Project Title:
Empowering Latinas to Obtain Breast Cancer Screenings

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1.0 Project Summary/Abstract

Latinas suffer disproportionately from breast cancer relative to non-Latina Whites (NLWs), including late stage detection. While there have been controversies in breast cancer screening, non-adherence to guideline-concordant screening continues to be a modifiable determinant of breast cancer outcome disparities. Thus, increasing participation in breast cancer screening among Latinas, especially care that corresponds with clinical and academic guidelines, is a public health priority.

Participatory approaches are popular methods to improve screening within this group and have included approaches that deliver education to non-adherent Latinas and train motivated community members' interventions (community health workers, breast cancer survivors) to engage in breast health promotion. The latter approach, empowerment interventions, concern training participants to engage in social outreach (e.g., having conversations with family and friends about breast health) and volunteering (e.g., helping in health fairs, engaging in civic campaigns about breast cancer programs). Patient activation and volunteerism literature suggest that empowerment interventions may have 'added value' over delivering education in terms of preventive health psychosocial factors and practices. Relative to education interventions, empowerment interventions may also affect women's networks, as they may be more likely to lead to disseminate evidence-based breast health promotion among their family and friends. To date, little research has compared interventions' effects on individual-level outcomes or used formal social network analysis to examine network effects.

The proposed work adds to the literature through conducting a trial to compare the two approaches (education versus empowerment) on three sets of outcomes: 1) women's own screening, 2) women's own self-efficacy, norms, support, knowledge; and 3) women's networks (measured by egocentric analysis). We will recruit 150 Latina women to participate in the Intervention. 75 women will be recruited from The Resurrection Project and 75 women will be recruited from Centro Comunitario Juan Diego.

We will be conducting educational classes at the two participating sites. We will also administer several surveys at different sessions. The variations in the implementation of Phase 3 will be the Workshops at each site. Each site will conduct a Breast Cancer Education session. However, TRP will conduct Communication and Volunteerism workshops, whereas Juan Diego will conduct Diet and Physical Activity workshops. The Intervention is broken down into 3 sessions at each site across 3 consecutive weeks. Each session will be held with 5-8 recruited participants. We will hold 5 – 9 sessions at each participating site for three consecutive weeks.

Ancillary studies and analytic studies include: 1) qualitative data collection with participants' family and friends (Phase 4); 2) cost data collection and cost-effectiveness analysis (Phase 5); and, 3) community volunteerism data abstraction (e.g., preferences regarding events; number of contacts; barriers, if any, during contact; decisions/solutions made, if any during contact; interest in event participation; type of event; and attendance at event) and secondary analysis of Phase 3 volunteerism data (Phase 6). During Phase 7, 20 former intervention participants will participate in focus groups to provide their perspectives on their experiences and suggestions for future interventions.

2.0 Background/Scientific Rationale

Multiple community-based participatory research (CPBR) interventions exist that have sought to improve breast cancer screening among Latinas. For example, there have been >10 CBPR education breast cancer screening interventions for Latinas using community health workers (CHW).[9] Participants were breast health promotion recipients. As well, there are few CBPR empowerment interventions strove to build community infrastructure to improve screening among Latinas.[25-28] Participants were trained to become breast health promotion agents in social outreach (e.g., how to discuss breast health information) and volunteerism (e.g., how to participate in health fairs and policy).

Of which we are aware, no study has compared the relative efficacy of these interventions. First, with regard to screening uptake, empowerment interventions may result in greater screening than education interventions, given documented benefits of patient activation and volunteerism in other disease models.[16-20,35] Second, activating Latinas to become breast health promotion agents may lead to interest and skills for monitoring evidence, resulting in lay individual knowledge that is longitudinally concordant with academic and clinician recommendations. Promoting social outreach and volunteerism may also lead to greater exposure to informed peers, resulting in more sustained perceived social norms, support, and self-efficacy associated with guideline-concordant screening. Third, empowerment interventions are effective in reaching participants' networks and broader communities and may be more effective in reaching networks than education interventions due to intervention materials specific to teaching women how to engage in social outreach.

Toward the goal of addressing these gaps in the literature, we will conduct a trial that compares education and empowerment interventions on these outcomes.

3.0 Objectives/Aims

The primary goal of this proposed work is to develop materials and conduct a trial that would examine the relative efficacy of education and empowerment interventions to improve breast cancer screening among Chicago-based Latinas. With regard to our objectives, we proposed to:

Aim 1: Develop and compare the efficacy of a breast health empowerment intervention on guideline-concordant screening compared to an education intervention, using an area-level treatment control group design with a community-based sample of 150 Latinas. The empowerment arm will include breast health and empowerment information (e.g., how to begin conversations, where to volunteer). The education arm will include only breast health information. Content draws from my team's existing materials. Hypothesis: Empowerment participants will have increased screening compared to education participants.

Aim 2: Compare interventions' effects on psychosocial facilitators of screening across six months. Hypothesis: Empowerment participants will have sustained increases in self-reported self-efficacy, norms, support, and knowledge about breast cancer screening compared to education participants.

Aim 3: Compare interventions' network effects through egocentric network analysis. Hypothesis: Empowerment participants will have greater social connectedness related to breast health and network size and will have referred a greater number of peers to participate in the study compared to education participants.

Aim 4: Characterize intervention effects on family and friends of intervention participants.

Aim 5: a) Determine the incremental costs for each additional woman screened for the empowerment approach relative to the education approach, combining new cost data with existing effect measures in our trial. Hypothesis: The empowerment intervention will have low incremental costs for each additional woman screened, especially when including indirect effects. b) Use those data and published literature to compare approaches in terms of achieving HP2020 goals and costs for additional life-years gained across 10 years, using existing simulation platforms. Hypothesis: The empowerment intervention will be more cost-effective than the education intervention in terms of life years gained.

Aim 6: a) quantify the relative effects of education and empowerment interventions on intention to volunteer, volunteerism behaviors, intention to participate in civic engagement, and civic engagement behaviors; and, b) characterize the feasibility of a community-based civic engagement and community development navigation program for Latinas.

Aim 7: Characterize the perspectives and experiences of intervention participants, based on focus groups (n=20).

Toward that goal, we will first run semi-structured focus groups with 20 Latinas who will not be eligible for the future trial and 10-15 CHW/CHV/promotoras who would be eligible to deliver the intervention in order to: 1) identify relevant topics to incorporate into interventions; and 2) examine circumstances that may facilitate implementation. No contact information on women who have participated in any previous focus groups or will we re-contact any woman who has already participated in a focus group for future trial. We will only invite new recruits for each focus group that is held. This phase of the project will be called Phase 1.

We will then create materials based on this feedback and consultation from the UIC CCTS Community Engagement Advisory Board.

Next, we will run semi-structured focus groups with a second set of 20 Latinas who would be eligible for the future trial and 10-15 CHW/CHV/promotoras who would be eligible to deliver the intervention in order to 1) verify the appropriateness and logic of the updated material; and 2) identify alternative content areas and approaches. This phase of the project will be called Phase 2.

To date, we have worked on the first part of Aim 1 through Phases 1 and 2. Specifically, with regard to development, we ran semi-structured focus groups with 20 Latinas who will not be eligible for the Phase 3 (i.e., Intervention Implementation) and 10-15 CHW/CHV/promotoras who would be eligible to deliver the Phase 3 Intervention in order to: 1) identify relevant topics to incorporate into interventions; and 2) examine circumstances that may facilitate implementation. This phase of the project will be called Phase 1. We created materials based on this feedback and consultation from the UIC CCTS Community Engagement Advisory Board. Finally, we ran semi-structured focus groups with a second set of 20 Latinas who would be eligible for the future trial and 10-15 CHW/CHV/promotoras who would be eligible to deliver the intervention in order to 1) verify the appropriateness and logic of the updated material; and 2) identify alternative content areas and approaches. This phase of the project was called Phase 2. We completed the semi-

structured Phase 1 and Phase 2 focus groups. Data from these activities was used to develop Phase 3 Invention materials.

We will now work on implementing the intervention and assessing changes across interventions with regard to Aims 1-3 outcomes (screening, psychosocial facilitators, network effects). We plan on recruiting 150 Latina women to participate in the Intervention. 75 women will be recruited at The Resurrection Project and 75 women will be recruited from Centro Comunitario Juan Diego. No contact information on women who have participated in any previous focus groups or will we re-contact any woman who has already participated in a focus group for future trial. We will only invite new recruits for the intervention. We will be conducting educational classes and workshops at the two participating sites. The Intervention is broken down into 3 sessions at each site across 3 consecutive weeks. Each session will be held with 5-8 recruited participants. We will hold 5 – 9 sessions at each participating site for three consecutive weeks until we reach our target population of 150 Latina women. The variations in the implementation of Phase 3 Intervention will be the Workshops at each site. Besides each site conducting a Breast Cancer Education session at Session 1, TRP will conduct Communication and Volunteerism workshops at Session 1 and 2. Juan Diego will conduct Diet and Physical Activity workshops at Session 1 and 2. Our outcomes will be measured by Surveys assessed during Session 1, Session 3, and six months post-participation in workshops for 20-30 minutes. At the end of Phase 3, participants who have agreed to be contacted again will be contacted by study staff by phone and given the opportunity to learn about preliminary analyses. Participants will be offered information regarding preliminary analyses of the study. They will have the opportunity to decline learning about study results without any negative impact/costs to their relationships with the study sites or UIC. Script for these calls was submitted as part of Amendment #24.

For Aim 4, we will conduct 20 interviews with family and friends of intervention participants (10 affiliated with empowerment participants, 10 affiliated with education participants). Phase 4 participants will be 18 years or older, have not participated in the study, and identify as family/friends of intervention participants. These individuals will be recruited by Phase 3/intervention participants. Phase 3 participants will learn about the opportunity to recruit individuals for Phase 4 when they learn about the opportunity for peer referral in workshops. Phase 3 participants who have completed the intervention sessions will learn about the opportunity during booster calls. Each interview will take place where the participant prefers, will be in the language the participant prefers (English/Spanish), will be audio-recorded, and will take approximately 1-hour.

