Title

Increased Colorectal Cancer Screening Sustained with Mailed Fecal Immunochemical Test Outreach

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Organized Mailed Fecal Immunochemical Test Outreach on Adherence to Colorectal Cancer Screening Over Time: A Randomized Controlled Trial

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Abstract

Background:
Despite the effectiveness of mailed fecal immunochemical test (FIT) outreach in improving colorectal cancer (CRC) screening, use of mailed outreach in safety-net health systems and reports of its effectiveness over time among those without prior FIT testing are limited.

Methods:
Patients in a safety-net health setting aged 50-75 years who were not up to date (UTD) with CRC screening were randomly assigned to outreach intervention or usual care. The intervention arm received an advanced notification call and informational postcard prior to the mailed FIT. Usual care was at the discretion of the primary care provider and care team. Patients were followed for up to 2.5 years. The primary outcome was the cumulative proportion of patients who completed FIT screening assigned to outreach compared to usual care. Screening was further examined as the proportion of time UTD with FIT screening and as consistent (completed 2 of 2 FITs), intermittent (1 of 2), or non-adherent (0 of 2) with FIT.

Results:
A total of 5,410 patients were randomized to usual care and 5,361 patients were randomized to outreach intervention. The cumulative proportion who completed FIT screening was higher in the outreach intervention (73.2% vs. 55.1%, $p < 0.001$). Similarly, the proportion of time covered by screening was significantly higher in the intervention group (46.8% vs. 27.3%, Δ19.6%, 95% CI 18.2% - 20.9%). Patients assigned to FIT outreach were more likely to consistently complete a FIT (50.1% vs. 21.8%, $p < 0.001$), were less likely to complete any FIT if they had no prior FIT testing (52.5% vs. 83.9%, $p < 0.001$), and were unlikely to complete the test during the second cycle if they did not complete it during the first cycle (17.8% vs. 37.0%, $p < 0.001$).

Conclusions:
Organized mailed FIT outreach significantly increased CRC screening over multiple years in this safety-net health system. While mailing was effective overall, the results were modest in certain situations (e.g. no history of FIT screening, did not complete FIT in first cycle of intervention).

Introduction

Despite being highly preventable, colorectal cancer (CRC) continues to be a leading cause of cancer deaths,[1,2] especially among low-income and safety-net populations.[3–5] Fecal immunochemical testing (FIT) has been demonstrated to be an effective outreach strategy,[6–8] and increasingly an attractive option in the era of telehealth.[9,10] Already, there has been a significant expansion of telehealth platforms, highlighting the need for alternative solutions to reach patients remotely.[11–13]

Successful FIT screening in the United States entails annual retesting for those with negative results.[1] However, studies assessing FIT outreach often focus on short-term metrics evaluating the completion of CRC screening in a one-time intervention with limited follow-up.[14–20] In addition, studies often do not account for prior FIT testing behavior, which has been shown to strongly predict one-time completion of a mailed FIT.[17]

We conducted a multiyear, randomized mailed FIT intervention in a safety-net health system. Though we previously showed a mailed FIT intervention is effective,[17] there is a lack of studies assessing the difference in FIT participation for patients over time and in certain situations such as a history of FIT completion. Our objective was to use measures of longer-term success to more comprehensively evaluate a mailed FIT program.

Methods

Study Setting and Population

We conducted a multisite study in the San Francisco Health Network (SFHN), a safety-net health system providing services to low-income populations, from 2016 to 2018. The SFHN consists of 12 adult primary care clinics and one specialty medical center, Zuckerberg San Francisco General Hospital (ZSFG). Eight of the clinics allowed patients to be randomly assigned to receive the outreach intervention versus usual care.

Study Intervention

The intervention is described in detail elsewhere[17] but in brief, patients aged 50-75 years who were not UTD with CRC screening were included. Specifically, previously screened patients became eligible 365 days after a previous negative FIT, 5 years after a normal sigmoidoscopy, and 10 years after a normal colonoscopy. Patients were excluded if they were homeless, had an abnormal FIT but no colonoscopy, colectomy, late stage cancer, or other advanced comorbidities. Patients were stratified by clinic, gender, race/ethnicity, and history of FIT; they were then randomly assigned 1:1 to the outreach intervention or usual care. Outreach included mailing an advanced notification postcard and phone call followed by FIT kit mailing, and up to two reminder phone calls if the FIT was not returned after two weeks. Interpreter services were available for all languages. Usual care was at the discretion of providers in the eight participating clinics.

