Promotora Navigator - Culturally Appropriate Patient Navigator

NCT03557801

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Project Title:
Impact of a Culturally Appropriate Patient Navigator (Promotora Navigator) on Trust and Communication in the Screening Mammography Setting

Brief Overview/Objectives:

1. To assess the relationship between level of trust in the healthcare system and active engagement in a mammography screening program in the local Hispanic population.
2. To assess the relationship between health literacy and active engagement in a mammography screening program in the local Hispanic population.
3. To determine whether a Promotora Navigator improves Hispanic women's measures of trust in the healthcare system and provider compared to those receiving standard of care treatment in the screening mammography setting.
4. To determine whether a Promotora Navigator improves Hispanic women's measures of satisfaction with communication when compared to those receiving standard of care treatment in the screening mammography setting.

Project Plan:

Background:
Although there has been interval improvement in reducing disparity in mammography utilization in medically underserved communities since the 1990s, significant disparities persist and should be addressed[1]. Culturally adapted patient-targeted healthcare interventions can help reduce ethnic inequalities in access to cancer screening programs[2]. "Promotoras", culturally appropriate patient navigators have been shown to increase screening mammography rates in the Hispanic population[3]. However, there is little evidence on the impact of a Promotora Navigator (PN) program on patient trust in the healthcare system and satisfaction with communication in this setting. This proposal aims to assess the impact of a PN on women's trust in the healthcare system and satisfaction with communication when compared to those receiving standard of care.

The study design is the final outcome of a Partnership Development Grant (PDG) awarded by the Meharry-Vanderbilt Community Engaged Research Core (CERC) to Dr. Lucy Spalluto of Vanderbilt University Medical Center and the Mid-South Division of the American Cancer Society. This PDG provided an opportunity to engage numerous community stakeholders in collaboration. The parent study was designed by both academic and community partners and then presented to a community engagement studio for refinement. The final design outcome was submitted for and successfully awarded a CERC Community Engaged Research Grant. Matthew Walker Comprehensive Health Center (MWCHC) will serve as a primary community partner moving forward, providing clinic facilities. MWCHC is an ideal community partner given the center's proven record of providing healthcare services and health education to the local community, regardless of economic status.

As proposed, community partners benefit from education and potential development of a sustainable model for caring for women in developing minority groups. The community will benefit from an increase in well woman screening provided to the local Hispanic population (including those in the control arm). Academic partners will benefit from patient-centered outcomes data on the impact of the PN in the screening mammography setting.

Research Questions/Hypotheses:

Do trust in the healthcare system and/or health literacy impact engagement in a screening mammography program in the local Hispanic population? *We hypothesize that higher levels of trust and health literacy are positively related to engagement in a screening mammography program.*

Does a PN improve Hispanic women's measures of trust in the healthcare system and satisfaction with communication in the screening mammography setting when compared to those receiving standard of care? *We hypothesize that women with access to a PN will have higher levels of trust in the healthcare system and satisfaction with communication than women receiving the standard of care.*

Methods:

Study Design: The study design is a randomized control trial. In this pilot study, 100 participants will be randomized to either a) the intervention, in which they receive care from the PN or b) the control, in which they receive the standard of care.

PN Identification and Education:

A PN will be identified and trained by Claudia Barajas, VICC Community Health Educator. Dr. Spalluto will supplement educational materials.

Inclusion/Exclusion Criteria:

Inclusion criteria will be Hispanic women meeting United States Preventive Services (USPSTF) criteria for screening mammography and criteria for clinical service coverage through the TN Breast and Cervical Cancer Screening Program.

Inclusion Criteria:

- Women
- Identifying as Hispanic ethnicity
- Age 40-64 if no previous mammogram in last two years

**If uninsured or limited health insurance coverage, TN Breast and Cervical Cancer Screening Program will pay for mammogram

- Annual household income of less than $41,150 for a family of 2 persons
- Reside in Tennessee

Exclusion Critiera:

- Personal history of breast cancer
- Current breast symptoms (palpable mass)

