Published in final edited form as:

J Rural Health. 2014 ; 30(3): 322–332. doi:10.1111/jrh.12052.

Evaluation of a Home-Based Colorectal Cancer Screening Intervention in a Rural State

Mary E. Charlton, RN, PhD^{1,2}, Michelle A. Mengeling, PhD^{1,3}, Thorvardur R. Halfdanarson, MD⁴, Nader M. Makki, MD³, Ashish Malhotra, MD¹, J. Stacey Klutts, PhD, MD^{5,6}, Barcey T. Levy, PhD, MD^{2,7}, and Peter J. Kaboli, MD, MS^{1,3}

¹VA Office of Rural Health, Rural Health Resource Center – Central Region and the Comprehensive Access and Delivery Research and Evaluation (CADRE) Center at the Iowa City VA Healthcare System, Iowa City, IA

²Department of Epidemiology, University of Iowa College of Public Health, Iowa City, IA

³Division of General Internal Medicine, Department of Internal Medicine, University of Iowa Carver College of Medicine, Iowa City, IA

⁴Division of Oncology, Department of Internal Medicine, Mayo Clinic, Scottsdale, AZ

⁵Department of Pathology, University of Iowa Carver College of Medicine, Iowa City, IA

⁶Pathology and Laboratory Medicine, Iowa City VA Healthcare System, Iowa City, IA

⁷Department of Family Medicine, University of Iowa Carver College of Medicine, Iowa City, IA

Abstract

Purpose—Distance from health care facilities can be a barrier to colorectal cancer (CRC) screening, especially for colonoscopy. Alternatively, an improved at-home stool-based screening tool, the Fecal Immunochemical Test (FIT), requires only a single sample and has a better sensitivity-specificity balance compared to traditional guaiac fecal occult blood tests. Our objective was to determine if FITs mailed to asymptomatic, average-risk patients overdue for screening resulted in higher screening rates versus mailing educational materials alone or no intervention (ie, usual care).

Methods—Veterans ages 51–64, asymptomatic, at average risk for CRC, overdue for screening and in a VA catchment area covering a large rural population were randomly assigned to 3 groups: 1) Education only (Ed) group: mailed CRC educational materials and a survey of screening history and preferences (N=499); 2) FIT group: mailed the FIT, plus educational materials and survey (N=500); 3) Usual Care (UC) group: received no mailings (N=500).

Findings—At 6 months post-intervention, 21% of the FIT group had received CRC screening by any method compared to 6% of the Ed group (and 6% of the UC group) ($P < .0001$). Of the 105

Corresponding Author Information: Mary E. Charlton, RN, PhD, Iowa City VA Health Care System, 601 Hwy 6 West, Iowa City, IA, 52246. Phone: (319) 338-0581 Ext. 93877. Fax: (319) 887-4932. mary-charlton@va.gov.

Conflict of Interest Statement: No financial disclosures were reported by any authors.

This research was presented at the 2012 Annual VA Health Services Research and Development Meeting in Washington, D.C.

respondents from the FIT group, 71 (68%) were eligible to take the FIT. Of those, 64 (90%) completed the FIT and 8 (12%) tested positive.

Conclusions—This low-intensity intervention of mailing FITs to average risk patients overdue for screening resulted in a significantly higher screening rate than educational materials alone or usual care, and may be of particular interest in rural areas.

Keywords

colorectal cancer screening; fecal immunochemical test; access to care; health services research; program evaluation

Colorectal cancer (CRC) is the third-leading cause of cancer-related deaths in the US, with a lifetime risk of approximately 5% in the general population.¹ The majority of people who develop CRC have no major risk factors such as family history or inflammatory bowel disease.^{1,2} Since most CRC arises from pre-cancerous polyps or adenomas, population screening approaches focused on early detection and removal of these polyps can significantly decrease incidence.³ Risk of CRC increases with age; 90% of new cases occur in those over age 50.¹ Screening approaches therefore typically target individuals who are 50 years or older.

CRC is particularly relevant to the Veterans Administration (VA), given that veterans over 45 years old make up over 80% of the total veteran population.⁴ VA guidelines recommend screening beginning at age 50, unless the presence of high-risk conditions warrant earlier screening. VA screening options include annual fecal occult blood test (FOBT), flexible sigmoidoscopy or double-contrast barium enema (DCBE) every 5 years, or colonoscopy every 10 years for average risk veterans and should take into consideration patients' preferences and clinical factors. While overall CRC screening rates are high among VA users (80%)⁵ compared to the non-VA population (63%),⁶ 1 in 5 VA users remain unscreened. Previous reports have suggested transportation problems (eg, lack of a driver), difficulty following pre-procedural instructions (eg, colonoscopy preparation), rural residence, and longer drive times to the nearest medical facility as potential barriers to screening, particularly colonoscopy.^{7–12}

Of the 8.3 million veterans enrolled in the VA, approximately 3.4 million (41%) live in rural areas.¹³ Rural veterans are more likely to live farther from VA facilities and face longer drive times to access VA care; 21% of enrollees live more than 60 minutes from the nearest VA community-based outpatient clinics and 42% live more than 90 minutes from the nearest VA Medical Center (VAMC).¹⁴ Colorectal cancer screening services may be challenging for rural veterans because colonoscopy is only performed in VAMCs, leaving FOBT as the only option available in VA outpatient clinics.

