Official title of the study

A Multilevel CBPR Intervention to Improve Colorectal Cancer Screening in Underserved Vietnamese Americans

NCT number: NCT03413605

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1) Abstract of the study

Colorectal cancer (CRC) is the second most commonly diagnosed cancer and the third highest cause of mortality in Vietnamese and Asian Americans. CRC incidence is rising rapidly in Vietnamese Americans, but they have among the lowest rates of CRC screening (14%) and are more likely to be diagnosed with advanced stage disease, which is highly preventable. Over 85% of Vietnamese Americans in our region (PA, NJ and NYC) are foreign-born with limited English proficiency, have low SES, and live in economically disadvantaged neighborhoods. Many lack knowledge about CRC risks and screening benefits, and have limited access to culturally appropriate preventive care. Center for Asian Health, Temple University will be working with Vietnamese CBOs to address their critical health disparities. **Specific Aim** is to test the hypothesis that the proposed multilevel CRC intervention will yield higher CRC screening rates compared to the control at 12-month follow up. This project represents the first large-scale community-based randomized controlled trial of a multilevel, culturally-appropriate intervention to increase CRC screening among underserved Vietnamese. If effective, this innovative CRC intervention can be used as a model program that has potential generalizability and sustainability in Asian American and other underserved ethnic communities to impact preventive behaviors at population level.

2) Objectives

The overall goal is to use a CBPR approach to collaborate with Vietnamese CBO partners to increase CRC screening by reducing multilevel healthcare access barriers for underserved Vietnamese Americans.

The purpose of the study is to determine the effectiveness of a multilevel, theory- and evidence-based CBPR intervention to increase CRC screening in underserved Vietnamese. The proposed multilevel CRC intervention will be guided by Social Ecological Model that addresses sociocultural, behavioral and environmental determinants and intervention strategies at individual, interpersonal, and community organizational levels for obtaining CRC screening.

Specific Aims: Aim 1 is to test the hypothesis that CPS + multilevel CRC intervention will yield higher CRC screening rates compared to CPS control at 12-month follow up; Aim 2 is to examine whether CPS + multilevel CRC intervention (which includes CHW-led group education, automated and interactive text messaging and phone-based peer support) is more effective in changing screening determinants (e.g. KAB, self-efficacy, risk factors, lifestyles, social support, social norms, access barriers) than CPS control condition.

It is hypothesized that the multilevel CRC intervention will yield higher CRC screening rates compared to CPS control at 12-month follow up.

3) Resources and Setting

All key personal involved in this study were trained for this protocol, have meetings regarding the materials development, timeline and process of this study to ensure that all key personals were on the same page along with the study progress. The study PI and senior key staff members will provide detailed training about the study to all personal involved in this study including project coordinator, community health workers, collaborating community leaders and designated staff from collaborating partners.

The study will be conducted in greater Philadelphia area including (south NJ, DE and PA areas) and New York City with our long collaborating community partners. All participants in the described study will be identified and recruited by collaborating community partners, and consented by trained team staff of Center for Asian Health, Temple University.

4) Study Design

a) Recruitment Methods

In total, 900 participants will be recruited, including:

- 800 study participants
- 40 CBO leaders/staff from 20 collaborating CBO partners
- 60 family members or close friends of study participants.

The research team will recruit subjects after the TU IRB office approves the protocol.

Participants will be recruited through collaboration with Vietnamese community-based organization partners located in greater Philadelphia area including (south NJ, DE and PA areas) and New York City. Over the past 16 years, the Center for Asian Health has established solid collaboration relationships with these partners. In this study's recruitment effort, the Center has received collaboration commitment from the community leaders during grant proposal development stage. Planning meeting will be conducted with collaborating community leaders.

A total of $45 incentive for completing all survey forms before and after workshop and the telephone interview (or in-person survey form collection) at 12-month after the workshop (*additional $20 incentive will be provided for completing the expanded 12-month follow up survey form*).

b) Inclusion and Exclusion Criteria

Inclusion Criteria:

- Study participants (N=800) will be included in the study if they meet the following criteria:

1) self-identified Vietnamese ethnicity, 2) age 50 and above, 3) accessible by cell telephone, 4) presence in the same geographic study area for a period of one year

(to minimize participant attrition); 5) not enrolled in any CRC intervention (to prevent a potential program impact), 6) do not have colorectal polyp, CRC cancer or a family history of CRC (first degree relative). The guidelines recommended by American Cancer Society will be used to determine participants' screening eligibility: No FIT in past year or no sigmoidoscopy in past 5 years, no double-contrast barium enema in the past 5 years, or no colonoscopy within the past 10 years

- CBO leaders/staff (n=40) will be included in the study if they meet the following criteria: 1) Self-identified Vietnamese ethnicity, 2) CBO leader involved in the study, 3) Accessible by telephone or cell telephone.
- Family members or close friends of study participants (n=60) will be included in the study if they self-identified as a family member or a close friend of the study participant, who provided help to study participant during his/her health care activities.

c) Study Procedures, Method, and Data Analysis Plan

Research design/method- This is a 2-arm randomized controlled trial with baseline, post-education test and 12-month assessments. Collaborating Viet community partners will be randomly assigned into either intervention group, or comparison group; participants enrolled from each participating community partner will be automatically assigned to their CBO study group: intervention or comparison.

Group education workshops will be arranged in working collaborating community partners. The education session is a curriculum-based group education; each group will be having about 15-20 participants. All group education sessions will take place at collaborating Viet community partners' sites, and delivered in Vietnamese language, with offering of refreshment. We will allow 5-7 minutes for participants to get to know each other and to get comfortable talking to the group.

In addition to information collection from study participants, we will conduct telephone interview with 40 leaders/staff from 20 collaborating CBO partners (2 persons per partner site) to gain feedback about the intervention when field research activities is completed.

Feedback about the intervention will also be gathered from 60 family members (or close friends) of 60 study participants.

For data analysis approach, first, we will perform analysis using Viet community organization as unit of analysis. For testing main null hypothesis of no difference in primary endpoint (conversion to screening compliant) and secondary endpoints, we will use randomization tests with a randomization distribution in accord with stratified randomization of the experimental design. Second, we will also perform statistical analyses using individual as unit of analysis. For these analyses, we will use the generalized linear mixed models for the regression analysis of correlated binary response data with covariates specific to the individual.