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Implementation of mailed colon cancer screening testing

Submission date 02/01/2024	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 08/01/2024	**Overall study status** Ongoing	
Last Edited 09/01/2024	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
In the Veterans Health Administration, traditionally, colon cancer screening is offered only when a Veteran is seen by their provider. Therefore, if a Veteran does not regularly meet with their provider, they may not be screened for colon cancer or be under-screened. Mailed colon cancer screening testing (FIT kits) programs have been successfully implemented in select VAs in the U. S. Therefore, to improve cancer screening rates, the goal of this project is to evaluate if patients are more likely to complete colon cancer screening if they are mailed a home test kit.

Who can participate?
Veterans ages 45-75 living in the U.S.

What does the study involve?
A post-card will be mailed to eligible Veterans stating that they will be mailed a FIT kit and instructions. There will also be instructions on who to reach if they have had a colonoscopy elsewhere or wish no further contact. Two weeks later they will receive a packet that contains an information letter, instructions, FAQs and a FIT kit with a pre-addressed pre-paid return envelope. After 2 weeks, nonresponders will be called with a pre-recorded scripted phone call, reminding them to complete their FIT kit or call to schedule a colonoscopy. In another 2 weeks, non-responders will be mailed a final reminder letter to complete their FIT kit screening or call to schedule a colonoscopy. Two weeks after that, a templated note will be placed in their electronic health chart to alert their PCP that the Veteran did not respond to the multi-step screening invitation outreach and that they should proceed as they see best regarding screening that patient. If the Veteran mails their FIT kit back, it will be processed by the clinical lab.

What are the possible benefits and risks of participating?
Benefits are increased rates of colon cancer screening which can lead to catching colon cancer earlier thereby improving mortality. Additionally, many patients can complete colon cancer screening in the convenience of their home rather than requiring a colonoscopy. Risks include false positive results.

Where is the study run from?
Minneapolis VA Health Care System (USA)

When is the study starting and how long is it expected to run for?
February 2024 to March 2026

Who is funding the study?
U.S. Department of Veterans Affairs (USA)

Who is the main contact?
Susan Lou, MD, susan.lou2@va.gov

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Implementation of mailed (faecal immunochemical test) FIT outreach

Study objectives
Patients that are sent a colonoscopy screening test in the mail will have increased completion of colon cancer screening compared to standard of care.

Ethics approval required

Ethics approval not required

Ethics approval(s)
This project was submitted to the Minneapolis VA Institutional Review Board (IRB) and they determined on 30/11/2023 that, as a quality improvement project, it did not meet the definition of research and therefore did not require IRB oversight

Study design
Prospective pragmatic trial with 2 arms

Primary study design
Interventional

Study type(s)
Screening

Health condition(s) or problem(s) studied
Completion of colon cancer screening

Interventions
Patients who are average risk, asymptomatic, and due for colon cancer screening will be identified via a national VA cohort identification tool. Primary care providers will be split into two arms. Eligible patients of the primary care providers in arm "A" will receive the intervention while eligible patients of primary care providers in arm "B" will serve as the control. For those in the intervention arm, a post-card primer will be mailed to eligible Veterans stating that they will be mailed a FIT kit and instructions. There will also be instructions on who to reach if they have had a colonoscopy elsewhere, are not otherwise average risk, or wish no further contact. A “return service requested” will be enabled to track both undeliverable and changes of address. Two weeks after receiving the postcard, Veterans will receive a packet that contains an information letter, instructions, FAQs and a FIT kit with a pre-addressed, pre-paid return envelope. After 2 weeks, nonresponders will be called with a pre-recorded scripted phone call, reminding them to complete their FIT kit or call to schedule a colonoscopy. In another 2 weeks, non-responders will be mailed a final reminder letter to complete their FIT kit screening or call to schedule a colonoscopy. Two weeks after that, a templated note will be placed in their electronic health chart to alert their PCP that the Veteran did not respond to the multi-step screening invitation outreach, and that they should proceed as they see best regarding screening that patient. If the veteran mails their FIT kit back, it will be processed by the clinical lab.

Intervention Type
Other

Primary outcome(s)
Completion of colon cancer screening completion four weeks after being mailed a FIT kit measured using patient records

Key secondary outcome(s))
Reach of the intervention - proportion of patients that schedule a colonoscopy following a positive test measured using patient records at the end of the study

Completion date

01/03/2026

Eligibility

Key inclusion criteria
1. Is not deceased
2. Is a Veteran
3. Must have deliverable address
4. Active or pending primary care provider assignment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
45 years

Upper age limit
75 years

Sex
All

Key exclusion criteria
1. Exclude patients from Northern Mariana Islands, Armed Forces Pacific, Palau, Virgin Islands, American Somoa, Armed Forces AF, EU, ME, CA, Puerto Rico, or any foreign country
2. CAN score with 1 year mortality rate of >50%
3. Have received hospice care in the last two years
4. Have received palliative care in the last year
5. Have had ulcerative colitis diagnosis in the last year
6. Have had crohn disease diagnosis in the last year
7. History of adeoma in the last year
8. Have had metastatic cancer diagnosis in the last year
9. Any total colectomy procedures in the last year
10. Frailty and advanced illness diagnosis in the last year
11. Clopidogrel (or other thienopyridine) prescription in the last four months of prescription and no prescription for 121-365 days prior
12. Have had FOBT in the last 10 months
13. Have had colonoscopy in the last 112 months
14. Have had a CT colonography in the last 54 months
15. Have had a DNA FIT in the last 33 months
16. Have had a Flex Sigmoid in the last 4.5 years
17. Active/pending/scheduled colonoscopy consults in the last 90 days
18. Have existing mailed FIT orders

Date of first enrolment
01/02/2024

Date of final enrolment
02/01/2026

Locations

Countries of recruitment
United States of America

Study participating centre
Minneapolis VA Health Care System
1 Veterans Dr
Minneapolis
United States of America
55417

Sponsor information

Organisation
Minneapolis VA Health Care System

ROR
https://ror.org/02ry60714

Funder(s)

Funder type
Government

Funder Name
U.S. Department of Veterans Affairs

Alternative Name(s)
Department of Veterans Affairs, United States Department of Veterans Affairs, US Department of Veterans Affairs, U.S. Dept. of Veterans Affairs, Veterans Affairs, Veterans Affairs Department, VA, USDVA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes