


Increasing Breast Cancer Screening in Chinese Immigrants
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	Protocol Name:	Increasing breast cancer screening in Chinese immigrants
	Principal Investigator:	Lina Jandorf
	Primary Contact Name/Contact Info:	Suzanne Vang, Suzanne.vang@mssm.edu , 212-824-7641
	Date Revised:	July 22, 2020
	Study Number:	GCO 19-1320

HRP-503 PROTOCOL TEMPLATE


Brief Summary of Research (250-400 words):

The purpose of this study is to develop and pilot test a culturally- and linguistically-tailored health education intervention to increase breast cancer screening amongst Chinese immigrant women. The overall goal is to promote Chinese women to adhere to 1- and 2-year screening mammogram guidelines and complete follow-ups in a timely manner. Healthy People 2020 aims to have ~81% of screening eligible women undergo mammography; however, less than 61% of Chinese immigrant women across the U.S. meet screening guidelines. In New York City (NYC), immigration from China has increased ~50% in the past two decades. This rapid immigration makes NYC an ideal testing ground for investigating strategies to improve Chinese immigrant women's adherence to screening mammography. Research with Chinese immigrants in NYC has revealed that only 23-30% of women from this community had ever had a mammogram in their lifetime. This is a population with great need for increased access to breast cancer education and screening.

The Health Belief Model (HBM) provides a framework for addressing cultural health barriers related to preventive health care and cancer screening by positing that making a decision to engage in a health behavior is determined by weighing perceived threats versus benefits. Health education programs addressing individual and community-level barriers developed using HBM constructs, specifically the Witness Project, has successfully increased participants' breast cancer knowledge and mammography screening uptake. The evidence-based Witness Project uses narrative communication (e.g., storytelling, personal testimonials) to educate, persuade, and engage target communities about cancer prevention and screening. The appeal and success of narrative communication stem from its familiarity as a basic mode of human interaction. Our work in minority and immigrant communities has demonstrated that narrative communication can increase participation in breast cancer screening. However, the efficacy of these interventions has not been empirically tested among Chinese immigrants. By integrating individual and community-level approaches, group-based narrative educational programs could play a significant role in promoting adoption and repeat use of breast cancer screening amongst Chinese women.

1) Objectives

We seek to identify cultural beliefs and attitudes Chinese immigrant women have toward breast cancer screening; and to utilize these findings to adapt and subsequently pilot test a narrative-based breast health education program for increasing screening mammograms in Chinese immigrant women. We hypothesize that our culturally- and linguistically-adapted breast health education program will improve screening mammography rates in Chinese immigrant women.

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Aim 1. Culturally and linguistically adapt the Witness Project, a narrative-based breast cancer education program for Chinese immigrant women. We will conduct individual interviews with community members (n=30) and gatekeepers/stakeholders (n=30) and draw from our preliminary work and literature review to identify and test components of the Witness Project that should be adapted for Chinese immigrant women. Preferred language, English language proficiency, cultural beliefs, access to health care, preferred format (group-based vs. individual education), knowledge of breast cancer screening guidelines, and HBM predictors of screening behaviors will be assessed.


To be submitted later:

Aim 2. Pilot test feasibility and acceptability of the Witness Project for Chinese immigrant women. We will pilot test the adapted intervention using 12 programs (4 each in Cantonese, Mandarin, and English) to assess feasibility and acceptability and to determine effect sizes for a future large-scale trial. Receipt of screening mammography and intentions to undergo mammography, as well as other HBM constructs (i.e., perceived risk, barriers, fatalism, and breast cancer knowledge) will be compared in a pre-post test design stratified by language (N=96).

