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Hub-and-Spoke centralized intervention to optimize colorectal cancer screening and follow-up: A pragmatic, cluster-randomized controlled trial protocol

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Abstract

Background—Guidelines recommend screening for colorectal cancer (CRC), but participation and abnormal test follow up rates are suboptimal, with disparities by demography. Evidence-based interventions exist to promote screening, but community adoption and implementation are limited.

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Declaration of interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Methods—The San Diego Accelerating Colorectal Cancer Screening and Follow-up through Implementation Science (ACCSIS) program is an academic-community partnership testing regional implementation of a Hub-and-Spoke model for increasing CRC screening and follow-up. The “hub” is a non-academic, non-profit organization that includes 17 community health center (CHC) systems, serving over 190 rural and urban clinic sites. The “spokes” are 3 CHC systems that oversee 11 – 28 clinics each, totaling over 60 clinics. Using a cluster-randomized trial design, 9 clinics were randomized to intervention and 16 to usual care. Within intervention clinics, approximately 5,000 eligible patients not up-to-date with CRC screening per year were targeted for intervention. Interventions include an invitation primer, a mailed fecal immunochemical test with completion instructions, and phone and text-based reminders (hub) and patient navigation protocol to promote colonoscopy completion after abnormal FIT (spoke). Outcomes include: 1) proportion of patients up-to-date with screening after three years in intervention versus non-intervention clinics; 2) proportion of patients with abnormal FIT completing colonoscopy within six months of the abnormal result. Implementation science measures are collected to assess acceptability, intervention and usual care adaptations, and sustainability of the intervention strategies.

Conclusion—This large-scale, regional cluster randomized trial among CHCs serving diverse populations is anticipated to accelerate progress in CRC prevention in underserved populations.

Trial registration: NCT04941300

Keywords

community health centers; colorectal cancer screening; abnormal fecal immunochemical test follow-up; cancer disparities

1. Background

CRC is the second leading cause of cancer death in the US(1). Inequities in screening participation, incidence, and mortality by race, ethnicity, socioeconomic status, and health insurance are well established (2) (3). Screening and appropriate follow-up of abnormal screening tests can reduce incidence and mortality from CRC(4). Until 2021, the US Preventive Services Task Force (USPSTF) recommends CRC screening using stool tests, such as the fecal immunochemical test (FIT), high sensitivity guaiac fecal occult blood test (gFOBT), and the FIT-DNA test, as well as more invasive tests such as sigmoidoscopy, colonoscopy, and CT colonography for individuals aged 50 to 75 years; which since has been extended to 45–75 years (5–10). The potential impact of screening on CRC-related deaths is significant: for every 1000 CRC FIT screenings, 22 cancer deaths can be averted(11). The national CRC screening rate (up-to-date with gFOBT/FIT, sigmoidoscopy, or colonoscopy) for adults 50 −75 years increased from 67% in 2018 (2) to 72% in 2020 (12); yet still below the National Colorectal Cancer Roundtable Table target of 80%(13). Screening rates are particularly low in Hispanics (47%), Asians (52%), recent immigrants (34%), low-income (47%), and the uninsured (25%) (14–16). Further, health systems that disproportionately care for underserved populations, such as Community Health Centers (CHCs), including Federally Qualified Health Centers (FQHCs), report low screening rates, with an average screening rate of 41.9% in 2021 nationally among FQHCs, and a range of

8.0 to 65.9% across 12 CHC systems in Southern California in 2021, which included 3 of the CHC systems in this study (17). Guideline appropriate follow-up of abnormal screening tests is also suboptimal, with substantial variation across settings. For example, while some integrated health systems report completion rates of 83%(18), reported completion rates across CHC systems are much lower, ranging from 18–57% in a sample of 8 Southern California CHCs, far short of the nationally recommended 80% goal for completion of both outcomes (13, 19). Failure to follow-up represents a missed opportunity for cancer control, as lack of complete colonoscopy after abnormal FIT has been associated with a 2.4-fold increased risk for CRC death(20) and a 2-fold increased risk of developing advanced stage CRC(21).

The National Cancer Institute's Accelerating Colorectal Cancer Screening and follow-up through Implementation Science (ACCSIS) Cancer Moonshot℠ initiative supports research to understand how evidence-based multilevel interventions (EBIs) can be implemented and scaled to reduce the burden of CRC in the United States among underserved populations. The San Diego ACCSIS-funded study focuses on identifying regional solutions for the adoption and sustainability of a comprehensive, multilevel evidence-based approach to increase CRC screening and follow-up in CHC systems. Working at both the CHC system level and the central organization that coordinates care and quality improvement for the CHC organizations, implementation burden is postulated to be shifted away from clinics, which addresses challenges highlighted in recent literature(22). The goal is to provide scalable and sustainable solutions that could be adopted and adapted in additional CHC system settings in the region and beyond.

Although CRC screening rates have increased in the U.S., these remain low in individuals who receive primary care in CHCs systems. Furthermore, it is important to note that screening rates decreased because of the COVID-19 pandemic (23, 24) and the consequences of this reduction are yet to be revealed. While implementation strategies and EBIs exist to increase CRC screening, few CHCs systems have adopted these, and their evaluation is limited. Importantly, a rigorous assessment of multilevel (i.e., patient, provider, health system) approaches in CHCs for CRC screening, follow-up, and referral-to-care is lacking. Follow-up rates for abnormal stool testing are low and reasons for lack of colonoscopy completion are poorly understood. The San Diego ACCSIS pragmatic trial addresses these gaps by assessing the implementation and effectiveness of a multilevel intervention to increase CRC screening, follow-up, and referral-to-care in CHC systems in Southern California.

2. Methods

2.1. Study design

The 2-arm pragmatic cluster randomized trial was designed to evaluate the implementation, scalability, and sustainability of a multi-level Hub-and-Spoke implementation strategy on: 1) improvement in proportion up-to-date with CRC screening; and 2) proportion with abnormal FIT who complete diagnostic colonoscopy within 6 months; 3) proportion diagnosed with CRC receiving primary care provider referral to surgeon and/or oncologist and completion of first treatment visit. The RCT will compare the impact of the Hub-and-Spoke model on

intervention vs. usual care clinics. The Hub-and-Spoke model refers to an implementation strategy in which a central community-based organization (hub) provides centralized support to 1) deliver mailed FIT outreach and reminders; 2) coordinate navigation for abnormal FIT follow-up and referral-to-care; 3) provide expert advice on implementation of EBI to member CHC organization (spokes) where care for individuals targeted by this intervention occurs.

2.2. Conceptual framework and implementation science measures

An adaptation of the Conceptual Model of Implementation Research (CMIR) (25) was used as an overarching framework for our study(26). CMIR frames the translation of evidence-based interventions for promoting CRC screening and abnormal test follow up into multi-level, multi-component intervention strategies targeted to influence critical outcomes, including CRC screening participation, and colonoscopy follow up after abnormal FIT (Figure 1). The Practical Robust Implementation and Sustainability Model (PRISM) was used to complement CMIR to guide implementation and evaluation. PRISM includes a set of multi-level and multi-perspective contextual domains (i.e., intervention, recipients, implementation and sustainability infrastructure, and external environment) and the broadly utilized Reach, Effectiveness, Adoption, Implementation, Maintenance outcomes(27). Outcomes were further expanded by measures of feasibility and acceptability for the early phase of the study. Scalability and sustainability will be evaluated using the PRISM constructs of Implementation & Sustainability Infrastructure and External Environment and the RE-AIM Maintenance outcome. The San Diego ACCSIS team's substantial experience and engagement with a regional CHC consortia enhances potential for sustainability and scalability.

2.3. Study setting

This project is the result of an academic-community health center partnership with Health Quality Partners of Southern California, a subsidiary of Health Center Partners of Southern California (HCP) in San Diego, and three participating community health center systems: San Ysidro Health, Neighborhood Healthcare, and Vista Community Clinic. HCP has substantial reach throughout Southern California and extends into a large region Southern California, with approximately three-quarters of a million patients and over three million patient encounters annually. San Diego County does not operate a county hospital and provides very limited direct primary care services to medically underserved communities, making CHCs systems the primary providers for the safety net population. In fact, 1 of every 6 San Diego residents receives health care at a CHC system (28, 29). Table 1 shows participating patient and CHC system characteristics. These show the substantial racial and ethnic diversity of patients, including a large Hispanic (ranging from 55 to 73%) and non-English speaking (range 28% to 50%) population, who are known to have low CRC screening rates(14). Among the participating CHCs systems, the CRC screening age-eligible population included approximately 60,000 men and women.

2.4 Eligibility and participant recruitment

Within intervention clinics, all age-eligible individuals who were active patients, had health insurance, but not up-to-date with CRC screening were assigned to receive mailed FIT

outreach. Participating staff at each intervention clinic were trained in best practices for care coordination and patient navigation in abnormal FIT follow up. As such, within each intervention clinic, patients age-eligible for screening with an abnormal FIT are exposed to the navigation intervention, regardless of whether they were screened through the ACCSIS program or not. Patients had the option to opt out of study participation. Patients who declined participation did not have subsequent interventions or data collection.

Eligible participants include men and women aged 50 to 75 years who are not up-to-date with CRC screening at one or more health center visits in the 12 months, insured by Medicare, Medicaid, or private insurance, with a current valid County address and phone number. The study team uses the Universal Data Set (UDS) CRC screening measure that CHCs systems are required to report to the Health Resources Services Administration annually to identify patients up to date with CRC screening(29). Among patients served by intervention clinics, the planned recruitment target included mailing FIT kits to approximately 5000 eligible individuals annually across a three-year period. At intervention clinics, protocolized abnormal FIT follow-up is provided for all patients with an abnormal FIT. This includes: 1) All patients with an abnormal FIT because of the ACCSIS mailed outreach, and 2) Patients with an abnormal FIT because of usual care in intervention clinics. At non-intervention clinics, CRC screening and follow up are delivered per usual care; a usual care survey is implemented biannually to track strategies being used by each CHC system for usual care.

This research study involved human subjects and was approved by all participating institutional review boards. A waiver of informed consent was utilized in this study given that study procedures were standard of care. The study does not have a Data and Safety Monitoring Board.

2.5. Randomization

Randomization was conducted at the clinic level (i.e., clusters). A stratified randomized sampling was used to assign CHC clinic sites to study group (Figure 2). The stratification variable was at the CHC system. Thus, within each CHC system, clinics were randomly assigned to be intervention and usual care. The pool of clinics (n=33) identified for random assignment was selected based on guidance from CHC leaders (e.g., clinics that did not serve patients in the target age range were excluded). Patients were blinded to group assignment, but due to the pragmatic and multi-level nature of the study, providers, the system, and individuals executing intervention activities were not blinded to group assignment. While 33 clinics were available, pre-randomization, two clinic sites were consolidated into one site due to being in the same site, two clinic sites were excluded due to future site closures/consolidation. Of the 30 randomized clinic sites, an additional four clinic sites were removed due to a health system withdrawing from our study prior to mailed FIT implementation and one clinic site was removed due to unanticipated closure, yielding 25 clinics available for randomization, to a multilevel intervention (n= 9) or usual care (n=16).

2.6. Interventions

2.6.1. Mailed FIT—The mailed FIT intervention includes HQP Hub-based coordination of the delivery of centralized mailed FIT to patients served by individual CHCs-spokes and a standardized telephone-based care coordination strategy delivered by CHCs for abnormal FIT follow-up. A third party vendor delivers mailed FIT packages annually to patients from the three participating CHCs systems (approximately 1,250 from each CHC systems) as well as reminders (via automated calls and text messages). The mailed FIT approach follows Centers for Disease Control-recommended best practices for mailed FIT outreach(30). Specifically, a mailed primer is sent 2 weeks prior to the intervention package to "prime" the participant. The package includes (See Supplementary Appendix) a 1) FIT kit with instructions in English and Spanish for completion, 2) one-page invitation letter inviting FIT completion, which includes contact information for questions and the option to opt out of the interventions, and 3) postage-paid envelope for return of the FIT kit. The brand of FIT kit matches the FIT kit covered by the patient's insurance and contracted lab of the health center. In addition, since the intervention was initiated in the same year as the onset of the COVID-19 pandemic, a COVID-19 messaging card is included to address possible concerns for FIT completion due to the pandemic, which is part of the San Diego ACCSIS pandemic adaptations (31). While the intervention was completely mail- and remote-based, thus suitable for this time, a COVID-19 messaging card instructed patients that they were due for cancer screening, and reinforced the importance of regular cancer screening, even in absence of signs of symptoms, and that this cancer screening could be done safely from home. Invitations and return address are matched to the patient's health center. Previously tested reminders to complete FIT were updated based on National Colorectal Cancer Roundtable (NCCRT) strategies(32). For non-compliant individuals (i.e., individuals who do not return a completed mailed FIT), "automated" reminder phone calls and text messages are delivered beginning 3 weeks after the initial mailing, which has been shown to be effective(33). In subsequent intervention years two and three, mailed FIT will continue to be offered to patients who completed prior mailed FIT with normal test results, as well as patients not up-to-date with screening.

2.6.2. Abnormal FIT follow-up—In intervention clinics, bilingual care coordinators were trained to implement best follow-up practices for individuals who have an abnormal FIT test during the observation period. FIT test results are populated in the EHR and available to the Hub and the Spokes. A standard protocol was implemented for phone-based patient navigation, which was developed and is coordinated by the Hub and implemented by the Spokes for: a) patients with usual care abnormal FIT in intervention clinics and b) all patients with abnormal FIT resulting from mailed outreach. Table 2 describes the key steps and intervention activities for patient navigation to facilitate colonoscopy completion following an abnormal FIT. These include procedures that we have used in prior and ongoing studies taking place in the Spoke CHC clinics, as well as previously reported best practices for promoting colonoscopy completion after abnormal FIT (18, 34–36).

2.7. Study outcomes

The pragmatic trial tests the implementation, effectiveness, and scalability of a Hub and Spoke intervention in CHCs systems in Southern California. Table 3 provides a summary

of the study outcomes and measures. The primary outcome for mailed outreach is the proportion of age-eligible patients who are up-to-date with screening in intervention vs non-intervention clinics after 3 years of intervention implementation. The rationale for choosing this outcome is that this reflects national UDS reporting requirements for monitoring CRC screening. Secondarily, repeat annual FIT screening will also be measured. The primary outcome for abnormal FIT follow-up is the proportion of patients who complete colonoscopy within six months of receiving the abnormal FIT results. Additional outcomes of interest include the proportion with abnormal FIT who have colonoscopy ordered, as well as time to colonoscopy completion.

2.8. Analysis and power estimates

2.8.1. Mailed FIT—In the primary analysis, the proportion of patients up to date with screening 3 years post implementation initiation in intervention versus non-intervention clinics, accounting for clustering, is compared, using an intent-to-screen approach in which clinics will be analyzed in the group to which they were originally assigned. Generalized estimating equations (GEE) modeling will be used to test the effectiveness of the multilevel intervention between the intervention and usual care groups (37). The model will include a random effect for clinic to account for correlations between participants in the same clinic. These analyses will determine if the intervention effects are maintained over the follow-up period(38). Adjustments will be made to account for baseline imbalances across groups and to adjust for variables known to influence the outcome independent of the intervention, which include age, sex, and CHC system. As secondary outcomes, among patients receiving mailed FIT, the following will be measured: 1) number of mailings that come back as return to sender; 2) number of kits returned to lab which cannot be processed; 3) number of completed kits; 4) repeat testing among patients with initial normal FIT offered repeat testing; 5) cumulative number with abnormal FIT. (Table 3).

The estimated sample size of clinics required for this study was based on several parameters, including the number of clinics within each CHC health system cluster, the number of patients served by each clinic within a CHC system, and the estimated number of patients in each clinic within a CHC system not up-to-date, eligible for CRC screening. Based on preliminary work, it was estimated that these health systems will contribute a sample size of 60,000 individuals who will be evaluated as part of the research for the primary outcome of CRC screening in the first year of the 3-year study. It is estimated that about 30,000 (50%) of these 60,000 individuals are not up to date with CRC screening across the 3 CHC systems and thus eligible for the study. Thus, the target population for sampling is 30,000 not-up-to-date.

The usual care screening rate is predicted to increase to a minimum of 65% from the previously identified baseline of 50% across the 3-year intervention period, based on usual care practices outside of the intervention that may increase screening. Power estimates were made to detect differences of 10 and 15% across a range of different number of clinics and different values (.01-.05) for intraclass correlation among participants from the same CHC system and clinic within a CHC system. A two-tailed test with alpha=0.05 was used. With 8 clinics drawn from across the 3 CHC systems per arm and 3750 patients per arm,

there is >80% power to detect an absolute improvement of 10–15% for an ICC ranging from 0.01–0.02. Increasing number of clinics to 12 per arm (n=2500 patients/arm) improves power, with only one scenario resulting in <80% power (10% difference, ICC=0.05). As such, across a wide range of clinic assignment criteria, we will have adequate power to detect differences of interest.

The theoretical power calculations using 8 clinics per arm and 12 clinics per arm were used to guide estimating the sample size required to detect clinically relevant differences in the primary outcome, and to demonstrate feasibility in the funding proposal. Our ultimate selection of 9 intervention clinics was guided by a goal of delivering the intervention to an estimated 5,000 individuals not up to date with screening per year in the intervention clinics. First, across the 3 FQHC systems, we identified 25 candidate clinics eligible for study inclusion. Next, we randomly selected 9 intervention clinics based on estimated numbers of patients not up to date. Then, since data on the primary outcome (proportion up to date with screening) could be obtained with similar effort and resources for 9 non-intervention clinics vs. all eligible clinics not assigned to be intervention clinics, we made a pragmatic decision to assign all 16 of the remaining clinics that were not randomly selected as intervention clinics to the non-intervention group.

2.8.2. Abnormal FIT Follow-up—The primary outcome of interest will be proportion of patients with abnormal FIT who complete colonoscopy within 6 months of receiving the abnormal FIT results. Additional outcomes of interest will include proportion with abnormal FIT who have colonoscopy ordered, as well as time to colonoscopy completion. In the primary analysis, colonoscopy completion outcomes will be made for all patients with abnormal FIT at intervention clinics vs. usual care clinics over the 3-year intervention period. The analytical approach is similar to Aim 1. Only patients with abnormal FIT will be included in the analysis and the outcome is a binary variable to measure whether colonoscopy screening is completed within 6 months. Time to colonoscopy completion will be considered as an additional outcome, which will be assessed by survival analysis and cluster effect of clinic will be adjusted using frailty model.

Using methods similarly to mailed FIT screening, we assumed a FIT positivity rate of 7%(39), and then we conservatively estimate over the 3-year intervention period that 1200 patients (75 patients per clinic assuming 16 clinics enrolled in the study) will have abnormal FIT across control and intervention clinics. Assuming a two-sided alpha of 0.05 and 45% colonoscopy completion rate within 6 months of abnormal FIT in control group, there will be 80% power to detect an absolute improvement of 13–19% in colonoscopy completion rate (i.e., 58–64% for intervention) in intervention clinics for an ICC of 0.02–0.06.

2.8.3. Implementation methods and outcomes—PRISM will be used to guide the evaluation of key implementation outcomes. Specifically, a mixed-methods approach will be used to collect qualitative and quantitative data for each outcome dimension of reach, adoption, implementation, and maintenance. Table 4 provides an overview of the RE-AIM dimensions, proposed measures, the level at which these measures are collected, and the proposed data source. A combination of validated measures developed in previous studies and newly developed measures and instruments informed by PRISM will be used, with a

critical focus on outcomes that are important for the implementation, service, and diffusion of programs into real world settings(26, 40, 41).

A rapid qualitative approach will be used to analyze interviews. Codes will be pre-defined based on the key domains of PRISM. Operational definitions for each of the PRISM constructs will be created to be specifically appropriate for this study. A focus for this analysis will be a template approach using constructs from prior work and contextual factors outlined in PRISM. A web-based qualitative analysis program, Dedoose (42), will be used to support coding and qualitative analysis. Coding will be undertaken by the Implementation Science Core members, including two study co-investigators. Interview data results will be triangulated or merged to substantiate equivalent results from related UCSD Moores Cancer Center (MCC) assessments. Triangulation is a method frequently used in mixed methods research to check and establish validity, as well as deepening and widening interpretive understanding via multiple perspectives (43). Findings from the interviews and quantitative surveys will be summarized and shared with each participating CHC partner. Engagement of CHC and HQP partners will take place to support sense-making and develop action items based on these results.

3. Discussion

The study protocol describes the San Diego ACCSIS pragmatic, cluster randomized trial conducted in three CHC systems in Southern California. The CHC patients, which include a large Hispanic population, have historically had low screening and abnormal test follow up rates (2), underscoring the significance of the trial. The study approach tests a novel Hub-and-Spoke strategy for implementing EBIs that we postulate is highly scalable to other CHCs if shown effective. The study's strengths include the strong community-engaged foundation for the research, use of a cluster randomized design that allows comparison of intervention to usual care, and application of best practices from implementation science in a real-world health care setting. The study is part of a larger network of trials supported by the ACCSIS Cancer Moonshot℠ initiative. Collaborative studies pooling data and lessons learned across ACCSIS sites will further expand the understandings of how to best disseminate and implement evidence-based interventions for colorectal cancer screening and follow up among populations vulnerable to adverse colorectal cancer outcomes.

The pragmatic trial was initiated during the onset of the COVID-19 pandemic, which resulted in a temporary halt in cancer screenings worldwide. Fortunately, given the pragmatic nature of the trial and that CRC screening modalities allow for adoption of strategies that are COVID-resilient, it was possible to continue the trial activities with minor disruptions. These modalities leverage mail, telephone, and text for promoting screening and follow-up, and will allow for understanding the effectiveness and scalability of the proposed approaches in an era where COVID is endemic, and where in person visit-based care is heavily complemented by telemedicine interactions between healthcare staff and patients (31). Second, this trial was also initiated at a time when CRC screening guidelines were changing from 50 years and up to 45–75 years. The United States Preventive Service Task Force(12) released the updated guidelines in 2021, however, it took time for the FQHCS to adopt and roll out these guidelines. Once usual care practices at the clinics included 45–49

years (beyond our initial study year 1), the intervention inclusion criteria was expanded to include those aged 45–49 years. In this paper, we present the original intended sample of 50–75 years of age. Lastly, this trial did not include uninsured patients. However, in our region, there are no safety net hospitals to provide colonoscopies and associated cancer treatments for the uninsured. It was therefore not ethical to enroll uninsured patients, and thus this study is not positioned to make observations about the impact of our proposed interventions on uninsured individuals.

4. Conclusion

CRC is a major public health problem. Though guideline concordant screening and abnormal test follow up can reduce CRC incidence and mortality, participation remains suboptimal, particularly among individuals with Medicaid insurance, lower socioeconomic status, and who are racial/ethnic minorities, as reflected in the Southern California community and beyond. EBIs for improving screening and follow up are well established, but best methods to promote implementation and scale up across populations have not been identified. The San Diego ACCSIS study fills this important gap. Results will provide pragmatic, effective, and sustainable approaches to increase EBIs to increase CRC screening in CHCs, systems that serve a large proportion of diverse medically under-served patients, with potential for larger scale implementation.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Data Availability

De-identified data will be available through the ACCSIS 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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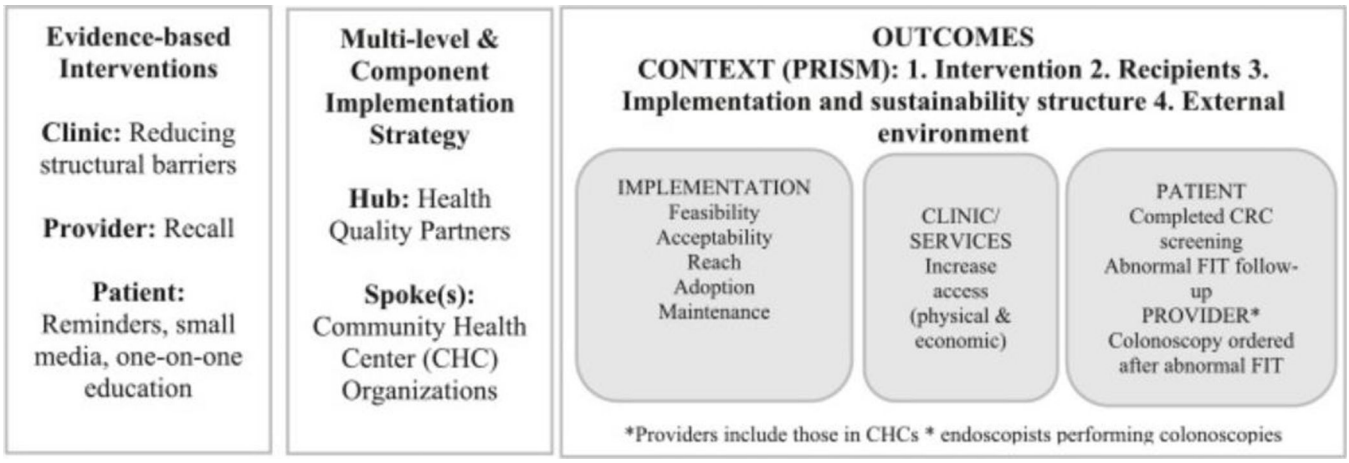

Figure 1.
San Diego ACCSIS Conceptual Model

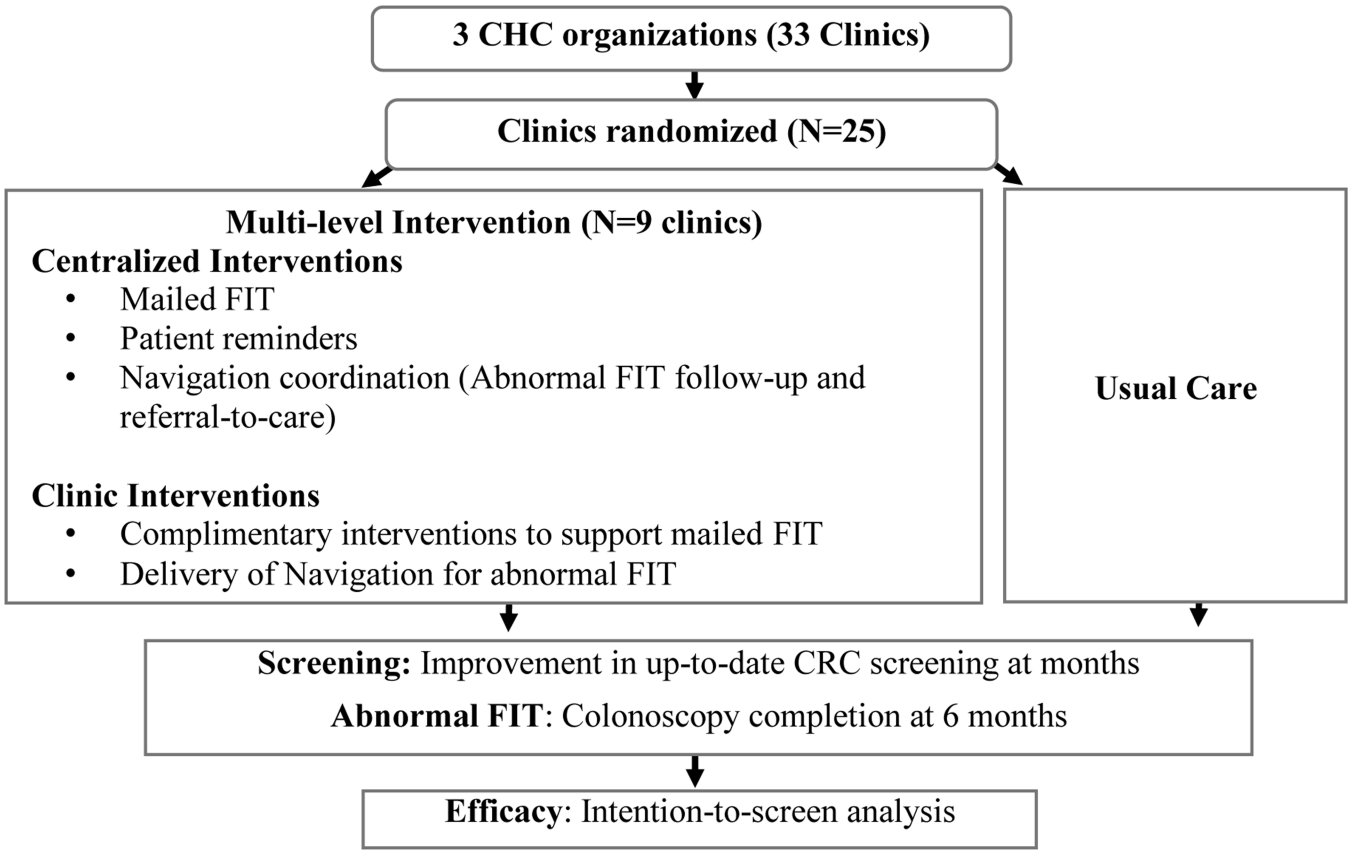

Figure 2.
RCT Study Flow

Table 1.

Patient and Clinic Characteristics

CHC Characteristics	System 1	System 2	System 3
Total patients	66,150	77,895	109,504
% Adult 50–75 y *	20	23	25
% Racial-Ethnic minority	71.4	66.5	88.0
% Hispanic	62.4	55.1	72.8
% Best served in other language	28.2	38.3	49.5
% At or below 200% of poverty	95.3	94.3	92.6
% Uninsured	24.1	14.8	19.3
% Medicaid/CHIP	61.4	78.2	57.5
% Medicare	5.5	8.4	14.1
% CRC screening up-to-date	36.7	51.4	52.2

Source: 2021 Uniform Data System(29)

* screen-eligible population based on 2017 data.

Table 2.

Summary of standardized protocol for promoting colonoscopy follow up after abnormal FIT

Checklist Step	Intervention Activities
Identification of individuals with abnormal FIT	EHR queries identify patients with abnormal FIT in need of diagnostic colonoscopy; these patients are flagged for entry into an abnormal FIT registry.
Results review and colonoscopy order by provider	If not documented, 5 business days after FIT results are available, navigator reminds provider to review results and/or order colonoscopy.
Results reporting to patient	Once colonoscopy is ordered, navigator calls patients. Using a standardized script, results are explained, and 2 options are offered: 1) primary care visit (within 2 weeks) to review results; or 2) a telephone follow-up to facilitate next steps for pre-colonoscopy scheduling following insurance approval.
Insurance approval for colonoscopy	Navigator works with referral coordinators to obtain approval and any additional information required from patient.
Colonoscopy scheduling	Once insurance is approved, navigator provides patient with information for pre-colonoscopy visit scheduling and addresses any barriers to scheduling
Bowel preparation & Colonoscopy completion	Navigator obtains colonoscopy date & provides reminders to patient about bowel preparation & colonoscopy process. Navigator uses motivational interviewing techniques and other strategies to address barriers and concerns.
Colonoscopy results provided to patient and CHC	3 weeks after scheduled colonoscopy, navigator monitors chart to ensure that colonoscopy results have been provided to the patient and their CHC primary care provider.
Referral-to-Care for patients with CRC (if necessary)	For the rare patient with CRC, navigator ensures primary care provider has completed referral to surgeon and/or oncologist, facilitates, verifies patient insurance, helps schedule 1st specialty clinic visit. Formal navigation ends after 1^{s} visit is completed but navigator is available as patient resource.

Table 3.

Key Effectiveness and Quality Outcomes

	Outcome	Definition
Screening	Screening up to date (primary)	Proportion of age-eligible patients with clinic visit in measurement year up to date with screening (FIT or FOBT in prior 12 months, sigmoidoscopy in last 5 years, colonoscopy in last 10 years).
	FIT completion	Proportion of patients who have FIT ordered as part of usual care or interventions who complete FIT within 12 months.
	Repeat screening	Proportion of patients who complete one normal FIT with repeat FIT within 12–14 months This will be measured as an exploratory outcome due to paucity of data on repeat testing.
Abnormal FIT follow-up	Colonoscopy after abnormal FIT (Primary)	Proportion of patients with abnormal FIT who complete colonoscopy within 6 months.
	Time to colonoscopy after abnormal FIT	Median time to colonoscopy completion after abnormal FIT
	Follow-up process	Proportion of patients with abnormal FIT with a) colonoscopy ordered; b) insurance approval completed; c) pre-colonoscopy visit scheduled; d) pre-colonoscopy visit completed; e) adequate bowel preparation at time of colonoscopy; f) treatment evaluation referral initiated and first visit completed if CRC found.

Table 4.

Proposed Measures, Sources, and Level of Data for Select RE-AIM Dimensions

RE-AIM Dimension	Proposed Measures	Data Source	Level
Reach			
Absolute number, proportion, & representativeness of patients who participate in CRC screening compared to eligible non-participants	• % & description of age-eligible patients who are screened and unscreened for CRC	• Patient HER query	• Patient
Adoption			
Absolute number, proportion, & representativeness of settings (clinics) & intervention agents (i.e., providers) who are willing to *initiate a program* compared to eligible non-participants	• % & description of clinics & providers using study CRC screening interventions & specific implementation strategies	• Provider QC query & survey • CHC & Clinic leader interview	• CHC • Clinic • Provider
Implementation of Multilevel Intervention			
At the setting level, implementation is the intervention agents' fidelity to elements of an intervention's protocol (includes consistency of delivery as intended), adaptations to the intervention	• % & description of clinics & providers implementing study CRC screening interventions & specific implementation strategies with fidelity • Implementation dose for each implementation component • Documented adaptations to the intervention and implementation strategy • Barriers & facilitators to implementation	• CHC & Clinic leader interview • Provider QC Query & survey • Adaptation tracking	• CHC • Clinic • Provider
Maintenance			
Extent to which a program or policy becomes institutionalized or part of the routine organizational practices & policies	• % & description of interventions & implementation strategies maintained one year post implementation • Barriers & facilitators of maintained use	• CHC & Clinic leader exit interview • Provider exit QC Query & survey	• CHC • Clinic • Provider

Interviews with purposefully selected site administrative and program staff and clinicians will be used to assess key factors affecting the reach, adoption, implementation, and potential maintenance of the program. Semi-structured interviews will be conducted by experienced implementation scientists at two time points (mid-implementation and late implementation).