For Aim 5, cost data will be collected from community-based organization (personnel and non-personnel costs), participant (costs for intervention participation, knowledge transfer, receipt of screening), and healthcare system perspectives (direct medical costs). This information will be collected from surveys as well as from different observational records (participant encounter logs, behavioral logs). The incremental costs will then be combined with the trial's effects measurement, which include direct (additional # of participants screened) and indirect effects (additional # of participants' family and friends screened). We will conduct one-way sensitivity analyses to identify cost and effect drivers. To note, Aim 5 will not involve any new participants – only Phase 3 participants who complete informed consents with information about Aim 5 (up to 80-82 participants). All of these data will also inform a subsequent simulation model, which will include inputs from published literature as well as data collected through data described above.

For Aim 6, secondary analyses will be conducted of Phase 3 data and community data for Phase 3 participants who agree to the release of their data from partners' existing community volunteerism databases (e.g., if they were called by community partners, if they agreed to participate, if they attended).

For Aim 7, we will run semi-structured focus groups with 20 Latinas who participated in our intervention in order to understand their experiences and recommendations for future interventions. We will only invite women who have previously participated and have provided permission for re-contact.

There will be a total of 300 participants enrolled in our study, including Phase 1 and 2 participants (40 Latinas, 15-30 community health workers), Phase 3 and 5 participants (240 Latinas who enroll, of which 150 estimated to complete entire study), and Phase 4 participants (20 family/friends).

4.0 Eligibility

4.1a Inclusion criteria for target participants:

- Age 52-75 years old;
- Identification as Latina/Hispanic/Chicana female;
- Residence in Pilsen, Little Village, East Side or South Chicago;
- No history of health volunteerism;
- No history of breast cancer; and
- Lack of a mammogram within the last two years

4.1b Inclusion criteria for target interventionists:

- Age 52-75 years old;
- Identification as Latina/Hispanic/Chicana female;
- Residence in Pilsen, Little Village, East Side or South Chicago;
- A history of health volunteerism;

4.1c Inclusion criteria for Phase 4 participants:

- Age 18 years or older;
- No history of participating in Phase 3; and,
- Identification as family/friend of a Phase 3 participant

4.2 Exclusion criteria:

- Not meeting all inclusion criteria;
- Participation in Phase 1 or 2

4.3 Inclusion of Vulnerable Populations

The inclusion of Latinas in this research is justified as this research is designed to test two interventions (empowerment, education) with the potential to directly benefit members of this population.

5.0 Subject Enrollment

There will be a total of 300 participants enrolled in our study, including Phase 1 and 2 participants (40 Latinas, 15-30 community health workers), Phase 3 and 5 participants (240 Latinas who enroll, of which 150 estimated to complete entire study), and Phase 4 participants (20 family/friends).

5.1 Recruitment

For Phase 3, we will recruit approximately 150 Latina women (75 at TRP and 75 at Juan Diego):

- Flyers will be posted at Centro Comunitario Juan Diego, The Resurrection Project and other community venues within target areas (Pilsen, Little Village, East Side and South Chicago,) and be distributed by electronic listservs in English and Spanish.
- Participants may also recruit their peers through sharing flyers/coupons and/or providing Dr. Molina's contact information for screening. Participants will have the opportunity to take recruitment coupons throughout the three intervention sessions. They will be told that they can recruit other women until the third survey/they complete participation in the project. If they choose to take coupons, study staff will record which numbers belong to which participant via their participant id. The number of coupons given to each participant will depend on the participant's interest in distribution and how many they want. The study staff will record the total number each person obtains as well as the respective codes. When recruiting others, seed participants will provide individuals with coupons that have unique tracking codes. How many coupons are distributed and to whom will depend on the seed participants' interests and actions after they take the coupons from study staff. When interested individuals call, they will provide the unique tracking code on their coupon. After the call, the staff member will update the file that includes identifiable elements by inputting the coupon code. That said, no other information from the event will be kept in the database, including whether the individual agreed to be screened or ultimately participated.
- They will be compensated $15 for each peer who contacts the study team, regardless of whether the peer is eligible and the extent to which they choose to undergo screening, consent, or participating in the intervention.
- Interested participants will call the PI, Dr. Yamile Molina, or UIC staff [Appendix P], who will enter the name, address and phone number in a Call Log; screen women for eligibility; and obtain scheduling information.
- For peer-referrals, women will be probed for perceived coercion, will be told that the study is voluntary, will be told that peers will receive compensation regardless of whether they choose to participate or not, and that the peer will not know about the extent to which women choose to participate (e.g., in screening or in intervention sessions).
- Women who call to inquire about the study will listed in a Call Log. We will utilize the call log to invite the women to participate in the interventions. Dr. Molina and UIC Staff (Appendix P) are bilingual to handle any calls from only Spanish and only English speaking subjects.
- Participants have the right to be removed from the research study at any point. This is a development study and therefore, no further information will be collected on the subject. The PI will be notify the participant that any information collected will remain confidential and any further contact by the research staff will cease.

For Phase 4, we will recruit approximately 20 individuals (10 related to empowerment and 10 related to education):

- Phase 3 participants will be told about the opportunity to recruit their family and friends through sharing flyers/coupons and/or providing Dr. Molina's contact information for screening. Participants will have the opportunity to take recruitment flyers throughout the three intervention sessions. The number of flyers given to each participant will depend on the participant's interest in distribution and how many they want. The study staff will record the total number each person obtains as well as the respective codes. When recruiting family and friends, seed participants will provide individuals with flyers. How many flyers are distributed and to whom will depend on the seed participants' interests and actions after they take the flyers from study staff. When interested individuals call, they will be told not to provide information from the seed participants. Given this, there will be no record of which Phase 3 participant referred whom nor of which potential Phase 4 participants called, screened, and participated.
- Interested participants will call the PI, Dr. Yamile Molina, or UIC staff [Appendix P], who will enter the name, address and phone number in a Call Log; screen individuals for eligibility; and obtain scheduling information.
- Individuals will be probed for perceived coercion, will be told that the study is voluntary and that the peer will not know about the extent to which individuals choose to participate (e.g., in screening or in interviews).
- Individuals who call to inquire about the study will listed in a Call Log. We will utilize the call log to invite the women to participate in the interventions. Dr. Molina and UIC Staff (Appendix P) are bilingual to handle any calls from only Spanish and only English speaking subjects.
- Participants have the right to be removed from the research study at any point. This is a development study and therefore, no further information will be collected on the subject. The PI will be notify the participant that any information collected will remain confidential and any further contact by the research staff will cease.

For Phase 5, we will use effects data collected in Phase 3 as well as will collect cost data. Cost data will be reported in aggregate and by study staff, mostly (Organizational Surveys, Behavioral Logs). For individual-level data (Participant Encounter Logs, modified T2 and T3 surveys), we will only collect data on Phase 3 participants who complete informed consents describing Phase 5 procedures (up to 80-82 participants). The simulation model will not include any participants, but aggregate data from cost data gathered in Phase 5 and effects data gathered in Phase 3.

For Phase 6, we will use survey data collected in Phase 3 as well as will abstract data from community partners for Phase 3 participants who agree to release their data concerning volunteerism (e.g., preferences regarding events; number of contacts; barriers, if any, during contact; decisions/solutions made, if any during contact; interest in event participation; type of event; and attendance at event) to the UIC-based study team. Phase 3 participants will not be asked for additional data – Phase 6 will only include survey data (Phase 6a) and community study records for Phase 3 participants who agree to have their data released to UIC (Phase 6b). We are requesting a waiver of documentation and alteration for Phase 6. This requested waiver will not adversely affect the rights and welfare of subjects and is the only way for study staff to obtain objective data regarding subjects' participation in community volunteerism. Community partners will upload data in encrypted, password-protected files to a Box Health Data Folder (BHDF). Subsequently those data will be transferred to the UIC/SPH R drive (R =Research) and the assigned folder will be locked down the folder and restricted access only for the PI and UIC study staff. The School of

Public health's secure network server will have Active Directory controlled access and BitLocker encryption.

For Phase 7, we will re-contact Phase 3 participants who provided permission for study staff (Appendix P) to recontact them. Study staff (Appendix P) who were involved in Phase 3 and are familiar with Phase 3 participants will lead phone calls. We will attempt up to 3 contacts per individual. Study staff listed in Appendix P will use Phase 7 Telephone Recruitment scripts during phone calls. Phase 7 Call Log will be used to track contact attempts and the result after a successful contact (e.g., interested; scheduling availability). All data will be stored in the UIC/SPH R drive (R =Research) and the assigned folder will be locked down the folder and restricted access only for the PI and study staff (Appendix P). The School of Public health's secure network server will have Active Directory controlled access and BitLocker encryption. The PI and study team are bilingual to handle any calls from only Spanish and only English speaking subjects. Participants have the right to be removed from the research study at any point. The study team will be notify the participant that any information collected will remain confidential and any further contact by the research staff will cease.

6.0 Study Design and Procedures

6.1 Study Design

6.1 Recruitment – Phase 1 and Phase 2

We will recruit approximately 60-70 Latina women (40 target population; 20-30 target interventionists):

- Flyers will be posted at Centro Comunitario Juan Diego, The Resurrection Project and other community venues within target areas (Pilsen, Little Village, East Side and South Chicago,) and be distributed by electronic listservs in English and Spanish.
- Participants may also recruit their peers through sharing flyers/coupons and/or providing Dr. Molina's contact information for screening. They will be compensated $15 for each peer who contacts the study team, regardless of whether the peer is eligible and the extent to which they choose to undergo screening, consent, or engaging in focus groups.
- Interested participants will call the PI, Dr. Yamile Molina, or UIC students [TBA], who will enter the name, address and phone number in a Call Log; screen women for eligibility; and obtain scheduling information.
- For peer-referrals, women will be probed for perceived coercion, will be told that the study is voluntary, will be told that peers will receive compensation regardless of whether they choose to participate or not, and that the peer will not know about the extent to which women choose to participate (e.g., in screening or in focus groups).
- Women who call to inquire about the study will listed in a Call Log. We will utilize the call log to invite the women to participate in the study focus groups. Dr. Molina is bilingual to handle any calls from only Spanish and only English speaking subjects.
- Participants have the right to be removed from the research study at any point. This is a development study and therefore, no further information will be collected on the subject. The PI will be notify the participant that any information collected will remain confidential and any further contact by the research staff will cease.