2) Background

Although there are multiple social/environmental determinants of cancer screening, screening involves an individual deciding whether or not to engage in the screening behavior.^{48,49} The HBM asserts that an individual's attitudes and beliefs (e.g., perceived benefits, perceived barriers) will determine their behavioral intentions.⁵⁰ Therefore, improving breast cancer screening rates in Chinese immigrant women requires a deep understanding of the factors that influence decisions about breast cancer screening uptake. Health decision-making models theorize that decisions about a behavior are a function of an individual's perceptions of the expected utility (benefit-cost ratio) of the behavior and of other cognitive factors (e.g., self-efficacy, perceived risk).¹⁻³ Expected utility and Social Cognitive Theory constructs, such as observational learning through modeling of screening mammogram exams have been shown to predict engagement in cancer screening behaviors.⁴⁻⁷ Specifically, several of our own studies in colorectal cancer screening have provided data on attitudes and barriers regarding colorectal cancer screening including fear, fatalism, less perceived disease risk, medical mistrust, lack of knowledge and insurance access.⁸⁻¹⁴

However, to our knowledge, few studies have focused on attitudes and beliefs regarding breast cancer screening exams among Chinese immigrant women. Chinese immigrant women in NYC emigrated primarily from Fujian province, a very low resource region, and are linguistically, socioeconomically, and culturally different from Chinese women who have settled elsewhere in the US.¹⁵⁻¹⁹ Studies conducted by Chen²⁰ and Chen et al.²¹ found that only 54-67% of Chinese immigrant women in NYC had ever had a clinical breast exam and only 23% had ever completed a mammogram. Their studies also reported that English-speaking ability and greater years spent in the US were positive significant predictors of having undergone a clinical breast


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examination.^{20,21} Culturally specific barriers and facilitators were not examined, which could have provided more information on how to address the breast cancer screening needs of this population. We found no existing intervention targeting mammography screening in NYC Chinese immigrants, though pilot studies with Chinese immigrants elsewhere in the US have indicated that improving access, knowledge, and attitudes toward breast cancer screenings through health education programs can improve breast cancer screening intentions.²²⁻²⁶

Our preliminary work with Chinese women in NYC show that only 30% have had a mammogram in the past year and only 64% have had a mammogram within the past 2 years (manuscript under review). Because we were unable to assess years in the US or immigrant status in our preliminary work, we expect these numbers to be much lower for NYC Chinese women who are immigrants. *Nonetheless, our findings demonstrate the need for education regarding breast cancer screening and adherence to screening mammogram guidelines within this population.*

We have conducted robust, culturally-targeted outreach into several minority communities. The Witness Project (WP) is a community-based breast cancer education program designed to meet educational and cultural levels of underserved African American women. The WP model is a belief and theory-based intervention incorporating the HBM, locus of control beliefs, social learning theory, transtheoretical model of change and the 4MAT System.^{27,28} The program begins with a narrative presentation by a breast cancer survivor who briefly shares her personal experience of breast cancer, from diagnosis to treatment and survivorship. Lay volunteers present educational information about breast cancer risks and protective factors, demonstrate how to perform a breast self-examination and a question and answer session concludes the program. Research by Jandorf (PI) et al. successfully replicated WP in 22 states at 40 unique sites including NYC.^{29-30,27-28,31} Replication was achieved using an implementation guide, locally produced, award winning video, and training curriculum developed by Erwin and Jandorf (now on NCI Cancer Control Planet RTIP). In NYC, we conducted hundreds of programs at a variety of community sites and have educated over 3,000 participants.³²⁻³⁵ *This research demonstrates our ability to reach culturally targeted members in the community and our experience of over 15 years in community-based research.*

Development of *Esperanza y Vida*: A unique aspect of the Witness Project is the ability to adapt the program to another culture as evidenced by *Esperanza y Vida* (EyV). In 2003, Jandorf (PI) and colleagues initiated EyV to expand this breast educational program among Latina populations in a culturally and linguistically congruent, community-based approach.^{33,34} EyV development was conducted with members of the target group, including qualitative studies, to ensure the adaptation would be culturally appropriate and meaningful.³⁴⁻³⁶ The social network characteristics and language preferences (Spanish) assessed and integrated into the intervention to include such factors of where to present the programs (e.g. both community and faith-based locations) and the need to educate men about issues related to women's health.^{34,37} *This successful replication and adaptation demonstrates our ability to adapt education programs through vigorous qualitative methods and pilot testing, as well as to address linguistic needs of different cultural groups.*

