

## **STOP CRC Program (NIH R01) Protocol**

**Official Trial Title:** Culturally Adapted Multilevel Decision Support Navigation Trial To Reduce Colorectal Cancer Disparity Among At-Risk Asian American Primary Care Patients

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## Introduction

Cancer is the leading cause of death among Asian Americans, and mortality from colorectal cancer is ranked as the second most common in cancer deaths among Asian Americans. However, recent data show that colorectal cancer screening rates are substantially lower for Chinese and Korean Americans compared with other racial/ethnic groups. To date, a small number of community-based studies have reported on the use of single level (participant level only) interventions to increase colorectal cancer screening rates among Chinese and Korean Americans; however, very little is known about the impact of multi-level (patient-oriented and provider-oriented) interventions on colorectal cancer screening adherence among Chinese and Korean American patients in primary care setting. Furthermore, our preliminary data indicate physician's recommendation as the strongest facilitator of colorectal cancer screening among Chinese and Korean Americans. Thus, the primary objective of the study is to address this important knowledge gap by conducting a randomized controlled trial to determine the impact of a multi-level culturally-sensitive decision support intervention on colorectal cancer screening adherence among 400 Chinese and Korean American primary care patients. Previous studies found that facilitating patient decision-making through decision support and providing patient navigation can increase colorectal cancer screening among diverse primary care patients.

## Public Health Relevance

Cancer is the leading cause of death among Asian Americans, but colorectal cancer screening rate remains low in this population. The goal of this study is to increase colorectal cancer screening among underserved Chinese and Korean Americans through cultural adaptation and implementation of a decision support navigation trial provided in primary care setting. With growing need for linguistically and culturally competent care, more decision support, language facilitation, and navigation efforts may come into care settings; therefore, having tested interventions ready for the target population will be timely, and medical systems may benefit from having multilevel best practices known and tested for Chinese and Korean Americans.

## Study Aim

The aim of the study is to determine the impact of a multi-level culturally-sensitive intervention on colorectal cancer screening adherence among 400 Chinese and Korean American primary care patients. The specific aims are to:

- (1) Implement a randomized controlled trial among 400 Chinese and Korean American primary care patients to compare colorectal cancer screening outcomes between the culturally-adjusted decision support navigation intervention and advanced control;
- (2) Determine overall colorectal cancer screening adherence and change in colorectal cancer screening decision stage in the culturally adapted decision support navigation intervention versus advanced control; and
- (3) Evaluate intervention reach, effectiveness, adoption, implementation, and maintenance.

## Study Design

This study employed a cluster randomized control trial intervention study design. Participants were assigned to either the advanced control group or culturally adapted decision support navigation intervention group

## Study Population

### Enrollment

Twenty Chinese and Korean primary care physicians will participate in the study. Twenty Chinese and Korean American participants will be recruited from each participating primary care physicians' clinics in Maryland and Northern Virginia (in total, 400 Chinese and Korean American patients will participate in the study).

### Inclusion Criteria

Eligible participations met the following inclusion criteria: male and female Chinese and Korean American patients aged 50 to 75, who are not up to date for colorectal cancer screening.

### Exclusion Criteria

Those with a family history, previous history of removing polyps, inflammatory bowel disease, or diagnosis of colorectal cancer.

## Procedures

(1) Ten primary care physician clinics will be randomized to advanced control and other 10 primary care physician clinics will be randomized to the culturally adapted decision support navigation intervention. Accordingly, 200 Chinese and Korean Americans (20 participants from 10 primary care physician clinics) will be randomized to the advanced control and other 200 Chinese and Korean Americans (20 participants from 10 primary care physician clinics) will be randomized to the culturally adapted decision support navigation intervention. In total, 400 Chinese and Korean Americans will participate in this project.

(2) All 400 participants will be invited to primary care physician's clinic or community organization, where the participant will provide informed consent and HIPAA authorization form and complete a baseline survey (see sample). Participants' height, weight and waist/hip circumference, blood pressure, blood glucose and cholesterol levels will be measured by trained research staff.

(3) Those randomized to the advanced control group will receive informational booklet regarding colorectal cancer and colorectal cancer screening, colonoscopy instructions, stool blood test kit and a result of body measurements as a free service. They will receive a reminder by mail after 45 days of random assignment.

