Contemporary Clinical Trials 38 (2014) 344–349

Contents lists available at ScienceDirect

Contemporary Clinical Trials

journal homepage: www.elsevier.com/locate/conclintrial

Strategies and Opportunities to STOP Colon Cancer in Priority Populations: Design of a cluster-randomized pragmatic trial☆

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ARTICLE INFO

Article history:
Received 28 March 2014
Received in revised form 4 June 2014
Accepted 7 June 2014
Available online 14 June 2014

Keywords:
Colorectal cancer screening
Fecal immunochemical test
Pragmatic study
Cluster-randomized study

ABSTRACT

Background: Colorectal cancer is the second-leading cause of cancer deaths in the United States. The Strategies and Opportunities to Stop Colorectal Cancer (STOP CRC) in Priority Populations study is a pragmatic trial and a collaboration between two research institutions and a network of more than 200 safety net clinics. The study will assess the effectiveness of a system-based intervention designed to improve the rates of colorectal-cancer screening using fecal immunochemical testing (FIT) in federally qualified health centers in Oregon and Northern California.

Material and methods: STOP CRC is a cluster-randomized comparative-effectiveness pragmatic trial enrolling 26 clinics. Clinics will be randomized to one of two arms. Clinics in the intervention arm (1) will use an automated, data-driven, electronic health record-embedded program to identify patients due for colorectal screening and mail FIT kits (with pictographic instructions) to them; (2) will conduct an improvement process (e.g. Plan-Do-Study-Act) to enhance the adoption, reach, and effectiveness of the program. Clinics in the control arm will provide opportunistic colorectal-cancer screening to patients at clinic visits. The primary outcomes are: proportion of age- and screening-eligible patients completing a FIT within 12 months; and cost, cost-effectiveness, and return on investment of the intervention.

Conclusions: This large-scale pragmatic trial will leverage electronic health record information and existing clinic staff to enroll a broad range of patients, including many with historically low colorectal-cancer screening rates. If successful, the program will provide a model for a cost-effective and scalable method to raise colorectal-cancer screening rates.

1. Introduction

Despite the potential of colorectal cancer (CRC) screening to reduce CRC mortality, CRC remains the second-leading cause of cancer deaths [1]. In 2014, an estimated 137,000 adults in the U.S. will be diagnosed with CRC, and 50,000 will die from the disease [2]. Identification and removal of pre-cancerous polyps can reduce the rate of invasive disease [3].

Despite the clear benefits of screening, data from the National Health Interview Survey (NHIS) show that, in 2010,

☆ Clinicaltrials.gov number: NCT01742065.

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http://dx.doi.org/10.1016/j.cct.2014.06.006
1551-7144/

41% of adults aged 50–75—nearly 35 million people—were not up-to-date on CRC screening [4]. Nearly 30% of eligible adults have never had any type of CRC screening [5]. These rates are well below goals set by the American Cancer Society (75% by 2015) [1] and by Healthy People 2020 (70.5%) [6]. NHIS data from 2000 to 2010 consistently show lower rates of screening among adults who are typically served by federally qualified health centers (FQHCs); that is, those with minimal education, low income, or no health insurance. Rates were also disproportionately low among recent immigrants, those with no usual source of care or physician visit in the past year, and Hispanics [4]. Low utilization of screening leads to delayed detection of CRC, diagnosis at more advanced stages, and higher CRC-related morbidity and mortality [1]. Accelerating adoption of screening could reduce CRC mortality more than 50% by 2020 [7].

Colonoscopy allows for removal of polyps at the time of screening and is considered the gold standard for screening by many professional organizations [8]. However, fecal immunochemical testing (FIT) is a low-cost screening method that is easily scalable, easy to do, and preferred by multiple patient populations [9]. Inadomi recently demonstrated that patients who were offered either FOBT or a choice between FOBT and colonoscopy were more than twice as likely to complete CRC screening. Gupta and colleagues conducted a study involving a safety net health system and compared colorectal screening rates among 5970 patients who were offered one of three testing options: (1) free FIT; (2) free colonoscopy; or (3) usual care, which was opportunistic screening. Findings from his study showed that over 40% of those offered free FIT were screened; this compared to 25% and 12% of those offered free colonoscopy and usual care, respectively [10]. Both studies, however, report rates of fecal testing over a single year, though annual testing over 10 years is needed to confer the same adherence as a single colonoscopy.