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Narrative communication methods are a widely recognized tool for mitigating barriers and effectively increasing a variety of health behaviors including cancer screening.^{38,39} Transporting narratives, or immersion into a story, can successfully change beliefs and motivate action.⁴⁰ Narrative communication is a comfortable way of presenting information because people communicate with each other and learn in everyday life primarily through stories.¹⁵ By creating a feeling of similarity to and identification with the communicator, narrative communication can increase an individual's perceived risk regarding a particular health related behavior.¹ People with personal experiences make credible, believable messengers. Additionally, narratives can be particularly useful for conveying cancer information because they reduce counterarguments which can help individuals overcome barriers to seeking treatment.⁴⁰ Narratives also diminish negative feelings towards unknown, difficult, or frightening procedures (e.g., screening), provide role models for behavior change and create new attitudes that are based on cognition and emotion.⁴⁰ Four distinct capabilities of narrative health communication are: "overcoming resistance, facilitating information processing, providing surrogate social connections, and representing emotional and existential issues."⁴¹ Narrative means of communication have been shown to lead to significant emotional responses, which subsequently have a large impact on behavioral decisions.^{42,43} This feature is a major strength of the narrative approach.³⁸

There is substantial evidence that community-based group narrative education cancer screening programs can be effective in fostering positive health behavior change.^{28,29,39,44} Narrative communication has been shown to reduce message counterarguments, increase positive affect, foster identification with the communicator and lead to better engagement with the message; thereby reducing perceived barriers, increasing message recall, and promoting discussion with family members.^{39,45} One study has found that participants exposed to narrative messages were two to four times more likely to engage in health promoting actions and information-seeking behavior than those unexposed.⁴⁶ While numerous studies have illustrated the success of narrative communication over didactic communication in terms of various types of behavior change, narrative education formats have not been developed within the context of Chinese immigrants. However, one study with immigrant women in Canada suggests Chinese women might be receptive to interventions involving narrative stories.⁴⁷


Replicating and expanding the application of this model to Chinese immigrant women will not only potentially improve the health outcomes of this population, but can also demonstrate the effectiveness of the HBM in yet another minority population, increasing the robustness of this approach.

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3) Setting of the Human Research

Due to the COVID-19 pandemic, all interviews will be conducted over the phone and audio recorded so that we can create transcripts of the information. Participant recruitment, as well as pilot testing of the educational intervention in Year 2 will be conducted at community and faith-based partner sites, including, but not limited to:

Saint Margaret's House: 49 Fulton Street, New York, NY 10038

Henry Street Settlement: 334 Madison Street, New York, NY 10002


Chinese American Planning Council: 4101 8th Avenue, Brooklyn, NY 11232

4) Resources Available to Conduct the Human Research

Our team has successfully recruited Chinese-speaking participants into previous research (e.g., IRB-18-00111) and have demonstrated prior recruitment rates of over 70% from immigrant and minority groups. The PI, Jandorf is a Professor and the Director of the Office of Community Engagement at the Tisch Cancer Institute at Mount Sinai. She is an expert in qualitative research and has over 20 years of experience conducting community-based research. Furthermore, we have strong collaborations with community site leaders who have helped recruit participants and hosted programs with us in the past (and have provided a Letter of Support for this proposal). Thus, we are confident that we will be able to identify and consent 60 eligible subjects (30 community members and 30 gatekeepers/stakeholders) for qualitative interview calls for Aim 1.