(4) Those randomized to the culturally adapted decision support navigation intervention group will receive everything the advanced control receives, and will receive a phone call from a patient navigator. The patient navigator will verify the participant's preferred colorectal cancer screening test. During this encounter, the patient navigator will also use a theory-based online Decision Counseling Program© to identify barriers to and facilitators of preferred test performance, determine the likelihood of test performance, and develop a personal screening plan. The counseling call will take about 45 minutes. The patient navigator will print out this screening plan and share it with the participant and primary care physician's office. After 45 days of random assignment, those in the culturally adapted decision support navigation intervention group will receive a reminder by mail.

(5) Six months after randomization, trained and blinded bilingual survey interviewers will contact each participant by telephone and administer a 6-month Survey. This will take about 20 minutes. Six-month medical record review will be also completed by the survey interviewer.

(6) The patient navigator will create a colorectal cancer screening status report for participants in the culturally adapted decision support navigation intervention, and share it with the primary care physician and office manager. The report will indicate whether the participant adhered to the screening, and if the participant needs diagnostic follow-up for an abnormal stool blood test result.

(7) At 12 months after randomization, an endpoint medical record review will be performed on all study participants to assess colorectal cancer screening adherence. Self-reported colorectal cancer screening data will be collected by phone. Survey interviewer will ask participants if they had colorectal cancer screening in past 6 months.

## Outcomes

Participants will complete a pen and pencil questionnaire at baseline. At 6-month follow-up, participants will participate in phone survey and their medical records will be reviewed. At 12-months after randomization, the medical records of all participants will be reviewed by research team staff. Phone follow-up will be conducted to collect self-reported data on colorectal cancer screening. Previously validated measures to assess belief, attitude, cohesion, self-resilience and knowledge about

colorectal cancer screening and colorectal cancer, health literacy, religion, social support, acculturation and colorectal cancer screening adherence will be used in baseline and 6-month surveys.

### Primary Outcome Measure:

- **Colorectal Cancer Screening Adherence**
  - Description: measure to assess colorectal cancer adherence among participants
  - Time Frame: at 6-month and at 12-month
- **Overall colorectal cancer screening adherence by self-report and medical record review**
  - Description: measure overall colorectal cancer screening adherence by self-report and medical record review
  - Time Frame: at 6 months and at 12 months
- **Colorectal cancer screening decision stage for stool blood test and colonoscopy**
  - Description: measure colorectal cancer screening decision stage for stool blood test at baseline and 6 month
  - Time Frame: Baseline and 6-month
- **Change in colorectal cancer screening decision stage for stool blood test and colonoscopy**
  - Description: measure change in colorectal cancer screening decision stage for stool blood test and colonoscopy
  - Time Frame: 6 months
- **Colorectal cancer screening test-specific adherence for stool blood test and colonoscopy**
  - Description: measure the fraction of participants who undergo a stool blood test and colonoscopy
  - Time Frame: at 6 months and at 12 months

## **Ethical Considerations**

This study was reviewed and approved by the University of Maryland, College Park Institutional Review Board. Prior to participation in the study, participants will provide informed consent.

## **Potential Risks and Discomforts**

There are minimal risks to participants involved in this study. It is possible that thinking about cancer could cause stress or anxiety for some participants. Some participants may feel uncomfortable when the research team conducts body measurement. These are routine procedures that participants usually go through in their check-up; however, if they feel uncomfortable, participants can choose not to participate in it. Although somewhat likely, these risks are not considered serious because the questionnaires and body measurement assess only minimally sensitive issues and they pose little risk. Lastly, loss of confidentiality is always a risk with human participants; however we consider this risk minimal and have adopted multiple safeguards to ensure that confidentiality is protected.

## **Benefits**

We believe there are benefits associated with learning about cancer screening and other health promotion behaviors. The intervention may increase the salience or awareness of the importance of these behaviors to participants. We also believe that learning about one's body measurements will help them to maintain healthy lifestyle. Furthermore, the study may work as a reminder for participating primary care physicians to recommend colorectal cancer screening to their other patients who are not participating in the study.

## **Confidentiality**

Confidentiality will be assured in the following way. Participants will be assigned a four-digit participant identification number, at the time of enrollment. Participant identifiers will be stored electronically in password-protected databases and in hard copies stored in locked file cabinets. In order to reduce the risk of loss of confidentiality, access to personal identification information will be limited to the study's Principal Investigator (Dr. Lee) and the research staff. We have used these methods in past research and they have been extremely effective in protecting against potential risks. All research records will be kept for 10 years. After 10 years, all electronic records will be deleted from computer and all hard copies of data will be shredded.