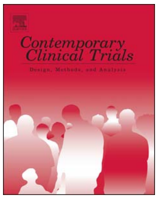
Contemporary Clinical Trials 67 (2018) 11–15

Contents lists available at ScienceDirect

Contemporary Clinical Trials

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



Participatory Research to Advance Colon Cancer Prevention (PROMPT): Study protocol for a pragmatic trial

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ARTICLE INFO

Keywords:
Colon cancer screening
Fecal immunochemical test
Pragmatic study
Community-based participatory research
Boot camp translation

ABSTRACT

Background: Colon cancer is the second leading cause of cancer deaths in the United States. The Participatory Research to Advance Colon Cancer Prevention (PROMPT) study is a collaboration between two research institutions and a federally qualified health center (FQHC). The study seeks to raise colon cancer screening rates using a direct-mail fecal immunochemical testing (FIT) and reminder program in an FQHC serving a predominantly Latino population in California.
Methods: PROMPT is a pragmatic trial enrolling 16 clinics. The study will test automated and live prompts (i.e., alerts, reminders) to a direct-mail FIT program in two phases. In Phase I, we tailored and defined intervention components for the pilot using a community-based participatory research approach called boot camp translation. We then plan to conduct a three-arm patient-randomized comparative effectiveness trial in two pilot clinics to compare 1) automated prompts, 2) live prompts, and 3) a combination of automated plus live prompts to alert and remind patients to complete screening. In Phase II, the adapted best practice intervention will be spread to additional clinics within the FQHC (estimated population 27,000) and assessed for effectiveness. Patient and staff interviews will be conducted to explore receptivity to the program and identify barriers to implementation.
Discussion: This pragmatic trial applies innovative approaches to engage diverse stakeholders and will test the effectiveness and spread of a direct-mail plus reminder program. If successful, the program will provide a model for a cost-effective method to raise colon cancer screening rates among Latino patients receiving care in FQHCs.
Trial registration: National Clinical Trial (NCT) Identifier NCT03167125.

1. Introduction

Colon cancer is the second leading cause of cancer-related death in the United States [1]. In 2017, an estimated 135,000 persons will be diagnosed with the disease and about 50,000 will die from it [2]. Regular screening is effective in reducing the incidence and mortality of colon cancer by detecting precancerous polyps or cancer at early curable stages [3]. However, colon cancer screening rates are marked by a pronounced disparity, with Latinos residing in the United States for fewer than ten years and uninsured Latinos having especially low rates [4,5]. Since these individuals typically receive care at one of over 1200 federally qualified health centers (FQHCs) nationwide, FQHCs are the ideal setting for interventions to increase screening rates in this population [6].

Studies have shown that mailing fecal immunochemical test (FIT) kits directly to a patient's home (i.e., "direct-mail") can increase colon cancer screening among FQHC populations [7–12]. Among underserved patients whose screenings were not up-to-date, direct-mail FIT outreach invitations resulted in significantly higher colon cancer screening compared with usual care [11]. However, a recent systematic review found that while reminders following direct-mail programs were associated with higher FIT kit returns, studies provided limited comparative detail on optimal timing, content, or format of reminder prompts (i.e., text alerts, automated phone calls) [12]. Little is known about the effectiveness of these prompts in diverse populations, such as those who receive care at FQHCs. Low screening rates among this population may also be attributed to low awareness about the need for screening and challenges understanding patient health information [13,14]. If

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https://doi.org/10.1016/j.cct.2018.02.001
Received 6 November 2017; Received in revised form 18 January 2018; Accepted 1 February 2018
1551-7144/

patients are unable to understand a health condition and related screening options, they will experience difficulties engaging in meaningful conversation with a health care provider, choosing appropriate health action, or adhering to recommended screening measures [15].

To address the need for optimally-timed FIT kit reminders and culturally-tailored colon cancer screening messages to improve FIT kit return rates in underserved populations, we implemented boot camp translation [15], a community-based participatory research approach in a predominantly Latino-serving FQHC in southern California. As part of the Participatory Research to Advance Colon Cancer Prevention (PROMPT) study, we used boot camp translation to gather input from patients and clinic staff to choose optimal timing and mode of delivery of screening reminders, and refine colon cancer screening messages for an FQHC direct-mail FIT program. We will use key findings to define the intervention components of the PROMPT pilot and follow-up implementation study.

This paper describes the design of this National Institutes of Health (NIH) funded study, which seeks to test the effectiveness of alerts and reminders to a direct-mail colon cancer screening program, and spread the direct-mail and reminder program throughout a large Latino-serving FQHC. PROMPT applies novel strategies to engage stakeholders in adapting the intervention for a Latino population, defining the intervention components, and selecting a best practice for spread. The research aims are threefold: 1) develop personalized messages and define an intervention using boot camp translation to increase colon cancer screening among Latino populations, 2) assess the reach and effectiveness of a three-arm colon cancer screening program among Latino FQHC patients in two pilot clinics, and 3) further refine and test the effectiveness and spread of the program across additional clinics using a two-arm stepped-wedge approach, and develop an implementation guide that includes outreach materials, strategies for incorporating patient input, and resources.