5) Study Design

a) Recruitment Methods

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All participants will be recruited from Chinese immigrant communities in NYC. We have well-established collaborative relationships with gatekeepers from over 50 community organizations serving the Chinese immigrant community) and have successfully recruited Chinese immigrant women into prior studies (manuscripts under review), and therefore anticipate successful recruitment for this proposed research.

For Aim 1:

As we have done before, we will distribute IRB-approved flyers through various venues (e.g., at community sites, community newsletters, community listservs) and will ask partner site staff to identify/reach out to individuals who might be interested and share our contact information with these individuals. All participants will receive \$30 for their participation. HIPAA authorization and informed consent will be obtained prior to participation.

Individuals who are interested in participating will work with our research staff to set up a time for a phone interview at the time most convenient for them. At this time, all aspects of the study will be explained and those interested in participating will undergo the informed consent process. Signed consent will be captured electronically through the RedCap platform or via phone consent with a witness.

b) Inclusion and Exclusion Criteria

For the qualitative interviews (Aim 1):

Inclusion criteria:

Individuals are eligible to participate in the community member interviews if they are:


- 1) 40 years of age or older,
- 2) female,
- 3) born in China, and
- 4) speak Cantonese, Mandarin, or English

Individuals are eligible to participate in the gatekeeper/stakeholder interviews if they are:

- 1) 18 years of age or older and:
- 2) a leader in the Chinese immigrant community or
- 3) are affiliated with a Chinese-serving organization

Exclusion criteria:

Individuals who do not agree to be audio recorded will be excluded.

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c) Number of Subjects

We aim to enroll 60 individuals (30 community members and 30 gatekeepers/stakeholders) for the individual interviews in Aim 1.

d) Study Timelines

Duration of an individual subject's participation in the study:

- Individual interview (including consent): 45-60 mins

Duration anticipated to enroll Aim 1 study subjects: 12 months

Estimated dates for the investigator to complete the study: 2 years

e) Endpoints

N/A

f) Procedures Involved in the Human Research

For Aim 1, individuals who consent will be invited to participate in audio-recorded interviews regarding Chinese immigrant women's views and experiences with breast cancer screening, potential barriers and facilitators to utilizing screening mammograms, and beliefs about breast cancer. Interviews are expected to last 45-60 minutes. We will interview subjects at various times and days to accommodate their schedules (e.g., evenings, weekends) and in Cantonese, Mandarin, or English, as preferred. All participants will receive a \$30 gift card as an incentive for participating.

Each participant will receive a \$30 giftcard for participating.


g) Specimen Banking

N/A

h) Data Management and Confidentiality

We will collect name and phone number and/or email of potential subjects in order to contact them. After the subject is done with study and gift card has been sent, we will remove subject's phone number and/or email collected. All data will be de-identified and participants will be assigned a numeric code linked with their data so they cannot be identified in study data analyses, publications, or presentations. Only the PI and approved study personnel will have access to the files. Any physical copies of identifying information will be kept in locked cabinets until the information can be transferred into electronic form, at which point any physical copies will be destroyed. All data will be saved on the department's secure, encrypted server. This data will be stored for 7 years.

i) Provisions to Monitor the Data to Ensure the Safety of Subjects

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This study does not involve more than minimal risk to subjects.

j) Withdrawal of Subjects

A subject may request to withdraw from the study at any time by notifying the PI (or if withdrawal occurs during the interview or educational program, the research assistant). The PI's email and phone number will be provided to all participants prior to beginning the interviews or programs and will be listed on the consent forms.

Procedures for Investigator to Withdraw Subjects:

There are no anticipated circumstances under which subjects will be withdrawn from the research without their consent.

5) Risks to Subjects

Some participants may become stressed or anxious when thinking or discussing breast cancer, undergoing screening, and potential development of breast cancer.

To minimize risk in our study, research personnel will adhere to a strict protocol developed by the PI and Co-Is. Prior to starting the interview or program, research assistants will inform participants of the potentially sensitive nature of the topic and remind participants of their right to withdraw from the study at any time or to decline to answer any questions that make them feel uncomfortable.

