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A pragmatic randomized trial of mailed fecal immunochemical testing to increase colorectal cancer screening among low-income and minoritized populations

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CONFLICT OF INTEREST STATEMENT

Samir Gupta has been a consultant for Guardant Health, Universal Diagnostics, Freenome, InterVenn Biosciences, Mallinckrodt, CellMax Life, and Geneoscopy and holds stock options with CellMax Life. The other authors declare no conflicts of interest.

This trial was registered at ClinicalTrials.gov (NCT04941300).

SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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Abstract

Background: Colorectal cancer (CRC) screening is underused, particularly among low-income and minoritized populations, for whom the coronavirus disease 2019 (COVID-19) pandemic has challenged progress in achieving equity.

Methods: A hub-and-spoke model was used. The hub was a nonacademic organization and the spokes were three community health center (CHC) systems overseeing numerous clinic sites. Via a cluster-randomized trial design, nine clinic sites were randomized to intervention and 16 clinic sites were randomized to usual care. Patient-level interventions included invitation letters, mailed fecal immunochemical tests (FITs), and call/text-based reminders. Year 1 intervention impact, which took place during the COVID-19 pandemic, was assessed as the proportion completing screening among individuals not up to date at baseline, which compared intervention and nonintervention clinics accounting for intraclinic cluster variation; confidence intervals (CIs) around differences not including 0 were interpreted as statistically significant.

Results: Among 26,736 patients who met eligibility criteria, approximately 58% were female, 55% were Hispanic individuals, and 44% were Spanish speaking. The proportion completing screening was 11.5 percentage points (ppts) (95% CI, 6.1–16.9 ppts) higher in intervention versus usual care clinics. Variation in differences between intervention and usual care clinics was observed by sex (12.6 ppts [95% CI, 7.2–18.0 ppts] for females; 8.8 ppts [95% CI, 4.7–13.9 ppts] for males) and by racial and ethnic group (13.8 ppts [95% CI, 7.0–20.6 ppts] for Hispanic individuals; 13.0 ppts [95% CI, 3.6–22.4 ppts] for Asian individuals; 11.3 ppts [95% CI, 5.8–16.8 ppts] for non-Hispanic White individuals; 6.1 ppts [95% CI, 0.8–10.4 ppts] for Black individuals).

Conclusions: A regional mailed FIT intervention was effective for increasing CRC screening rates across CHC systems serving diverse, low-income populations.

Keywords

colorectal cancer screening; community health centers; disparities; fecal immunochemical test; minoritized populations

INTRODUCTION

Colorectal cancer (CRC) is the second-leading cause of cancer death in the United States.[1] Screening for CRC can reduce incidence and mortality and is underused.[2] According to the National Health Interview Survey, in 2021 the screening rate was 58% among 45- to 75-year-old individuals, with marked differences across sociodemographic characteristics.[1] Specifically, screening participation was lower for younger versus older adults and for American Indian/Alaska Native (AI/AN), Hispanic/Latino, and Asian individuals versus non-Hispanic White (NHW) individuals.[1] Importantly, these national data also show that low-income individuals and those without private or Medicare insurance have among the

lowest CRC screening rates of any sociodemographic group. Screening rates have also been affected by the coronavirus disease 2019 (COVID-19) pandemic,[3–5] with uncertainty as to whether catch-up screening will prevent associated increased CRC incidence and mortality.[6,7]

Randomized trials have consistently shown that mailed fecal immunochemical test (FIT) outreach, which typically consists of a mailed invitation to complete screening with a FIT and mailed, telephone, or text message reminders, substantially increases screening rates.[8–10] Given the ability to deliver the intervention without an in-person health care visit, mailed FITs have also been promoted as a solution for addressing lower screening rates both during and after the COVID-19 public health emergency.[11,12] However, there are limited data on how well mailed FIT outreach can be adapted for delivery to large, diverse populations in the community outside of integrated insurance/health delivery systems,[13] and whether mailed FITs are effective for maintaining or improving screening rates during public health emergencies such as the COVID-19 pandemic. To address these evidence gaps, we conducted a large-scale, community-based, randomized controlled trial (RCT) of implementing mailed FIT outreach via a partnership within a primary care consortium of member community health centers (CHCs), which took place during the COVID-19 pandemic. The aim of this article is to present the effectiveness of a regional mailed FIT intervention at year 1 among participants who were not up to date with CRC screening at the time of randomization.

MATERIALS AND METHODS

Hub-and-spoke model and CHC recruitment

The San Diego Accelerating Colorectal Cancer Screening and Follow-Up Through Implementation Science project represents a partnership testing regional implementation of a hub-and-spoke model for increasing CRC screening and follow-up. The hub is Health Quality Partners of Southern California, a nonacademic, nonprofit organization. The spokes are three CHC systems, all designated federally qualified health centers—Neighborhood Healthcare, San Ysidro Health, and Vista Community Clinic—which oversee clinic sites throughout the San Diego region. Recruitment methods have been reported elsewhere.[14] The study was approved by the institutional review board of the University of California San Diego. A waiver of written documentation of informed consent was obtained given that the study was embedded into standard care and the risk to patients was considered minimal.

Study design, randomization, and patient eligibility

Via a cluster-randomized trial design, 33 clinic sites from four CHC systems were identified for study inclusion and assigned as intervention or usual care clinics via stratified randomized sampling (Figure 1). Although originally four CHC systems were randomized, after randomization and before the initiation of study interventions one CHC system and its four clinics dropped out of the study, which resulted in three CHCs and 29 clinics remaining. Of the remaining 29 clinics, four were subsequently removed before the initiation of study interventions (one clinic was consolidated and three clinics were closed). This resulted in 25 clinic sites randomly assigned: nine as intervention sites and 16 as usual care sites.

After random assignment of intervention and usual care clinics and before the initiation of the current study observation window, June 1, 2021, through May 31, 2022, electronic health record queries were conducted in patients assigned to intervention clinics to identify individuals meeting the following eligibility criteria: (1) men and women aged 50–75 years who were not up to date with CRC screening (the intervention was implemented before the change in screening guidelines that reduced the age to 45 years)[15]; (2) patients who had >1 health center visit in the prior 12 months; and (3) Medicaid, Medicare, or private insurance patients with a current valid address and phone number. Uninsured individuals were not included because of the inability to guarantee follow-up care, although it should be noted that 13%–18% of patients cared for at the three CHCs are uninsured.[16] The three CHCs had the opportunity to review the data generated by the queries to confirm the appropriateness for mailed outreach based on insurance. CHC 3 had to randomly select a fraction of eligible patients at intervention clinics for mailed outreach instead of selecting all eligible individuals because the size of the eligible population exceeded budget allotment, which was approximately 1600 per CHC system. At the time of the query, 6631 individuals met eligibility criteria and were selected for mailed FIT outreach among all three CHCs. Eligible patients had the opportunity to opt out of study participation and subsequently not participate in the intervention or data collection; 581 individuals opted out of mailed FIT outreach after receiving a primer letter.

Intervention

The intervention spanned the time period of June 1, 2021, through May 31, 2022. Patients in the clinic sites assigned to receive mailed FIT outreach received interventions, following Centers for Disease Control–recommended best practices,[17] which include a primer, FIT kit with instructions in English and Spanish, invitation letter with the option to opt out of the intervention, and postage-paid envelope for return of the completed FIT. Intervention materials were delivered by a third-party commercial vendor, Previon, and included two call- and text-based reminders. Because the intervention was initiated during the COVID-19 pandemic, a COVID-19 messaging card was developed by the study team and also included to address possible safety concerns due to the pandemic and emphasize the importance of completing CRC screening.[18] During the study observation period, usual care included opportunistic, visit-based offers to complete screening, facilitated by electronic health record flags of patients not up to date. At CHC 1, usual care also included reviewing lists of patients not up to date to deliver phone outreach and to offer a FIT be sent by mail or picked up at the clinic laboratory. At CHC 2, if the visit-based offer for screening was a telehealth visit, the FIT was mailed to the patient as part of the encounter.

Study outcomes and statistical analysis

The denominator for the analytic sample consisted of patients assigned to intervention or usual care clinics meeting the following criteria: (1) aged 50–75 years, not up to date with screening as of June 1, 2021; (2) having a health center visit within the observation window of June 1, 2021, to May 31, 2022; and (3) having Medicaid, Medicare, or private insurance. The primary outcome was the proportion of individuals who were not up to date with screening who completed CRC screening (any modality) within the 12-month period from June 1, 2021, to May 31, 2022. In addition, we assessed the proportion of those

who completed screening stratified by age, sex, race and ethnicity, preferred language, and health insurance. Data were abstracted from electronic health records. Effectiveness was assessed as the proportion of individuals completing screening by comparing intervention and usual care clinics by using generalized estimating equation analyses and specifying the clinic as a clustering variable. Effectiveness is reported as absolute differences and their 95% confidence interval (CI) between intervention and usual care clinics, and estimates were weighted to account for clinic size. For the primary analysis, we interpreted absolute differences with CIs not including 0 as consistent with a statistically significant increase in the proportion completing screening. A similar approach was used for within-subgroup analyses; we did not do formal statistical testing to compare effects between subgroups. We also assessed the unweighted proportion of participants who completed mailed FITs among the 6631 individuals within intervention clinics who were ultimately selected to receive mailed FIT intervention. SPSS statistical software was used to conduct the analysis.

RESULTS

Patient characteristics

Among the 25 participating clinics, 26,736 patients who met eligibility criteria and were not up to date with CRC screening at the time of randomization were included for analysis, with 11,681 patients assigned to nine intervention clinics and 15,055 patients assigned to 16 usual care clinics (Figure 1). Patient characteristics according to study arm are presented in Table 1. There were no significant differences in patient characteristics by intervention arm. There were more females (approximately 58%) than males in the study sample. The study population included high proportions of Hispanic/Latino Individuals (51.7% in the intervention group; 57.0% in the usual care group), individuals with primary language other than English (>50%), and a high percentage of Medicaid-insured patients (60.6% in the intervention arm; 61.5% in the usual care arm).

CRC screening outcomes

Table 2 presents CRC screening proportions by randomization arm with adjustment for clinic clustering. For the total population, CRC screening completion was 11.5 percentage points (ppts) (95% CI, 6.1–16.9 ppts) higher for intervention clinics (34.7%; 95% CI, 29.7%–40.2%) versus usual care clinics (23.2%; 95% CI, 18.4%–28.1%). As shown in Figure 2 and Table 2, variation in estimated differences in CRC screening between intervention and usual care clinics was observed by sex: females, 12.6% (95% CI, 7.2%–18.0%); and males, 8.8% (95% CI, 4.7%–13.9%). Variation in estimated differences by randomization arm was also observed by race and ethnicity, with significant differences between intervention and usual care sites observed for all racial and ethnic groups except for AI/AN individuals, for whom sample size was modest. Within groups in whom significant differences were observed, the highest absolute difference in screening was shown for Native Hawaiian/Pacific Islander (NHPI) individuals (18.5%; 95% CI, 4.0%–33.0%) and multiracial individuals (16.5%; 95% CI, 7.4%–25.6%), followed by Hispanic/Latino individuals (13.8%; 95% CI, 7.0%–20.6%) and Asian individuals (13.0%; 95% CI, 3.6%–22.4%). The lowest significant difference was observed among Black or African American individuals (6.1%; 95% CI, 0.8%–10.4%). Differences in CRC screening between

intervention and usual care clinics were observed for participants whose preferred language was Spanish (11.9%; 95% CI, 5.5%–18.4%) and in those who preferred English language (9.0%; 95% CI, 4.6%–13.4%). By age strata, significant differences were present among 5-year groups. Significant differences between intervention and usual care clinics were observed for individuals who were Medicare insured (12.2%; 95% CI, 7.0%–17.4%) and Medicaid insured (10.7%; 95% CI, 5.6%–15.8%) and for those with private insurance (10.5%; 95% CI, 4.8%–16.2%).

Mailed FIT return

Among the 6631 individuals within intervention clinics selected to receive mailed FIT outreach, FIT return was 31.4% (95% CI, 30.2%–32.5%; Table 3). Return rates were slightly higher in females (32.8%; 95% CI, 31.3%–34.3%) than males (29.4%; 95% CI, 27.7%–31.1%) and lower for individuals aged 50–54 years (27.4%; 95% CI, 25.1%–29.7%) than for other age groups. Variation in return rate was observed by race and ethnicity. The lowest proportion was among Black or African American individuals (19.4%; 95% CI, 14.8%–24.7%). The return rate was higher among Spanish-speaking individuals (35.2%; 95% CI, 33.1%–37.4%) than English-speaking individuals (26.1%; 95% CI, 24.7%–27.5%). By insurance type, the highest return rate was observed among Medicare-insured participants (37.9%; 95% CI, 35.1%–40.8%). Within one of the CHC systems, not all eligible individuals received mailed FITs. Differences in sociodemographic characteristics between individuals who were selected for mailed FITs and those who were not are presented in Supplementary Materials.