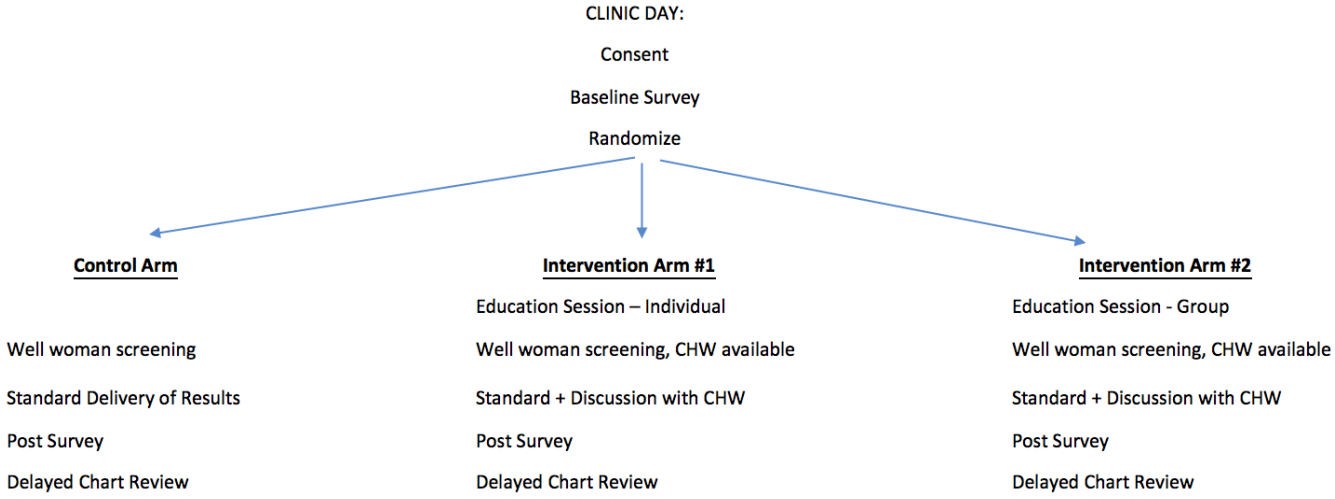
Recruitment:
We aim to recruit 100 women total. All participants will be informed that well woman screening is free under the TN Breast and Cervical Cancer Screening Program. Participants will be offered $40 gift cards for compensation for participation. Two recruitment methods will be used.:

1. The research team will identify and recruit women meeting inclusion criteria from the MWCHC electronic medical record. Eligible participants identified from the MWCHC will be contacted via telephone. **[See recruitment material].**
2. The research team will identify and recruit women from the local Hispanic community through churches, community organizations, and community events. We will also use radio announcements and Facebook for recruitment **[See recruitment material].**

At the time of recruitment, women will be assisted in scheduling an appointment at MWCHC for well woman screening during a "Hispanic Clinic Day".

Hispanic Clinic Days:
Women will be scheduled during one of five dedicated "Hispanic Clinic Days". Each clinic day will host up to 20 women, to a target 100 participants. Each day there will be a morning session for 10 women and an afternoon session for 10 women. The bilingual research assistant and bilingual PN will be present during the Hispanic Clinic Days. At the start of each session, consent will be obtained from all potential participants, followed by baseline assessments, randomization and clinical care. Gift cards will be distributed at time of written consent.

HISPANIC CLINIC DAY FLOW CHART



Consent:
Written informed consent will be obtained for all participants by the research assistant in person at MWCHC **[see attached consent].**

Baseline Assessment:
Immediately following consent, all participants will complete a baseline assessment (English or Spanish according to participant preference) to collect demographic information, trust in healthcare system assessment, and health literacy assessment **[see baseline survey].** This assessment will be collected by paper and pencil with the help of the research assistant.

Randomization:
Women will be randomized to the control arm, the intervention arm 1 (individual education), or the intervention arm 2 (group education) immediately following consent. Randomization will be performed using the random number generator software available in the R statistical package (www.r-project.org).

Control Arm:
Immediately following consent and completion of the baseline assessment, women in the control arm will receive standard of care well woman screening. The control arm will receive screening results per MWCHC protocol.

Intervention Arm 1:
Immediately following consent and completion of the baseline assessment, women in the intervention arm 1 will participate in a 20-30 minute educational session **[see educational slides]** alone with the PN. Well woman screening will follow the educational session. The PN will be available to assist with questions and language interpretation as necessary. After standard delivery of screening results, the PN will contact these participants to answer any questions about their screening results and to assist with scheduling any additional tests necessary.