2. Methods and design

The PROMPT study was approved by the Institutional Review Board of Kaiser Permanente Northwest (Portland, OR), with ceding agreements from Oregon Health & Science University (OHSU) (Portland, OR) and a large FQHC in southern California. OHSU's Oregon Rural Practice-based Research Network provided boot camp translation expertise.

2.1. Setting

The performance site for PROMPT is a large independent FQHC with 26 medical clinics serving 280,000 patients, the majority of whom are Latino (82%). Colon cancer screening has been an enterprise strategic goal for this clinic system over the last several years. In-clinic distribution of FIT kits and a direct-mail FIT program have improved screening rates from 39 to 64% over the past four years. Due to the minimal risk of the intervention, the requirement for informed consent was waived. The study is registered on ClinicalTrials.gov (NCT03167125).

2.2. Research aims

PROMPT builds on previous research conducted by our research team to pilot-test automated and live reminders to promote colon cancer screening [16–19].

PROMPT has two phases: Phase I (Years 01–02) will design and evaluate a pilot study of a randomized-controlled trial to test systems-based, automated and non-automated prompts to increase colon cancer screening using a direct-mail program. Phase II (Years 03–05) will spread the program to additional clinics (estimated age-eligible patient population 27,000) and assess its effectiveness. Fig. 1 provides an overview of the study design.

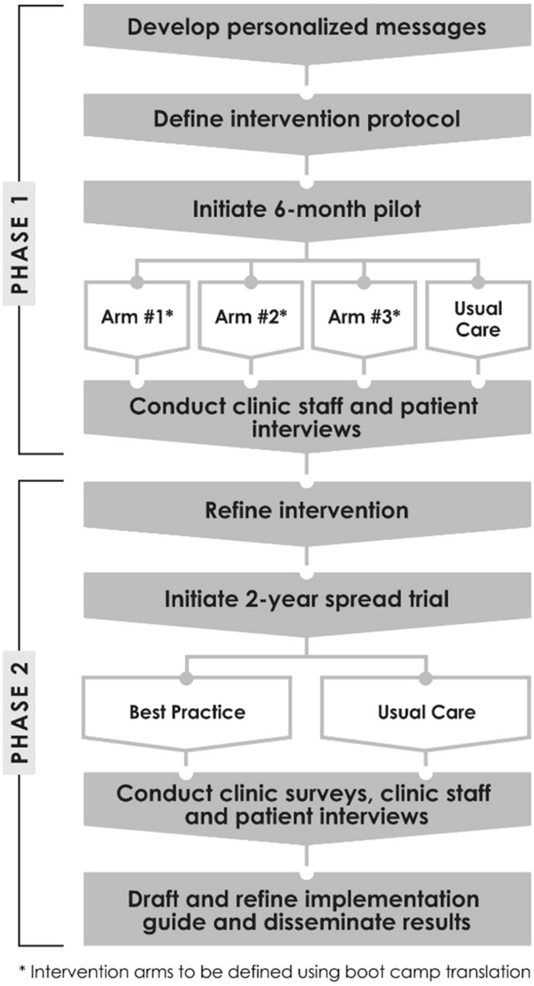

Fig. 1. PROMPT Study Design.

The design and evaluation of both phases will be guided by the RE-AIM framework [17–19] using Intervention Mapping (IM) focused on Latino patients served by the performance site. We will use IM, developed by Bartholomew and others [20], to identify these factors and to plan each step of the intervention with key stakeholders. The IM model has been implemented in multiple settings and specifies six components that lead to improved program outcomes: needs assessment, matrices, theory and practice, program, implementation, and evaluation [20]. IM is increasingly used to systematically plan preventive care interventions and ensure stakeholder input is incorporated in each step [21–23].

2.3. Boot camp translation [Phase I]

During the first six months of the study, we used an adapted version of boot camp translation to develop culturally tailored program materials (e.g., reminder phone scripts for automated calls and text messages) to define the components of the intervention arms in the pilot. Boot camp translation is a method for engaging diverse stakeholders in a consensus-building process [15]. It uses an iterative, flexible schedule of face-to-face meetings combined with short, focused teleconferences. The process addressed two questions: ‘What do we need to say in our message to patients?’ and ‘How do we deliver that message to patients?’ The typical boot camp translation process requires about 20 to 25 h of participant time over a 4- to 12-month time period [15]. In our adapted version, participants were asked to commit eight hours of time over the course of three months [24].

Our research team aimed to recruit 12 patient participants for each of the English- and Spanish-language versions of boot camp translation.