DISCUSSION

We report on the regional implementation of a mailed FIT outreach RCT to increase CRC screening via a hub-and-spoke model partnering with three large CHC systems that provide primary care services to a population where >90% are at or below federal poverty guidelines and at high risk for experiencing health disparities.[16] Implementing mailed FITs in a sample of approximately 27,000 CHC patients not up to date with CRC screening at baseline resulted in a large, 11.5-ppt improvement in the proportion of patients becoming up to date with screening over a 1-year period compared to usual care. Improvements in the proportion of patients becoming up to date were notable among Asian and Hispanic/Latino individuals, who have traditionally had lower rates of participation compared to NHW individuals. Taken together, our initial results show that a regional mailed FIT program can be implemented across multiple CHC systems of racially and ethnically diverse patients, spread across a large region, which can result in increased rates of screening participation.

These findings confirm and extend results from prior randomized trials and observational studies.[8–10,13,19] First, we demonstrate the feasibility of scaling up a regional mailed FIT program across three distinct CHC systems, which adds to the results of prior randomized trials set in single health systems and observational studies of integrated health insurance/delivery systems.[8–10,13] Second, our results complement findings from the only other large, pragmatic trial of mailed FIT outreach across eight CHC systems with 13 clinics assigned to intervention versus usual care that included largely English-speaking, White patients.[19]

In that study, intervention clinics were provided with electronic record–embedded tools for identifying patients not up to date and delivering mailed FIT outreach including a primer letter, FIT kit with instructions, and reminder letter. Their results showed 3.4- and 3.8-ppt higher differences in patients completing a FIT and any screening test, respectively, compared to those in the usual care group. Importantly, differences in completion varied on the basis of the extent to which CHC systems were able to implement the intervention, with an observed 17.6-ppt difference in FIT completion between intervention and nonintervention clinics in the system where mailed FITs were offered to the majority (68%) of eligible patients and substantially lower effects in clinics where mailed FITs could not be offered to most eligible patients. In our approach, because of the hub-and-spoke model of offering centralized mailed FIT outreach, the majority of intervention clinic patients eligible at the time of electronic health record queries preceding the intervention were offered mailed FITs, and we observed an 11.5-ppt increase in screening completion versus usual care. Notably, we postulate that the difference might have been even higher if our process allowed for "real-time" assessment of eligibility and mailed FIT outreach to all individuals who were not up to date at the beginning of the observation window for outcomes. Furthermore, because our study population included a racially and ethnically diverse group of patients, with over 50% Hispanic/Latino individuals and approximately 45% Spanish-speaking participants, we were able to demonstrate that mailed FIT outreach is scalable and effective in diverse CHC settings. More research is needed to help understand the tradeoffs of decentralized and centralized approaches for expanding access to mailed FIT outreach interventions.

Data on the effectiveness of CRC screening among different racial and ethnic groups in safety net clinical settings are limited. Our prior RCT of Hispanic/Latino individuals who were receiving care at a single clinic site located along the United States–Mexico border of California showed that mailed FIT outreach was associated with a substantially higher screening completion rate (77.2%; 95% CI, 0.71%–0.83%) compared to usual care (27.5%; 95% CI, 0.21%–0.34%).[20] Results from a pragmatic trial conducted in a safety net health system in Fort Worth, Texas, showed higher participation in mailed FIT outreach among Hispanic/Latino and Black individuals than NHW individuals.[21] Data from two observational studies[6,7] showed that past-year stool-based testing increased during the COVID-19 pandemic, which was most pronounced among Hispanic individuals. Given the lower national CRC screening rates among Asian and Hispanic/Latino individuals compared to NHW individuals,[1] as well as among Spanish-speaking individuals,[22] our results offer a potential solution for increasing screening uptake in these populations. Notably, in our study, Black/African American individuals had the lowest uptake in screening participation when comparing intervention to usual care clinics. Understanding reasons for this lower uptake is important for designing targeted interventions to improve reach and uptake in this racial group.

The intervention period for this analysis spanned June 1, 2021, through May 31, 2022, which included the Delta and Omicron waves of the COVID-19 pandemic.[23] Although there are published reports on the pandemic's impact on CRC screening,[6,7] these are based on observational data. On the one hand, to our knowledge, these are among the first trial results to demonstrate that mailed FIT outreach can be a robust intervention for increasing CRC screening participation in the face of a public health emergency. On the other hand, we are

unable to gauge whether the results would have been different had the pandemic not been in an acute phase. Our year 2 and 3 intervention data will allow us to assess differences between the acute phase and an endemic phase of the COVID-19 pandemic. From a public health perspective, these results indicate that mailed FIT outreach is an acceptable CRC screening option in the face of a pandemic, which can help overcome the exacerbation of existing disparities due to low screening uptake in low-income and minoritized racial and ethnic communities.[18] Furthermore, with the growing demand to shift testing for cancer screening out of the provider's office to individuals' homes, our study offers evidence of successful adaptation of this change in practice.

