Study Protocol Document

Community Collaboration to Advance Racial/Ethnic Equity in CRC Screening

NCT Number: NCT05714644

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Description of Study:

This is a pragmatic, multilevel randomized clinical trial with randomization at the level of the Community Health Center (CHC) to compare two population outreach approaches to increase colorectal cancer (CRC) screening uptake among diverse and multilingual patients: (1) mailed FIT outreach with text reminders, and (2) mailed FIT-DNA with the standard manufacturer's patient support program. Participants with an abnormal FIT or FIT-DNA result are offered telephone navigation to encourage colonoscopy completion. We hypothesized that (1) CRC screening participation would increase in both study arms; and (2) that the FIT-DNA arm would have higher participation given the centralized patient support program and appeal of the 3-year screening interval.

Objective:

The objective of this study was to compare two mailed population outreach approaches to increase colorectal cancer screening uptake among screening-eligible adults in community health centers. The primary outcome was CRC screening test completion rate using any screening modality (FIT, FIT-DNA, colonoscopy) at 90 days after the screening test was mailed in each study arm. Secondary outcomes included the screening completion rate at 180 days and the rate of completion of follow-up colonoscopy within 180 days (6 months) of an abnormal stool test result among participants with an abnormal screening test result.

Design:

This was a cluster randomized controlled trial conducted in 8 CHCs and an additional site in a non-randomized parallel protocol.

Methods:

Individuals in the designated CHCs were eligible if they were: (1) age 45 to 75; (2) overdue for CRC screening (no FIT or fecal occult blood test [FOBT] in the past year, FIT-DNA in the prior 3 years, or colonoscopy in the past 10 years); (3) under the active care of a primary

care provider at the site; and (4) spoke English or Spanish. Individuals were excluded who did not have a physical mailing address or phone number listed in the electronic health record (EHR), had prior documentation of CRC, Crohn's Disease, or ulcerative colitis, or had prior abnormal colonoscopy result (i.e., prior adenoma, sessile serrated lesion).

Randomization was limited to the 8 CHCs in Boston and LA. We used CHC-level cluster randomization to minimize the chance of contamination within practices. Within each region, we considered the permutations of assigning the four CHCs into two arms. We chose the permutation with the closest patient volume, racial distribution, and baseline CRC screening rate, then randomly assigned the groups to one of the two study arms. Neither patients nor sites were blinded to the allocation.

In both arms, participants received an invitation letter that provided elements of informed consent via mail with the opportunity to opt out of the study. Intervention components were delivered in English or Spanish, based on patient preference as recorded in the EHR.

FIT-DNA arm. Participants were mailed a FIT-DNA kit from Exact Sciences with instructions on how to complete and return the kit to their laboratory using a standard pre-paid mailer. Participants in this arm received the standard patient support program delivered by Exact Sciences, including telephone calls, text messages, and emails in the users' preferred language to encourage completion of the kit.

FIT arm. Patients received a primer text message to inform them that a FIT kit would soon arrive at their home address. Participants then received the FIT kit in a separate mailing with a graphic instruction sheet. Two additional reminder text messages were sent. In each CHC, we used the FIT kit brand already in routine use (Boston: Polymedco; LA and SD: Hemosure iFOB test).

Navigation for patients with abnormal FIT or FIT-DNA. Participants in Boston and LA with an abnormal FIT or FIT-DNA result were offered standardized phone navigation by non-clinical team members proficient in English or Spanish, to address barriers to colonoscopy and encourage completion. In SD, patients with an abnormal FIT or FIT-DNA result received usual care follow-up, which included non-standardized outreach from clinical staff.