Intervention Arm 2:
Immediately following consent and completion of the baseline assessment, women in the intervention arm will participate in a 20-30 minute group educational session **[see educational slides]** from the PN. Well woman screening will follow the educational session. The PN will be available to assist with questions and language interpretation as necessary. After standard delivery of screening results, the PN will contact these participants to answer any questions about their screening results and to assist with scheduling any additional tests necessary.

Post Assessment 2-5 Days After Delivery of Results:
All participants will be contacted via telephone by the bilingual research assistant 2 -5 days after results are distributed by standard method for post assessment. This will be conducted in English or Spanish according to participant preference. This post assessment will repeat the measures of trust. It will also assess measures of satisfaction with care, satisfaction with communication, relationship with the promotora and intent to follow-up **[see attached post assessment].** After the post

assessment, the existing Vanderbilt Ingram Cancer Center (VICC) Breast and Cervical Cancer pamphlet **[see attached VICC Breast and Cervical Cancer pamphlet].**

Delayed Chart Review:
The bilingual research assistant will perform delayed chart review 2-4 weeks following delivery of results to assess whether patients needing follow-up diagnostic studies returned. Delayed chart review may also occur in 2-3 years to assess adherence to continued screening.

Data Collection:
Baseline assessment data will be collected by paper and pencil (in Spanish or English language per patient request) immediately following consent at MWCHC. The bilingual research assistant will be available to assist as necessary. Post assessment data will be collected electronically in REDCap by bilingual research assistant via telephone. Return for Follow-Up data will be accessed via patient medical record. Data will be stored in a REDCap.

Item Development:
Baseline Assessment: The baseline assessment will collect demographic information. Additionally, the baseline assessment will assess trust in the healthcare system using the Healthcare System Distrust Scale[4] and health literacy using the Self-Reported Health Literacy Scale[5].

Post Assessment: Measures of healthcare system distrust will be repeated in the post assessment. The post assessment will include multiple items to assess satisfaction with care using the Patient Satisfaction with Cancer Scale[6], satisfaction with communication adapted from the Interpersonal Processes of Care Survey[7], and satisfaction with the promotora[8]. The post assessment will also assess intent to follow up.

Statistical Considerations:
Descriptive statistics will be used to analyze the demographic characteristics of participants. Comparison of knowledge in baseline and post assessments will be assessed with χ^2, Student *t* tests and Fischer exact tests as necessary. Open-ended responses will be analyzed qualitatively. Post assessment comparison between "intervention" and "control" groups will be assessed with χ^2, Student *t* tests and Fischer exact tests as necessary. Open-ended responses will be analyzed qualitatively.

Sample Size:
For this pilot study, the proposed sample size of 50 patients/group provides at least 80% power to detect a 29% improvement of the success rate, i.e. 40% vs 69%, with 2 sided Type 1 error = 5%. This calculation was based on the Chi squared test with the normal approximation correction for continuity.

<u>Anticipated Outcomes:</u>

Primary Outcome:
Assess relationship between trust in healthcare system and engagement in screening mammography program in local Hispanic women.

Secondary Outcome:
Assessment of PN impact on Hispanic women's measures of satisfaction with communication when compared to those receiving standard of care treatment in the screening mammography setting.

Timeline:

Month	
1-2	Identify and Educate Promotora Navigator, Identify and Educate Research Assistant
3-6	Recruitment Host Hispanic Clinic Days Collect Data
7-8	Delayed chart review for Return for Necessary Follow-Up Data analysis
24-36	Delayed chart review for follow-up screening

References:

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4. Shea JA, Micco E, Dean LT, et al. Development of a Revised HealthCare System Distrust Scale. J Gen Int Med. 2008;23(6):727-32.
5. Sarkar U, Schillinger D, Lopex A. Validation of Self-Reported Health Literacy Questions Among Diverse English and Spanish-Speaking Populations. J Gen Intern Med. 2010;26(3): 265-71.
6. Pascal JP, Fiscella K, Freund KM, et al. Structural and Reliability Analysis of a Patient Satisfaction with Cancer-Related Care Measure. Cancer 2011;117:854-61.
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