Strengths of this study include utilization of a pragmatic RCT design, inclusion of three distinct CHC systems, and involvement of a large, diverse patient population at high risk for health disparities. Several limitations may be considered in interpreting this report. The results are based on a 1-year follow-up period, and the primary outcome was the proportion of patients who were not up to date becoming up to date, which limits the interpretation of sustainability and impact on overall screening rates within the clinic sites. This limitation will be addressed in a future publication that will compare the proportion of patients up to date with screening after 3 years in intervention versus usual care clinics. Among patients within intervention clinics not up to date with screening at the beginning of our observation window, not all were selected for mailed FIT outreach by one CHC site as a result of budget limitations. As such, our results might underestimate the potential for mailed FIT outreach to increase screening participation. The intervention was delivered within the context of a research project, which may raise concerns about generalizability to nonresearch settings. However, the study intervention was delivered by a nonprofit group whose mission includes supporting access to primary medical care and quality improvement initiatives at CHC systems. In the setting of the present trial, the organization employed a commercial vendor to deliver mailed FIT outreach and reminders. This may suggest that similar programs can be developed outside of a research project, given sufficient resources. We postulate that we lacked sufficient sample size to assess effectiveness in certain racial groups, including Black, NHPI, and AI/AN individuals. Efforts to increase CRC screening in these communities are urgently needed given the high CRC burden in these populations.[1] Addition of subsequent years of data for this trial may aid in this assessment. Uninsured individuals were not included in this study, which limits the ability to assess the generalizability of intervention effects to this important, vulnerable population.

In conclusion, the results of this RCT have demonstrated that a large-scale, centralized, regional mailed FIT program delivered across three distinct CHC systems can achieve superior rates of screening participation compared to usual care. The intervention was resilient throughout the COVID-19 public health emergency, and was effective in increasing participation across multiple groups with traditionally low screening rates, including Hispanic/Latino and Asian populations as well as Spanish-speaking individuals. Policies that support more widespread implementation of mailed FIT outreach, such as via support of regional programs, are likely to have a substantial impact on improving screening participation among individuals at risk for nonparticipation.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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DATA AVAILABILITY STATEMENT

Deidentified data will be available via the Accelerating Colorectal Cancer Screening and Follow-Up Through Implementation Science coordinating center after the trial is complete at https://accsis.rti.org/. Materials and methods are available by contacting the corresponding authors.