Patients were followed for up to 2.5 years. Assignment to outreach intervention or usual care did not change. Patients were censored for the following reasons: 365 days after an abnormal FIT result, lost to follow up (e.g., no encounter for 2 years, transferred care out of partnering clinic), received colonoscopy, reached an age of 76 years old, or died. Patients were followed until end of study if they continued to meet eligibility criteria outlined above. Patients who were lost to follow-up were assumed to have not completed FIT screening if the patient had not completed screening before being lost to follow-up.

Statistical Analysis

Patient demographic characteristics were summarized by treatment group using proportions and compared using chi-square tests. The primary outcome was an intention-to-screen analysis that included all patients assigned to outreach and usual care, reporting the cumulative FIT completion, which was plotted over time and reported as the proportion of patients who completed at least one FIT. Cumulative FIT completion was also evaluated according to history of prior FIT, based on the presence or absence of any completed FIT preceding study enrollment that was available in the electronic medical records. In addition, the proportion of time covered (PTC) by screening was calculated as number of days UTD with screening divided by number of days from cohort entry until study end or censoring. PTC has

been used to evaluate medication adherence[21,22] and hepatocellular carcinoma screening,[23,24] and more recently CRC screening[25,26] with the advantage of accounting for follow-up time and tests performed outside of screening intervals. We analyzed PTC among those assigned to outreach was compared to usual care stratified by gender, age, race/ethnicity, insurance, primary language, marital status, history of prior FIT, and clinic.

In a secondary analysis, we evaluated longer-term adherence to FIT completion among patients with at least 2 years of follow-up. Adherence was categorized as consistent (completed 2 of 2 expected FITs), intermittent (1 of 2), or non-adherent (0 of 2) using unadjusted proportional odds models. Adherence by this measure was also evaluated according to history of prior FIT.

We used Stata (version 16; StataCorp LP, College Station, Texas) and SAS (version 9.4; SAS Institute Inc., Cary, NC) for all statistical analyses. All tests were two-sided and a p-value < 0.05 was considered statistically significant.

Results

Patient Demographics

A total of 5,410 patients were randomized to usual care and 5,361 patients were randomized to outreach intervention. The primary language spoken was significantly different between the two arms as outreach staff verified

language preferences in the intervention arm (Table 1). Patient characteristics were otherwise not significantly different between the outreach and usual care arms.

Cumulative FIT Completion

At the end of study follow-up, the cumulative proportion of patients with FIT completion was significantly higher in the outreach group compared to the usual care group (73.2% vs. 55.1%, $p < 0.001$, Fig. 1). In patients who previously completed a FIT, mailed outreach increased cumulative FIT completion (83.9% vs. 71.8%, $p < 0.001$, Figure 2); similarly, outreach increased FIT completion in patients who had not previously completed a FIT, although the absolute completion rates were more modest (52.5% vs. 37.2%, $p < 0.001$). Patterns of FIT participation in each cycle by intervention group and prior FIT completion history is detailed Supplemental Fig. 1 and 2. Notably, in patients who did not complete a FIT in the first cycle, a second round of mailed FIT outreach did not increase FIT completion rates (17.1% Outreach vs. 17.8% Usual Care, Supp. Fig. 1).

Proportion of Time Covered

When CRC screening was measured by PTC, the time covered by screening among patients in the outreach arm was 46.8%, compared to 27.3% in the usual care arm (difference of 19.6%, 95% CI 18.2% - 20.9%, Table 2). There was evidence for effect modification of the mailing by insurance status

(interaction p = 0.02), language (interaction p < 0.01) and clinic (interaction p = 0.01) on the PTC (Table 2).

Consistency of Adherence

A total of 1,607 patients in the usual care group and 1,725 patients in the intervention group had at least 2 years of follow-up. Patients assigned to the intervention were more consistently adherent (50.1% vs. 21.8%) and were correspondingly less intermittently (23.1% vs. 33.3%) or not adherent (26.8% vs. 44.9%, p < 0.001, Table 3). Similar patterns of intervention effect on adherence were observed in patients with and without prior FIT completion (Supp. Table 1).

Discussion

Our study evaluated the effectiveness of an organized mailed FIT outreach in a randomized controlled trial over multiple years. Though some groups have evaluated multiple cycles of FIT screening, much of the existing literature focuses on single-cycle, short-term adherence, and do not incorporate prior history of FIT completion.[14,15,17–19] We found that cumulative FIT completion, proportion of time covered by screening, and consistency of adherence were significantly higher for patients receiving outreach. We also identified that continuing mailed FIT provides no benefit above usual care for those who did not respond to previous mailed FIT; in these instances, only 17.1% complete a FIT over the next year. Overall, our results illustrate that organized mailed

FIT outreach is effective over two years, though there are areas for improvement and settings for tailored approaches.

