

Title: Web-Based Communication Education for Breast Cancer Survivorship Care

Date approved by Georgetown University Institutional Review Board: 1/30/2017

NCT Number: N/A

Study Protocol

1. Purpose of project:

This two-phase research plan will develop and test a culturally relevant, web-based patient education program, hereafter known as E-Talkcare. The intervention aims to empower Chinese cancer patients to effectively communicate with different providers in different healthcare settings.

2. Study design (for example, hypothesis, research questions, standard and experimental procedures/drugs/devices or equipment, etc.):

Our specific aims are to: 1) develop and test the usability and acceptability of a web-based intervention called E-Talkcare for Chinese immigrant breast cancer survivors using qualitative interviewing and analysis; 2) assess the efficacy of the E-Talkcare intervention in enhancing Chinese immigrant survivors' communication competence, perceived control, and self-efficacy in cancer care communication (intermediate outcomes) relative to the usual care control arm, and 3) obtain preliminary data on the efficacy of the E-Talkcare intervention (vs. usual care) in improving patient-reported symptoms, adherence to breast cancer survivorship care guidelines, and quality of life (QoL) (distal outcomes) and explore the mediating role of the intermediate outcomes on distal outcomes. The study includes two phases: 1) conduct qualitative research to develop the E-Talkcare intervention and 2) conduct a pilot RCT to examine the efficacy of the intervention (vs. usual care).

In Phase I, we will conduct 2-hour focus groups or individual interviews (n=16 in total) to obtain Chinese immigrant survivors' suggestions and preferences for the development of E-Talkcare. We will consider additional focus groups as needed until data saturation is reached. We will use a semi-structured interview guide to understand 1) what system functions Chinese survivors expect in E-Talkcare; 2) what benefits Chinese survivors expect from E-Talkcare; 3) what barriers to adoption of E-Talkcare Chinese survivors foresee for people similar to them. Participants will be asked to consider their own specific needs and concerns pertaining to their treatment and stage. Survivors who were diagnosed with stage 0-III breast cancer within the past 10 years will be invited to participate. They will be enrolled from the PI's established community networks in the Washington DC area (R01CA121023; R01CA142941). Focus group discussions and individual interviews will help ensure cultural sensitivity of the narratives, video scripts, and format of E-Talkcare. Our community advisory board has endorsed the drafted web modules as stated below and will be significantly involved in the content development and design of a symptom reporting and question database. All CAB and team members will review the focus group and individual interview results, discuss, and approve all text and formatting across modules via conference calls to ensure that the intervention messages bridge Eastern and Western cultural values and linguistic nuances, that the level of health literacy is appropriate, that healthcare information is accurate, and that its format will be user friendly in clinical and community settings. All the text will be written at a sixth-grade reading level (99% of our target patients' education level). The CAB will participate in dissemination of study results and suggest next steps.

Although the results from our formative work will inform the development of the intervention, we anticipate that the intervention will consist of three web modules: 1) Culture and autonomous communication, 2) On-line symptom reporting and questions, and 3) Question database and prompt lists. The first module will educate Chinese women about the US values of patient autonomy and how to actively help providers understand their needs in order to make personalized care plans. Specifically, we

will shoot three culturally tailored videos (~4 minutes each) to model how Chinese survivors can seek, provide, and verify information (three essential communication skills) to remedy the three communication issues: 1) encouraged them to ask cancer-related questions, 2) ensured that they understood all the information doctors provided, and 3) provided sufficient information. We will incorporate culturally relevant messages into the scripts. For example, a script will portray a cultural practice where Chinese patients tend not to ask questions as a sign of respect when they observe that their doctors have limited time. The video will be shot to contrast passive and active communication by presenting the following scenarios, for example: a) a doctor did a quick examination and left before a Chinese survivor had a chance to ask questions (passive, Chinese style); b) the survivor calls her doctor back and asks if s/he can give her a few more minutes to know what exam was done and its results (active, autonomous style). Drafted scripts will be based on breast cancer survivors' stories from our prior research and revised iteratively based on the focus group, individual interviews and CAB reviews. The videos will be available in Chinese and English, similar to our Chinese mammography video. Second, intervention women will report the PROMIS symptoms and QoL variables monthly during the 3-month intervention period and post their top three symptom questions (either in English or Chinese) on the web. Researchers and CAB members will then review and refine the three questions if necessary. For symptom questions derived from specific treatment (surgery, radiation, and adjuvant therapy), we will consult with our clinicians in their specialty areas before providing women with suggested questions posted online within a week. For questions posted in Chinese, we will use Google translate to provide English translations via a link. Our bilingual research assistant (RA) will review and modify the translations as needed. Then, we will mail the women their bilingual symptom reports and an individualized QPL (both can also be printed at home) for use during medical visits. Third, all questions will be anonymously collected and posted on the web by topic (e.g., fatigue and pain). Using this question database, women can build a QPL relevant to their conditions and needs for medical visits within the study period. Using QPL helped patients actively engage in clinical communication. In this website, didactic information (text, image, video formats) and interactive elements (reporting symptoms with open-ended comments, posting and reading questions) will be incorporated throughout. A culturally adaptive interface and content will be written and designed based on our formative work in phase I. To enhance accessibility among individuals with limited computer literacy, most pages will include audio narration of the content. Clear written instructions will walk these users through a linear trajectory.