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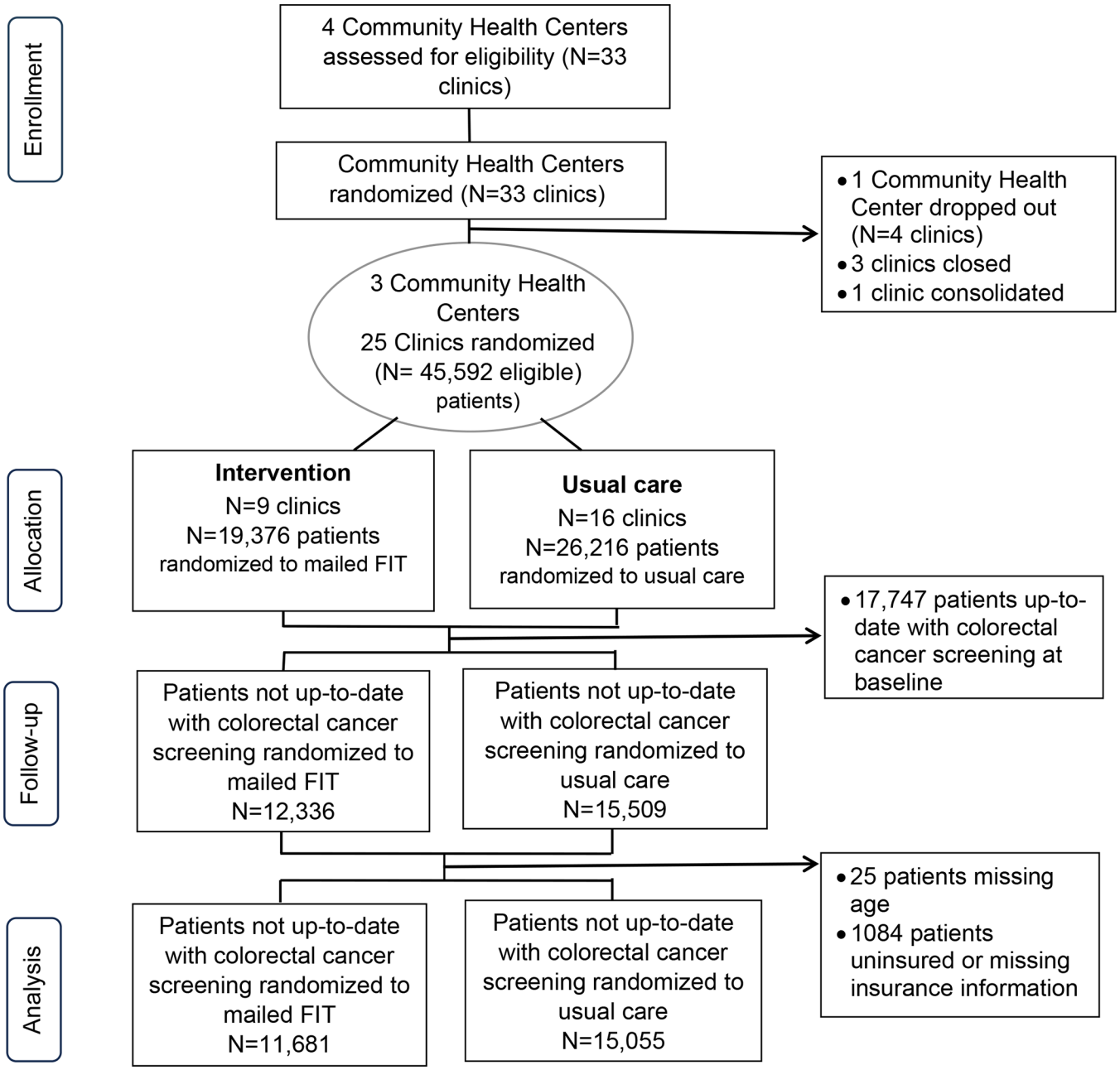

FIGURE 1.

Cluster-randomized trial Consolidated Standards of Reporting Trials flowchart. Enrollment and random assignment of community health center clinics. FIT indicates fecal immunochemical test.

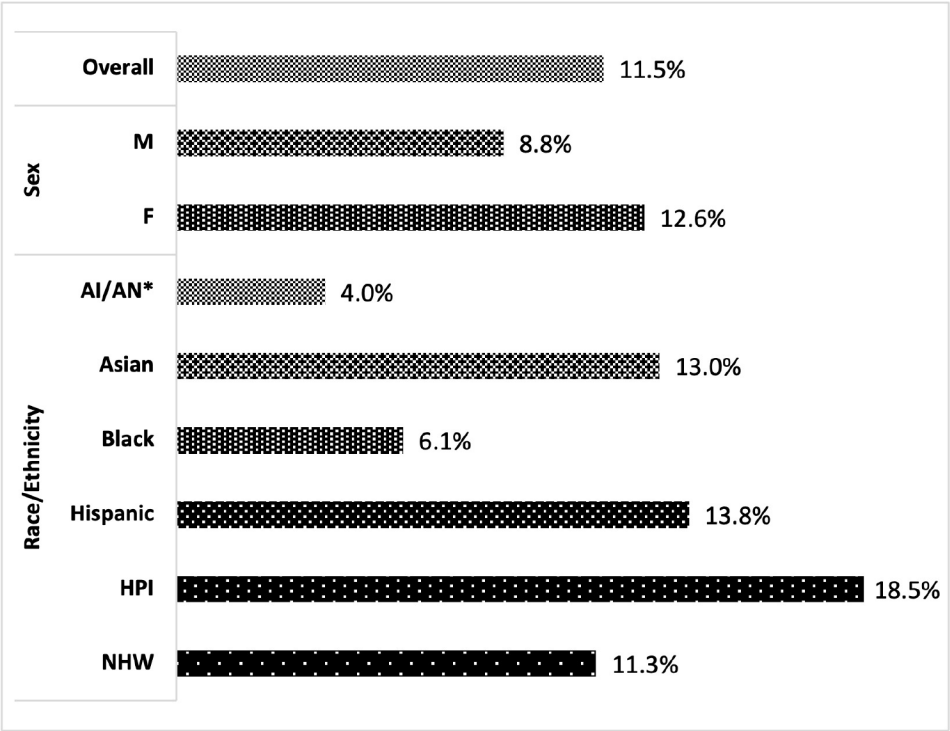

FIGURE 2.

Absolute differences in colorectal cancer screening uptake between mailed fecal immunochemical test outreach intervention and usual care groups among patients not up to date at baseline 1 year after group assignment across three southern California community health center systems, June 1, 2021, to May 31, 2022 (N = 26,736). All differences between usual care and intervention groups overall, and by strata, were statistically significant, with confidence intervals not including 0, except for the comparisons for American Indian/Alaska Native, Black, and Native Hawaiian/Pacific Islander individuals. AI/AN indicates American Indian/Alaska Native; F, female; M, male; NHPI, Native Hawaiian/Pacific Islander; NHW, non-Hispanic White. *The confidence interval surrounding the difference for AI/AN individuals included 0 and was not statistically significant.

TABLE 1

Baseline characteristics of the patient population by intervention and usual care clinics (N = 26,736).

	Intervention (n = 11,681)		Usual Care (n = 15,055)	
Characteristic	**No.**	**%**	**No.**	**%**
Age, years				
50–54	2873	24.6	3707	24.6
55–59	2941	25.2	3831	25.4
60–64	2768	23.7	3590	23.8
65–69	1892	16.2	2433	16.2
70–75	1207	10.3	1484	9.9
Sex				
Male	4919	42.1	6368	42.3
Female	6762	57.9	8687	57.7
Race and ethnicity				
American Indian/Alaska Native	26	0.2	45	0.3
Asian	559	4.8	1000	6.6
Black or African American	628	5.4	705	4.7
Hispanic/Latino	6044	51.7	8587	57.0
Native Hawaiian/Pacific Islander	52	0.4	51	0.3
Non-Hispanic White	3387	29.0	3312	22.0
Two or more races	108	0.9	128	0.9
Non-Hispanic, race unknown	234	2.0	242	1.6
Unknown	643	5.5	985	6.5
Preferred language				
English	5911	50.6	7102	47.2
Spanish	4874	41.7	7009	46.6
Not English or Spanish	896	7.7	944	6.3
Insurance				
Medicare	2405	20.6	3084	20.5
Medicaid	7074	60.6	9252	61.5
Private	1827	15.6	2272	15.1
Other	375	3.2	447	3.0
Community health center				
1	2185	18.7	3742	24.9
2	2772	23.7	3034	20.2
3	6724	57.6	8279	55.0

TABLE 2

Screening completion at year 1 among patients not up to date at baseline for intervention versus usual care clinics: intention-to-screen analysis (N = 26,736).