There are several studies to which we can compare our findings. In a separate study evaluating 2 cycles of a mailed test in a safety-net setting,[27] the intervention group had a 44-48% cumulative completion rate. This rate is lower than the cumulative completion rate of 73% in our study; however, this study was conducted at one clinic site, using the traditional guaiac test, and did not specify prior FIT participation. Another study in a safety-net setting with one group randomized to mailed FIT found that approximately 16% are consistently adherent (3 FIT completed over 3 years) but the adherence behavior over two years was not available.[28] This study and other non-randomized multi-year studies did not specify prior history of CRC screening and did not evaluate cumulative FIT.[7,25,28,29] Additionally, these studies included multiple screening modalities.[7,25,26,28]

Our study further demonstrated that even though patients with no history of FIT have decreased completion rates, they still derived benefit from the first cycle of the intervention. However, strategies to improve FIT completion in patients who do not participate are warranted. Indeed, resending another FIT kit does not appear to be effective.

Screening coverage time has been used previously to evaluate multiyear CRC screening adherence. In one study conducted in a safety-net system without FIT mailing, the PTC was 29%, similar to the usual care arm in our study.[25] Another randomized outreach intervention using multiple screening modalities over 5 years in an integrated healthcare system found an improvement in PTC by arm (15% compared to 19% in our study).[26] Together, these findings demonstrate another measure of screening adherence. When comparing PTC with cumulative FIT completion, the PTC was a substantially lower value. Gaps in screening between FIT completion cycles, which will lower PTC rates, are likely of little clinical consequence; indeed, screening can be biannual in some countries.[30,31] As an example, if 50% of patients are consistently screened on time, the PTC may approximate 50%. Similarly, 50% PTC can be achieved with 100% of patients completing the test once during the 2-year cycle. Clinicians should favor a higher cumulative completion over two years as it captures the depth and reach of a screening intervention.

In our study, there was evidence of effect modification by insurance, language, and clinic. Of note there seemed to be a decreased effect of outreach in Clinic 8. This clinic actively used medical assistants to reach out to patients not up to date with screening to come into the clinic, likely moderating the effect of the organized outreach intervention.

Our findings are subject to limitations. First, this study was conducted in safety-net setting with a diverse patient population and may not be generalizable to all healthcare environments. In safety-net populations, patients are more likely to have changes in contact information, such as addresses and phone numbers, which may impact outreach effectiveness. Additionally, our study followed annual stool-based screening guidelines whereas other settings may define up-to-date as 2 years after FIT completion. Furthermore, effective stool-based programs require not only adherence to FIT testing, but also colonoscopy follow-up of positive results which was not evaluated in this study. Lastly, a small proportion of patients were censored earlier (e.g., left the health system, death, change in insurance) due to information gathered during an outreach call, which may overestimate the effect of screening in the outreach group.

Overall, organized FIT outreach significantly increased CRC screening over multiple years. Moreover, because the control in our study may no longer representative of usual care in a quickly expanding tele-healthcare environment, the expected benefit from outreach may be greater than described. We found that compared to usual care, patients who received the mailed FIT intervention had a significantly higher cumulative completion, proportion of time up-to-date with screening, and consistent adherence. Future avenues of inquiry include a focus on longer follow-up while

identifying alternative strategies for patients who do not complete FIT. Continued FIT completion seems to persist after the first cycle and should be followed to see how long the benefit may persist; determining when future participation declines may implicate an optimal time for a potential “booster” intervention. Given the variety of metrics used to evaluate CRC screening programs, it would be valuable to assess how metrics correlate with outcomes such as colonoscopy for positive tests, interval cancers, and mortality.

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Tables and Figures

Table 1. Baseline characteristics of patients assigned to usual care and outreach.
Table 2. Proportion of time covered by FIT screening for patients assigned to usual care and outreach.
Table 3. Categorized adherence with FIT screening over two years for patients assigned to usual care and outreach intervention

Fig. 1. Cumulative FIT completion during the 2.5 years after randomization. Patients assigned to outreach had a higher cumulative FIT completion compared to those assigned to usual care (73.2% vs. 55.1%, $p < 0.001$).
Fig. 2. Cumulative FIT completion in patients by history of FIT completion during the 2.5 years after randomization. Patients with a history of FIT had higher cumulative FIT completion (83.9% Outreach, 71.8% Usual Care) compared to those with no history (52.5% Outreach, 37.2% Usual Care). Outreach was associated with higher cumulative FIT completion compared to usual care, regardless of FIT history ($p < 0.001$).