FOBTs are often referred to as “at home tests” because they are typically sent home with the patient and returned by mail, which makes them ideal for patients who face distance barriers to receiving more invasive testing such as colonoscopy. Furthermore, previous studies have illustrated that more people prefer to take non-invasive, home-based, CRC screening than colonoscopy.^{15–18} Guaiac-based FOBT (gFOBT) is a convenient, low-cost, and non-

invasive screening option, but it has limitations which can impact compliance (eg, 3 samples are required) and cause false positives (eg, certain foods and medications must be avoided prior to testing). The Fecal Immunochemical Test (FIT), a type of FOBT that detects globin rather than peroxidase activity, has recently been approved for use in the VA, but it has not yet been widely adopted throughout the VA. Advantages of FIT, in comparison to gFOBT, are that only one sample is required, results are not affected by diet or medications, and FIT has a better sensitivity/specificity balance.^{19–21} Studies have also shown that completion rates for FIT are significantly greater than those for gFOBT.^{22,23}

Studies that have involved mailing FITs to subjects have employed multiple steps to improve response rates, such as introductory automated phone calls offering the FIT,²³ or an initial mailing with a post card to return if subjects are interested in participating and a phone call to confirm eligibility.²² These methods used by large health systems are ideal, but not always feasible in smaller, rural health practices that want to implement quality improvement (QI) initiatives to improve CRC screening. Despite the size and national scope of the VA, programs are often implemented and tested on a local or regional basis before being considered for widespread national implementation. Furthermore, not all VA Health Care Systems or private sector facilities/clinics have the staffing or funding to develop mechanisms for patient contact and follow-up, particularly those in rural areas. The objective of this study was to test whether a simple one-step mailing of a FIT to veterans' homes accompanied by educational materials resulted in improved screening rates in an average risk, asymptomatic population overdue for screening compared to 2 other groups: 1) a group receiving education materials only and 2) a usual care group (no intervention).

METHODS

Participants

Regular users of VA primary care services, defined as having 2 or more primary care visits in the prior 13 months in the Iowa City VA Health Care System, were identified using the Veterans Integrated Service Network (VISN) 23 Clinical Data Warehouse. Only regular users were included to reduce potential biases that may result by including veterans with only occasional VA use.¹⁶ The sample included patients aged 51–64, excluding those over age 65 due to their likelihood of using non-VA services covered by Medicare.

Only those overdue for screening were included in this study. Veterans were excluded if they were up-to-date on screening (ie, colonoscopy in past 10 years, flexible sigmoidoscopy or double contrast barium enema (DCBE) in past 5 years, FOBT in past 13 months) according to VA records. Subjects were also excluded if they were experiencing symptoms potentially related to colorectal cancer (eg, rectal bleeding, anemia, anorexia/abnormal weight loss) warranting colonoscopy, or had a medical or family history that would require more frequent surveillance with colonoscopy (eg, personal or family history of CRC, polyps, inflammatory bowel disease). While recent guidelines suggest some patients with positive family histories may still be considered “average risk,”^{24,25} we did not have sufficient information on the medical histories of subjects' family members to adequately stratify by risk, nor did we want to take the chance that a potentially false-negative FIT result could provide false reassurance to higher-risk veterans who should have colonoscopy. Previously

developed International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) criteria were applied to exclude those with symptoms and/or positive medical histories.²⁶

In order to include as many women as possible to allow for examination of gender differences in the intervention groups, women were oversampled such that approximately 90% of women veterans overdue for screening were included in the intervention groups. A Random Sequence Generator²⁷ was used to randomize assignment of 500 men and women to each of the intervention groups: the education plus FIT (FIT) group or the education only (Ed) group. In addition, 500 veterans who were not assigned to either FIT or Ed group were randomly selected to serve as a usual care (UC) comparison group. Figure 1 displays a diagram of the number of veterans included/excluded per study criteria.

The VA catchment area targeted in this study includes a large number of rural veterans, and it was selected because many of these rural veterans face substantial driving distances to their nearest VA Medical Center. To keep the intervention simple and administratively non-burdensome, urban veterans were also included in the study population and were used as a comparison group. Rurality was defined according to the VA Urban/Rural/Highly Rural Classification, in which urban areas include those with census tracts belonging to Urbanized Areas, highly rural areas include counties with average population density < 7 residents per square mile, and rural areas include everything not classified as urban or highly rural.²⁸

Intervention

In April 2011, all veterans assigned to the FIT or Ed groups were mailed a packet containing: 1) a letter explaining the study, 2) educational materials from the Centers for Disease Control and Prevention's Screen for Life program, 3) consent and HIPAA forms, 4) eligibility screen, 5) brief survey, and 6) postage-paid, self-addressed envelope to return completed materials. In addition, veterans assigned to the FIT group received a Polymedco OC FIT-CHEK® (Polymedco, Inc., Cortlandt Manor, New York) kit with instructions and a postage-paid, self-addressed envelope to return the test directly to the laboratory in the VA Medical Center. Veterans in the UC group received no mailings from the study team; however, it is important to note that the VA employs a clinical reminder system to prompt primary care providers to assess need for CRC screening during visits. At the time of intervention, the percentage of CRC screening clinical reminders that were resolved was 71.6%; reminders for patients who have refused CRC screening can be considered "resolved" for up to 6 months.²⁹

FIT group participants with positive FIT results were contacted by a study physician, a note was placed in their electronic medical record, and their primary care provider was notified. The study physician discussed appropriate follow-up and facilitated appointments with VA gastroenterology specialists when appropriate. All participants were mailed a thank you letter documenting FIT results, and for positive results, physician follow-up recommendations.