	Intervention (n = 11,681), % (95% CI)	Usual care (n = 15,055), % (95% CI)	Difference, % (95% CI)
All patients	34.7 (29.7 to 40.2)	23.2 (18.4 to 28.1)	11.5 (6.1 to 16.9)
Age, years			
50–54 (n = 6580)	32.6 (27.0 to 38.8)	20.7 (17.0 to 25.1)	11.9 (5.9 to 17.9)
55–59 (n = 6772)	33.8 (27.9 to 40.2)	23.8 (18.7 to 40.2)	10.0 (3.8 to 16.2)
60–64 (n = 6358)	35.4 (30.7 to 40.4)	24.2 (18.9 to 30.5)	10.2 (5.1 to 15.3)
65–69 (n = 4325)	36.2 (30.9 to 41.8)	25.9 (19.7 to 33.2)	10.3 (4.6 to 16.0)
70–75 (n = 2701)	35.5 (28.9 to 42.7)	27.5 (20.1 to 36.5)	8.0 (0.8 to 15.2)
Sex			
Male (n = 11,287)	31.8 (26.6 to 37.5)	23.0 (17.9 to 28.9)	8.8 (4.7 to 13.9)
Female (n = 15,449)	36.5 (31.3 to 42.0)	23.9 (18.9 to 29.8)	12.6 (7.2 to 18.0)
Race and ethnicity			
American Indian/Alaska Native (n = 71)	20.4 (10.2 to 36.5)	16.4 (13.1 to 20.3)	4.0 (−9.1 to 17.1)
Asian (n = 1559)	42.1 (33.3 to 51.1)	29.1 (22.9 to 36.2)	13.0 (3.6 to 22.4)
Black or African American (n = 1339)	24.1 (19.2 to 29.8)	18.0 (15.1 to 21.3)	6.1 (0.8 to 10.4)
Hispanic/Latino (n = 14,631)	41.1 (34.6 to 48.0)	27.3 (22.4 to 32.8)	13.8 (7.0 to 20.6)
Native Hawaiian/Pacific Islander (n = 103)	38.5 (26.0 to 52.6)	20.0 (9.4 to 37.6)	18.5 (4.0 to 33.0)
Non-Hispanic White (n = 6699)	27.9 (22.8 to 33.6)	16.6 (14.1 to 19.6)	11.3 (5.8 to 16.8)
Two or more races (n = 236)	31.6 (23.3 to 41.2)	15.1 (11.4 to 19.7)	16.5 (7.4 to 25.6)
Non-Hispanic, race unknown (n = 476)	30.2 (19.5 to 43.6)	17.6 (11.5 to 25.8)	12.6 (0.2 to 30.0)
Unknown (n = 1628)	22.4 (16.3 to 29.9)	12.9 (9.9 to 16.6)	9.5 (2.6 to 16.4)
Language preference			
English (n = 13,013)	27.8 (23.6 to 32.3)	18.8 (14.9 to 23.3)	9.0 (4.6 to 13.4)
Spanish (n = 11,883)	43.8 (32.7 to 50.1)	31.9 (27.1 to 37.1)	11.9 (5.5 to 18.4)
Not English or Spanish (n = 1682)	38.2 (30.0 to 47.1)	23.4 (18.0 to 29.9)	14.8 (6.0 to 23.6)
Insurance type[a]			
Medicare (n = 5489)	38.2 (33.5 to 43.1)	26.0 (19.6 to 33.7)	12.2 (7.0 to 17.4)
Medicaid (n = 16,326)	33.6 (28.9 to 38.8)	22.9 (17.8 to 28.9)	10.7 (5.6 to 15.8)

	Intervention (*n* = 11,681), % (95% Cl)	Usual care (*n* = 15,055), % (95% Cl)	Difference, % (95% Cl)
Private (*n* = 4099)	32.5 (24.6 to 41.5)	22.0 (18.2 to 26.2)	10.5 (4.8 to 16.2)
Other (*n* = 822)	33.1 (25.3 to 41.9)	26.8 (23.1 to 30.8)	6.3 (−2.2 to 14.8)

Abbreviation: Cl, confidence interval.

[a] A total of 1906 participants with missing values or other insurance or who were uninsured were not included.

TABLE 3

Mailed fecal immunochemical test return for year 1 in intervention clinics among individuals receiving mailed outreach ($N = 6631$).

	Intervention, No. returned/total	Intervention, % (95% CI)
All patients	2079/6631	31.4 (30.2–32.5)
Age, years		
50–54	406/1484	27.4 (25.1–29.7)
55–59	541/1732	31.2 (29.1–33.5)
60–64	523/1675	31.2 (29.0–33.5)
65–69	395/1105	35.7 (32.9–38.7)
70–75	214/635	34.7 (30.0–37.5)
Sex		
Male	813/2766	29.4 (27.7–31.1)
Female	1266/3862	32.8 (31.3–34.3)
Race and ethnicity		
American Indian/Alaska Native	*a*/*a*	37.5 (15.2–64.6)
Asian	89/220	40.5 (33.9–47.3)
Black or African American	52/268	19.4 (14.8–24.7)
Hispanic/Latino	769/2199	35.0 (33.0–37.0)
Native Hawaiian/Pacific Islander	10/18	55.6 (30.8–78.5)
Non-Hispanic White	867/2833	30.6 (28.9–32.3)
Multiracial	31/88	35.2 (25.3–46.1)
Non-Hispanic, race unknown	60/236	25.4 (20.0–31.5)
Unknown	195/753	25.9 (22.9–29.2)
Language preference		
English	1012/3882	26.1 (24.7–27.5)
Spanish	674/1915	35.2 (33.1–37.4)
Insurance type		
Medicare	430/1135	37.9 (35.1–40.8)
Medicaid	993/3147	31.6 (29.9–33.2)
Commercial/private	241/678	35.5 (31.9–39.3)

Abbreviation: Cl, confidence interval.

[a]The number is suppressed because of the small cell size.