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Scaling Colorectal cancer screening through Outreach, Referral, and Engagement (SCORE)

Submission date
03/06/2020

Recruitment status
No longer recruiting

Registration date
09/06/2020

Overall study status
Completed

Last Edited
14/04/2025

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Colorectal cancer (CRC) is a leading cause of cancer death in the United States. In North Carolina, as in many parts of the United States, CRC screening is substantially underused in vulnerable and marginalized populations. Uninsured, underinsured, and medically underserved populations rely on community health centers for their healthcare and thus patients served by North Carolina's community health centers are particularly likely to benefit from efforts and resources to improve CRC screening. The United States Preventive Services Task Force recommends several tests to screen for CRC, including annual screening with a fecal immunochemical test (FIT), for patients ages 50-75 years.

Mailed fecal testing programs have shown promise as an effective approach for increasing CRC screening. Although the effectiveness of mailed FIT-based screening programs has been demonstrated within organized health systems, it is unclear whether this approach is effective, feasible, acceptable, and cost-effective in community health centers, which tend to be under-resourced.

This pilot study was designed to assess the effectiveness, feasibility, acceptability, and cost-effectiveness of mailing FITs from a central location to patients served by two community health centers. Patients who have a positive (abnormal) FIT result need a follow-up (diagnostic) colonoscopy to determine the cause of the positive result; thus, this pilot study also includes a patient navigation component to help patients get a follow-up colonoscopy. Therefore, this pilot study also assessed the effectiveness, feasibility, acceptability, and costs of delivering patient navigation from a central location to facilitate follow-up colonoscopy for patients with a positive (abnormal) FIT result.

Who can participate?
Patients at the participating community health centers aged between 50 and 75 years at average risk for colorectal cancer.

What does the study involve?
Eligible participants will be randomly allocated to receive either usual care or mailed fecal immunochemical test (FIT) screening.

For the mailed fecal immunochemical test (FIT) screening, the study team will mail participants an introductory letter advising them that they should expect to receive a FIT kit in the mail. Next, the study team will mail participants a packet that includes a cover letter, CRC information sheet, FIT instruction sheet, and FIT kit consisting of sample collection materials and a pre-paid return envelope. Participants will receive up to two mailed letters reminding them to complete and return the FIT. Participants will receive their FIT results via letter or phone call. For participants with a positive (abnormal) FIT result, a patient navigator will call them to offer support for completing follow-up colonoscopy. Navigation support includes assessment and resolution of barriers to follow-up colonoscopy including, but not necessarily limited to, information/education, finances, language, and transportation.

What are the possible benefits and risks of participating?
A possible benefit from being in this study is a convenient way to complete colon cancer screening. Screening can help find colon cancer early, when it is small, has not spread to other parts of the body, and might be easier to treat. Risks from being in this study are small. The FIT is an approved colon cancer screening test that is similar to or the same as the one already used by the participants' doctor's office.

Where is the study run from?
University of North Carolina Lineberger Comprehensive Cancer Center (USA) and two community health centers in North Carolina (USA)

When is the study starting and how long is it expected to run for?
From September 2018 to December 2021

Who is funding the study?
National Cancer Institute (USA)

Who is the main contact?
Dr Daniel Reuland
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
NCT04406714

Secondary identifying numbers
Nil known

Study information

Scientific Title
Scaling Colorectal cancer screening through Outreach, Referral, and Engagement (SCORE): a state-level program to reduce colorectal cancer burden in vulnerable populations

Acronym
SCORE

Study objectives
This pilot study aims to assess the effectiveness, feasibility, acceptability, and cost-effectiveness of mailed fecal immunochemical test (FIT) screening, compared to usual care, among patients of two community health centers who are due for colorectal cancer (CRC) screening

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/10/2018, the University of North Carolina at Chapel Hill Office of Human Research Ethics (720 Martin Luther King, Jr. Blvd. Bldg. 385, 2nd Floor CB #7097 Chapel Hill, NC, USA 27599-7097; irb_questions@unc.edu; +1 (919)-966-3113), ref:18-1074

Study design
Randomized controlled pilot study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Screening

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Colorectal cancer

Interventions
Patients at two community health centers will be randomly selected and allocated to receive either the intervention or usual care (control).

Intervention: The study team will mail participants an introductory letter advising them that they should expect to receive a fecal immunochemical test (FIT) kit in the mail. Next, the study team will mail participants a packet that includes a cover letter, colorectal cancer (CRC) information sheet, FIT instruction sheet, and FIT kit consisting of sample collection materials and a pre-paid return envelope. Participants will receive up to two mailed letters reminding them to complete and return the FIT. Participants will receive their FIT results via letter or phone call. For participants with a positive (abnormal) FIT result, a patient navigator will call them to offer support for completing follow-up colonoscopy. Navigation support includes assessment and resolution of barriers to follow-up colonoscopy including, but not necessarily limited to, information/education, finances, language, and transportation.

Usual care (control): Patients randomized to this arm will receive usual care. Current usual care at the participating community health centers consists of a visit-based FIT distribution approach.

