceptability criteria under favorable and unfavorable characteristics are shown in **Table 3**. For example, if the true retention rate is high (80%), we will have a 94% chance of meeting the feasibility criteria of 70%, but if the true retention rate is low (55%), we will only have a 7% chance of falsely declaring feasibility.

Table 3. Feasibility and Acceptability Determination

Criterion	Decision rule	True favorable rate	True unfavorable rate	Probability correctly declaring feasibility	Probability incorrectly declaring feasibility
Enrollment	≥40% (≥ 30/75 approached)	50%	30%	97%	4%
Retention	≥70% (≥21/30 enrolled)	80%	55%	94%	7%
Completion	≥60% (≥18/30 enrolled)	70%	45%	92%	7%
Acceptability	≥75% (≥14/18 endorsing)	85%	55%	88%	4%

Feasibility will be measured through study accrual, retention, and intervention completion. The following rates will be used as benchmarks for feasibility: Enrollment ≥ 40% of eligible candidates; retention ≥ 70%; and intervention completion ≥ 60%. Although we achieved very high enrollment, retention, and completion rates in our previous pilot study, these estimates are lowered as we will be recruiting a larger sample of clinicians, many of whom will be from outside FCCC. **Acceptability** will be determined in two stages. First, at the individual level, we determine whether the individual met our acceptability criteria, which means endorsing 75% of the 6 primary acceptability items for both podcast episodes (12 items total; satisfaction, informativeness, relevance, ease of listening, likelihood to recommend, likelihood to impact practice) favorably ("Quite a bit"/"Very"). For participants who complete only one set of these items, as in the case that they listen only to podcast episode 1 and complete that survey but not the one after episode 2, we will consider 5/6 items rated favorably as meeting the threshold for acceptability. Second, if 75% of the sample (shown above at the minimal number needed to meet the completion benchmark, or 18) meets that definition, then we will be able to say that overall the study meets the standard set for acceptability.

Other data obtained from the acceptability surveys (e.g., length of time listened to each podcast, qualitative survey responses) will be analyzed descriptively or using thematic analysis as appropriate. Exploratory intervention usage data will be analyzed descriptively.

Prior to conducting analyses of outcome data, we will conduct analyses of internal reliability on the outcome measures. The sum of all items answered correctly will be used as the score for knowledge in analyses; if there are missing data on the item level, we may substitute percentage correct for the sum

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of correct answers. For beliefs and communication behaviors, mean scores across all items on these scales will be used as the scores for these measures in analyses, assuming that the internal reliability for these measures is acceptable (Cronbach's alpha > .60). Otherwise, individual item scores may be used. We may also present data on individual items in an exploratory fashion to facilitate interpretation of findings. In line with recommendations for the analysis of data from pilot studies,[91,92] preliminary outcome data will be analyzed descriptively, 95% confidence intervals will be calculated, and these data will be used to summarize the data at the three assessments.

14.0 Data Safety Monitoring Plan

The PI will take responsibility for monitoring the safety of all phases of the research study. Because of the nature of the research as involving procedures without significant risk (e.g., surveys; listening to audio podcasts) there are unlikely to be any adverse events. Study staff will report any adverse events they observe to the PI within 24 hours. The consent form will contain the contact information for the PI and the Institutional Review Board (IRB), and state that participant may contact her or the IRB at any time. A DSMB is not required for the current study.

15.0 Adverse Events

Because of the nature of the research as involving procedures without significant risk (e.g., qualitative interviews; surveys; listening to an audio podcast) there are unlikely to be any serious adverse events and adverse events are likely to be rare. Possible risks include feeling worried, anxious, or concerned during questionnaire completion, during the cognitive interview, or while listening to the podcast. All participants are informed of possible adverse psychological reactions associated with participating in the study during the informed consent process.

Any unexpected or adverse event that occurs during data collection or study procedures is reported immediately to the Principal Investigator, who is responsible for documenting all adverse events with the FCCC IRB within 24 hours. For participants who are experiencing psychological distress reactions, the study team member or research assistant alerts the Principal Investigator, who would provide the participant with a referral to appropriate services. At FCCC counselors in the Department of Social Work are trained to provide psychological support services or to make specific referrals to other psychological counseling or psychiatric services in the area as needed.

The research team will keep a log tracking the number, nature, and frequency of adverse events as part of each phase of the research plan. In accordance with FCCC guidelines, this protocol will employ the following mechanisms for adverse event reporting: 1) alert the FCCC review committees of any and all reports of adverse events; 2) inform all members of the study team of any all reports of adverse events. If 3 or more adverse events are reported, the study team will assess potential causes of the adverse events and, if events are clearly linked to study participation, discontinue the study.

16.0 Quality Assurance Procedures and Participant Confidentiality

Information about study subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Those regulations required a signed subject authorization informing the subject of the following: The protected health information (PHI) that will be collected from participant; who will have access to that information and why; who will use or disclose that information; the rights of a research subject to revoke their authorization or use their PHI. In the event that a participant revokes authorization to collect or use PHI, the investigator, by regulation, retains the ability to use all information prior to the revocation of subject authorization. To ensure confidentiality identifiers will be recorded and used with electronic data collected and all records

will be secured in a locked location. All computers with participant data will be password protected with access restricted to study staff. All participant data will be de-identified for analytic purposes, and none of the participants' information will be released to their employer, health care organization, or any other third party without the participants' permission.

17.0 Participant Informed Consent

Separate informed consent documents exist for participation in the cognitive interviews and the podcast pilot trial. Cognitive interview participants will sign written or online consent prior to completing the demographic survey and beginning the qualitative interview. Pilot trial participants will sign written or online consent after being approached for the study which will include consent to complete self-report surveys before the intervention, at post-episode one, and at post-episode two, and to participate in the iSHARE intervention.

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19.0 Appendices

- Consent Forms
    - Web and paper versions of cognitive interview consent
    - Web and paper versions of pilot trial consent
    - HIPAA Authorization
- Surveys
    - Cognitive Interview demographic survey
    - Pilot Trial baseline, post-intervention surveys
- Sample questions for Cognitive Interviews

IRB#: 18-1068MOD9 Approved: 9/4/2020 Expires: 8/16/2021