Recruitment – Phase 3

We will use convenience-based sampling to recruit 150 Latinas: 75 from The Resurrection Project (TRP) and 75 from Centro Comunitario Juan Diego. We will also recruit 1-2 Latina

community health workers/volunteers/promotoras from each participating site as well as 1 UIC student/staff that will be present at each session. Participants will also have the opportunity to take recruitment coupons throughout the three intervention sessions. They will be told that they can recruit other women until the third survey/they complete participation in the project. If they choose to take coupons, study staff will record which numbers belong to which participant via their participant id. The number of coupons given to each participant will depend on the participant's interest in distribution and how many they want. The study staff will record the total number each person obtains as well as the respective codes. When recruiting others, seed participants will provide individuals with coupons that have unique tracking codes. How many coupons are distributed and to whom will depend on the seed participants' interests and actions after they take the coupons from study staff. When interested individuals call, they will provide the unique tracking code on their coupon. After the call, the staff member will update the file that includes identifiable elements by inputting the coupon code. That said, no other information from the event will be kept in the database, including whether the individual agreed to be screened or ultimately participated.

Recruitment – Phase 4

We will ask Phase 3 participants to recruit their family/friends to participate in Phase 4. Participants will be told about this opportunity. If they are interested, study staff will record the number of flyers each person takes. The number of coupons given to each participant will depend on the participant's interest in distribution and how many they want. When recruiting individuals, seed participant will provide individuals with flyers or the contact information for Dr. Molina to undergo screening. How many flyers are distributed/how often women attempt to recruit and to whom will depend on the seed participants' interests and actions after they take flyers from study staff/interact with study staff. When interested individuals call, they will be told not to provide information from the seed participants. Given this, there will be no record of which Phase 3 participant referred whom nor of which potential Phase 4 participants called, screened, and participated.

Recruitment – Phase 5

Recruitment for Phase 5 uses the Phase 3 participant population. The simulation model will not include any participants, but aggregate data from cost data gathered in Phase 5 and effects data gathered in Phase 3.

Recruitment – Phase 6

Recruitment for Phase 6 uses the Phase 3 participant population. We are requesting a waiver of documentation and alteration for Phase 6. This requested waiver will not adversely affect the rights and welfare of subjects and is the only way for study staff to obtain objective data regarding subjects' participation in community volunteerism.

Recruitment – Phase 7

For Phase 7, we will re-contact Phase 3 participants who provided permission for study staff (Appendix P) to recontact them. Study staff (Appendix P) who were involved in Phase 3 and are familiar with Phase 3 participants will lead phone calls. We will attempt up to 3 contacts per individual. Study staff listed in Appendix P will use Phase 7 Telephone Recruitment scripts during phone calls. Phase 7 Call Log will be used to track contact attempts and the result after a successful contact (e.g., interested; scheduling availability). All data will be stored in the UIC/SPH R drive (R =Research) and the assigned folder will be locked down the folder and restricted access only for the PI and study staff (Appendix P). The School of

Public health's secure network server will have Active Directory controlled access and BitLocker encryption. The PI and study team are bilingual to handle any calls from only Spanish and only English speaking subjects. Participants have the right to be removed from the research study at any point. The study team will be notify the participant that any information collected will remain confidential and any further contact by the research staff will cease.

6.2 Procedures

Phase 1 and Phase 2
We will use convenience-based sampling to recruit 40 Latinas and 15-30 Latina community health workers/volunteers/promotoras to participate in semi-structured focus groups that will help us to identify factors needed for intervention material and examine circumstances that may facilitate implementation.

Centro Comunitario Juan Diego and The Resurrection Project will distribute physical flyers throughout community areas and send electronic flyers through listservs to recruit women. Peers will also distribute flyers and coupons. Neither the peers, Centro Comunitario Juan Diego nor The Resurrection Project will be involved in any recruitment or consenting activities or know which women contact staff, which women are screened, and which women ultimately consent and participate in focus groups. Study staff will have no contact information concerning the women who are reached by the peers, Centro Comunitario Juan Diego and The Resurrection Project, unless women contact study staff directly. Peers, Centro Comunitario Juan Diego and The Resurrection Project will not give any contact information to Dr. Molina and her team. Interested women will contact Dr. Molina and UIC assistants [Appendix P] who will record women's contact information, screen them for eligibility, and obtain scheduling information for focus groups. Once we have at least 6 women, Dr. Molina, Centro Comunitario Juan Diego and The Resurrection Project will determine a date and time for use of conference room and fits within recruited women's schedules and begin the scheduling process. Once a date and time has been confirmed, Dr. Molina and UIC student [TBA], will contact women two days prior to the focus group to remind them and reschedule, as needed.
Focus groups will be held by Dr. Molina and UIC assistants [Appendix P] at Centro Comunitario Juan Diego and The Resurrection Project offices or other community venues chosen by Centro Comunitario Juan Diego and The Resurrection Project within the target neighborhoods. Focus group/s will be conducted in both Spanish and in English. Dr. Molina who will be conducting the groups is bilingual and will address the group in both languages. Centro Comunitario Juan Diego and The Resurrection Project will not be involved in any recruitment, consenting or focus group activities. Prior to the start of the focus groups, participants will be provided informed consent and asked to sign a written informed consent document if they wish to participate. Participants will be told that the session will be recorded and will have the opportunity to withdraw if they do not want to be recorded.
Prior to the start of the focus groups and after Informed Consent is given, participants will be asked to complete a brief demographic form collecting data on the following variables:

- Age (age only and not DOB)
- Zip Code of Residence
- Race/Ethnicity
- Country of Origin
- Length of time residing in the United States
- Preferred language to speak at home

- Marital Status
- Health insurance status
- Education level
- Family income level
- Mammography history (date of last mammogram)

Afterward, Dr. Molina will use a digital recorder to lead an audio-recorded semi-structured focus group. For Phase 1, she will first briefly describe the future trial and second ask women questions about which factors should be included in interventions and under what circumstances the interventions would be best implemented. The Phase 1 focus group guides have all of this information. For Phase 2, she will provide women with sections of the developed materials and then ask questions. The Phase 2 focus group guides provide the order of what information will be shown and which questions will be asked subsequently.

For Phase 1 (the first set of focus groups), while the Informed Consents will be different, the focus group guide and questionnaires are the same for all individuals who participate in focus groups – they are the same forms for the Latinas who are non-adherent to mammography and represent the target population as well as for the Latinas who are community health workers/volunteers/promotoras and represent the target interventionists.

For Phase 2 (the second set of focus groups), other Informed Consents will be used, which include unique information about the materials presented and new types of questions used. Other focus group guides (Phase 2 focus group guides) will also be used concerning participants' perspectives on the materials developed from Phase 1 data. Thus, we are now able to conduct the focus groups in Pilsen/Little Village. Questionnaires however will remain the same across Phases.
After the group is completed, Dr. Molina will thank participants and give them $40 for their time and effort.

Once all groups are completed, Dr. Molina and her team [Appendix P] will lead a content analysis with inductive and deductive approaches[53, 54] in Atlas.ti.[55] She and two UIC students [TBA] will read transcripts and generate codes. We will compare notes, review data, cluster similar ideas into representative themes, and discuss areas of disagreement until consensus is reached. A final codebook will be used for re-analysis. Sample sizes are within the recommended range to meet thematic saturation.[53,54]

Referring peers will be identified once focus groups are complete, based on the Call Log. They will be identified by a unique tracking code that each woman who calls will give, which will be on the coupon given to referring peers by study team staff. Referring peers will get a lump sum. They will get compensated regardless of whether the referred participants choose or do not choose to participate in screening, focus groups, or any other part of the research study. Referring peers will be given this compensation in person or by mail, based on participants' preferences.

Phase 3
With regard to recruitment, Centro Comunitario Juan Diego and The Resurrection Project will distribute physical flyers throughout community areas and send electronic flyers through listservs to recruit women. Peers will also distribute flyers and coupons. Neither the peers, Centro Comunitario Juan Diego nor The Resurrection Project will be involved in any recruitment or consenting activities or know which women contact staff, which women are screened, and

which women ultimately consent and participate in interventions. Study staff will have no contact information concerning the women who are reached by the peers, Centro Comunitario Juan Diego and The Resurrection Project, unless women contact study staff directly. Peers, Centro Comunitario Juan Diego and The Resurrection Project will not give any contact information to Dr. Molina and her team.

Interested women who have received the recruitment flyers, will contact UIC student/staff who will record women's contact information, screen them for eligibility, and obtain scheduling information for the Intervention sessions. We will ask each participant at time of recruitment/ enrollment what language they prefer. Three 2-3 hour Workshop Sessions will then be scheduled for three consecutive weeks and held accordingly. For the Phase 3/Intervention, women will be informed that the sessions and workshops will be a "closed" group format. Once a woman agree to participate and enrolled in one of the 3 consecutive sessions, she cannot change or switch to another group's session.

With regard to interventions, once we have at least recruited 6-8 women per session, Centro Comunitario Juan Diego and The Resurrection Project will determine a date and time for use of conference room and fits within recruited women's schedules and begin the scheduling process. Once a date and time has been confirmed, UIC staff [Appendix P], will contact women two days prior to the session/s to remind them and reschedule, as needed. We will hold 5 – 9 sessions at each participating site for three consecutive weeks until we reach the targeted 150 Latina women.

Educational Sessions will be attended by the UIC Staff/Staff at Centro Comunitario Juan Diego /Staff at The Resurrection Project and will be located in Centro Comunitario Juan Diego offices or other community venues chosen by Centro Comunitario Juan Diego within the target neighborhoods. Empowerment Sessions will be attended by the UIC Staff/Staff at Centro Comunitario Juan Diego /Staff at The Resurrection Project and will be located in The Resurrection Project offices or other community venues chosen by The Resurrection Project within the target neighborhoods. UIC staff will be in contact with the participants and the participating site community health workers during the entire Intervention period. Community Health Workers from each participating site will conduct the educational sessions and the workshops. UIC staff will administer all the surveys and Informed Consent. Educational Sessions will be conducted in either Spanish or English and participants will have the choice of attending one in the language format they choose. Prior to the start of the sessions, UIC staff will discuss Informed Consent with participants who will be asked to sign a written informed consent if they wish to participate. UIC staff will meet with the women who have consented and who have agreed to attend the 3 sessions and workshops for the duration of the Intervention activities that will be held once a week for three consecutive weeks.