As part of this pilot study, the study team iteratively tested and refined the protocols for identifying eligible patients who met study inclusion criteria, using an automated query of the electronic health records at each community health center. Because electronic health records are based on best available information and may not reflect screenings performed at another facility, the study materials included a phone number for patients to contact the study team to self-identify as ineligible. Several queries were performed at each community health center throughout the pilot study to identify potentially eligible patients for each study wave. A computerized random number generator was used to randomly select patients for each wave. As part of the initial pilot testing of the mailed FIT intervention, randomly selected patients only were included in the mailed FIT intervention arm. For later waves, participants were randomly selected and assigned 1:1:1 to usual care, mailed FIT intervention, or mailed FIT intervention plus a telephone call reminder. Because so few patients completed a FIT after they were reached by phone, the study team determined that phone calls were unlikely to be a cost-effective method for increasing FIT completion in this context. For the latest study waves, the protocol was to randomly select and assign patients 1:1 to usual care or mailed FIT intervention.

Intervention Type
Behavioural

Primary outcome measure
The proportion of individuals who complete colorectal cancer (CRC) screening within 6 months, using any of the screening modalities recommended by the United States Preventive Service Task Force (fecal immunochemical test [FIT], fecal occult blood test [FOBT], FIT-DNA, colonoscopy, flexible sigmoidoscopy, flexible sigmoidoscopy with FIT, CT colonography), assessed through electronic health record review at 6 months.

Secondary outcome measures
1. Proportion of participants who return a completed mailed fecal immunochemical test (FIT) at 60 days assessed through electronic health record review at 60 days
2. Feasibility of a mailed FIT outreach program assessed using tracking data captured in a REDCap database to measure the proportion of bad mailing addresses, at 60 days
3. Acceptability of a mailed FIT outreach program assessed using semi-structured interviews with patients up to 24 months after initial FIT mailing
4. Cost-effectiveness of a mailed FIT outreach program assessed through comparison of the programmatic costs incurred and the number of individuals screened in the intervention arm compared to usual care (cost of intervention minus the cost of usual care, divided by the number screened in the intervention arm minus the number screened in usual care) through study completion, up to 36 months after initial FIT mailing

Overall study start date
20/09/2018

Completion date
30/12/2021

Eligibility

Key inclusion criteria

1. Aged between 50 and 75 years
2. At average risk for colorectal cancer (CRC). Average risk defined as those patients who do not have any of the following: history of CRC, colonic adenomas, Lynch syndrome, family history of CRC, or diagnosis of inflammatory bowel disease.
3. Active patient (seen within the past 18 months) of the community health centers

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1000

Total final enrolment
215

Key exclusion criteria
1. Record of fecal occult blood test (FOBT)/fecal immunochemical test (FIT) within 12 months or colonoscopy within 10 years, sigmoidoscopy within 5 years, barium enema within 5 years, or computed tomography (CT) colonography within 10 years
2. Record of any colorectal cancer diagnosis or total colectomy

Date of first enrolment
20/09/2018

Date of final enrolment
31/03/2021

Locations

Countries of recruitment
United States of America

Study participating centre
University of North Carolina Lineberger Comprehensive Cancer Center
450 West Drive
Chapel Hill
United States of America
27599

Study participating centre
Roanoke Chowan Community Health Center
120 Health Center Dr
Ahoskie
United States of America
27910

Study participating centre
Blue Ridge Health
2579 Chimney Rock Rd
Hendersonville
United States of America
28792

Sponsor information

Organisation
UNC Lineberger Comprehensive Cancer Center

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27599
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ResAdminOSR@unc.edu

Sponsor type
Hospital/treatment centre

Website
https://unclineberger.org/

ROR
https://ror.org/00qz24g20

Funder(s)

Funder type
Government

Funder Name
National Cancer Institute

Alternative Name(s)
Instituto Nacional del Cáncer, National Cancer Institute at the National Institutes of Health, Instituto Nacional del Cáncer de los Institutos Nacionales de la Salud, NCI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
09/01/2024

Individual participant data (IPD) sharing plan
Current IPD sharing statement as of 25/01/2023:

The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository, UNC Dataverse – Hosted by the Odum Institute for Research in Social Sciences (https://dataverse.unc.edu/dataverse/CCSI). The timing for availability is upon manuscript publication.

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Previous IPD sharing statement:

As outlined in the Notice of Award, each study site must make its Limited Data Set (LDS) accessible to other sites in the ACCSIS consortium. Information Management Services (IMS) will serve as the repository and have responsibility for creating a Limited Consolidated Data Set (LCDS) for analytic use of researchers both within and external to the ACCSIS consortium. Dataset items in the LDS are defined by the Common Data Elements. There also will be a "public use data set" that consists of the Common Data Elements, available to external researchers. IMS will use a systematic process to remove identifiers. In addition, all data that underlie results in publications will be available per Cancer Moonshot Notice of Award.

Access criteria: There are 2 classes of dataset requests: public use and special. Requests are submitted via the IMS website. Requestors electronically sign and submit necessary forms, including an agreement to acknowledge ACCSIS in publications and presentations. A public-use dataset containing common data elements is made available to external researchers by

application. IMS responds to public use dataset applications by sending the requestor one-time access to a data download link. External researchers may also request a more customized data set. Requestors must submit a brief concept form or ancillary studies form, for preliminary review by the ACCSIS Steering Committee (SC), before invitation to submit a full proposal. Full proposals receive administrative review by NCI and RTI before being sent to the SC for review and approval. Requestors report every 6 months and published articles or conference presentations to RTI. Requestors are encouraged to make articles available through PubMed Central.

IPD sharing plan summary

Stored in non-publicly available repository, Available on request, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			03/07/2020	No	Yes
Basic results		17/03/2025	14/04/2025	No	No