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Reach and effectiveness of a centralized navigation program for patients with positive fecal immunochemical tests requiring follow-up colonoscopy

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ABSTRACT

Completion rates for follow-up colonoscopies after an abnormal fecal immunochemical test (FIT) are suboptimal in federally qualified health center (FQHC) settings. We implemented a screening intervention that included mailed FIT outreach to North Carolina FQHC patients from June 2020 to September 2021 and centralized patient navigation to support patients with abnormal FITs in completing follow-up colonoscopy. We evaluated the reach and effectiveness of navigation using electronic medical record data and navigator call logs detailing interactions with patients. Reach assessments included the proportion of patients successfully contacted by phone and who agreed to participate in navigation, intensity of navigation provided (including types of barriers to colonoscopy identified and total navigation time), and differences in these measures by socio-demographic characteristics. Effectiveness outcomes included colonoscopy completion, timeliness of follow-up colonoscopy (i.e., within 9 months), and bowel prep adequacy. Among 514 patients who completed a mailed FIT, 38 patients had an abnormal result and were eligible for navigation. Of these, 26 (68%) accepted navigation, 7 (18%) declined, and 5 (13%) could not be contacted. Among navigated patients, 81% had informational needs, 38% had emotional barriers, 35% had financial barriers, 12% had transportation barriers, and 42% had multiple barriers to colonoscopy. Median navigation time was 48.5 min (range: 24–277 min). Colonoscopy completion differed across groups – 92% of those accepting navigation completed colonoscopy within 9 months, versus 43% for those declining navigation. We found that centralized navigation was widely accepted in FQHC patients with abnormal FIT, and was an effective strategy, resulting in high colonoscopy completion rates.

1. Introduction

Mailed stool-based test outreach programs are effective at increasing colorectal cancer (CRC) screening in diverse populations and settings in the United States (Brenner et al., 2018; Dougherty et al., 2018; Gupta et al., 2020; Issaka et al., 2019; Pignone et al., 2021). However, colonoscopy completion following abnormal stool tests (e.g., fecal immunochemical test or FIT) is often low, especially in safety-net populations such as Federally Qualified Health Centers (FQHCs) (Gupta et al., 2020; Issaka et al., 2019; Bharti et al., 2019; Chubak et al., 2016; Coronado et al., 2021; Escaron et al., 2022). For example, Bharti and colleagues reported that just 44% of a large sample of FQHC patients with abnormal FITs completed a follow-up colonoscopy (Bharti et al., 2019). These findings are concerning, because the ability for stool-based outreach programs to reduce CRC incidence and mortality depends on detection and treatment of pre-cancerous polyps and cancers resulting from

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follow-up colonoscopies.

Additionally, the timeliness (Thamarasseril et al., 2017; Sharma et al., 2022) and quality (Kazarian et al., 2008; Wagner et al., 2019) of colonoscopies after abnormal FITs in safety-net populations remain suboptimal. While there are no national guidelines on the acceptable time interval for colonoscopy completion after positive FIT (San Miguel et al., 2021), colonoscopies performed after 9 months are associated with higher overall and advanced-stage incidence of CRC versus those performed within 1 month of an abnormal stool test (Forbes et al., 2021; Corley et al., 2017). Despite the importance of reducing time to follow-up colonoscopy, FIT to colonoscopy time in safety-net populations has previously ranged from 3 to 7 months (Escaron et al., 2022; Thamarasseril et al., 2017; Breen et al., 2019; Issaka et al., 2017). Quality of follow-up colonoscopy also varies in safety-net populations. In particular, suboptimal bowel preparation impairs detection of polyps and cancer (Millien and Mansour, 2020), and can lead to incomplete exams (Kazarian et al., 2008).

Emerging evidence from studies conducted in the United States and internationally suggests patient navigation can be effective in increasing CRC screening and follow-up colonoscopy completion rates (Dougherty et al., 2018; Selby et al., 2017, 2021), including in high-risk and underserved populations (Honeycutt et al., 2013; Nelson et al., 2020; Percac-Lima et al., 2016; Rice et al., 2017). Navigation can also improve the timeliness and quality of colonoscopies in safety-net populations (Eberth et al., 2018; Idos et al., 2021; Rice et al., 2017). However, while the combination of mailed FIT and navigation programs is a promising opportunity, navigation can be highly variable across contexts (DeGroff et al., 2014). Programs differ with respect to services provided (e.g., financial, transportation, educational), experience and characteristics of navigators (e.g., nurse vs. lay navigators), and methods and intensity of communication with patients (e.g., in-person vs. phone, navigation time). Navigation is also a resource-intensive evidence-based intervention (EBI) relative to population-based EBIs like mailed FIT (DeGroff et al., 2019; Lamanna et al., 2016), requiring careful upfront planning to best optimize limited resources (e.g., staff time) to address individual needs. Therefore, additional data on the structure and effectiveness of navigation programs in safety-net populations is warranted.

Few studies report detailed information about specific barriers to colonoscopy addressed by navigators and documented during program implementation (Barrington et al., 2019). Idos and colleagues reported a nearly 6 percentage point increase in follow-up colonoscopy completion among safety-net patients with navigation, relative to no navigation, and an association between distance to endoscopy facility and colonoscopy completion, but their study did not track patient-reported barriers to colonoscopy (Idos et al., 2021). In Barrington's study of low-income and underinsured patients' barriers to cancer screening, patient navigators identified approximately 25 types of possible barriers to CRC screening; however, their survey relied on navigators' recall of activities rather than prospectively-collected patient-level data (Barrington et al., 2019).

Here, we report implementation outcomes associated with a centralized patient navigation program designed to support FQHC patients with abnormal FITs in the timely completion of follow-up colonoscopy. We report the reach of our navigation program, defined as the proportion of patients with a positive FIT who were contacted by phone and accepted navigation, along with the representativeness of this reach and intensity of navigation services provided (e.g., barriers addressed, amount of navigation time). We also evaluate the effectiveness of navigation with respect to colonoscopy completion, timeliness of follow-up colonoscopy, and bowel prep adequacy.

2. Methods

2.1. Overview of SCORE

Data were collected as part of a larger intervention study, called Scaling Colorectal Cancer Screening Through Outreach, Referral, and Engagement (SCORE), that compared the effectiveness of centralized mailed FIT plus patient navigation versus usual care at increasing CRC screening among North Carolina patients served by two FQHCs. The study protocol was previously published (Malo et al., 2021). Briefly, patients randomized to the intervention arm received an introductory letter notifying them that they were due for CRC screening, a mailed PolyMedco OC Auto FIT kit, and up to two reminder letters. For those with an abnormal FIT, the intervention also included navigation to follow-up colonoscopy, as described below. This study was conducted as part of the NCI-funded consortium The Accelerating Colorectal Cancer Screening and Follow-up through Implementation Science (ACCSIS) Program. The overall aim of ACCSIS is to conduct multi-site, coordinated, transdisciplinary research to evaluate and improve CRC screening processes using implementation science. The Institutional Review Board at the University of North Carolina at Chapel Hill approved this study (#20–0827 and 18–1074).

2.2. SCORE patient navigation

Patients in the SCORE intervention arm who completed a mailed FIT or a clinic-provided FIT during the intervention period and had an abnormal result were offered navigation to facilitate receipt of a follow-up colonoscopy (Fig. 1). We used a *centralized* navigation approach in which a single, dedicated patient navigator, who was not physically located at either FQHC site, provided individualized assistance to patients with a positive FIT to support them in scheduling, preparing for, and completing colonoscopy. This included coordinating with the FQHC clinical team and/or endoscopy providers as needed on behalf of individual patients. The navigator had secure, remote access to each FQHC's electronic medical record (EMR) to support care coordination and to facilitate direct communication with primary care providers and health system staff. The navigator was bilingual in English and Spanish. Translation services were available for other languages.

Navigation occurred primarily by phone. Informed by the previously-published New Hampshire Colorectal Cancer Screening Program patient navigation model (Rice et al., 2017) and our prior intervention research (Brenner et al., 2018; Reuland et al., 2017), the navigator offered four structured call types: 1) introduction to navigation and barrier assessment, 2) bowel preparation instructions, 3) pre-colonoscopy check-in, and 4) post-colonoscopy results and recommendations. The navigator contacted patients for the first time after their provider had notified them of their abnormal FIT result and, by directly mentioning the name of their provider, identified himself as a member of their care team. There was no specified limit to the total number or length of the navigation call types. This flexible structure was developed to provide necessary support throughout the full process, from abnormal FIT notification to receipt of colonoscopy findings, and to connect with patients about key aspects of colonoscopy completion (e.g., health education, transportation, etc.), while being tailored to the individual-level need. In addition to phone calls, the navigator mailed each patient with a positive FIT a letter describing navigation and the importance of follow-up colonoscopy completion. For patients who were unable to be contacted by phone, the navigator mailed a follow-up letter about the need to complete colonoscopy.

Before offering navigation, we developed methods for addressing commonly documented barriers (e.g., financial, transportation) to colonoscopy. These efforts included negotiating reduced colonoscopy rates for uninsured patients at partner endoscopy facilities, developing

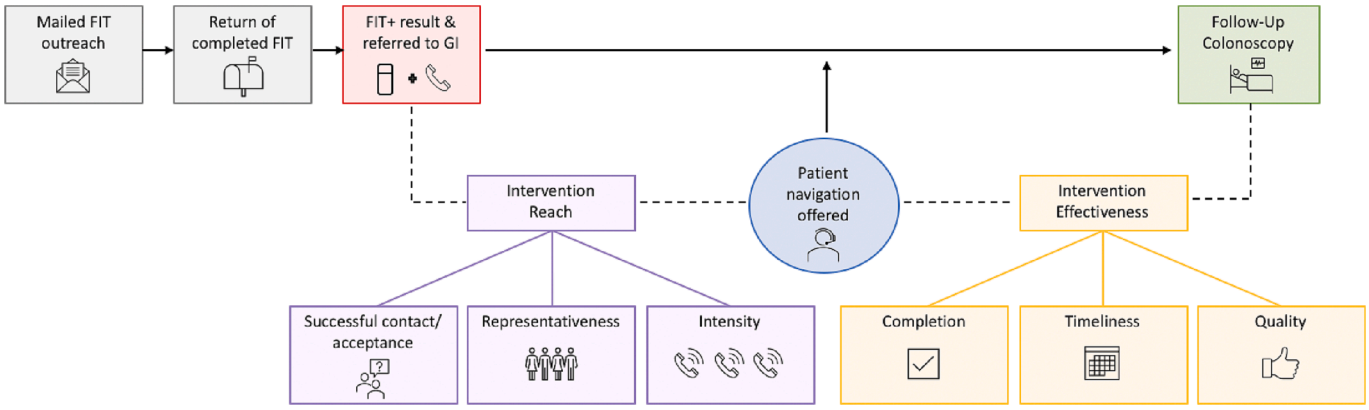

Fig. 1. Evaluation Framework. This framework identifies the two outcome domains of interest (reach and effectiveness) for this analysis and the specific measures within each domain used to evaluate the SCORE patient navigation program. FIT, fecal immunochemical test; GI, gastrointestinal; SCORE, Scaling Colorectal Cancer Screening Through Outreach, Referral, and Engagement.

mechanisms for covering bowel prep costs and colonoscopy fees for patients with financial need, and fostering relationships with transportation services affiliated with the FQHCs. For example, at one site, we expanded the existing transportation program to cover SCORE patients needing transportation to and from clinic appointments.