Prior to the start of the Session 1 Session at each site and after Informed Consent is given, participants will be asked to complete Survey 1 (T1), which includes demographics (years in US, country of birth, income, education, marital status, age – NOT DOB), volunteerism history, social interactions, breast cancer beliefs (cultural beliefs, perceived risks, norms and social interactions concerning breast cancer) and breast cancer screening variables.

During the Phase 3 Intervention, the Community Health Worker at each site (TRP and Juan Diego), will conduct the session. UIC student/staff will be present at each activity and will administer the Informed Consents as well as will help Community Health Workers as is needed.

After the Session 3, participants will be asked to complete Survey 2 (T2) before leaving the site. Survey 2 will collect information related to volunteerism history, social interactions, breast cancer beliefs (cultural beliefs, perceived risks, norms and social interactions concerning breast cancer) and breast cancer screening since Survey 1.

All participants will receive a "book" of the PowerPoint slides as well as will have the option to use Promise Letters to encourage adherence to goals. This material will be kept at the participating sites with the Community Health Worker in a locked cabinet in a locked office. None of the materials will have personal identifying information; they will have the participant's six digit random identification code. They will be collected by the UIC staff after Session 3.

UIC study staff and CHWs listed in Appendix P will begin conducting the Booster Calls (Follow-Up Calls) one month after the Educational Sessions. Everyone (UIC-based staff and CHWs) engaging in these calls will have access to the UIC/SPH R drive (R =Research), wherein all data will be stored. Each call will be approximately 10-20 minutes. The booster calls will be conducted every month for six months. These booster calls are intended to sustain successful behavior change and increase motivation.

Six months after participation in Session 3, participants will be asked to complete Survey 3, which will take about 20-30 minutes. Survey 3 will be administered or in person at Centro Comunitario Juan Diego or The Resurrection Project sites. The reminder script has been modified to include scheduling calls, including for Survey 3 as well as the focus groups. Survey 3 will collect information related to information related to volunteerism history, social interactions, breast cancer beliefs (cultural beliefs, perceived risks, norms and social interactions concerning breast cancer) and breast cancer screening since Survey 1. For participants were in Cohort 1 (who completed participation before approved consent addendum), they will be contacted by phone up to 3 times with a script including consent addendum information to be given that information, wherein they can elect to be notified about future studies, if they are interested. If they are not interested, their data will be eliminated from this file. For cohorts 2-15, after the participant completes the final/third survey, her data will be eliminated from this file, if she chooses not to be contacted for future studies. If she chooses to be contacted for future studies, her information name and phone number (nothing else) will be kept and it will be recorded that she has completed participation, but is willing to be contacted in the future. Subsequently, each time she is contacted, this file will be updated to include a summary of the call. During each call, UIC staff will query the woman about her interest in being contacted in the future. If she chooses not to be contacted from future studies, her name and phone number will be eliminated from this contact log. If she chooses to be contacted for future studies, her name and phone number will remain in the contact log. Participants' contact information will be kept until after participants decide to stop active participation or 5-7 years after the study is completed.

For participants who are still participating in June 2018 or who are enrolled after June 2018, mailed letters will be sent to participants who have non-working telephone numbers and/or for women who are non-responsive to 5 attempted phone calls. At the point when thank you cards are sent, the PI and UIC study team will note participants as "lost to follow up", which will indicate that no further contact should be made. If the participant responds/contacts the PI and study team and indicates they wish to continue to participate, the study team will change this status to "returned to study" and begin contact once again, based on participant preferences. If

they do not contact the PI, they will remain “lost to follow up” and no contact will be made. To note, none of UIC-based study staff will access to the mailing addresses of participants. Rather, the letter will be included in a stamped envelope that will be provided to community partners (Centro Comunitario Juan Diego, The Resurrection Project). Community partners regularly engage clientele of their organization through letters as well as phone calls, including women who they have recruited to participate in this study. We will give stamped envelopes with the UIC IRB-approved letter to community partners, who will print address labels and mail letters to participants. To note, no UIC-based staff will have access to these addresses and community partners will only mail letters to participants who have already previously provided their addresses for regular correspondence with Centro Comunitario Juan Diego and The Resurrection Project. Agencies are the primary recruitment sites and agency staff are study staff listed in Appendix P. We are now requesting a waiver of consent and alteration of consent to provide the agency with a list of names of participants for whom letters will be mailed, as 1) the waiver would not adversely affect the rights and welfare of subjects; and, 2) the only way for study staff to reach these subjects is through transfer of this information to the agency staff. Subjects will contact the PI directly if interested. We also now include a recruitment script for women who are interested and contact the PI and study staff. The PI and UIC staff will then update contact information in study records. The PI will only know how many subjects have been mailed 1 letter. The PI and UIC staff will not know how many are returned/are undeliverable/have left the community based organization altogether. Only one mailed letter will be sent for each participant who cannot be reached. Subjects will only contact the PI or study sites. At the point when thank you cards are sent, the PI and UIC study team will note participants as “lost to follow up”, which will indicate that no further contact should be made. If the participant responds/contacts the PI and study team and indicates they wish to continue to participate, the study team will change this status to “returned to study” and begin contact once again, based on participant preferences. If they do not contact the PI, they will remain “lost to follow up” and no contact will be made. The PI and UIC staff will not be able to contact the participants, given the information in study records is not up to date (e.g., number has changed/become disconnected). Subjects who are interested will contact the PI or study staff at TRP and CCJD. TRP and CCJD staff [only staff in research study – i.e., listed in Appendix P] will refer the participants to UIC staff, who will have a list of the interactions requested for each individual participant. This list will be a password-protected file that is kept in a password-protected computer in a locked office at UIC (R:drive). To note, only study staff who are listed in Appendix P/have human subjects training will respond and engage participants who call the study site to optimize patient confidentiality. If the participant contacts the study team at these sites or at UIC and indicates they wish to withdraw/not be contacted by the PI, the study team at these sites will inform participants that no further attempted contact will be made for this study.

With regard to payment, participants will obtain $80 in total throughout their participation in the trial. After Session 1, they will receive $10. After Session 2, they will receive $20. After Session 3, they will receive $25. After they complete the 20-30 minute Survey 3, six months after participating in Session 3, they will receive $25.

The materials for the workshops have been provided.

TRP 75 Latina Women	Compensation for Participants	Juan Diego 75 Latina Women
Three 2 Hour educational classes across 3 consecutive weeks	⟷	Three 2 Hour educational classes across 3 consecutive weeks

Sessions will be held with 5-8 recruited participants		Sessions will be held with 5-8 recruited participants
These are 'closed' group format (once a woman is enrolled in a particular group, she cannot change to another group and has to complete all 3 sessions).		These are 'closed' group format (once a woman is enrolled in a particular group, she cannot change to another group and has to complete all 3 sessions).
At Session 1, Participants will complete: 1) Informed consent 2) Survey 1; 3) 1 ½ Hour Breast Cancer Education session;	$10 Cash ⟷	At Session 1, Participants will complete: 1) Informed consent 2) Survey 1 3) 1 ½ Hour Breast Cancer Education session;
At Session 2, Participants will complete: 1) 1 ½ Hour Interpersonal Communication workshop.	$20 Cash ⟷	At Session 2, Participants will complete: 1) 1 ½ Hour Diet Educational workshop.
At Session 3, Participants will complete: 1) 1 ½ Hour Volunteerism; workshop 2) Survey 2;	$25 Cash ⟷	At Session 3, Participants will complete: 1) 1 ½ Hour Physical Activity workshop; 2) Survey 2;
Booster Calls one month after Session 3. Every month thereafter for 6 months.		Booster Calls one month after Session 3. Every month thereafter for 6 months.
At 6 months post-participation, participants will complete: 20-30 minute Survey 3	$25/Cash ⟷	At 6 months post-participation, participants will complete: 20-30 minute Survey 3

Referring peers will be identified once sessions/workshops are completed, based on the Call Log. They will be identified by a unique tracking code that each woman who calls will give, which will be on the coupon given to referring peers by study team staff. Peers will also be encouraged to recruit other women from their social networks to participate and will be compensated $15 for their time and effort. When recruiting, they will provide individuals with coupons that have unique tracking codes, which will be linked to the seed. The purpose of the coupons is twofold. First, it will be used as a type of snowball sampling, wherein participants will be able to recruit their family and friends to participate in the study. To note, individuals who are recruited will not participate within the same cohort as the seed participant (who will have already started the program and be in a closed session). As well, the seed participant will not know/be told by study staff who contacted them nor who ultimately decided to participate. Second, the use of coupons will be a behavioral measure with regard to participants' interest in disseminating information related to the study (Aim 3 outcome). In this case, we will be measuring the number of participants who are interested in taking flyers and the number of individuals they reach via who contacts for screening. To note, at no point will the screening process of those recruited be connected with participants' names.

The ‘seed’ will have the opportunity to take flyers throughout the three intervention sessions. They will be told that they can recruit other women until the third survey/they complete participation in the project. The study staff will record the total number each person obtains as well as the respective codes. When recruiting others, seed participants will provide individuals with coupons that have unique tracking codes. How many coupons are distributed and to whom will depend on the seed participants’ interests and actions after they take the coupons from study staff. When interested individuals call, they will provide the unique tracking code on their coupon. After the call, the staff member will update the file that includes identifiable elements by inputting the coupon code. That said, no other information from the event will be kept in the database, including whether the individual agreed to be screened or ultimately participated.

Referring peers will get a lump sum. They will get compensated regardless of whether the referred participants choose or do not choose to participate in screening, interventions, or any other part of the research study. Referring peers will be given this compensation in person or by mail, based on participants’ preferences.

At the end of Phase 3, participants who have agreed to be contacted again will be contacted by study staff by phone and given the opportunity to learn about preliminary analyses. Participants will be offered information regarding preliminary analyses of the study. They will have the opportunity to decline learning about study results without any negative impact/costs to their relationships with the study sites or UIC. Script for these calls was submitted as part of Amendment #24.