Supplemental Fig. 1. Diagram showing the FIT completion outcomes of all patients who were randomized to usual care and outreach throughout the 2.5 years of follow-up. Patients who were censored or lost to follow-up during a FIT cycle were not included in the following cycle.

Supplemental Fig. 2. Diagram showing the FIT completion outcomes of all patients who were randomized to usual care and outreach throughout the 2.5 years of follow-up stratified by prior FIT status. Patients who were censored or lost to follow-up during a FIT cycle were not included in the following cycle.

Supplemental Table 1. Categorized adherence with FIT screening over two years for patients stratified by history of FIT completion

Table 1. Baseline characteristics of patients assigned to usual care and outreach.

	Usual Care (n = 5,410)	Outreach (n = 5,361)	p
Gender (%)			0.45
Female	2569 (47.5)	2507 (46.8)	
Male	2841 (52.5)	2854 (53.2)	
Age (%)			0.88
50 – 54	1460 (27.0)	1407 (26.2)	
55 – 59	1443 (26.7)	1423 (26.5)	
60 – 64	1258 (23.3)	1256 (23.4)	
65 – 69	831 (15.4)	850 (15.9)	
70 – 75	418 (7.7)	425 (7.9)	
Race/Ethnicity (%)			0.80
Hispanic	1357 (25.1)	1300 (24.2)	
Non-Hispanic Black	1204 (22.3)	1184 (22.1)	
Non-Hispanic White	1221 (22.6)	1234 (23.0)	
Asian	1039 (19.2)	1033 (19.3)	
Other/Unknown	589 (10.9)	610 (11.4)	
Insurance (%)[x]			0.73
Medicaid	2716 (50.2)	2721 (50.8)	
Medicare	1038 (19.2)	993 (18.5)	
County Sponsored	474 (8.8)	455 (8.5)	
Healthy Worker*	725 (13.4)	758 (14.1)	
Uninsured	278 (5.1)	272 (5.1)	
Primary Language (%)			<0.01
English	3554 (65.7)	3485 (65.0)	
Spanish	946 (17.5)	1060 (19.8)	
Chinese	310 (5.7)	371 (6.9)	
Other/Unknown[†]	600 (11.1)	445 (8.3)	
Marital Status (%)			0.98
Single	2629 (48.6)	2608 (48.6)	
Married	1152 (21.3)	1123 (20.9)	
Divorced	432 (8.0)	448 (8.4)	
Separated	239 (4.4)	238 (4.4)	
Widowed	219 (4.0)	209 (3.9)	
Unknown	739 (13.7)	735 (13.7)	
History of FIT (%)			0.62
No	2182 (40.3)	2137 (39.9)	
Yes	3228 (59.7)	3224 (60.1)	
Clinic (%)			0.64
1	1280 (23.7)	1276 (23.8)	

2	582 (10.8)	611 (11.4)
3	338 (6.2)	325 (6.1)
4	432 (8.0)	471 (8.8)
5	1021 (18.9)	958 (17.9)
6	841 (15.5)	832 (15.5)
7	485 (9.0)	459 (8.6)
8	431 (8.0)	429 (8.0)

[x] Patients with other/unknown insurance not reported.

* Insurance type for in-home support service providers and temporary insurance for county employees

[†]The percentage of patients with other or unknown language was decreased in the intervention arm as outreach workers verified language preference.

Table 2. Proportion of time covered by FIT screening for patients assigned to usual care and outreach.

	Usual Care (n = 5,410)	Outreach (n = 5,361)	Difference (95% CI)	Subgroup Interaction with Intervention
Overall	27.3%	46.8%	19.6% (18.2%, 20.9%)	
Gender				p = 0.97
Female	29.9%	50.1%	20.2% (18.2%, 22.2%)	
Male	24.9%	44.0%	19.1% (17.2%, 20.9%)	
Age (%)				p = 0.29
50 – 54	24.1%	43.9%	19.7% (17.1%, 22.3%)	
55 – 59	27.7%	45.5%	17.7% (15.1%, 20.4%)	
60 – 64	28.7%	49.1%	20.3% (17.5%, 23.2%)	
65 – 69	29.0%	50.3%	21.3% (17.8%, 24.8%)	
70 – 75	28.7%	47.7%	19.0% (14.0%, 24.0%)	
Race/Ethnicity (%)				p = 0.78
Hispanic	31.4%	54.1%	22.6% (19.9%, 25.3%)	
Non-Hispanic Black	23.1%	39.5%	16.4% (13.7%, 19.2%)	
Non-Hispanic White	20.8%	39.9%	19.1% (16.3%, 21.8%)	
Asian	36.9%	58.5%	21.6% (18.4%, 24.8%)	
Other/Unknown	22.5%	39.8%	17.3% (13.2%, 21.4%)	
Insurance (%)				p = 0.02
Medicaid	25.3 %	44.0%	18.8% (16.9%, 20.7%)	
Medicare	28.0%	48.0%	20.0% (16.8%, 23.1%)	
County Sponsored	30.3%	52.4%	22.1% (17.5%, 26.6%)	
Healthy Worker*	37.7%	59.2%	21.5% (17.9%, 25.2%)	
Uninsured	15.8%	39.5%	23.7% (18.2%, 29.2%)	
Primary				p = 0.01