Measures

Six months after the mailing, information was extracted from the VISN 23 Clinical Data Warehouse about screening tests received by all who were mailed study packets. In addition, screening test information for the UC group was extracted for the same 6-month period. Analysis of historical controls was done entirely retrospectively via administrative records, and no patient contact was initiated; thus the requirement for patient consent was waived for this group by the Institutional Review Board and local VA Research and Development Committee.

One year after the mailing, individual electronic medical records (including clinical notes and pathology and procedure reports) of those with positive FIT results were reviewed by a study physician to determine outcomes and ensure appropriate follow-up. A second chart review was performed by the study coordinator to ensure completeness of information abstracted.

Survey Instrument

The mailed survey began with an eligibility screening tool developed for use in previous studies of CRC screening among non-veterans.^{11,30} Screening questions assessed whether subjects had blood in their stools, a change in bowel habits, thin/pencil-like stools, or great difficulty passing stools in the past 2 months, personal history of inflammatory bowel disease, colon polyps, CRC, or family history of CRC, adenomatous polyposis, or hereditary non-polyposis colon cancer. If respondents answered “yes” to any questions, they were instructed to stop, return the survey, and were subsequently contacted by a study team physician; appropriate referrals to care were made. Those who answered “no” to all eligibility questions were instructed to continue.^{11,30,31} Remaining questions assessed demographics (eg, current health, education, marital status, health care coverage, and if they had a non-VA primary care provider), history of colonoscopies, gFOBTs, and FITs, and reasons why a colonoscopy or at-home test (ie, gFOBT or FIT) were not taken, as applicable.

Analysis

Means and frequencies were computed for demographic variables for the full sample ($n=1,499$) by group (Ed, FIT, UC) based on administrative data available for all subjects, and between the Ed and FIT groups based on survey data from eligible subjects. Comparisons among all 3 study groups used Analysis of Variance (ANOVAs) with Tukey’s multiple comparison tests for continuous variables and chi-square tests for categorical variables. Differences between eligible respondents from the Ed and FIT groups were identified with Student’s *t*-tests for continuous variables and chi-square tests for categorical variables or Fisher’s Exact Test for small cell sizes. The primary outcome of interest was receipt of screening within 6 months following the mailing for all 3 study groups. Screening rates were calculated for each study group for the full sample and for eligible respondents only in the Ed and FIT groups. Additional analyses examined screening rates by gender and rurality. Reasons cited for not having sought colonoscopy or at-home tests in the past were summarized for all eligible survey respondents, and differences between study groups were examined. The study was approved by the local University-based Institutional Review

Board and the VA Research and Development Committee. All analyses were conducted using SAS[®] statistical software version 9.1 (SAS Institute Inc., Cary, North Carolina).

RESULTS

As shown in Figure 1, the final study population included 499 participants in the Ed group, 500 in the FIT group, and 500 in the UC group. Table 1 displays demographic characteristics for all sampled veterans, regardless of participation status. While there was a statistically significant difference in average age of subjects among the 3 study groups, the actual difference was less than 1.4 years. Ed and FIT groups had a smaller proportion of males compared to the UC group due to oversampling of women for the intervention groups, but all groups were predominantly male. There were no significant differences in rural residence or presence of a service-connected disability.

Full Sample

The primary outcome, overall CRC screening rate during the 6 months following the intervention, was retrospectively calculated for all veterans assigned to 1 of the 3 study groups and examined separately for the full sample and for only those meeting eligibility criteria. Among the overall study population, the FIT group had a significantly higher rate of CRC screening (21%) compared to either the Ed (6%) or UC (6%) groups ($P < .0001$ for both comparisons). Of note, 7 ineligible subjects returned a FIT despite instructions not to do so. In sensitivity analyses excluding these subjects, and assuming no screening would have been performed for them otherwise, the FIT group still had a significantly greater screening compared to Ed and UC groups (19%, 6%, 6%, respectively; $P < .001$).

Table 2 displays the initial type of CRC screening received by group following the mailing date. The percentage of veterans receiving colonoscopy and gFOBT was similar across groups. Rate of CRC screening (any method) was stratified by rural vs urban residence and females vs males (Table 3). No statistically significant differences were detected between genders or between rural/urban groups. Within each strata, the FIT group had a significantly greater rate of screening compared to the Ed and UC groups ($P < .001$).

Table 4 illustrates the CRC screening test results for the full sample (includes the 7 ineligible subjects who took the FIT). While the majority of subjects in each group receiving an initial colonoscopy had no polyps or hyperplastic polyps only, approximately one-third to one-half had tubular or tubulovillous adenomas detected, which have potential to grow into cancerous lesions. Among all those with positive FITs ($n=10$) or FOBTs ($n=2$), 9 underwent follow-up colonoscopy; just over half had no polyps detected and one-third had tubular or tubulovillous adenomas.

Eligible Respondents Only

Among the FIT group, 105 (21%) returned a consent and eligibility screen/survey. As illustrated in Figure 2, 34 (32%) of responders were ineligible to take the FIT due to personal/family medical history or current symptoms and were referred for appropriate care. Of the remaining 71 subjects eligible to take the FIT, 64 (90%) completed the test of which 56 (88%) were negative and 8 (12%) were positive. Of those with positive results, 6

received a colonoscopy, 3 of which had polyps removed (all 3 had tubular adenomas removed, 2 had hyperplastic polyps removed, and 1 had tubulovillous adenomas removed). The remaining 2 patients' providers advised against colonoscopy due to terminal conditions (ie, chronic lymphocytic leukemia and metastatic lung cancer).