Phase 4

With regard to recruitment, we will ask Phase 3 participants to recruit their family/friends to participate in Phase 4. Participants will be told about this opportunity. If they are interested, study staff will record the number of flyers each person takes. The number of coupons given to each participant will depend on the participant’s interest in distribution and how many they want. When recruiting individuals, seed participant will provide individuals with flyers or the contact information for Dr. Molina to undergo screening. How many flyers are distributed/how often women attempt to recruit and to whom will depend on the seed participants’ interests and actions after they take flyers from study staff/interact with study staff.

Interested individuals will contact Dr. Molina and UIC assistants [Appendix P] who will assess them for coercion, screen them for eligibility, record their contact information, and obtain scheduling information for interviews. When interested individuals call, they will be told not to provide information from the seed participants. Given this, there will be no record of which Phase 3 participant referred whom nor of which potential Phase 4 participants called, screened, and participated. Once scheduling information has been taken and a date and time has been confirmed, Dr. Molina and UIC student [TBA], will contact women two days prior to the interview to remind them and reschedule, as needed.

Interviews will be held by Dr. Molina and UIC assistants [Appendix P] in locations specified by participants. Interviews will be conducted in both Spanish and in English. All study staff who will be conducting the interviews are bilingual and will use the language preferred by the participant. Prior to the start of the interviews, participants will be provided informed consent and asked to sign a written informed consent document if they wish to participate. Participants will be told that

the session will be recorded and will have the opportunity to withdraw if they do not want to be recorded.
Prior to the start of the interviews and after Informed Consent is given, participants will be asked to complete a brief form collecting data on the following variables:

- Relationship to participant
- Communication frequency (on average, during intervention participation, post-intervention participation)
- Gender
- Age (age only and not DOB)
- Race/Ethnicity
- Country of Origin
- Length of time residing in the United States
- Preferred language to speak at home
- Marital Status
- Health insurance status
- Education level
- Family income level
- Mammography history (date of last mammogram)
- Weight and height
- Sedentary time

Afterward, UIC staff will use a digital recorder to lead an audio-recorded semi-structured interview. For Phase 4, we will ask questions concerning their awareness of the interventions, perceptions about how intervention participants have changed, and finally how the interventions have indirectly impacted them. After the interview is completed, we will thank participants and give them $25 for their time and effort.
Once interviews are completed, Dr. Molina and her team [Appendix P] will lead a content analysis with inductive and deductive approaches[53, 54] in Atlas.ti.[55] She and two UIC students [TBA] will read transcripts and generate codes. We will compare notes, review data, cluster similar ideas into representative themes, and discuss areas of disagreement until consensus is reached. A final codebook will be used for re-analysis. Sample sizes are within the recommended range to meet thematic saturation.[53,54]

Phase 5
During Phase 5, we will collect new data regarding costs through 1) modified T2 and T3 surveys tracking participant costs to participate in the study and to obtain a mammogram; 2) participant encounter logs that will track one-on-one interactions with participants who complete informed consents detailing Aim 5 (we anticipate 80-82 participants); 3) behavioral logs tracking time spent on various aspects of the study (to be completed in Appendix P; different for community health workers, field agents, and Molina office-based lab staff, as they all have different responsibilities); and, 4) organizational surveys tracking costs to organizations implementing Phase 3 (to be completed by individuals in Appendix P). Cost data will be reported in aggregate and by study staff, mostly (Organizational Surveys, Behavioral Logs). For individual-level data (Participant Encounter Logs, modified T2 and T3 surveys), we will only collect data on Phase 3 participants who complete informed consents describing Phase 5 procedures (up to 80-82 participants).

In addition to these materials, we will also include UIC expense reports for this project to assess printing and other office supply costs. The instruments will give us the amount of time spent, which will we use along with self-reported and national salaries of personnel/participants to

calculate costs, self-reported costs, and local market prices to incorporate changes in cost across time (e.g., annual property depreciation per zip code). Research costs will not be included. Cost data will be standardized to 2017 US dollars.48 All of this information will be collected by study staff listed in Appendix P.

Subsequently, we will estimate "effects" data for each program, using data from Phase 3. These data will come from Phase 3, whose primary goal is to assess these outcomes. For each program, we will calculate the:

1) Number of participants obtaining breast cancer screening
2) Number of 54-74 year-old women (participants + Program Director/Principal Investigator (Last, First, Middle): Molina Y. Participant family/friends) who are told about breast cancer screening
3) Number of women obtaining breast cancer screening (participants + participants' family/friends).

After this, we will use these data and published literature to conduct a simulation model on a platform like CAN*TROL to compare the cost-effectiveness of different cancer control interventions across up to 40 years. We will design a model to estimate effects across 10 years (2010-2020).

We will use the 2010 Chicago Latina female population aged 50 to 74 years old as the general population. Intervention programs are only administered to non-adherent Latinas. The model will incorporate this rule, using the percentage of non-adherent Latinas as estimated from the Behavioral Risk Factor Surveillance System and assuming that 25% of these women are enrolled in the intervention (either education or enrollment).

For each run, individuals will be assigned to one of 109 states, including a healthy state, 105 cancer states, a cured state, a dead of cancer state, and a dead of other causes states. Each state tracks individual age via 100 one-year age groups. During each cycle, an individual will remain in a given state or shift according to embedded transition probabilities.

Literature reviews concerning program effectiveness and costs. Ms. San Miguel will conduct two literature searches. First, published studies focused on effectiveness of empowerment and education interventions on improving Latinas' breast cancer outcomes will be identified via a systematic literature search in PubMed and MEDLINE, using terms/phrases such as "Latina" or "Hispanic"; "breast cancer education"; "mammography"; "intervention"; "train-the-trainer"; and, "community health worker." Given our target time frame, articles will be reviewed by the following criteria: 1) have been published between 2010-2017; 2) have used a CHW to deliver an in-person, group-based education or empowerment approach to promote breast cancer screening; 3) have focused exclusively on Latinas or have all relevant data stratified to obtain Latina-specific estimates; and, 4) have breast cancer care utilization (screening, diagnostic care, etc.) and outcomes (e.g., stage at distribution) rates for participants and/or for members of their social networks. Where possible, we will rely exclusively on studies that use medical records. A second systematic literature review will use the same protocol to identify studies focused on the cost of empowerment and education interventions on improving Latinas' breast cancer outcomes. All eligibility criteria will be identical to the first search, except for the fourth, which will be changed to: have cost data. We will subsequently attempt to use summary statistics via Mantel-Haenszel tests to create estimates for the model. If not possible, due to heterogeneity, we will use the median and possible ranges of effects (e.g., screening rates).

Published literature and resources concerning population-level and breast cancer characteristics. Ms. San Miguel and staff will abstract Latina-specific data from representative surveys and study populations (e.g., screening rates from Behavioral Risk Factor Surveillance System; Breast Cancer Care in Chicago registry-linked mortality data) to estimate population screening rates (for baseline), ranges of false-positive rates, and breast cancer state transition probabilities. Cost data regarding breast cancer care services will also be drawn from published literature and resources on free/low-cost mammography services, including the National Breast and Cervical Cancer Early Detection Program. NCI Surveillance Epidemiology and Ends Results (SEER) data will be abstracted for Latinas aged 50-74 years old in terms of age-adjusted prevalence cases of invasive breast cancer, incidence rates, stage distribution (0, I, II, III, IV), and stage-specific survival.

Simulation model building and implementation. The following input data will be used for program-specific runs: population data (SEER; literature-based estimates); cancer data (SEER); and, session information (Study cost and effects data; literature-based estimates). The baseline/no intervention program will include patient and healthcare system costs relevant to breast cancer care; no other costs will be included. The intervention runs will respectively use program-specific cost data. For each intervention run, there will be two runs: one wherein only the behaviors of intervention participants are considered and one wherein the behaviors of intervention participants and their female family/friends are considered.

Costs will be incorporated across 10 years and be dependent on individuals' behaviors and state (e.g., costs for women with 1 false-positive event include provider visit, screening, and diagnostic care; for women with a definitive cancer diagnosis, includes all costs, including those for subsequent surveillance screening). The following beginning list includes assumptions and rules we will make for the model: 1) guideline-concordant screening is defined as obtaining a mammogram every 2 years for women aged 50-74 years old; 2) screening occurs between 2010 and 2020; 3) screening, staging, and mortality rates for future years (e.g., 2018-2020) are estimated based on population-level trends and 2010-2017 rates; 4) expected changes to stage distribution of breast cancer are based on program effect estimates; 5) a discount rate of 0.03 is used; and, 6) cost data will be standardized to 2017 US dollars. Each run will be programmed to provide the following outputs per year for 10 years: 1) cumulative net costs; 2) breast cancer screening; 3) stage distribution; and, 4) age-adjusted mortality rates.

Phase 6

Phase 6 will only include survey data (Phase 6a) and community study records for Phase 3 participants who agree to have their data released to UIC (Phase 6b). Phase 3 will not be asked for any additional data. We are requesting a waiver of documentation and alteration for Phase 6. This requested waiver will not adversely affect the rights and welfare of subjects and is the only way for study staff to obtain objective data regarding subjects' participation in community volunteerism.

For Phase 6a, we will conduct secondary analyses regarding study arm differences in Phase 3 survey data (T1, T2, T3) regarding community volunteerism, including volunteerism intention, civic engagement intention, volunteerism behaviors, and civic engagement behaviors. We will use multiple imputation techniques to handle missing data. For analyses, we will conduct Generalized Estimating Equation models with main effects (Study arm, time) and interaction terms (study arm*time) for all outcomes, except for civic engagement intention, which was not measured at multiple time points. Based on power analyses to estimate the minimal detectable effect size for study arm differences among 100 Latinas (assuming maximum attrition, given current attrition rates) across nested surveys (ICC = 0.0-0.5), $p < .05$, power=0.80, and two-

tailed tests, we would be able to detect a medium-sized effect for a study arm*time interaction effect. For civic engagement intention, we will conduct a logistic regression. We will cluster by cohort/group and adjust for demographic covariates in all models.