Language (%)				
English	24.8%	41.0%	16.1% (14.5%, 17.8%)	
Spanish	33.6%	56.2%	22.5% (19.4%, 25.6%)	
Chinese	45.9%	68.1%	22.2% (16.8%, 27.6%)	
Other/Unknown†	22.2%	52.8%	30.7% (26.2%, 35.1%)	
Marital Status (%)				p = 0.36
Single	28.9%	46.2%	20.8% (18.8%, 22.7%)	
Married	35.1%	55.7%	20.6% (17.6%, 23.6%)	
Divorced	28.9%	46.2%	17.3% (12.5%, 22.1%)	
Separated	24.9%	46.9%	22.0% (15.6%, 28.4%)	
Widowed	25.6%	47.4%	21.9% (15.0%, 28.8%)	
Unknown	22.3%	36.1%	13.8% (10.3%, 17.3%)	
History of FIT (%)				p = 0.49
No	14.3%	29.7%	15.4% (13.5%, 17.3%)	
Yes	36.0%	58.2%	22.2% (20.4%, 23.9%)	
Clinic (%)				p = 0.01
1	33.1%	56.4%	23.3% (20.4%, 26.1%)	
2	28.5%	43.9%	15.5% (11.2%, 19.7%)	
3	22.3%	47.2%	24.9% (19.8%, 30.1%)	
4	27.5%	53.7%	26.2% (21.7%, 30.7%)	
5	29.4%	45.2%	15.8% (12.6%, 19.0%)	
6	19.2%	39.4%	20.2% (17.0%, 23.4%)	
7	22.3%	39.8%	17.5% (12.9%, 22.0%)	
8	28.1%	40.0%	12.0% (7.2%, 16.7%)	

* Insurance type for in-home support service providers and temporary insurance for county employees

†The percentage of patients with other or unknown language was decreased in the intervention arm as outreach workers verified language preference.

Table 3. Categorized adherence with FIT screening over two years for patients assigned to usual care and outreach intervention

Adherence with FIT Screening	Usual Care (n=1,607)	Outreach (n=1,725)	
None	722 (44.9%)	462 (26.8%)	p<0.001
Intermittent	535 (33.3%)	399 (23.1%)	
Consistent	350 (21.8%)	864 (50.1%)	

Figures

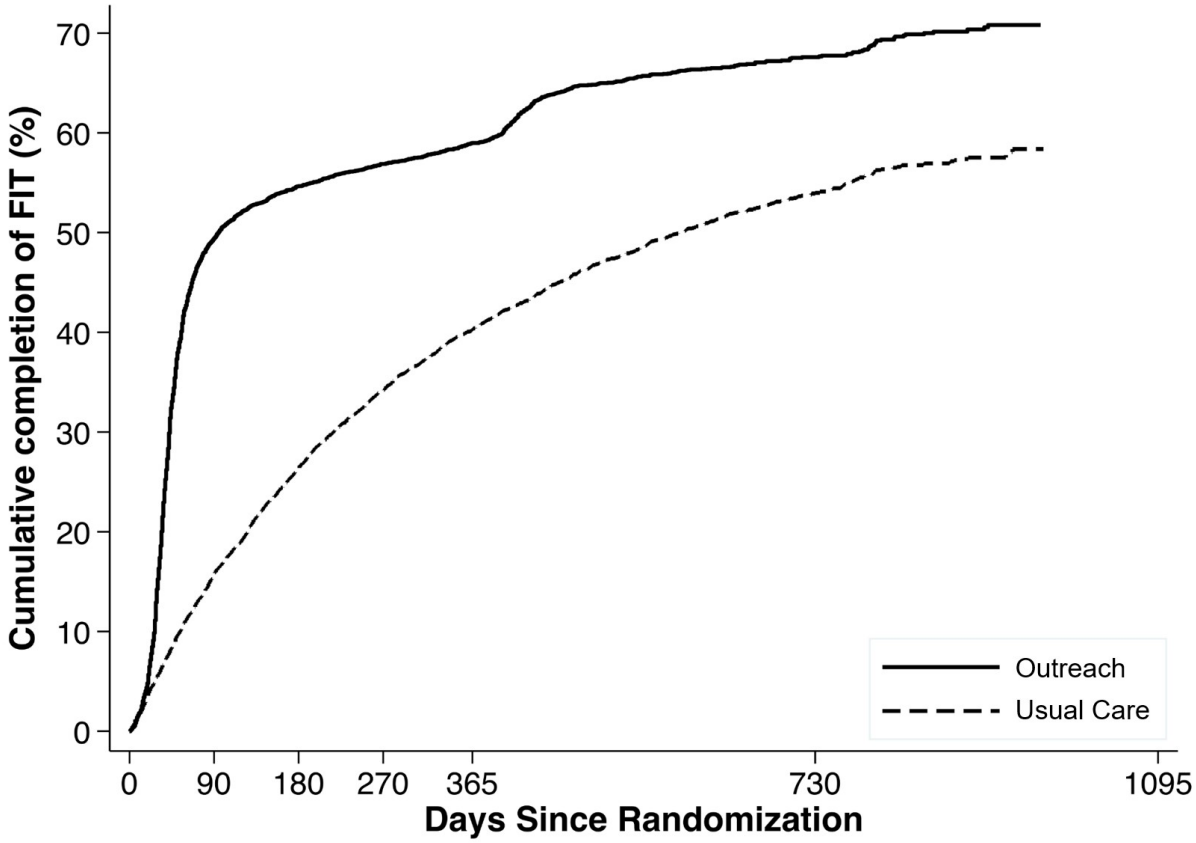


Fig. 1. Cumulative FIT completion during the 2.5 years after randomization. Patients assigned to outreach had a higher cumulative FIT completion compared to those assigned to usual care (73.2% vs. 55.1%, $p < 0.001$).

