Parent Study Protocol

Effectiveness and cost of a centralized FIT outreach in an integrated safety-net system

Introduction

Colorectal cancer (CRC) is the second leading cause of cancer deaths in the United States.[1] While screening for CRC is effective,[2,3] it remains underutilized, especially among racial/ethnic minorities and low-income populations.[4,5]

Fecal immunochemical testing (FIT) is acceptable by many patients[6] and increasingly used to support population-level screening.[7-9] Because FIT testing can be done at home, CRC screening participation is an ideal preventive health outcome to test the effectiveness and cost of an organized approach to population-level outreach.

The objective of this study is to examine the effectiveness and cost of a centrally organized outreach care model using direct mailing of FIT kits to improve CRC screening in partnership with multiple primary care clinics serving safety-net patients.

Methods

Study Setting and Design

This multi-site randomized controlled trial is based in the San Francisco Health Network (SFHN). SFHN is a publicly funded, integrated safety-net health system comprised of 14 community- and hospital-based adult primary care clinics (PCC), 12 serving the adult population, and one specialty referral center, Zuckerberg San Francisco General Hospital (ZSFG). SFHN clinics share an integrated electronic health records (EHR) platform,[10] a clinical laboratory and one Gastroenterology (GI) referral unit at ZSFG. [11] The pragmatic trial has been approved by the University of California San Francisco Institutional Review Board (IRB, 14-14861, NCT02613260).

Study Population

This study will include men and women aged 50-75 who have not completed a FIT within 365 days, sigmoidoscopy within 5 years, or colonoscopy within 10 years. Patients will be excluded from the parent clinical trial if they are homeless, have abnormal FIT but no follow-up colonoscopy completed, have a diagnosis of CRC or colectomy, or have had limited life-expectancy.

Study Arms

Patients will be stratified by clinic, gender, race/ethnicity, and prior FIT participation, and will be randomized 1:1 to the outreach intervention or usual care (Supplementary Figure 1). Usual care is at the discretion of providers in the respective PCCs. Outreach will include mailing an informational postcard preceding FIT kit mailing, mailing of a FIT kit packet, and up to two

reminder phone calls if the FIT kit was not returned after two weeks. The FIT kit packet will include a letter with basic information about CRC, the FIT kit, glove, lab requisition, prepaid and preaddressed return envelope, and low-literacy wordless instruction for completing the test. The reasons for failing to initially return the FIT kit will be documented in patients who were reached during the reminder phone calls.

Analytic Plan

The primary outcome will be the time from randomization to FIT screening, and will be summarized by the proportions of patients in the usual care and intervention groups who are up-to-date 90 and 365 days after study enrollment. An intention-to-treat analysis will be utilized for all patients assigned to the outreach intervention. Model assessments and sensitivity analyses will be used to check for influential points, as well as for interactions between treatment and randomization stratum. The logistic and Cox models will be used to evaluate modification of the effect of treatment assignment on study outcomes. In addition, a per-protocol analysis excluding patients who were not sent a FIT kit was performed. The colonoscopy completion rate within the intervention and usual care groups will be examined in patients who had abnormal FIT results and had at least 6 months of follow-up time. Finally, the reasons for not returning FIT kits will be documented.

Power Calculations

There are over 25,000 patients distributed across the 12 SFHN clinics. Assuming that not all clinics will participate and not all patients will be available for randomization, we should still have at least half of the population available for randomization. Assuming 6,000 patients per arm, there is 80% power in two-sided tests with a type-I error rate of 5% to detect a difference of 2.4 percentage points in CRC screening completion rates, and potentially smaller differences in the 28-day FIT completion rate, depending on the control rate. Individual clinics have 1,000-3,000 patients aged 50-75, providing 80% power to detect differences of 3.5-9.4 percentage points. Minimum detectable effects within subgroups defined by race and language preferences, which we estimate to be about 3,000 for the major racial categories (Hispanic and non-Hispanic Whites, African Americans, and Asians), will be 5.4 percentage points. These are uniformly small effects.

References

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