When comparing screening by any method between the eligible respondents in the FIT and Ed groups within 6 months following the intervention (Table 2), the FIT group had a substantially higher rate of screening compared to the Ed group (92% vs 2%, respectively; $P < .0001$). Similar to the results of the overall analysis, there were no significant differences between study groups in proportions taking other CRC screening tests or in screening rates by rurality or gender (Table 3).

The Ed group had a significantly lower survey participation rate compared to the FIT group, as 74 subjects (15%) returned a consent and eligibility screen/survey compared to 21% of the FIT group ($P = .01$). There were no differences in response rates between urban and rural veterans. Of the 74 Ed group respondents, 41 (55%) met eligibility criteria, with the remainder reporting current symptoms or medical history warranting colonoscopy.

Of eligible respondents, 88% of the FIT group and 100% of the Ed group completed and returned the survey. There were no significant differences between the 2 groups in demographics, perceived health status, other health care coverage or prior CRC screening recommendations received from their providers. However, the Ed group was significantly more likely to report having both VA and non-VA primary care providers compared to the FIT group (55% vs 29%, respectively; $P = .01$).

Those who did not have colonoscopy in the past 10 years were asked about reasons for not having had one, and those who did not take an at-home test in the past year were asked about reasons for not taking one. With one notable exception, there were no significant differences found between the Ed and FIT groups, so group rates of agreement were combined (Table 5). The exception was that those in the Ed group were more likely to report that they preferred a colonoscopy to an at-home test compared to those in the FIT group (30% vs 6%, $P = .005$). The most frequently reported reasons for not having colonoscopy included concerns about pain (39%), not recommended by health care provider (37%), confusion about screening options (35%), and preference for at-home testing (34%). The overwhelming reason for not having at-home testing was that it was not recommended by their health care provider (62%).

DISCUSSION

This low-intensity intervention of mailing FITs to patients identified as overdue for screening resulted in a three-fold higher rate of screening compared to the Ed and UC groups; mailing education materials was no better than usual care. When examining only those who were asymptomatic and average risk according to the screening tool, the FIT group had a substantially higher rate of screening than the Ed group. Of note, almost one-third of those in the Ed group who responded to the survey indicated that they preferred a colonoscopy to an at-home test, whereas only 6% of FIT group responders indicated they

preferred a colonoscopy. It is possible that receiving the FIT and having the ability to examine it first-hand may convince people that it is an acceptable alternative to colonoscopy.

A higher than anticipated one-third of veterans overdue for screening were not eligible to take the FIT due to recently experienced potential symptoms or a medical/family history warranting diagnostic follow-up or surveillance, thus needing colonoscopy rather than FIT. These patients were referred to gastroenterology for appropriate screening and clinical follow-up, and highlight the need for programs like the one described in this report to remind and engage patients to receive care for previously unrecognized high-risk history or symptoms.

It is difficult to compare the overall FIT return rate with other studies due to varying eligibility and recruitment protocols and because our study included only those under age 65, who have been shown to have lower FIT return rates than those over age 65.^{23,30} In a previous study of veterans due for screening, 24% of those invited via postcard to complete an at-home test agreed to participate; 27% were ineligible and 66% of eligible subjects returned the FIT. When considering the total number receiving invitation letters, the overall FIT completion rate was approximately 7%, slightly less than our overall completion rate of 13%.²²

Among non-veteran populations, a study mailing FITs to primary care patients due for screening achieved a 25% FIT completion rate after a single mailing, which only increased to 26% after a reminder mailing; subjects were not required to sign an informed consent document and the recruitment letter was issued by the subjects' own provider.³² Levy et al³⁰ mailed recruitment invitations to primary care patients without prior knowledge of their CRC screening status, and offered subjects \$20 to complete a questionnaire. Responses were received from 24% of subjects, of whom 37% were eligible; 47% of eligible subjects returned the FIT. They therefore had a higher overall response rate related to the survey, but a lower FIT return rate among those who were eligible.

Other intervention studies have shown the effectiveness of reminder phone calls, although studies specifically related to mailing FITs or gFOBTs to patients' homes have yielded conflicting results regarding their benefit.^{30,33–35} Large systems such as Kaiser Permanente have employed automated phone calls to determine up-front willingness to take the FIT.²³ While this approach would certainly be an ideal future enhancement, the purpose of this study was to evaluate the impact of a single mailing to determine if the lowest-intensity intervention that could be most feasibly and quickly implemented into routine practice would result in improved screening rates.

Several limitations require consideration when interpreting this study. The study sample was limited to a mostly male veteran population under age 65 who use the VA for health care services, and it therefore may not generalize to other populations. However, the VA does represent a health care system that takes longitudinal responsibility for patients' health like an Accountable Care Organization, and it could be considered a model for integrated care. Also, the data did not capture instances of screening performed outside the VA. We

restricted our population to those who were regular VA users under 65 to reduce the likelihood of outside CRC screening, but it is certainly possible that these veterans received services outside the VA. Given our survey response rate of 18%, responses may not be representative of the total sample; however, increasing response rates in a population overdue for screening (ie, non-compliant) may be challenging regardless of outreach methods.

Another limitation is that a formal cost-effectiveness analysis was not completed. However, we estimate the costs of mailing the 500 FIT kits plus the postage to return them to the laboratory was approximately \$5,000. In contrast, the cost of treating one patient in the first year after a diagnosis of Stage III CRC has been estimated at \$41,796.³⁶ Given the subsequent rate of screening in the FIT group was triple that of the Ed or UC groups, it is highly likely that a single mailing approach would be cost-effective for practices that do not have the funds or resources to incorporate introductory or reminder phone calls. A priority in future studies will be to determine if the cost of the unused FIT supplies in a one-step mailing process is greater than the costs associated with the resources required to conduct introductory phone calls (live vs automated) or multiple mailings that would limit FIT supplies to those confirmed to be interested and eligible to take the test.

Conclusions

In conclusion, mailing FITs and educational materials to the homes of patients overdue for screening resulted in significantly higher CRC screening rates than mailing educational materials alone or usual care. This low-intensity intervention that transcends distance barriers could be incorporated into practices of small rural and remote clinics, and into the proactive approaches being adopted by the newly implemented VA patient-centered medical homes. This population overdue for screening reported concerns about colonoscopy being too painful and expressed preferences for at-home tests, which is consistent with interim results from a large randomized trial demonstrating higher likelihood of participation among the FIT group compared to the colonoscopy group.¹⁸ Unfortunately, this population also frequently reported that at-home tests were not offered to them. The positive FIT results that occurred in 12% of FIT participants may have been the motivating factor that caused most to follow through with getting a colonoscopy, which they may have otherwise avoided. In addition, this intervention identified a number of people at high risk for CRC due to current symptoms or personal/family history, and made them aware that they needed to seek diagnostic or surveillance services.

The VA system is a prime testing ground for this type of intervention because of the extensive information available via electronic health records, access to colonoscopy for those with positive results, and the hub-and-spoke model that allows VA Medical Centers to process FIT results for outlying clinics. Other health care systems that share these characteristics or can develop alternative models may also find this approach to be a low-intensity means of increasing screening rates, particularly among those who live great distances from colonoscopy services or have transportation issues.

Acknowledgments

Funding Source: The research reported here was supported by the Department of Veterans Affairs, Veterans Health Administration, Office of Rural Health, Veterans Rural Health Resource Center-Central Region (VRHRC-CR), and the VA Health Services Research and Development (HSR&D) Service, Center for Comprehensive Access and Delivery Research and Evaluation (CADRE) (HFP 04-149). The views expressed in this article are those of the authors and do not necessarily represent the views or policy of the Department of Veterans Affairs or the United States Government.

The authors would like to thank Stacy Wittrock and Ashley Cozad for their efforts in coordinating this study. We would also like to acknowledge Lindsey Davenport-Landry in the Iowa City VA laboratory for her work in managing all of the laboratory aspects of this project.

References

1. American Cancer Society. [Accessed December 10, 2012] Colorectal Cancer Facts & Figures. 2011–2013. Available at: <http://www.cancer.org/acs/groups/content/@epidemiologysurveillance/documents/document/acspc-028323.pdf>
2. Lynch HT, de la Chapelle A. Hereditary Colorectal Cancer. *N Engl J Med*. 2003; 348(10):919–932. [PubMed: 12621137]
3. Winawer SJ, Zauber AG, Ho MN, et al. Prevention of Colorectal Cancer by Colonoscopic Polypectomy. *N Engl J Med*. 1993; 329(27):1977–1981. [PubMed: 8247072]
4. El-Serag HB, Petersen L, Hampel H, Richardson P, Cooper G. The Use of Screening Colonoscopy for Patients Cared for by the Department of Veterans Affairs. *Arch Intern Med*. 2006; 166(20):2202–2208. [PubMed: 17101937]
5. Long MD, Lance T, Robertson D, Kahwati L, Kinsinger L, Fisher DA. Colorectal Cancer Testing in the National Veterans Health Administration. *Dig Dis Sci* Feb. 2012; 57(2):288–293.
6. Richardson LC, Rim SH, Plescia M. Vital Signs: Colorectal cancer screening among adults aged 50–75 years—United States, 2008. *MMWR Morb Mortal Wkly Rep*. 2010; 59(26):808–812. [PubMed: 20613704]
7. Garcia-Dominic O, Lengerich EJ, Wray LA, et al. Barriers to CRC Screening Among Latino Adults in Pennsylvania: ACCN Results. *Am J Health Behav*. 2012; 36(2):153–167. [PubMed: 22370254]
8. McLachlan S-A, Clements A, Austoker J. Patients' experiences and reported barriers to colonoscopy in the screening context—A systematic review of the literature. *Patient Educ Couns*. 2012; 86(2):137–146. [PubMed: 21640543]
9. Klabunde CN, Schenck AP, Davis WW. Barriers to Colorectal Cancer Screening Among Medicare Consumers. *Am J Prev Med*. 2006; 30(4):313–319. [PubMed: 16530618]
10. Wee CC, McCarthy EP, Phillips RS. Factors associated with colon cancer screening: the role of patient factors and physician counseling. *Prev Med*. 2005; 41(1):23–29. [PubMed: 15916989]
11. Levy BT, Dawson J, Hartz AJ, James PA. Colorectal Cancer Testing Among Patients Cared for by Iowa Family Physicians. *Am J Prev Med*. 2006; 31(3):193–201. [PubMed: 16905029]
12. Shell R, Tudiver F. Barriers to Cancer Screening by Rural Appalachian Primary Care Providers. *J Rural Health*. 2004; 20(4):368–373. [PubMed: 15551854]
13. VHA Office of Rural Health. [Accessed June 1, 2012] Fact Sheet: Information about the Office of Rural Health and Rural Veterans. Sep. 2011 Available at: http://www.ruralhealth.va.gov/docs/ORH_FactSheet_Issue_10_September2011.pdf
14. US Department of Veterans Affairs, Veterans Health Administration, Office of the Under Secretary for Health for Policy and Planning, Planning System Support Group. FY2005 Geographic access to Veterans Health Administration services. Washington D.C: Veterans Health Affairs; Mar. 2007
15. Almog R, Ezra G, Lavi I, Rennert G, Hagoel L. The public prefers fecal occult blood test over colonoscopy for colorectal cancer screening. *Eur J Cancer Prev*. 2008; 17(5):430–437. [PubMed: 18714185]

16. DeBourcy A, Lichtenberger S, Felton S, Butterfield K, Ahnen D, Denberg T. Community-based Preferences for Stool Cards versus Colonoscopy in Colorectal Cancer Screening. *J Gen Intern Med.* 2008; 23(2):169–174. [PubMed: 18157581]
17. Wolf RL, Basch CE, Brouse CH, Shmukler C, Shea S. Patient Preferences and Adherence to Colorectal Cancer Screening in an Urban Population. *Am J Public Health.* 2006; 96(5):809–811. [PubMed: 16571715]
18. Quintero E, Castells A, Bujanda L, et al. Colonoscopy versus Fecal Immunochemical Testing in Colorectal-Cancer Screening. *N Engl J Med.* 2012; 366(8):697–706. [PubMed: 22356323]
19. Dancourt V, Lejeune C, Lepage C, Gailliard MC, Meny B, Faivre J. Immunochemical faecal occult blood tests are superior to guaiac-based tests for the detection of colorectal neoplasms. *Eur J Cancer.* 2008; 44(15):2254–2258. [PubMed: 18760592]
20. Smith A, Young GP, Cole SR, Bampton P. Comparison of a brush-sampling fecal immunochemical test for hemoglobin with a sensitive guaiac-based fecal occult blood test in detection of colorectal neoplasia. *Cancer.* 2006; 107(9):2152–2159. [PubMed: 16998938]
21. van Rossum LG, van Rijn AF, Laheij RJ, et al. Random Comparison of Guaiac and Immunochemical Fecal Occult Blood Tests for Colorectal Cancer in a Screening Population. *Gastroenterology.* 2008; 135(1):82–90. [PubMed: 18482589]
22. Hoffman RM, Steel S, Yee EFT, Massie L, Schrader RM, Murata GH. Colorectal cancer screening adherence is higher with fecal immunochemical tests than guaiac-based fecal occult blood tests: A randomized, controlled trial. *Prev Med.* 2010; 50(5–6):297–299. [PubMed: 20307568]
23. Liles EG, Perrin N, Rosales AG, et al. Change to FIT increased CRC screening rates: evaluation of a US screening outreach program. *Am J Manag Care.* 2012; 18:588–595. [PubMed: 23145804]
24. Rex DK, Johnson DA, Anderson JC, Schoenfeld PS, Burke CA, Inadomi JM. American College of Gastroenterology Guidelines for Colorectal Cancer Screening 2008. *Am J Gastroenterol.* 2009; 104:739–750. [PubMed: 19240699]
25. Whitlock EP, Lin JS, Liles E, Beil TL, Fu R. Screening for Colorectal Cancer: A Targeted, Updated Systematic Review for the U.S. Preventive Services Task Force. *Ann Intern Med.* 2008; 149(9):638–658. [PubMed: 18838718]
26. Walter LC, Lindquist K, Nugent S, et al. Impact of Age and Comorbidity on Colorectal Cancer Screening Among Older Veterans. *Ann Intern Med.* 2009; 150(7):465–473. [PubMed: 19349631]
27. Random.org. [Accessed March 15, 2010] Random Sequence Generator. [Online]. Available at: <http://www.random.org/sequences/>
28. West AN, Lee RE, Shambaugh-Miller MD, et al. Defining “Rural” for Veterans’ Health Care Planning. *J Rural Health.* 2010; 26(4):301–309. [PubMed: 21029164]
29. Steffes, R. FY 2011. Minneapolis, MN: Veterans Health Affairs; Veterans Integrated Service Network 23 Clinical Reminders Monthly Trend Report.
30. Levy BT, Daly JM, Xu Y, Ely JW. Mailed Fecal Immunochemical Tests Plus Educational Materials to Improve Colon Cancer Screening Rates in Iowa Research Network (IRENE) Practices. *J Am Board Fam Med.* 2012; 25(1):73–82. [PubMed: 22218627]
31. Levy BT, Nordin T, Sinift S, Rosenbaum M, James PA. Why Hasn’t This Patient Been Screened for Colon Cancer? An Iowa Research Network Study. *J Am Board Fam Med.* 2007; 20(5):458–468. [PubMed: 17823463]
32. Daly J, Levy B, Merchant M, Wilbur J. Mailed Fecal-Immunochemical Test for Colon Cancer Screening. *J Community Health.* 2010; 35(3):235–239. [PubMed: 20127156]
33. Mosen DM, Feldstein AC, Perrin N, et al. Automated Telephone Calls Improved Completion of Fecal Occult Blood Testing. *Med Care.* 2010; 48(7):604–610. [PubMed: 20508529]
34. Myers RE, Sifri R, Hyslop T, et al. A randomized controlled trial of the impact of targeted and tailored interventions on colorectal cancer screening. *Cancer.* 2007; 110(9):2083–2091. [PubMed: 17893869]
35. Zhu JDJ, Taira DA. Screening rates and characteristics of health plan members who respond to screening reminders. *Prev Chronic Dis.* 2006; 3(2):A56. [PubMed: 16539797]
36. Lang K, Lines LM, Lee DW, Korn JR, Earle CC, Menzin J. Lifetime and treatment-phase costs associated with colorectal cancer: evidence from SEER-Medicare data. *Clin Gastroenterol Hepatol.* 2009; 7(2):198–204. [PubMed: 18849013]

Figure 1.
Sampling Flowchart

Figure 2.**FIT Group Screening Rates**

* Study team physician called all ineligible subjects to discuss their personal/family medical history or current symptoms and arrange for follow-up as appropriate; a note was also entered into the electronic medical record. Seven of these 34 subjects returned a FIT (2 with potential symptoms and 5 with personal/family histories that may warrant surveillance with colonoscopy) despite instructions not to do so.

Table 1

Demographic Comparisons by Group for Full Sample and for Eligible Respondents Only.

Variable	FTT n=500	Education n=499	Usual Care n=500	P value
<u>Full Sample</u> % (n)*				
Age, mean (SD)	59.1 (4.3)	58.7 (4.3)	60.1 (4.0)	<.001**
Male	87% (435)	84% (421)	99% (493)	<.001**
Rural or Highly Rural ^a	50% (249)	51% (252)	51% (256)	.92
Service Connected Disability ^b	37% (185)	39% (196)	43% (214)	.17
<u>All Respondents</u> n=105		n=69		
Eligible	67% (71)	59% (41)	NA	.76
<u>Eligible Respondents Completing Survey</u> n=60		n=41		
Age, mean (SD)	60.1 (4.4)	58.9 (4.2)	--	.19
Male	87% (52)	83% (34)	--	.60
Rural or Highly Rural ^a	42% (25)	56% (23)	--	.15
Service Connected Disability ^b	43% (26)	32% (13)	--	.24
Good Current Health ^c	75% (45)	73% (30)	--	.84
White	95% (57)	95% (39)	--	1.00 [†]
Some college education or more ^d	58% (35)	71% (29)	--	.20
Lives alone	32% (19)	32% (13)	--	1.00
Married or has a partner ^e	60% (36)	59% (24)	--	.88
Has someone to take him/her to health care appointments	93% (56)	98% (39)	--	.65 [†]
Other health care coverage in past year			--	
Private individual plan	7% (4)	15% (6)	--	.31 [†]
Private employer-sponsored plan	30% (18)	34% (14)	--	.66
Military-related plan (eg, Tricare/CHAMPUS, CHAMPVA)	5% (3)	7% (3)	--	.68 [†]

Variable	FIT	Education	Usual Care	P value
Medicaid	3% (2)	2% (1)	--	1.00 [†]
Medicare	8% (5)	5% (2)	--	.70 [†]
Sees both VA & non-VA primary care providers	29% (17)	54% (22)	--	.01

* Percent and number are presented for each variable unless otherwise specified.

** Tukey's test for multiple comparisons indicated the Usual Care group differed from the FIT & Education groups.

[†] Fisher's exact tests used instead of chi-square tests due to small cell sizes.

^a Rurality defined according to the VA Urban/Rural/Highly Rural Classification; *urban* areas: those with census tracts belonging to Urbanized Areas, *highly rural* areas: counties with average population density < 7 residents per square mile, and *rural* areas: everything else.²⁸

^b Percentages for Service Connection ranged from 10% to 100%. There were no significant differences among groups in mean Service Connection.

^c Participants who self-reported that their current health was good, very good, or excellent were categorized as "healthy."

^d Participants who answered that their highest level of education was "some college or technical school," "Technical school graduate or Associates Degree," or "College graduate (bachelor's degree) or higher" were grouped together.

^e Participants who answered they currently had a partner or were married. Participants may have answered "Partnered/Married" and also have answered that they live alone.

Table 2

Method of Colorectal Cancer Screening Within 6 Months of Mailing Intervention by Study Group for Full Sample and for Eligible Respondents Only.

Screening Type*	FIT % (n)	Education % (n)	Usual Care % (n)	P value
<u>Full Sample</u>	n=500	n=499	n=500	
No screening performed	79% (397)	94% (471)	94% (472)	
Fecal Immunochemical Test (FIT)	14% (71)	0% (0)	0% (0)	
Colonoscopy	6% (30)	5% (27)	4% (21)	
Guaiac FOBT (gFOBT)	0% (2)	0% (1)	1% (7)	
Total Screened (any method)	21% (103)	6% (28)	6% (28)	< .0001
<u>Eligible Respondents Only</u>	n=71	n=41		
No Screening performed	8% (6)	98% (40)	--	
Fecal Immunochemical Test (FIT)	90% (64)	0% (0)	--	
Colonoscopy	2% (1)	2% (2)	--	
Guaiac FOBT (gFOBT)	0% (0)	0% (0)	--	
Total Screened (any method)	92% (65)	2% (2)	--	<.0001

* Screening was classified according to the first test performed in the 6-month follow-up period.

Table 3
Colorectal Screening Rates (any method) by Study Group, Rurality and Gender for the Full Sample and for Eligible Respondents Only.

	FTT	Education	Usual Care	FTT	Education	Usual Care
By Rurality*						
		Rural			Urban	
Full Sample, n	249	252	256	250	245	244
Total Screened, % (n)	23% (57)	5% (13)	5% (14)	18% (45)	6% (15)	6% (14)
Eligible Respondents, n	28	23	--	36	18	--
Total Screened, % (n)	93% (26)	9% (2)		89% (32)	0% (0)	
By Gender*						
		Female			Male	
Full Sample, n	65	78	7	435	421	493
Total Screened, % (n)	26% (17)	6% (5)	14% (1)	20% (86)	5% (23)	5% (27)
Eligible Respondents, n	9	7	--	56	34	--
Total Screened, % (n)	100% (9)	0% (0)		89% (50)	6% (2)	

* Chi-square and Fisher's exact tests used to compare screening rates. All tests comparing rural to urban screening rates and male to female screening rates were non-significant ($P > .05$); All tests comparing screening rates across study groups within strata were significant at $P < .001$ level. One FTT participant and 2 Education participants were unable to be categorized as either Rural or Urban.

Table 4

Results of Colorectal Cancer Screening Tests Received by the Full Sample During the 6-Month Period Following Mailing Intervention.

	FIT n=500	Ed n=499	UC n=500
<u>First CRC Test received</u>	n=103	n=28	n=28
FIT	n=71 *	n=0	n=0
Negative	86% (61)	--	--
Positive	14% (10)	--	--
gFOBT	n=2	n=1	n=7
Negative	50% (1)	0% (0)	100% (7)
Positive	50% (1)	100% (1)	0% (0)
Colonoscopy	n=30	n=27	n=21
No polyps detected ^a	53% (16)	30% (8)	48% (10)
Non-cancerous ^b polyps only detected	17% (5)	26% (7)	5% (1)
Pre-cancerous ^c polyps detected	30% (9)	44% (12)	43% (9)
Unknown type of polyp (poor prep)	0% (0)	0% (0)	5% (1)
No screening performed	n=397	n=471	n=472
<u>Follow-up for all with positive FIT or FOBT</u>	n=11	n=1	n=0
Colonoscopy	n=8	n=1	n=0
No polyps detected ^a	63% (5)	0% (0)	0% (0)
Non-cancerous ^b polyps only detected	0% (0)	100% (1)	0% (0)
Pre-cancerous ^c polyps detected	38% (3)	0% (0)	0% (0)
No follow-up colonoscopy performed	n=3 **	n=0	n=0

* Results based on the full sample, which included 7 subjects who were ineligible due to symptoms or personal/family medical history but returned FIT; 2 received positive results.

** Two subjects had terminal conditions with limited life expectancies and one subject refused.

¹ Hemorrhoids or diverticulosis were often found among those with no polyps.

² Includes hyperplastic polyps, squamous papillomas and lymphoid aggregate polyps.

³ All subjects in this category had tubular adenomas; 1 subject in the FIT group and 1 subject in the Ed group also had tubulovillous adenomas.

Table 5

Reasons Endorsed by Eligible Respondents* for Not Having Sought Colonoscopy or At-Home Tests (gFOBT/FIT).

Reasons for not having test	Did not seek a Colonoscopy ^a		Did not take an At-Home Test ^b	
	N Responses	N (%)Endorsing Each Item ^c	N Responses	N (%)Endorsing Each Item ^c
Asked in relation to both colonoscopy & at-home tests				
Colorectal cancer screening options are confusing	40	14 (42%)	82	14 (17%)
Screening is too embarrassing	41	10 (26%)	83	11 (13%)
My health care provider did not recommend it	41	15 (26%)	85	53 (62%)
I was afraid	34	9 (24%)	81	4 (5%)
I did not know how to prepare for the test	41	8 (21%)	82	5 (6%)
I was too busy	41	8 (18%)	81	9 (11%)
I am very low risk for colorectal cancer	41	7 (15%)	81	18 (22%)
It takes too much time	41	6 (12%)	82	1 (1%)
The VA Medical Center is too far	40	5 (12%)	83	9 (11%)
I had another type of screening	40	5 (4%)	83	46 (55%)
Asked only in relation to colonoscopy				
I thought it would be painful	41	16 (41%)	--	--
I prefer to take an a-home test	41	14 (35%)	--	--
I did not have transportation	41	7 (18%)	--	--
The screening is too difficult to schedule	41	5 (12%)	--	--
Asked only in relation to at-home tests				
I prefer to take a colonoscopy ^d	--	--	81	13 (16%)

* Combined results for both eligible FIT and Ed group participants.

^a Includes all those who indicated on the survey they did not have a colonoscopy within past 10 years. There were 28 eligible FIT participants and 15 eligible Ed participants.

^b Includes all those who indicated on the survey they did not take an at-home test in the past year. There were 52 eligible FIT participants and 34 eligible Ed participants.

^c Percentages represent participants who endorsed "agree" or "strongly agree."

^d There was a statistically significant difference between subjects in the FIT and Ed groups; 10 out of 33 subjects (30%) in the Ed group endorsed this reason compared to 3 out of 48 subjects (6%) in the FIT group, $P = .005$.