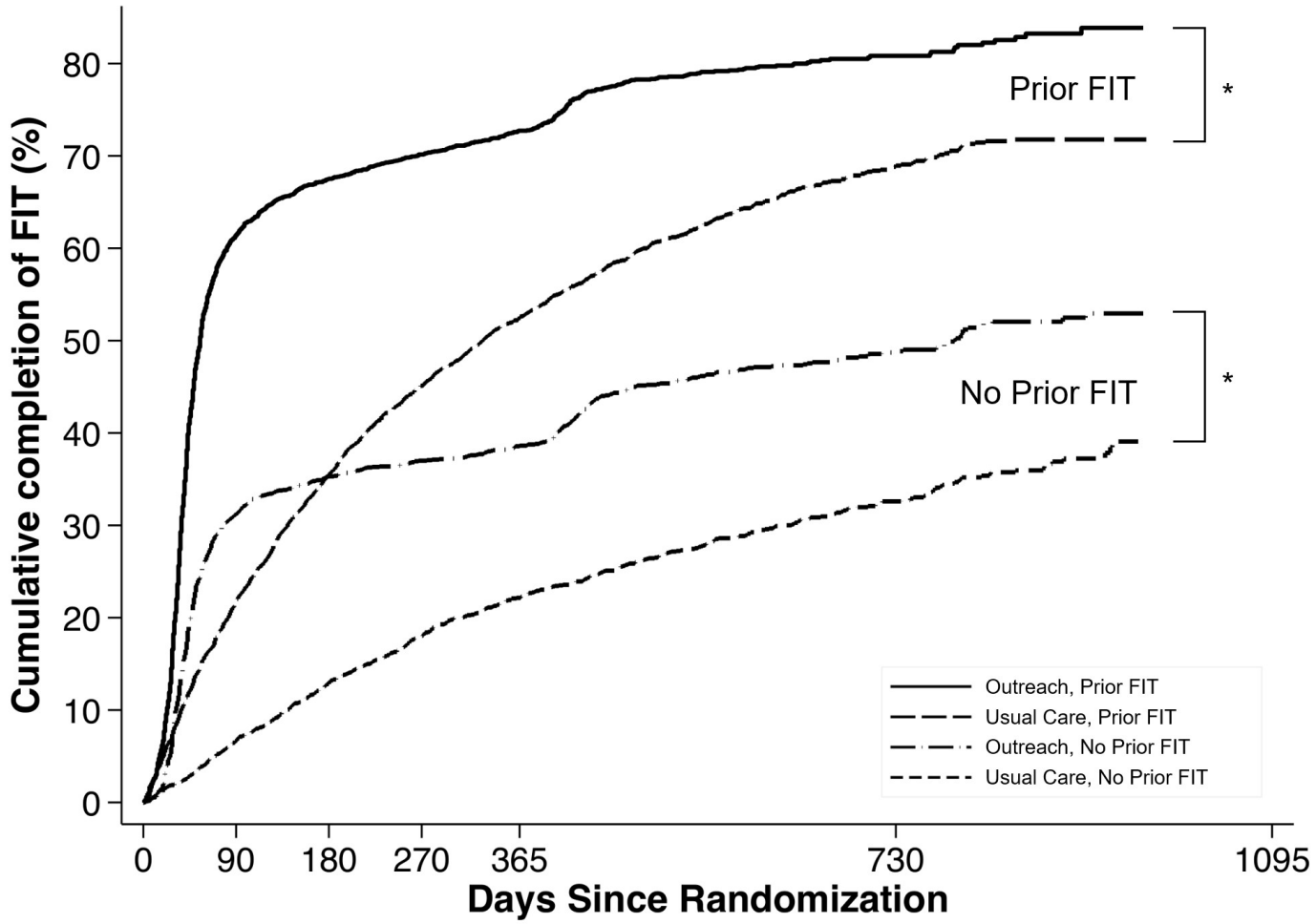
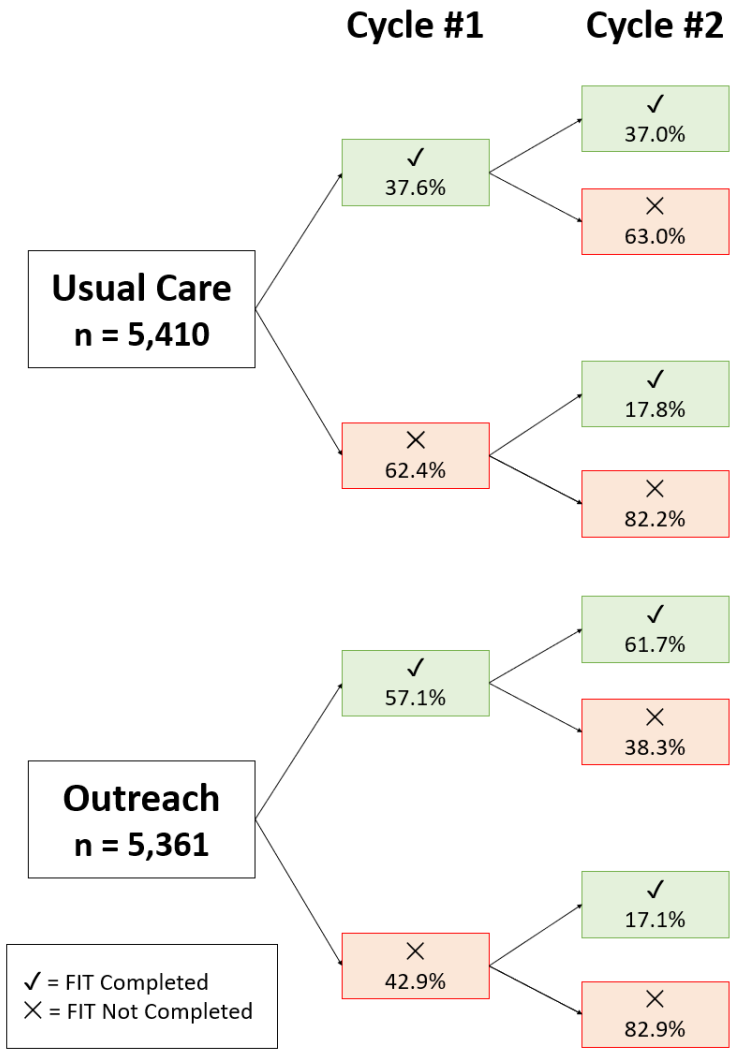
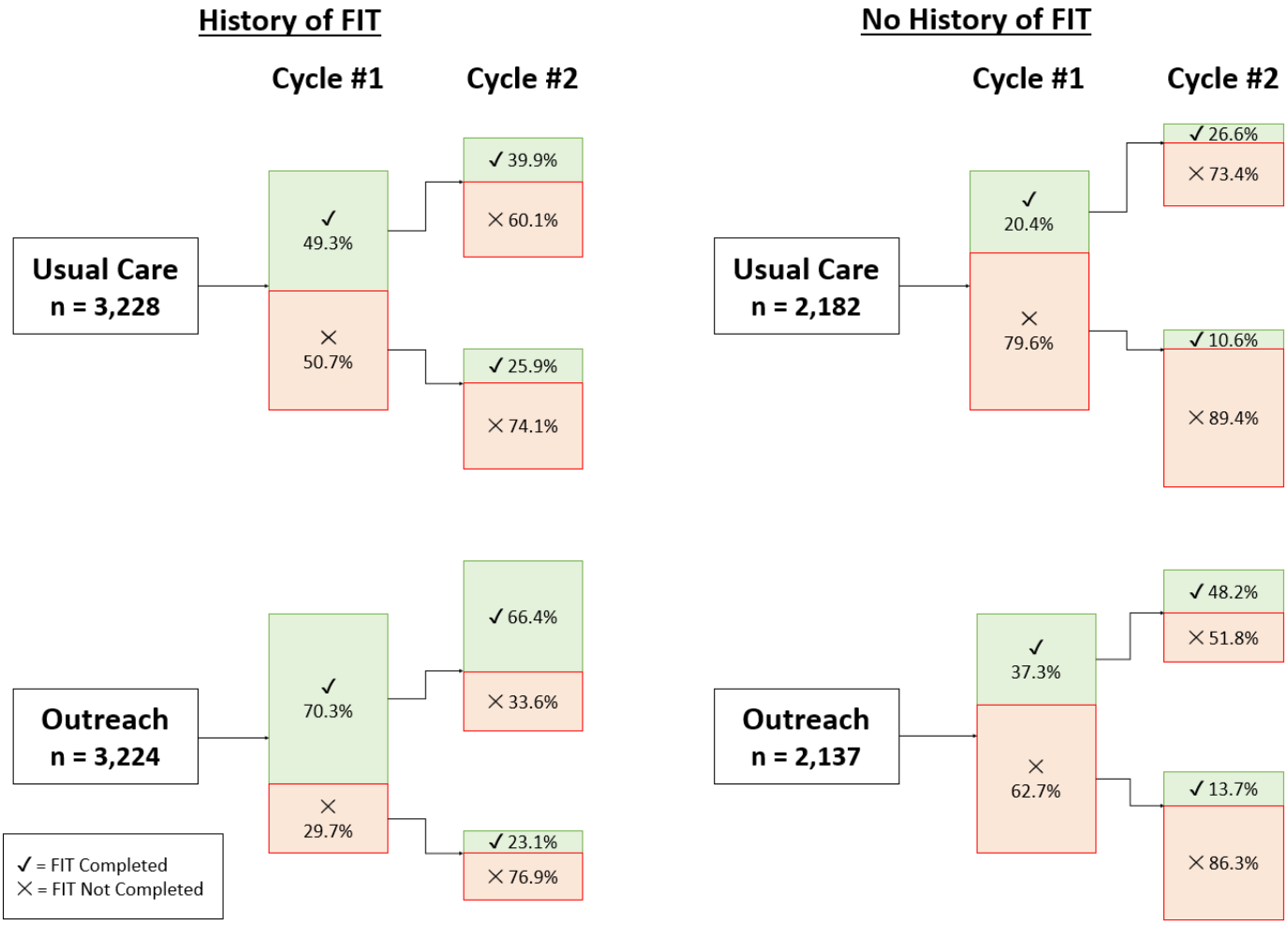