To ensure E-Talkcare is user-centered, we will conduct usability tests after "wireframes" (schematics showing information elements and page flows) are produced and the majority of development work is completed. We will invite 5-7 Chinese immigrant breast cancer survivors to participate in a 60-minute one-on-one session. This sample size is generally considered sufficient for uncovering about 80% of the usability issues. During the session, they will be given specific tasks to complete using the system and asked to talk aloud as they perform the tasks. Our RA will record how the tasks are completed (or failed). Right after the session, they will complete the System Usability Scale (SUS). An overall SUS score of 70 or above will be considered as acceptable usability. These test results will lead to modifications of ETalkcare. Next, we will ask the same survivors to take the second usability test to inspect if the problems have been fixed and then complete a perceived usefulness and acceptability questionnaire. Participants will be enrolled from the DC area, using the methods for the qualitative interview recruitment above. In Phase II, a pilot pre-post-test RCT will be conducted to test the efficacy of the intervention. Recruitment: We will enroll 118 eligible Chinese cases from the LA cancer registry. On

average, it takes 6 to 12 months after diagnosis for a case to be reported to the registry. Most cases will have completed treatment by the time they are initially contacted. Cases will be randomly selected from a list of potentially eligible cases. Dr. Liu at the LA registry will lead the identification of cases and send them to the PI. An RA at GU will mail an invitation letter to the cases, which will describe how the patient was identified, study objectives, and patient eligibility, involvement, and rights. It will include a self-addressed stamped response form for patients to opt in or out of this study. The RA will call women to answer questions and obtain consent if the response form is not received 10 days after mailing. In this call, the RA will ascertain patients' race/ethnicity and recurrence status. Those with multiple races will be excluded.

Randomization: After the baseline interview, participants will be randomly assigned to 1) E-Talkcare or 2) usual care in a 1:1 ratio. We will conduct variable permuted block randomization, using three block sizes of 2, 4, and 6, and run simple randomization in each block. This method can minimize the risk of imbalance due to unexpected enrollment shortfalls and facilitate planning and implementation of the intervention delivery. A RA who will not be one of our interviewers will assist the randomization.

Intervention delivery: After randomization, we will mail women in the intervention group the E-Talkcare web address, a user name, and a temporary password. Once a user signs in, she will be able to read or listen (through audio narration) to instructions on how to complete the intervention in order, though she can freely navigate between web modules. Each module will have an ever-present indicator (showing users' progress) and a link to for users to continue navigating through modules. We will design the full intervention to be about 30 minutes and able to complete with one visit as some women may not return to the webpage. For women with problems accessing the website, our RA will walk them through the website via telephone or ask our current community partners in the LA area to assist.

Elderly Chinese are usually taken care of by family members per our project experience who will be able to assist our older participants in accessing E-Talkcare. Per our data, about 60% of Chinese survivors visit their follow-up care doctors within 3 months and 93% within 6 months, consistent with the NCI report and recommended breast cancer care guidelines. We will ask participants to complete the full intervention within 3 months after intervention delivery and then complete a 3-month post-randomization interview (T1). The website will remain open for six months after intervention delivery to allow participants to use QPL if they wish. A 6-month post-randomization interview (T2) will then be administered.

Usual care: Survivors randomized to the usual care group will receive care from their doctors as usual, allowing us to compare the intervention against real-world practice to inform next steps. Since we do not know if the intervention will be efficacious, we decided not to provide a delayed intervention to control participants

3. Rationale and justification for study (i.e. historical background, investigator's personal experience, pertinent medical literature, etc.):

Communication with doctors (e.g., oncologists and primary care providers) is key to helping cancer survivors effectively manage treatment-related toxicities and side effects that affect one's QoL. Yet, Chinese-speaking (the largest and fastest growing Asian immigrant group) cancer patients have the worst communication with doctors and receive poorer coordination and responsiveness of care than NHW, Black, and Hispanic patients. They are also likely to have poorer functional status than NHW

survivors. Despite these documented disparities, research identifying effective strategies to improve Chinese immigrant survivors' communication quality and functional status is scarce.

Guided by Confucianism which values social harmony for overall success, Chinese are taught to defer to authorities. Thus, Chinese patients prefer not to disrupt harmony with doctors by making demands. In contrast, American culture values patient autonomy and encourages patients to be active, expressive, and assertive during medical communication. Cultural values regarding respect may make Chinese patients less likely to ask about and discuss their options (e.g., changing medicine, obtaining additional assessments, or getting referrals) with doctors, leading to more unresolved problems than NHW survivors. Communication quality was found to attenuate ethnic differences in cancer-related symptoms between Latino immigrant and NHW patients. Educating Chinese immigrants about the American value of patient autonomy and how asking questions to help doctors understand their needs is essential to obtaining needed information and care.

Quality communication with doctors often promotes patients' functioning by increasing patients' psychosocial and behavioral repertoire (e.g., perceived control and efficacy in communication). Communication researchers theorize that when patients seek, give, and verify information with doctors, doctors' responses to patients' needs increase. Patients who are effective in medical communication gain their doctor's informational and emotional support for symptom management and exhibit a greater sense of control over their disease, leading to enhanced physical functioning and decreased emotional uncertainty about healing. Although several studies did not find that communication training improved QoL, these studies failed to assess the proximal training effects of altering patients' perceived control and efficacy in communication and self-care. For Chinese immigrants with limited social networks and low social status impeding access to mainstream healthcare resources, doctors are crucial for resolving physical and emotional problems. Thus, we designed our intervention and measurement methods using concepts from communication and social cognitive theories and Street et al.'s pathways from communication to health outcomes.

Chinese American breast cancer survivors will increase greatly as their incidence rates have been annually increasing by 1-2%. Our E-Talkcare intervention aims to empower Chinese cancer patients to effectively communicate with different providers in different healthcare settings. National data shows that over 86% of Asian Americans have internet access. Using the internet for health communication will be increasing in the coming decades. The proposed study will not only advance the field of culture and cancer care communication about symptom management but also has potential to reduce ethnic inequity in access to quality care.

4. Primary objective:

The purpose of this study is to develop and test a culturally relevant, web-based patient education program among Chinese immigrant breast cancer survivors, and the efficacy of the intervention in enhancing Chinese immigrant survivors' communication competence, perceived control, and self-efficacy in cancer care communication (intermediate outcomes) relative to the usual care control arm.

5. Secondary objectives:

The secondary objective is to obtain preliminary data on the efficacy of the E-Talkcare intervention (vs. usual care) in improving patient-reported symptoms, adherence to breast cancer survivorship care

guidelines, and quality of life (QoL) and explore the mediating role of the intermediate outcomes on distal outcomes.

6. Inclusion criteria:

Eligible Chinese women must be: 1) \geq age 18, 2) foreign-born speaking Mandarin and/or Cantonese, 3) diagnosed with breast cancer at stage 0, I, II or III, 4) 1-3 years post-diagnosis and completed primary treatment (surgery, radiation, and chemotherapy), and have 5) no recurrence, and 6) internet access.

7. Exclusion criteria:

Women with other cancer types are ineligible due to different treatment complications. Women in Phase I will not be eligible for Phase II.

8. Treatment Plan:

View a website which includes three web modules: 1) Culture and autonomous communication, 2) Online symptom reporting and questions, and 3) Question database and prompt lists. The first module will educate Chinese women about the US values of patient autonomy and how to actively help providers understand their needs in order to make personalized care plans. Second, intervention women will report the PROMIS symptoms and QoL variables monthly during the 3-month intervention period and post their top three symptom questions (either in English or Chinese) on the web. Third, all questions will be anonymously collected and posted on the web by topic (e.g., fatigue and pain). Using this question database, women can build a QPL relevant to their conditions and needs for medical visits within the study period. Using QPL helped patients actively engage in clinical communication.

9. Please state the relative importance/value of the trial, considering standard therapy and competing trials:

The study is the first culturally relevant, theory-guided communication program for Chinese immigrant cancer survivors. Although some web programs to help general cancer survivors communicate with oncologists exist, none of these consider cultural context. Web-based communication programs improve cancer patients' interactions with doctors, symptom distress, and QoL. Using CBPR principles, our intervention will be adapted to Chinese survivors' cultural views and preferences in order to motivate them to change their communication practices. Providers could use the web tool to deliver culturally appropriate care, either distributing the web link to educate Chinese patients via web vendors or adding it to existing patient portals. Second, we will collect and refine our Chinese survivors' questions for them to build bilingual (English and Chinese) question prompt lists (QPL) for follow-up care visits. We will thus create the first resource database equipping Chinese patients to competently seek medical information. Third, the NIH patient-reported outcome measurement system (PROMIS) has been underused in assessing Chinese cancer patients' symptoms (e.g., fatigue, sleep, pain) and QoL, although symptom severity thresholds have been established. We will utilize Chinese PROMIS short forms to help Chinese women generate a bilingual symptom report to discuss with doctors. Fourth, we will study a growing, hard-to-reach, and underserved survivor population.