6) Provisions for Research Related Harm/Injury

This study involves minimal risk to subjects.


7) Potential Benefits to Subjects

Subjects might not derive any direct benefit from the research. However, possible benefits to subjects may be increased knowledge about breast cancer, breast health, and breast cancer screening.

8) Provisions to Protect the Privacy Interests of Subjects

Collected information will be stored on the department's secured intranet drive. Following participation and after gift cards have been mailed/emailed to the subject, we will not need to keep any contact information and will delete this information from files.

Confidentiality of each subject's information will be protected with utmost care. All subjects will be assigned a numeric code for record-keeping purposes. A cross-referencing file containing identifying information and numeric codes will be password protected and stored on the Department's secured intranet drive and will only be accessible to the PI and approved study personnel. In addition, all data will kept in a file on the encrypted on the Department's intranet drive. Any and all physical documents with subject information will be kept in a locked file cabinet in the PI's office at the Icahn School of Medicine at Mount Sinai until they are

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scanned (and the paper copies destroyed) and stored on the Department's secure intranet drive in a password-protected file accessible only to the study staff.

9) Economic Impact on Subjects

There are no anticipated economic impact on the participants. We will provide subjects with a \$30 gift card as a token of appreciation for their time.

10) Payments to Subjects

Subjects will receive a \$30 gift card as a token of appreciation for their time.

11) Consent Process

The standard "SOP HRP-090 Informed Consent Process for Research" will be utilized to obtain permission from subjects to participate in the research study.

Eligible patients who are interested in the study will be provided with the informed consent form. Research assistants will go through the consent form with eligible patients and answer any questions. For Aim 1, informed consent will be conducted through the RedCap platform, modeled after the standard MSH informed consent form, or via phone consent with a witness, depending on patient preference.

The consent form will explicitly state that the study involves research regarding Chinese immigrant women's barriers and facilitators to breast cancer screening. It will include that risk to the patient is minimal. We will explain that data will be de-identified and kept encrypted and password protected. We will explain who and how to contact for answers to pertinent questions about the research and research subjects' rights, including withdrawal processes. The consent will include a statement that participation is voluntary, refusal to participate will involve no penalty or decrease in benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Children


Children will not be enrolled in this study because children are not routinely screened for breast cancer.

Cognitively Impaired Adults – N/A

English and Chinese (both Mandarin and Cantonese) speaking Chinese women will be allowed to participate in the study.

12) Process to Document Consent in Writing

The standard PPHS consent template will be used, "SOP-091 Written Documentation of Consent." For Aim 1 participants, consent will be documented electronically via REDCap or over the phone with a witness, depending on participant preference.

	Protocol Name:	Increasing breast cancer screening in Chinese immigrants
	Principal Investigator:	Lina Jandorf
	Primary Contact Name/Contact Info:	Suzanne Vang, Suzanne.vang@mssm.edu , 212-824-7641
	Date Revised:	July 22, 2020
	Study Number:	GCO 19-1320

13) Vulnerable Populations

Indicate specifically whether you will include (target) or exclude each of the following populations:

<i>Include</i>	<i>Exclude</i>	<i>Vulnerable Population Type</i>
	X	<i>Adults unable to consent</i>
	X	<i>Individuals who are not yet adults (e.g. infants, children, teenagers)</i>
	X	<i>Wards of the State (e.g. foster children)</i>
X		<i>Pregnant women</i>
	X	<i>Prisoners</i>

Some women participating in the study may be pregnant. Women who are pregnant will not be excluded from our study, as pregnant women are not prohibited from receiving routine screening mammograms.

14) Multi-Site Human Research (Coordinating Center)

N/A

15) Community-Based Participatory Research

N/A

16) Sharing of Results with Subjects

N/A

17) External IRB Review History

N/A

18) Control of Drugs, Biologics, or Devices

N/A