Fig. 2. Cumulative FIT completion in patients by history of FIT completion during the 2.5 years after randomization. Patients with a history of FIT had higher cumulative FIT completion (83.9% Outreach, 71.8% Usual Care) compared to those with no history (52.5% Outreach, 37.2% Usual Care). Outreach was associated with higher cumulative FIT completion compared to usual care, regardless of FIT history ($p < 0.001$).



Supplemental Fig. 1. Diagram showing the FIT completion outcomes of all patients who were randomized to usual care and outreach throughout the 2.5 years of follow-up. Patients who were censored or lost to follow-up during a FIT cycle were not included in the following cycle.



Supplemental Fig. 2. Diagram showing the FIT completion outcomes of all patients who were randomized to usual care and outreach throughout the 2.5 years of follow-up stratified by prior FIT status. Patients who were censored or lost to follow-up during a FIT cycle were not included in the following cycle.

Supplemental Table 1. Adherence with FIT screening over two years stratified by history of FIT completion

Adherence with FIT Screening	No History of FIT			History of FIT		
	Usual Care (n = 729)	Outreach (n = 748)		Usual Care (n = 878)	Outreach (n = 977)	
None	467 (64.1%)	352 (47.1%)	p<0.001	255 (29.0%)	110 (11.3%)	p<0.001
Intermittent	187 (25.7%)	202 (27.0%)		348 (39.6%)	197 (20.2%)	
Consistent	75 (10.3%)	194		275 (31.3%)	670 (68.6%)	

	(25.9%)
481	