For Phase 6b, we will abstract data from community partners for Phase 3 participants who agree to release their data concerning volunteerism (e.g., preferences regarding events; number of contacts; barriers, if any, during contact; decisions/solutions made, if any during contact; interest in event participation; type of event; and attendance at event) to the UIC-based study team. As described in Recruitment, Phase 1, 2, and 3 participants were originally recruited by community partners – The Resurrection Project and Centro Comunitario Juan Diego. These community organizations have multiple programs and events, which allow their clients (including participants of this project) to get involved in their community. To examine the feasibility of such volunteerism navigation, UIC-based study staff will: 1) call Phase 3 participants to discuss Phase 6 procedures; 2) obtain consent to abstract data from the community volunteerism databases; 3) coordinate data transfer with community partners; and, 4) link data in UIC-based listservs. As a first step toward assessing feasibility, we will assess the: 1) number and types of civic engagement and community development activities; 2) number of women who indicate interest; and, 3) number of women who attend. Secondary analyses include: 1) describing the number and types of barriers to participation; and, 2) characterizing predictors to participation via bivariate regressions. Community partners will upload data in encrypted, password-protected files to a Box Health Data Folder (BHDF). Subsequently those data will be transferred to the UIC/SPH R drive (R =Research) and the assigned folder will be locked down the folder and restricted access only for the PI and UIC study staff. The School of Public health's secure network server will have Active Directory controlled access and BitLocker encryption.

Phase 7

We will use convenience-based sampling to recruit 20 Phase 3 participants who agreed to be recontacted to participate in semi-structured focus groups that will help us to obtain qualitative data on their experiences during the intervention and recommendations for future studies.

For recruitment, study staff (Appendix P) who were involved in Phase 3 and are familiar with Phase 3 participants will lead phone calls. We will attempt up to 3 contacts per individual. Study staff listed in Appendix P will use Phase 7 Telephone Recruitment scripts during phone calls. Phase 7 Call Log will be used to track contact attempts and the result after a successful contact (e.g., interested; scheduling availability). All data will be stored in the UIC/SPH R drive (R =Research) and the assigned folder will be locked down the folder and restricted access only for the PI and study staff (Appendix P). The School of Public health's secure network server will have Active Directory controlled access and BitLocker encryption. The PI and study team are bilingual to handle any calls from only Spanish and only English speaking subjects. Participants have the right to be removed from the research study at any point. The study team will be notify the participant that any information collected will remain confidential and any further contact by the research staff will cease.

Once we have at least 6 women, Dr. Molina, Centro Comunitario Juan Diego and The Resurrection Project will determine a date and time for use of conference room and fits within recruited women's schedules and begin the scheduling process. Once a date and time has

been confirmed, Dr. Molina and study staff [TBA], will contact women two days prior to the focus group to remind them and reschedule, as needed.

Focus groups will be held by Dr. Molina and study team [Appendix P] at Centro Comunitario Juan Diego and The Resurrection Project offices or other community venues chosen by Centro Comunitario Juan Diego and The Resurrection Project within the target neighborhoods. Focus group/s will be conducted in both Spanish and in English. Dr. Molina who will be conducting the groups is bilingual and will address the group in both languages. Prior to the start of the focus groups, participants will be provided informed consent and asked to sign a written informed consent document if they wish to participate. Participants will be told that the session will be recorded and will have the opportunity to withdraw if they do not want to be recorded. Participants will also be told to not use their or each other's names to protect their privacy/confidentiality as much as is possible.

Afterward, Dr. Molina will use a digital recorder to lead an audio-recorded semi-structured focus group. For Phase 7, she will first briefly describe the past study and distribute materials from the the intervention (e.g., presentation materials). Subsequently, she will ask questions regarding what they thought about those materials/follow-up calls, what could be done to improve interventions in the future, the programs' effects on behaviors (health, communication), and their perspectives on their neighborhoods and interaction with Centro Comunitario Juan Diego and The Resurrection Project. Throughout the project, Dr. Molina will emphasize that participants can withdraw at any time and do not have to answer any questions that make them feel uncomfortable. After the group is completed, Dr. Molina will thank participants and give them $40 for their time and effort.

Once all groups are completed, audio-recordings and verbatim transcripts will be stored in a folder only accessible to UIC-based study staff in the UIC/SPH R drive (R =Research). The School of Public health's secure network server will have Active Directory controlled access and BitLocker encryption. Dr. Molina and the study team [Appendix P] will lead a content analysis with inductive and deductive approaches [53, 54] in Atlas.ti.[55] She and two individuals students [TBA] will read transcripts and generate codes. We will compare notes, review data, cluster similar ideas into representative themes, and discuss areas of disagreement until consensus is reached. A final codebook will be used for re-analysis. Sample sizes are within the recommended range to meet thematic saturation.[53,54]

6.3. Overall procedures and protocols

Throughout this study, all paper copies of questionnaires will first be scanned and then shredded. Audio-recordings and scanned materials will be stored in password-protected computers that will be housed within locked rooms in the School of Public Health. Hard copies of informed consents will be kept in a locked cabinet in a locked office. Only Dr. Molina and UIC students [Appendix P] will be able to access 1) the room and 2) the computer. Materials will be kept until the completion of the trial. Afterward, all electronic copies will be destroyed in protocols recommended by SPH's IT office. All presentations will be in aggregate, wherein participants' personal identifying information will not be used (name, age, etc.).

6.4 Engagement of Target Population and Interventionists

There will be a total of 300 participants enrolled in our study, including Phase 1 and 2 participants (40 Latinas, 15-30 community health workers), Phase 3 and 5 participants (240 Latinas who enroll, of which 150 estimated to complete entire study), and Phase 4 participants (20 family/friends).

Phase 1 and Phase 2
We will engage the target population to verify the appropriateness and logic of intervention materials and procedures.

Once materials and protocols have been completed, we will recruit a second set of 20 Latinas who would be eligible for the trial and 10-15 community health workers/volunteers/promotoras who would be eligible to deliver the intervention material. All procedures described above will be used in an identical manner for these focus groups. Content will vary, in that Dr. Molina will present the materials and protocols and elicit feedback from women on their appropriateness and any current gaps that should be addressed (e.g., addressing specific barriers to volunteerism).

Once the second set of focus groups have been completed, Dr. Molina will conduct analyses in the identical fashion as described above and will have a second meeting with the Community Engagement Advisory Board, wherein she will present the materials, procedures, as well as aggregate focus group data.

Phase 3
We will now work on implementing the intervention and assessing changes across interventions with regard to Aims 1-3 outcomes (screening, psychosocial facilitators, network effects). We plan on recruiting 150 Latina women to participate in the Intervention. 75 women will be recruited at The Resurrection Project and 75 women will be recruited from Centro Comunitario Juan Diego. No contact information on women who have participated in any previous focus groups or will we re-contact any woman who has already participated in a focus group for future trial. We will only invite new recruits for the intervention. We will be conducting educational classes and workshops at the two participating sites. The Intervention is broken down into 3 sessions at each site across 3 consecutive weeks. Each session will be held with 5-8 recruited participants. We will hold 5 – 9 sessions at each participating site for three consecutive weeks until we reach our target population of 150 Latina women. The variations in the implementation of Phase 3 Intervention will be the Workshops at each site. Besides each site conducting a Breast Cancer Education session at Session 1, TRP will conduct Communication and Volunteerism workshops at Session 1 and 2. Juan Diego will conduct Diet and Physical Activity workshops at Session 1 and 2. Our outcomes will be measured by Surveys assessed during Session 1, Session 3, and six months post-participation in workshops for 20-30 minutes. For participants were in Cohort 1 (who completed participation before approved consent addendum), they will be contacted by phone up to 3 times with a script including consent addendum information to be given that information, wherein they can elect to be notified about future studies, if they are interested. If they are not interested, their data will be eliminated from this file. For cohorts 2-15, after the participant completes the final/third survey, her data will be eliminated from this file, if she chooses not to be contacted for future studies. If she chooses to be contacted for future studies, her name and phone number (nothing else) will be kept and it will be recorded that she has completed participation, but is willing to be contacted in the future. Subsequently, each time she is contacted, this file will be updated to include a summary of the call. During each call, UIC staff will query the woman about her interest in being contacted in the

future. If she chooses not to be contacted from future studies, her name and phone number will be eliminated from this contact log. If she chooses to be contacted for future studies, her name and phone number will remain in the contact log. Scripts for these calls will be submitted in future amendments/for other protocols focused on these future studies. Participants' contact information will be kept until after participants decide to stop active participation or 5-7 years after the study is completed. For participants who are still participating in June 2018 or who are enrolled after June 2018, mailed letters will be sent to participants who have non-working telephone numbers and/or for women who are non-responsive to 5 attempted phone calls. At the point when thank you cards are sent, the PI and UIC study team will note participants as "lost to follow up", which will indicate that no further contact should be made. If the participant responds/contacts the PI and study team and indicates they wish to continue to participate, the study team will change this status to "returned to study" and begin contact once again, based on participant preferences. If they do not contact the PI, they will remain "lost to follow up" and no contact will be made. To note, none of UIC-based study staff will access to the mailing addresses of participants. Rather, the letter will be included in a stamped envelope that will be provided to community partners (Centro Comunitario Juan Diego, The Resurrection Project). Community partners regularly engage clientele of their organization through letters as well as phone calls, including women who they have recruited to participate in this study. We will give stamped envelopes with the UIC IRB-approved letter to community partners, who will print address labels and mail letters to participants. To note, no UIC-based staff will have access to these addresses and community partners will only mail letters to participants who have already previously provided their addresses for regular correspondence with Centro Comunitario Juan Diego and The Resurrection Project. Agencies are the primary recruitment sites and agency staff are study staff listed in Appendix P. We are now requesting a waiver of consent and alteration of consent to provide the agency with a list of names of participants for whom letters will be mailed, as 1) the waiver would not adversely affect the rights and welfare of subjects; and, 2) the only way for study staff to reach these subjects is through transfer of this information to the agency staff. Subjects will contact the PI directly if interested. We also now include a recruitment script for women who are interested and contact the PI and study staff. The PI and UIC staff will then update contact information in study records. The PI will only know how many subjects have been mailed 1 letter. The PI and UIC staff will not know how many are returned/are undeliverable/have left the community based organization altogether. Only one mailed letter will be sent for each participant who cannot be reached. At the point when thank you cards are sent, the PI and UIC study team will note participants as "lost to follow up", which will indicate that no further contact should be made. If the participant responds/contacts the PI and study team and indicates they wish to continue to participate, the study team will change this status to "returned to study" and begin contact once again, based on participant preferences. If they do not contact the PI, they will remain "lost to follow up" and no contact will be made. Subjects who are interested will contact the PI or study staff at TRP and CCJD. TRP and CCJD staff [only staff in research study – i.e., listed in Appendix P] will refer the participants to UIC staff, who will have a list of the interactions requested for each individual participant. This list will be a password-protected file that is kept in a password-protected computer in a locked office at UIC (R:drive). To note, only study staff who are listed in Appendix P/have human subjects training will respond and engage participants who call the study site to optimize patient confidentiality. If the participant contacts the study team at these sites or at UIC and indicates they wish to withdraw/not be contacted by the PI, the study team at these sites will inform participants that no further attempted contact will be made for this study.