Previous evaluations of clinic-based programs to improve rates of CRC screening have shown that direct mailing of fecal occult blood tests (gFOBT) or fecal immunochemical tests (FIT) consistently led to 6–30% increases in CRC screening, regardless of clinical setting [11–15,16]. Some studies have shown that the use of health educators and screening information tailored to specific cultural and language needs can be effective in raising CRC screening rates [11,13,17–19]. While some of these studies showed promising results, none have resulted in widespread adoption of CRC screening practices because the screening system relied on stand-alone tracking or was not integrated into routine care. The presence of practice-level systems to support the translation of physician recommendation into care delivery is an important influence on CRC screening uptake [12,20]. None of the previous interventions embedded registry functions directly into the electronic health record (EHR), and into existing clinical staff workflows, diminishing the opportunity for sustaining these interventions over time.

This paper describes the design of the Strategies and Opportunities to STOP Colon Cancer in Priority Populations (STOP CRC), a pragmatic study that seeks to automate and embed, using real-time EHR data, systems to identify patients who need CRC screening. We will also track CRC-related outcomes using routine processes of care at FQHCs. STOP CRC consists of a pilot study and a larger multi-site pragmatic study that began in 2014 and is testing a scalable option for promoting CRC screening in populations least likely to be screened.

2. Materials and methods

STOP CRC is a large, multi-site, cluster-randomized pragmatic study that will test the effectiveness of automated strategies to raise CRC screening rates in safety-net clinics. This demonstration project was funded by the National Institutes of Health (NIH), Health Care Systems Research Collaboratory program, whose aim is to provide a framework of implementation methods and best practices that will enable the participation of many and varied health-care systems in clinical research [21]. The study was approved by the Institutional Review Board of Kaiser Permanente Northwest (Protocol # 4364), with ceding agreements from Group Health Research Institute, and OCHIN. OCHIN is a non-profit health information technology (IT) organization that provides EHR systems and support to FQHCs and small practices in several states. The OCHIN health IT organization and the OCHIN Practice Based Research Network collaborate to help FQHC clinics improve population health, patient care, and care efficiency. At the onset of our study, the OCHIN PBRN was affiliated with over 50 FQHCs and safety net health centers with more than 200 individual clinics, all using a single OCHIN-supported EHR system, Epic© (version 2010; Verona, WI). Due to the minimal risk of the intervention, the requirement for informed consent was waived. The trial is registered at ClincalTrials.gov (NCT01742065).

STOP CRC is based on two prior studies conducted by our study team that tested direct-mail CRC screening programs in two different clinical settings. The first was a pilot study conducted in 2007–2009 with an FQHC in western Washington. This study tested the program among 500 low-income Latinos who receive their care in safety-net clinics, but the methods relied on manual medical-chart review to identify patients and track screening outcomes [11]. A second study consisted of a randomized controlled trial conducted in a Health Maintenance Organization (Group Health Cooperative) that used an EHR-linked system for patient identification and tracking, but the tracking tools were managed by a research team (not embedded into the clinic workflows) [12]. Both studies and the researchers who conducted them helped guide the design of STOP CRC.

STOP CRC has two phases: The first, Phase 1, was a pilot phase [22]. During the pilot phase we developed our EHR tools and tested two interventions in two FQHC clinics belonging to a single health organization. Phase 2 is a larger two-arm cluster-randomized study involving 26 FQHC clinics and 8 health organizations. Phase 1 pilot findings showed an overall 37 percentage point increase in CRC screening in intervention, compared to Usual Care (UC) clinics (38% vs. 1% over a 6 month period, based on intention-to-treat analyses) [22]. Here, we describe the Phase 2 study design and protocol.

2.1. Recruitment

To aid with issues regarding intervention adaptation and cultural relevance, we convened an Advisory Board comprised of project investigators, clinic staff, and community members. Our Advisory Board for Phase 1 helped establish