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Comparative effectiveness of mailed reminders with and without fecal immunochemical tests for Medicaid beneficiaries at a large county health department: A randomized controlled trial

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Abstract

Background: Colorectal cancer (CRC) screening is effective but underutilized. Screening rates among Medicaid beneficiaries are lower than for other insured populations. No studies have examined a mailed fecal immunochemical testing (FIT)-based outreach programs for Medicaid beneficiaries.

Methods: We conducted a patient-level randomized controlled trial comparing a mailed CRC screening reminder with and without a FIT from an urban health department to Medicaid beneficiaries. The Reminder Group could request a FIT. Completed FITs were processed by the health department lab. Respondents were notified of normal results by mail. Abnormal results were given via phone from a patient navigator who provided counselling and assistance with follow-up care. The primary outcome was FIT return.

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Results: We identified 2,144 beneficiaries at average CRC risk and no evidence of screening using Medicaid claims data. We randomized 1,071 to the Reminder+FIT Group and 1,073 to the Reminder Group, of whom 307 (28.7%) in the Reminder+FIT Group and 347 (32.3%) in the Reminder Group were unreachable or ineligible (previous screening). FIT return was significantly higher in the Reminder+FIT Group than the Reminder Group (21.1% vs 12.3%; difference 8.8%; 95% CI 3.7%, 13.9%; $p < 0.01$). Eighteen (7.2%) individuals who completed FIT tests had abnormal results, and 15 were eligible for follow-up colonoscopy; 66.7% (10) completed a follow-up colonoscopy.

Conclusions: A health department-based mailed FIT program targeting Medicaid beneficiaries was feasible. Including a FIT kit resulted in greater screening completion than a reminder letter alone. Further research is needed to understand comparative cost-effectiveness of these interventions.

Condensed Abstract:

A feasible patient-level randomized controlled trial was conducted to compare a mailed CRC screening reminder with and without a FIT kit in an urban health department. The results indicate including a FIT kit resulted in greater screening completion than a reminder letter alone.

Introduction

Despite its well-proven efficacy, colorectal cancer (CRC) screening is underutilized, particularly in vulnerable populations. CRC is the third most common cancer diagnosis and the second leading cause of cancer death in the United States.¹ Screening is effective in reducing CRC incidence and mortality.² Although CRC screening has increased in the past two decades, CRC screening rates remain modest, with less than two thirds of age-eligible adults in the United States up-to-date with screening and 68% of age-eligible adults in North Carolina up-to-date.^{3,4} The United States Preventive Services Task Force recommends several stand-alone tests to screen for CRC, including colonoscopy and fecal blood tests such as fecal immunochemical testing (FIT).⁵ The population-level benefit of screening in terms of cancer mortality reduction depends on widespread participation in CRC screening programs.⁶ Vulnerable populations have particularly low CRC screening rates, with Medicaid beneficiaries having the lowest rates of CRC testing (<50%) compared with other insured populations.^{3,7-10} Increasing CRC screening among vulnerable populations will be crucial to reach the Healthy People 2020 and National Colorectal Cancer Roundtable goals of having 70.5–80% of the age-eligible population up-to-date with CRC screening.^{11,12}

The CDC Community Guide to Preventive Services recognizes several effective and cost-effective means of increasing CRC screening, including interventions to decrease structural barriers (such as mailed, at-home stool testing).¹³ FIT-based outreach programs have shown promise as an effective means of increasing screening use, including for vulnerable populations. Gupta, et al., found that a mailed FIT-based outreach program could increase screening by nearly 30 percentage points among vulnerable patients in a safety-net system in Texas.¹⁴ Several other studies have found mailed fecal testing programs to be effective in increasing screening rates in insured populations¹⁴⁻¹⁷; however, to date, such programs have not been implemented and tested specifically in Medicaid populations.

The Medicaid program in North Carolina is unique in that beneficiaries are proactively connected to Community Care of North Carolina (CCNC), an innovative medical home model which coordinates care through regional public-private networks. Each CCNC patient is enrolled with a primary care physician who leads a larger multidisciplinary healthcare team tasked with managing and navigating the patient through the complex healthcare environment.¹⁸ CCNC has been heralded as a national model for care coordination, and independent evaluations of CCNC have shown significant improvements in Medicaid beneficiaries' outcomes and nearly a billion dollars in cost-savings.¹⁹ CRC screening is an important quality indicator for healthcare organizations like CCNC and therefore a compelling focus for a mailed FIT demonstration project.²⁰

Challenges remain in implementing programs of mailed FIT screening broadly. While the effectiveness of mailed FIT-based screening programs has been demonstrated within organized health systems^{14,17,21}, a large proportion of unscreened individuals are not enrolled in such systems, and may not even have a regular source of care. Further, safety-net health systems, where a large portion of Medicaid beneficiaries receive care, often lack resources for robust outreach programs such as this one. State and local health departments, which serve as safety-net providers for many patients, are increasingly interested in the prevention and control of non-communicable diseases as these are the leading causes of morbidity and mortality in our society. Public health departments may be an untapped resource for community outreach for preventive care delivery but, to date, no pragmatic trials have tested the effectiveness of FIT-based outreach programs based in a county health department.

Further, trials testing mailed FIT outreach programs have compared against usual care; it is not known whether it is more effective to proactively include FITs with a reminder letter or whether a simple reminder letter with clear instructions for accessing FIT might be similarly effective. We report here the comparative effectiveness of two mailed screening strategies in Medicaid beneficiaries in one populous metropolitan county in North Carolina with a large public health department.

Methods

Study Design and Setting

We conducted a randomized trial comparing two strategies designed to increase CRC screening through outreach from a large county health department to Medicaid beneficiaries. The first group (Reminder+FIT Group) received a packet including a letter encouraging screening completion and a FIT kit with instructions for completion. The second group (Reminder Group) received the same letter described above and instructions for obtaining a FIT kit from the health department either in person or by mail. All participants who returned a completed FIT were notified of their results either by mail or by phone, and those with abnormal (positive) FIT results additionally received navigation to follow-up care from local Medicaid care coordinators. The study protocol was registered at [ClinicalTrials.gov](https://clinicaltrials.gov) on June 2017. This study was exempt from Institutional Review Board approval at the University of North Carolina at Chapel Hill. Data were collected between October 2016 and December 2017.

Recruitment and Enrollment

We identified the recipient cohort through Medicaid enrollment and claims data. We focused on a large urban county, Mecklenburg, that was identified in prior claims-based analyses as having among the lowest rates of CRC testing among Medicaid beneficiaries in the state of North Carolina (i.e., approximately 40% tested for CRC in the absence of intervention, relative to other counties with testing rates as high as 82%).¹⁰ Eligible participants were those: 1) currently enrolled in Medicaid and the Medicaid CCNC program (thus, with a PCP on record) 2) with primary residence in Mecklenburg County, NC (which contains Charlotte); 3) no history of CRC, total colectomy, or major mental illness; 4) no record of recent CRC screening (FOBT within 12 months, colonoscopy within 5 years, sigmoidoscopy within 5 years, barium enema within 5 years, CT colonography within 5 years); and 5) aged 52–64 years. Because the Medicaid claims database retained only 5 years of historical data, we were unable to know the full 10-year history of colonoscopy or CT colonography. Additionally, we were unable to verify the beneficiary mailing addresses prior to the initial mailings. Recipients of the initial mailing were allowed to update screening history, address, and primary care provider information, or opt-out of the program, by returning a health information form.

Study Activities and Randomization

The recipient cohort was randomly assigned (1:1) to the Reminder+FIT Group or the Reminder Group using a computer-generated randomization scheme. The Reminder+FIT Group received a packet containing: 1) a letter notifying the recipient that according to our records, he or she may not be up-to-date with CRC screening and encouraging screening completion; 2) a health information form to indicate prior screening or to opt out of the screening outreach program 3) a Polymedco OC-Light® 1 sample FIT Kit with instructions for completion; and 4) a pre-paid mailer to return the FIT to the health department's lab for processing. The Reminder Group received a packet containing: 1) a letter notifying the recipient that according to our records, he or she may not be up-to-date with CRC screening and encouraging screening completion; 2) a health information form to indicate prior screening or to opt out of the screening outreach program; and 3) instructions for obtaining a Polymedco OC-Light® 1 sample FIT kit (via request on the postage paid health information form or by a telephone call or in-person visit to the Health Department lab). Mailings, reminder phone calls, and FIT kit receipt and processing were conducted by Health Department staff and other county employees and interns. All printed study materials were sent in both English and Spanish. Study team members had access to an interpreter for all reminder calls. For pragmatic reasons, initial mailings took place in four waves between November 2016 and January 2017.

Two reminder letters were sent at approximately 4 and 6 weeks after the initial mailing to recipients with valid addresses who did not respond to the initial mailing. Reminder phone calls were made at approximately two-week intervals after reminder letters were mailed. Participants were able to request up to 2 additional FIT kits. For pragmatic reasons (staff time and cost), we did not make any additional attempt to contact beneficiaries with invalid addresses. Completed FIT kits were returned to the Health Department lab. Staff at the lab

processed the kits manually, according to manufacturer instructions. A claim for all returned FIT kits was sent to Medicaid.

For participants with negative results, the health department sent letters notifying participants and the PCP practice of the test results. For participants with positive results, a patient navigator from CCNC was notified and tasked with calling FIT-positive participants to schedule and complete follow-up colonoscopy. The PCP practice was notified and additionally informed that the patient would receive navigation assistance to ensure that a follow-up colonoscopy was completed. Importantly, CCNC navigators were already in place to ensure smooth transitions to follow-up colonoscopy and other care. The navigator initiated contact with patients with abnormal test results within 1 week. An interpreter was available for Spanish-speaking patients. The Navigator made at least 3 attempts to reach each patient by phone. If the patient was deemed unreachable, a certified letter was mailed to ensure that the patient was notified of the positive test results. The Navigator assisted the patient in overcoming barriers to completing the diagnostic colonoscopy, including, but not limited to, assistance with scheduling and paperwork, financial barriers, identifying transportation resources, and education about colon preparation.

Outcome Measures

The primary outcome of interest was the proportion of eligible participants completing the mailed FIT kit within 12 months (assessed in October and December 2017), measured using returned FIT data in the study database. We conducted a secondary analysis among participants who completed FIT screening to assess the proportion who had abnormal (positive) FIT results and to describe the proportion of positives who scheduled and completed follow-up colonoscopy. Completion of follow-up colonoscopy was assessed through confirmation in the electronic health record, recorded by the patient navigator in the study database.

Statistical Analysis

We used a modified intention-to-treat approach; all identified Medicaid beneficiaries were randomized, but those who either never received the intervention due to bad addresses or those found to be ineligible (Figure 1) were excluded from analysis. We estimated the overall difference in proportion screened between the two groups using a Pearson's chi-squared test. Bivariate log-binomial regression, which estimates risk ratios (RRs), was used to estimate crude RRs and 95% confidence intervals (CIs) comparing the proportion screened between the groups. As an exploratory analysis, we conducted subgroup analyses to examine whether the effectiveness of the mailed FIT intervention differed by sex and age at randomization. In a sensitivity analysis, we reproduced the above FIT completion estimates using a standard intention-to-treat analysis, comprised of all randomized participants prior to exclusions, to assess the robustness of the primary results to different analytical approaches. All analyses were performed using SAS 9.4 (SAS Institute, Cary, NC).

RESULTS

Participants

We identified 2,144 Medicaid beneficiaries who had no evidence of being up-to-date with CRC screening. We randomized 1,071 individuals to the Reminder+FIT Group and 1,073 to the Reminder Group. In the Reminder+FIT Group, 307 (28.7%) individuals were excluded from the analysis, compared to 347 (32.3%) in the Reminder Group. The most common reasons for exclusion were bad address (17.5% Reminder+FIT Group vs. 20.7% Reminder Group) and self-report of being up-to-date with screening (10.1% Reminder+FIT Group vs. 11.0% Reminder Group). Among those reporting screening, three quarters reported colonoscopy within the past 10 years. Figure 1 provides a detailed view of the progression of randomized individuals through the various eligibility criteria.

Among eligible participants, no differences were observed between the Reminder+FIT Group and Reminder Group in terms of either the age or sex distributions. The mean (standard deviation) age at baseline was 57.6 (3.6) years in the intervention arm and 57.5 (3.5) years in the control arm. Excluded participants were characteristically similar to those who were included. As a result, selection bias introduced by the exclusion criteria was not a major concern. See Table 1.

Proportion Screened

The proportion of recipients who returned a completed FIT test (Table 2) was statistically significantly higher in the Reminder+FIT Group than in the Reminder Group (21.1% vs 12.3%; difference 8.8%; 95% CI 3.7%, 13.9%; $p<0.001$). We found that those that received a FIT kit in the initial mailing were 1.72 times as likely to complete a FIT than those who received the reminder alone (95% CI, 1.35, 2.18; $p<0.01$).

The mailed FIT intervention (Figure 2) was slightly more effective among males (adjusted RR, 2.06; 95% CI, 1.44, 2.94) than females (adjusted RR, 1.47; 95% CI, 1.07, 2.03), but the interaction was not statistically significant (interaction $p=0.17$). There was no evidence of interaction with treatment assignment in age subgroups.

In sensitivity analysis, we observed similar FIT completion trends when using a standard intention-to-treat approach conducted in the full randomized population (Appendix Table 1). In this analysis, we identified twenty additional participants who returned a completed FIT but had been previously excluded from the primary analysis due to self-reported prior screening. As expected, the proportion of recipients who returned a completed FIT test was reduced in both groups but was still significantly higher in the Reminder+FIT Group (16.5% vs 8.7%; difference 7.9%; 95% CI 3.7%, 12.1%; $p<0.001$). The adjusted RR for FIT completion increased to 1.90 (95% CI, 1.50, 2.41; $p<0.01$). We observed a corresponding increase in subgroup RRs for FIT completion, but subgroup trends remained consistent (Appendix Figure 1).

Follow-up Colonoscopy

Eighteen (7.2% of modified ITT) individuals who completed FIT tests across both arms had abnormal (positive) test results. Three participants were ineligible for follow-up colonoscopy due to death (one participant) or significant co-morbidity due to other cancers (two participants). Of the remaining 15 individuals with abnormal FITs, 10 (66.7%) participants with positive FIT tests scheduled follow-up colonoscopy; all scheduled colonoscopies were completed. Reasons reported for not scheduling follow-up colonoscopy included 1) inability to reach participant (three participants); 2) participant refused follow-up (one participant); and 3) participant waiting for medical transportation (one participant). Of the colonoscopies that were completed, nine reported normal results (no polyps, hyperplastic polyps only, or 1–2 tubular adenomas of <1cm) and one reported abnormal result (3–10 adenomas, adenomas of ≥1cm, villous histology or high-grade dysplasia). Participants were pooled across intervention status because they all received the same navigation services and because the proportion of scheduled and completed colonoscopies was comparable between the two groups.

DISCUSSION

We report the results of a comparative effectiveness trial, targeted at Medicaid beneficiaries in need of CRC screening. We compared two mailed outreach programs that included a CRC screening reminder letter with or without an included FIT kit, mailed from, and processed by, a large county health department. We found that including a FIT kit in the initial mailing resulted in an 8.8 percentage point increase in screening completion compared to a reminder letter alone. After adjusting for age and sex, we estimate that those receiving a FIT kit in the initial mailing were 1.72 times as likely to complete a FIT than those who received a reminder letter alone. The intervention was effective across age and sex subgroups and appears to be somewhat more effective in men than women; this is an important finding, as men tend to be less often up-to-date with CRC recommendations compared to women.³

Our results provide additional context for the growing body of literature supporting the effectiveness of mailed outreach campaigns that include home stool blood tests for CRC screening. Such mailed outreach campaigns have almost universally shown increases in screening completion rates, but the magnitude of effect has been variable. Implementation context may be a key factor contributing to the variability. Previous studies or demonstration projects using mailed FITs have nearly all been based in clinical settings. In a rural Veteran's Administration hospital, Charlton and colleagues²² implemented a similar intervention to ours, comparing CRC education alone with education plus an included FIT kit. This intervention yielded a 21% response in the FIT group, compared with 6% in the education only group. Singal¹⁵ and Gupta¹⁴ have reported on similar FIT outreach programs targeting uninsured, charity care-enrolled patients of two integrated Federally Qualified Health Center systems, each observing a 29 percentage-point improvement in screening completion over usual care. One community pharmacy based study compared, in a time-block randomized controlled trial, pairing FIT distribution vs CRC screening educational materials with seasonal flu shots. They found that 59.3% of those in the FIT arm, compared with 14.8% in the education arm, went on to complete screening.²³

When layering on additional interventions, response to mailed FIT approaches tends to increase, but it is not clear whether additional interventions are cost-effective. Patient navigation, for example, has been layered on top of outreach approaches. Baker and colleagues, for example, intervened in a group of community health centers, mailing FIT kits and providing two additional automated reminder phone calls and one personal telephone outreach by a CRC screening navigator for those who did not initially respond. This intervention produced a substantial 44.9 percentage point increase in screening. However, nearly half of the response occurred before any additional patient navigation was delivered. Additionally, Green conducted a stepped patient support intervention, looking at the incremental effectiveness of layering automated reminders, telephone support, and nurse navigation on top of a centralized mailed stool test. Green found that each additional intervention produced a somewhat greater response (usual care, 26.3%; automated, 50.8%; assisted 57.5%; navigated 64.7%), but also somewhat greater cost per participant screened (\$21 (automated) to \$27 (navigated)).²⁴

This is the first study, to our knowledge, to test a population-based, mailed FIT program using a county health department. Our response rate was slightly lower than other mailed stool test outreach programs. One possible explanation of this difference is that existing studies of mailed FIT are focused on individuals engaged in a clinical setting or medical home. Previous research has shown that greater trust in medical care provider is associated with CRC screening completion.²⁵ In the context of an intervention situated in an urban community health center network,²⁶ patients who reported a higher level of trust in their primary care providers were more likely to complete screening. County residents may not have ever sought services at the health department and may not, therefore, perceive the health department as being a provider of care. However, this study is a population-based intervention among individuals in the state Medicaid program who may not have a source of medical care or medical home at all. This may result from barriers to engaging in medical or preventive care activities (i.e. disabilities), stigma or bias in the health care system, or individual attitudes of mistrust or cynicism about traditional medical care.

FIT campaigns are promising, particularly in vulnerable populations, but additional work is needed to understand how to sustain FIT adherence over time. It is known that providing FIT as an option for CRC screening, either exclusively or along with colonoscopy, increases screening completion.^{26,27} However, FIT, as recommended, must be complete annually.²⁸ Previous studies have shown that adherence to FIT may diminish over time. Even with continued intervention, studies have shown moderate²⁹ to substantial³⁰ attenuation of intervention effect. When removing the intervention entirely, screening rates have been shown to revert to pre-intervention rates.³¹ Further study is needed to determine if a population-based intervention such as ours should focus only on follow-up of current participants, or continue to try to engage additional individuals who did not participate in the initial invitation.

Another important potential lesson for FIT campaigns is the challenge of ensuring continuation to follow-up colonoscopy for those with abnormal results. We were able to provide individual patient navigation for our participants with abnormal results. Our aggressive follow-up protocol in which a trained patient navigator made at least 31 phone

call attempts, four mailed attempts (certified mail) and engaged the patients primary care provider when possible, resulted in 66.7% (n=10) of our participants with abnormal results completing a colonoscopy. This is consistent with outreach and navigation attempts in other settings. Oluloro and colleagues reported a 57% rate of follow-up colonoscopy within 18 months of an abnormal FIT in a vulnerable patient population.³² Understanding how best to address this gap is critical for the future success of FIT-based screening campaigns.

Our study has limitations. First, our initially identified and randomized cohort had a somewhat large number of beneficiaries who were either ineligible or unreachable. This occurred for two primary reasons: 1) the NC Medicaid claims database only retains 5 years of historical data, meaning that colonoscopies completed outside of that window were not findable; 2) Medicaid populations tend to be fairly transient and NC Medicaid registration data, including mailing address and phone number, is not continually verified, meaning that many addresses were inaccurate. Because we randomized the cohort prior to sending out the mailings, there were a large number of post-randomization exclusions. However, the number of post-randomization exclusions was not different across groups and the remaining recipients were not measurably different. Second, the Mecklenburg County Health Department is much larger and better resourced than many other health departments. Another health department may not have the capacity to manage all aspects of a similar program, such as internal lab processing of FIT kits. Finally, we may not have allowed a long enough period of time to observe completion of follow-up colonoscopy among participants with abnormal FIT results, thus potentially missing some completed tests. This would, however, bias our results toward the null. Additionally, we are currently completing a query of NC Medicaid claims data, in which we will have a full 12 months of follow-up.

Our study also has strengths. First, we were able to target the entire population of Medicaid beneficiaries enrolled in the care management network in one county. Second, our partnership with the local health department was a novel method of expanding the medical neighborhood. We determined that it is feasible to deliver CRC screening services outside of a traditional primary care environment. Finally, our FIT-to-colonoscopy navigation program was built on an existing care management program, illustrating a potential model for this critical component of a FIT-based CRC screening program that may be sustainable.

Conclusions

A mailed FIT-based outreach campaign targeted at Medicaid beneficiaries and based in a large county health department is feasible and effective. Beneficiaries receiving a FIT kit in the initial mailing were 1.72 times as likely to complete a FIT than those receiving a reminder letter alone, with slightly more uptake among men, a traditionally hard-to-reach population for CRC screening. Future analyses will reveal whether including a FIT in the initial mailing is more cost-effective than providing a method for requesting a FIT kit.

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Appendix

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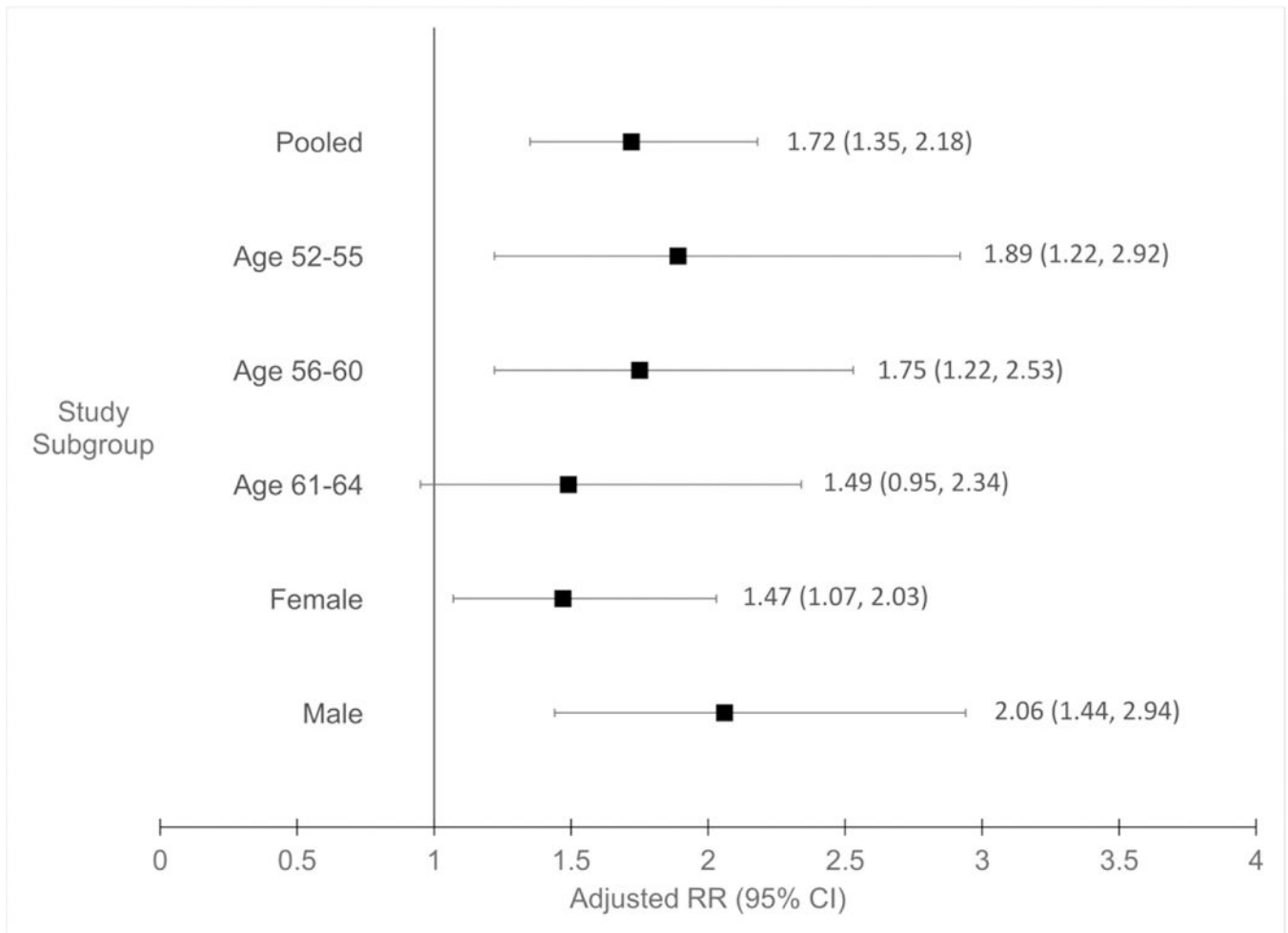
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Appendix Figure 1.
Comparative Effectiveness of Mailed Reminder (Reminder + FIT vs. Reminder Only), by Study Subgroup, Standard Intention-to-Treat Analysis

Appendix Table 1.

Proportion Screened among Participants Randomized to Mailed Reminders ± FIT Test Kit, Pooled and by Study Subgroup, Standard Intention-to-Treat Analysis

	Reminder + FIT Screened/Total (%)	Reminder Only Screened/Total (%)	Crude RR* (95% CI)
Proportion Screened	177/1071 (16.5)	93/1073 (8.7)	1.91 (1.51, 2.42)
Age			
52-55	58/349 (16.6)	27/360 (7.5)	
56-60	71/430 (16.5)	41/463 (8.9)	
61-64	48/292 (16.4)	25/250 (10.0)	
Gender			

	Reminder + FIT Screened/Total (%)	Reminder Only Screened/Total (%)	Crude RR* (95% CI)
Proportion Screened	177/1071 (16.5)	93/1073 (8.7)	1.91 (1.51, 2.42)
Female	90/556 (16.2)	54/563 (9.6)	
Male	87/515 (16.9)	39/510 (7.6)	

* Note: RR = risk ratio

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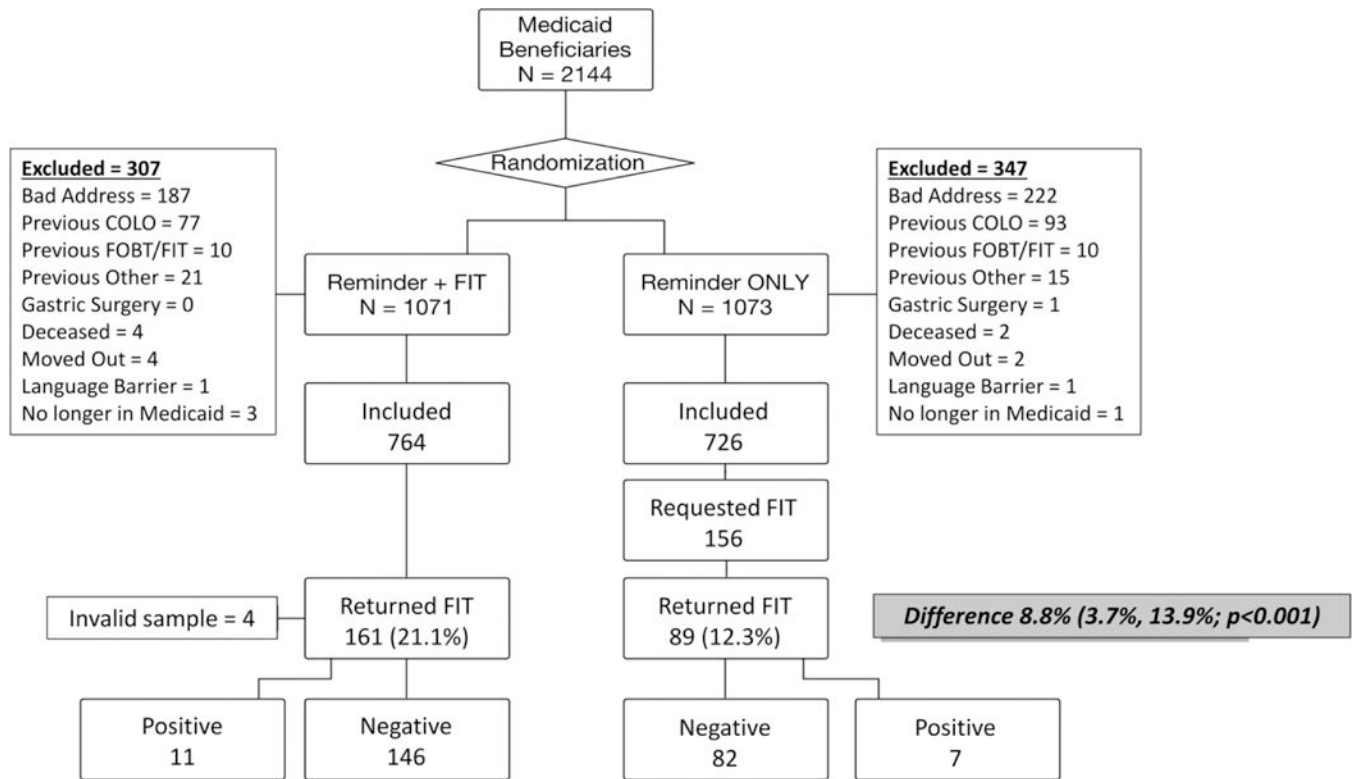


Figure 1.
Study Population Flow Chart

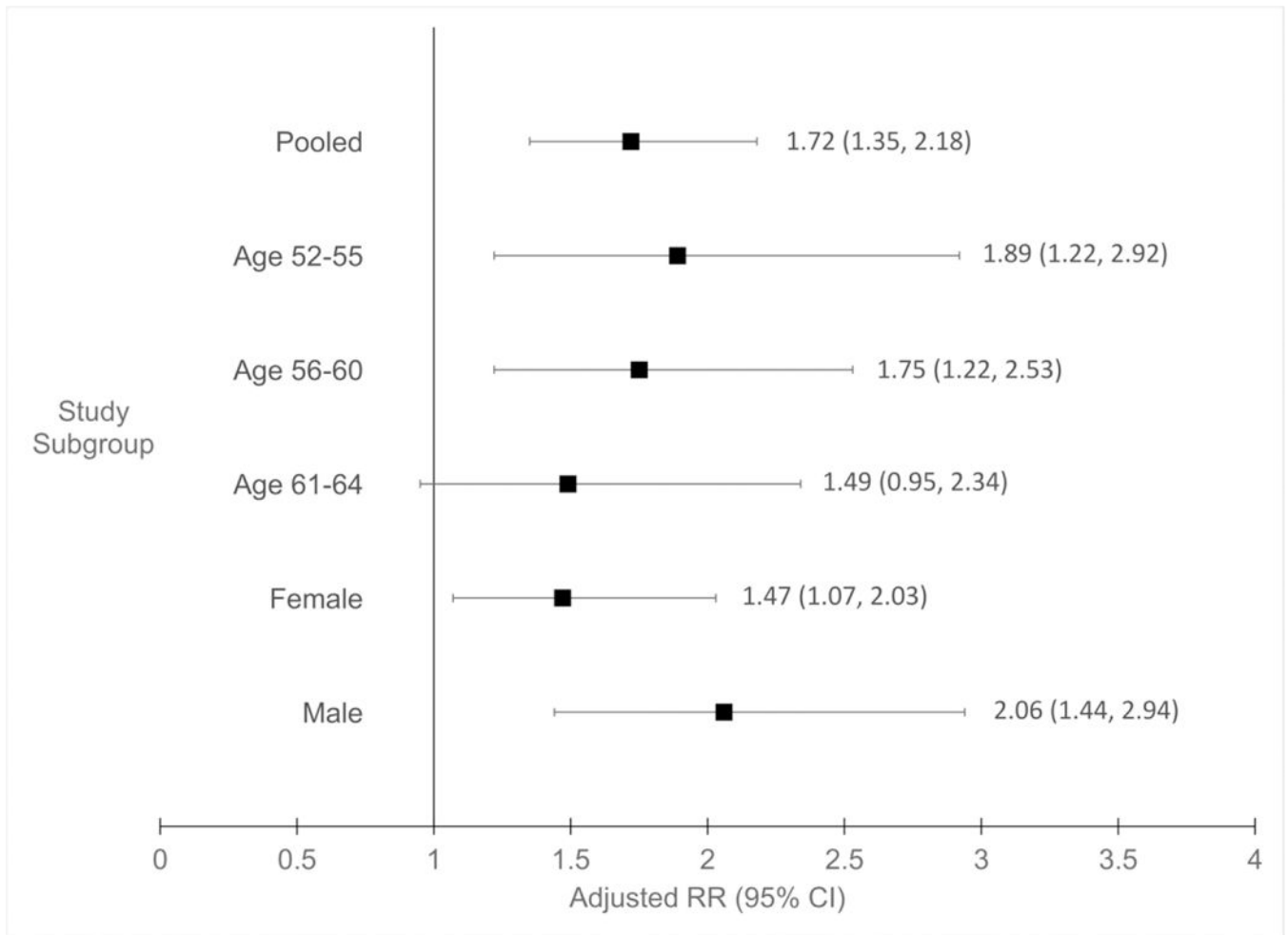


Figure 2. Comparative Effectiveness of Mailed Reminder (Reminder + FIT vs. Reminder Only), by Study Subgroup, Modified Intention-to-Treat Analysis

Table 1.

Characteristics of Participants Randomized to Mailed Reminders ± FIT Test Kit

Characteristic	Reminder + FIT		Reminder Only	
	Included in Analysis N=764 n (%)	Excluded from Analysis N=307 n (%)	Included in Analysis N=726 n (%)	Excluded from Analysis N=347 n (%)
Age mean (sd)	57.6 (3.6)	58.0 (3.4)	57.5 (3.5)	57.4 (3.4)
52–55	260 (34.0)	89 (29.0)	245 (33.7)	115 (33.1)
56–60	304 (39.8)	126 (41.0)	307 (42.3)	156 (45.0)
61–64	200 (26.2)	92 (30.0)	174 (24.0)	76 (21.9)
Sex				
Female	388 (50.8)	168 (54.7)	382 (52.6)	181 (52.2)
Male	376 (49.2)	139 (45.3)	344 (47.4)	166 (47.8)

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Table 2.

Proportion Screened among Participants Randomized to Mailed Reminders ± FIT Test Kit, Pooled and by Study Subgroup, Modified Intention-to-Treat Analysis

	Reminder + FIT Screened/Total (%)	Reminder Only Screened/Total (%)	Crude RR* (95% CI)
Proportion Screened	161/764 (21.1)	89/726 (12.3)	1.72 (1.35, 2.18)
Age			
52–55	52/260 (20.0)	26/245 (10.6)	
56–60	66/304 (21.7)	38/307 (12.4)	
61–64	43/200 (21.5)	25/174 (14.4)	
Gender			
Female	78/388 (20.1)	52/382 (13.6)	
Male	83/376 (22.1)	37/344 (10.8)	

*Note: RR = risk ratio

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