At the end of Phase 3, participants who have agreed to be contacted again will be contacted by study staff by phone and given the opportunity to learn about preliminary analyses. Participants will be offered information regarding preliminary analyses of the study. They will have the opportunity to decline learning about study results without any negative impact/costs to their relationships with the study sites or UIC. Script for these calls was submitted as part of Amendment #24.

Phase 4
We will engage participants' family and friends to assess 'spill-over' intervention effects.

We will recruit 20 individuals who are 18 years or older, have not participated in the intervention, and identify as family/friends of intervention participants. We will recruit individuals through Phase 3 participants, who will be told about the opportunity, which is voluntary, to recruit their family and friends during workshop sessions and booster calls. All interview procedures described above will be used in an identical manner for these interviews. Once the interviews have been completed, Dr. Molina and study staff will conduct analyses in the identical fashion as described above.

Phase 5
We will conduct cost-effectiveness analyses, using data from Phase 3 participants.

To collect costs, we will use 1) modified T2 and T3 surveys tracking participant costs to participate in the study and to obtain a mammogram; 2) participant encounter logs that will track one-on-one interactions with participants who complete informed consents detailing Aim 5 (we anticipate 80-82 participants); 3) behavioral logs tracking time spent on various aspects of the study (to be completed in Appendix P; different for community health workers, field agents, and Molina office-based lab staff, as they all have different responsibilities); and, 4) organizational surveys tracking costs to organizations implementing Phase 3 (to be completed by individuals in Appendix P). Cost data will be reported in aggregate and by study staff, mostly (Organizational Surveys, Behavioral Logs). For individual-level data (Participant Encounter Logs, modified T2 and T3 surveys), we will only collect data on Phase 3 participants who complete informed consents describing Phase 5 procedures (up to 80-82 participants). All of this information will be collected by study staff listed in Appendix P.

Subsequently, we will estimate "effects" data for each program, using data from Phase 3. These data will come from Phase 3, whose primary goal is to assess these outcomes. For each program, we will calculate the:

1) Number of participants obtaining breast cancer screening
2) Number of 54-74 year-old women (participants + Program Director/Principal Investigator (Last, First, Middle): Molina Y. Participant family/friends) who are told about breast cancer screening
3) Number of women obtaining breast cancer screening (participants + participants' family/friends).

Phase 6
Phase 3 participants will not be asked for additional data – Phase 6 will only include survey data (Phase 6a) and community study records for Phase 3 participants who agree to have their data

released to UIC (Phase 6b). Phase 3 participants will not be asked for additional data. We are requesting a waiver of documentation and alteration for Phase 6. This requested waiver will not adversely affect the rights and welfare of subjects and is the only way for study staff to obtain objective data regarding subjects' participation in community volunteerism.

For Phase 6a, we will conduct secondary analyses regarding study arm differences in Phase 3 survey data (T1, T2, T3) regarding community volunteerism, including volunteerism intention, civic engagement intention, volunteerism behaviors, and civic engagement behaviors. We will use multiple imputation techniques to handle missing data. For analyses, we will conduct Generalized Estimating Equation models with main effects (Study arm, time) and interaction terms (study arm*time) for all outcomes, except for civic engagement intention, which was not measured at multiple time points. Based on power analyses to estimate the minimal detectable effect size for study arm differences among 100 Latinas (assuming maximum attrition, given current attrition rates) across nested surveys (ICC = 0.0-0.5), $p < .05$, power=0.80, and two-tailed tests, we would be able to detect a medium-sized effect for a study arm*time interaction effect. For civic engagement intention, we will conduct a logistic regression. We will cluster by cohort/group and adjust for demographic covariates in all models.

For Phase 6b, we will abstract data from community partners for Phase 3 participants who agree to release their data concerning volunteerism (e.g., preferences regarding events; number of contacts; barriers, if any, during contact; decisions/solutions made, if any during contact; interest in event participation; type of event; and attendance at event) to the UIC-based study team. As described in Recruitment, Phase 1, 2, and 3 participants were originally recruited by community partners – The Resurrection Project and Centro Comunitario Juan Diego. These community organizations have multiple programs and events, which allow their clients (including participants of this project) to get involved in their community. To examine the feasibility of such volunteerism navigation, UIC-based study staff will: 1) call Phase 3 participants to discuss Phase 6 procedures; 2) obtain consent to abstract data from the community volunteerism databases; 3) coordinate data transfer with community partners; and, 4) link data in UIC-based listservs. As a first step toward assessing feasibility, we will assess the: 1) number and types of civic engagement and community development activities; 2) number of women who indicate interest; and, 3) number of women who attend. Secondary analyses include: 1) describing the number and types of barriers to participation; and, 2) characterizing predictors to participation via bivariate regressions. Community partners will upload data in encrypted, password-protected files to a Box Health Data Folder (BHDF). Subsequently those data will be transferred to the UIC/SPH R drive (R =Research) and the assigned folder will be locked down the folder and restricted access only for the PI and UIC study staff. The School of Public health's secure network server will have Active Directory controlled access and BitLocker encryption.

Phase 7

We will engage Phase 3 participants to understand their perspectives on the effectiveness of our Phase 3 intervention content and activities.

All procedures described in Phases 1 and 2 above will be used in an identical manner for these focus groups. Content will vary, in that Dr. Molina will present the materials and protocols and elicit feedback from participants about their actual experiences as Phase 3 participants.

Once the Phase 7 focus groups have been completed, Dr. Molina will conduct analyses in the identical fashion as described above and will have a third meeting with the Community Engagement Advisory Board, wherein she will describe the results in aggregate of Phase 3 and emergent themes from Phase 7 for feedback/further recommendations.

7.0 Expected Risks/Benefits

7.1 Risks

There is a slight chance that a few individuals may experience some anxiety or distress when answering questions during the interventions. Individuals who are referred by peers may perceive coercion. Throughout the process, participants will be made aware of the voluntary nature of the study and their ability to withdraw from research at any point in time. For individuals who are referred by peers, we will probe for perceptions of coercion, will indicate that the study is voluntary, will note that peers will be reimbursed regardless of their activity, and will note that peers will not ultimately know the extent to which they engage in this project (e.g., proceed to screening, participation in interventions). Though we regard this risk as unlikely and relatively slight, if a participant does experience significant or enduring distress we will ensure that staff are trained to handle this adverse situation sensitively and with cultural competence, if a participant does experience significant distress during the intervention. If a person's distress is extreme or persists longitudinally, they will be referred to a clinical psychologist or psychiatrist for further evaluation and treatment.

Breach of confidentiality is the only other risk to individuals. Breach of confidentiality could entail divulging that individuals contacted staff to be screened and completed informed consent forms. The risk of divulging this confidential information is minimal and the potential for identity theft is limited by the way this data will be handled, given the encryption, password protection, and secure, locked office where the Call Log, electronic copies of informed consent forms and de-identified data will be stored and analyzed. De-identified data, including questionnaires, transcripts, individual-level Phase 5 observation documents (e.g., Participant Encounter Logs), and Phase 6 community volunteerism data, will not be linked in any way to any individual participants' contact information, which minimizes the possibility of identifying individuals or stealing personal information. Specifically, Call Logs will only be linked to electronic copies of signed informed consent forms – both of which will be kept in password-protected computers in locked offices. Neither of these will be linked to questionnaires, individual-level Phase 5 observation documents, and Phase 6 data, which will only be marked by a 6-digit identification code that has no relationship to participants' information, nor to transcripts, which will undergo a process such that no record of conversations during interventions will have personal identifying information. There is no possibility of conducting this investigation without the data being used.

7.2 Benefits

Participants will not receive any direct health benefit from taking part in this study. Participants may gain a feeling of satisfaction in knowing they can and are able to participate in the research process and are able to provide information that may help their communities in the future. Their participation will further lead to an intervention that incorporates their perspectives and tailors materials to meet the unique needs of their community and population.

8.0 Data Collection and Management Procedures

8.1 Collected forms

Collected forms will be scanned, shredded, and kept in encrypted, password-protected files and computers. Data team will be PI and UIC staff [Appendix P].

For Phase 6, community partners will upload data in encrypted, password-protected files to a Box Health Data Folder (BHDF). Subsequently those data will be transferred to the UIC/SPH R drive (R =Research) and the assigned folder will be locked down the folder and restricted access only for the PI and UIC study staff. The School of Public health's secure network server will have Active Directory controlled access and BitLocker encryption.

9.0 Data Analysis

Qualitative

For **Phase 1, 2, 4 and 7**, Dr. Molina and her team [Appendix P] will lead content analyses with inductive and deductive approaches[53, 54] in Atlas.ti.[55] She and two UIC students [TBA] will read transcripts and generate codes. We will compare notes, review data, cluster similar ideas into representative themes, and discuss areas of disagreement until consensus is reached. A final codebook will be used for re-analysis. Sample sizes are within the recommended range to meet thematic saturation.[53,54]

Quantitative

For **Phase 3,** our project will include 3 sets of analyses to examine the 3 outcomes – breast cancer screening, psychosocial facilitators (self-efficacy, norms, support, and knowledge), and social network dissemination. All analyses will be conducted in statistical packages (SPSS, SAS, R).

We will use multiple imputation techniques to handle missing data.[65] Measures will be assessed and included if they have adequate reliability (Cronbach's αs ≥0.70). We will first conduct descriptive statistics. We will identify covariates based on theory and bivariate analyses to examine 1) intervention differences in demographic, healthcare, and pre-study factors (e.g., screening history) and 2) the relationship of these factors to each other and outcomes (e.g., screening). We will conduct a multivariable logistic regression to examine study arm differences in guideline-concordant screening six months after participating in interventions. We will conduct sensitivity analyses, using only women 1) with complete medical record data and 2) recruited by Study Site staff. Based on power analyses to estimate the minimal detectable effect of study arm differences among 150 Latinas on screening, $p<.05$, power = .80 and two-tailed tests, we would be able to detect a medium/large effect in a logistic regression (OR = 2.8).

We will use identical procedures to handle missing data, assess measure reliability, and inform covariate selection for psychosocial factilitators as we did for screening. Next, we will use mixed modeling and will have two levels, with level 2 being participants and level 1 being the repeated surveys at different time points. We will assess within-participant change over time in each outcome (self-efficacy, norms, support, and knowledge) to identify whether it is best modelled as linear versus non-linear (quadratic). Once determined, we will expand models to examine if there are study arm and study arm*time interaction effects in change over time, adjusted for covariates. Sample size for these analyses include 450 level-1 units (survey time points) and 150 level-2 units (participants). Based on power analyses to estimate the minimal detectable effect size of for study arm differences among 150 Latinas across nested surveys concerning psychosocial facilitators (ICC = 0.0-0.5), $p<.05$, power = .80 and two-tailed tests, we would be

able to detect a small/medium effect for a study arm*time interaction effect using mixed modeling.

We will use identical procedures to handle missing data, assess measure reliability, and inform covariate selection for social network data as we did for screening amd psychosocial facilitators. We will first conduct network visualization using Egonet.[71] Network composition and density will be estimated from the first five names/alters women list, which has been documented as adequate and beneficial to minimize respondent burden during small field studies, such as this one.[72] We will next import data into a standard statistical package[73,74] and will conduct multivariable regressions or mixed modeling, depending on clustering (e.g., peers referred by peers), to examine study arm differences in Phase 3 outcomes. Based on power analyses for study arm differences among 150 Latinas in network outcomes, $p<.05$, power = .80 and two-tailed tests, we would be able to detect a small effect in multivariable linear regression models (Cohen's $f^2 = 0.05$).

For **Phase 5**, we will first quantify the difference in costs between education and empowerment programs. All costs will be calculated per participant and summed across cost categories and paying stakeholders (Community Based Organizations; Participants). We will also provide mean and standard deviation information for each cost category. To identify major cost drivers, sensitivity analyses will vary the costs of each input and measure the corresponding changes. Second, we will compute average cost-effectiveness ratios for each program in terms of every participant screened, 50-74 year old woman told about breast cancer screening, and additional woman (participant or non-participant) screened. Finally, we will compute an incremental cost-effectiveness ratios to examine incremental costs for the empowerment intervention relative to the education intervention. For the simulation model, we will using program-specific outputs. We will first assess if simulated programs reached or exceeded HP2020 goals of 10% improvement in guideline-concordant screening (81.1%), stage at diagnosis (42.2 new cases per 100,000), and cancer mortality (20.7 deaths per 100,000). Second, we will calculate average cost/effectiveness (C/E) ratios for each program, defined as cumulative net cost divided by total life-years saved. C/E ratios will be compared to commonly accepted thresholds (e.g., $100,000 per life-year gained). Finally, incremental cost-effectiveness ratios (ICER) will be computed: (cumulative net costs for empowerment-cumulative net costs for no intervention)/(total life-years saved for education-total life-years saved for no intervention) and (cumulative net costs for education-cumulative net costs for no intervention)/ (total life-years saved for empowerment-total life-years saved for no intervention). Finally, we will compare each program's ICER. To identify the major costs and effects drivers, we will conduct one-way sensitivity analyses varying each input. We will also vary the % of non-adherent Latinas enrolled in the study (0-50%).

For **Phase 6,** we will have two sets of analyses. For Phase 6a, we will conduct Generalized Estimating Equation models with main effects (Study arm, time) and interaction terms (study arm*time) for all outcomes, except for civic engagement intention, which was not measured at multiple time points. Based on power analyses to estimate the minimal detectable effect size for study arm differences among 100 Latinas (assuming maximum attrition, given current attrition rates) across nested surveys (ICC = 0.0-0.5), $p <.05$, power=0.80, and two-tailed tests, we would be able to detect a medium-sized effect for a study arm*time interaction effect. For civic engagement intention, we will conduct a logistic regression. We will cluster by cohort/group and adjust for demographic covariates in all models. For Phase 6b, we will assess the: 1) number and types of civic engagement and community development activities; 2) number of women who indicate interest; and, 3) number of women who attend. Secondary analyses include: 1)

describing the number and types of barriers to participation; and, 2) characterizing predictors to participation via bivariate regressions.

10.0 Quality Control and Quality Assurance

The PI will ensure adherence with the protocol and for accuracy in relation to source documents. Meetings with UIC students will be held regularly to ensure research study aims are being adhered. While Centro Comunitario Juan Diego and The Resurrection Project will be helping with recruitment, they will not be involved in administrative components of the research process, such as eligibility screening and obtaining consent. Further they will not have any access to data from this project.

The PI is responsible for the evaluation of data quality and how frequently this will be done.

11.0 Data and Safety Monitoring

Oversight of the progress and safety of the trial will be provided by the PI. Adverse events are not anticipated, but any occurring will be documented and reported according to UIC IRB policies and procedures. Study progress summary will be communicated to the IRB at the time of continuing review.

All participant information, including intervention development focus group audio-recordings and transcripts as well as the survey questionnaires, will be protected for confidentiality to the fullest extent possible. Dr. Molina will have a key to the office where data will be stored and will oversee all data management. The data will be stored on the UIC/SPH R drive (R = Research) and the assigned folder will be locked down the folder and restricted access only for the PI and UIC study staff. The School of Public health's secure network server will have Active Directory controlled access and BitLocker encryption.

All individuals who handle the data will be required to sign a form that they agree to handle the data in a confidential matter. Further, Dr. Molina will ensure that all investigators involved with the project undergo training through a general information technology security awareness program offered through the SANS Institute (*www.sans.org*).

With regard to the coded nature of the data, two master files will be created. The first will include identifiable elements, the participant identification code, the dates in which women have been contacted/interacted with staff (e.g., for screening; for scheduling; to participate in intervention sessions; for booster calls), coupon numbers assigned to them, and the number of individuals who have called with the coupon numbers assigned to them. This information will only be kept across the months in which the participant is enrolled in the study. For participants were in Cohort 1 (who completed participation before approved consent addendum), they will be contacted by phone up to 3 times with a script including consent addendum information to be given that information, wherein they can elect to be notified about future studies, if they are interested. If they are not interested, their data will be eliminated from this file. For cohorts 2-15, after the participant completes the final/third survey, her data will be eliminated from this file, if she chooses not to be contacted for future studies. If she chooses to be contacted for future studies, her information will be kept and it will be recorded that she has completed participation, but is willing to be contacted in the future. The file will be password-protected and stored within

a secured folder on The School of Public health's secure network server, which has an Active Directory controlled access and BitLocker encryption. Only UIC-based study staff will have access to this file in terms of the password and the location.

The second file will include the participant identification code and survey data, but will not have identifiable elements attached. This file will be kept in a separate location/folder within The School of Public health's secure network server.

Risk of access to participant computer-stored information will require simultaneous knowledge of data format, file name, password, and computer language. No individuals will be identified in any reports from the study. Confidentiality of participants will be protected in this project, in that their names and contact information will be kept in a separate file that has no connection to the identification codes used in questionnaires or anonymous transcripts. Transcripts, questionnaire and electronic medical record data will be coded and managed as separate files in a protected part of the computer network. Audio-recordings will be recommended in WAVE files. Transcripts will be saved as .pdf files. Personal health identifying (PHI) information will be saved in XML files. De-identified survey questionnaire data will be kept in standard statistical packages, including SPSS, SAS, and Stata. We will regularly make backups of data. No information will be released that could lead to identification of any participating individual. All files will be encrypted/password-protected. We will log dates when the data are handled.

We will have regular study team meetings to discuss data handling issues. Any breaches in confidentiality or privacy will be promptly reported to the UIC IRB for review and action.

12.1 Statistical Considerations

For Phase 1, 2, 4, and 7, sample sizes are within the recommended range to meet thematic saturation.[53,54]. For Phase 3, based on power analyses to estimate the minimal detectable effect of study arm differences among 150 Latinas on screening, $p<.05$, power = .80 and two-tailed tests, we would be able to detect a medium/large effect in a logistic regression (OR = 2.8). Although more computationally complex, we propose to first use mixed modeling for analysis of psychosocial facilitators relative to Generalized Estimating Equations, given its advantages in handling missing data.68 Based on power analyses for study arm differences among 150 Latinas in network outcomes, $p<.05$, power = .80 and two-tailed tests, we would be able to detect a small effect in multivariable linear regression models (Cohen's $f^2 = 0.05$). For Phase 5, our sample size is within the bounds of an exploratory cost-effectiveness analysis. Phase 6 is a pilot study.

13.0 Regulatory Requirements

13.1 Informed Consent

- Each study staff member will complete necessary IRB Research Subjects training prior to obtaining informed consent.
- Prior to the start of the group sessions, participants will be provided informed consent and asked to sign a written informed consent document if they wish to participate.
- Participants will be informed that the sessions will be recorded and will have the opportunity to withdraw if they do not want to be recorded.
- Informed Consent and other materials will be explained by UIC staff [Appendix P], who are native Spanish speakers and speak English fluently.

- Signed consent forms, similar to other materials, will be scanned and shredded.
- After completion of the trial, informed consents and all other electronic materials will be destroyed.

13.2 Subject Confidentiality

Study data will never be linked directly with participant names. The Call Log, which will be used for recruitment and scheduling and which has participant names and contact information will be kept in a password-protected computer in the PI's office to which only the PI and UIC students will have access.

All study data will be entered directly into the password-protected PI office computer.

13.3 Unanticipated Problems

Procedures for reporting unanticipated problems involving risks to subjects and others and adverse events will comply with the UIC IRB guidelines; a prompt reporting form will be submitted to the IRB, and a copy will also be maintained in the study files.

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