2.3. Evaluation

We evaluated the pathway between a positive FIT result and follow-up colonoscopy, focusing on two outcome domains of interest: intervention *reach* and *effectiveness* (Fig. 1). Consistent with prior implementation research (Glasgow et al., 2001), we defined *reach* as the proportion of the target population who were contacted (directly spoken to) by phone and agreed to participate in navigation. We also assessed differences in reach by socio-demographic characteristics (Glasgow et al., 2001). In addition, we evaluated navigation intensity, including types of barriers assessed and total navigation time, which captured time spent preparing for, participating in, and following up on calls with the patient and their care team. Within the *effectiveness* domain, we assessed colonoscopy completion within 9 months of abnormal FIT (a previously identified clinically meaningful target (Forbes et al., 2021); number of days from the lab processing the abnormal FIT to colonoscopy completion; and bowel prep adequacy as reported in the colonoscopy report. Appendix A describes how we defined and measured each outcome.

2.4. Eligibility

FQHC patients aged 50–75 and not considered up-to-date with CRC screening, based on the United States Preventive Services Task Force's 2016 recommendation (Bibbins-Domingo et al., 2016), were eligible to receive a mailed FIT through SCORE. This analysis included those who completed a mailed FIT or a clinic-provided FIT and had an abnormal result during the first round of the SCORE trial at both study sites. Mailed FIT outreach occurred from June 2020-September 2021 in waves. We followed patients for 9 months from the time of their abnormal FIT result.

2.5. Data collection

Throughout implementation, we collected comprehensive, prospective data on the reach and effectiveness of the centralized navigation program, all tracked in a secure REDCap database. The patient navigator documented all contact attempts and interactions with patients with abnormal FIT, plus case management activities involved in providing patient-specific care, such as contacts with providers and referral staff to confirm patients' appointments and address patients' questions. Information tracked included: number of calls and call attempts made to patients and on behalf of patients (for example, when connecting patients to needed services); navigation acceptance or refusal; total navigation time; patient barriers to colonoscopy addressed (categorized as informational, emotional, transportation, financial); and specific navigation services provided. The navigator also maintained a call log with detailed free text descriptions of the content of each call, including patient questions and concerns.

Patient characteristics and study outcomes were tracked. Patient characteristics (e.g., age, race/ethnicity, insurance status, etc.) were obtained from the FQHC's EMR. Colonoscopy reports were used to assess colonoscopy outcomes for patients with abnormal FIT – whether a follow-up colonoscopy was ever completed, number of days from the EMR posting of a positive FIT to follow-up colonoscopy completion, and adequacy of bowel prep (categorized as adequate vs. inadequate).

2.6. Analysis

We report descriptive statistics about the reach of centralized navigation offered through SCORE overall, by site, and by insurance status. We then compare each of our effectiveness assessments by intervention reach – for example, the timeliness of follow-up colonoscopy completion by whether the patient accepted or declined navigation. Analyses were conducted using Stata software, version 17.0 (StataCorp, College Station, TX).

3. Results

A total of 2,001 patients were randomized to receive the SCORE intervention across both sites, and 514 (25.7%) completed a FIT during the study period. Among patients who returned a FIT, 43 (8.4%) had a positive result, and 38 (88.4%) of these patients were eligible to receive navigation. The other five patients were excluded due to transferring care to a non-SCORE site or not being medically indicated for colonoscopy. Fig. 2 presents the navigation and colonoscopy outcomes for patients with abnormal FIT. Table 1 reports their characteristics overall and by site. Across sites, 58% of patients with abnormal FIT were female, 70% were aged 50–64, and 30% were aged 65–75. Sixty-three percent of patients with abnormal FIT were non-Hispanic White individuals and one-quarter (26%) were Black individuals. Patients with an abnormal FIT were diverse with respect to insurance status (35% Medicare, 23% commercially-insured, 21% Medicaid, and 21% self-pay/uninsured).

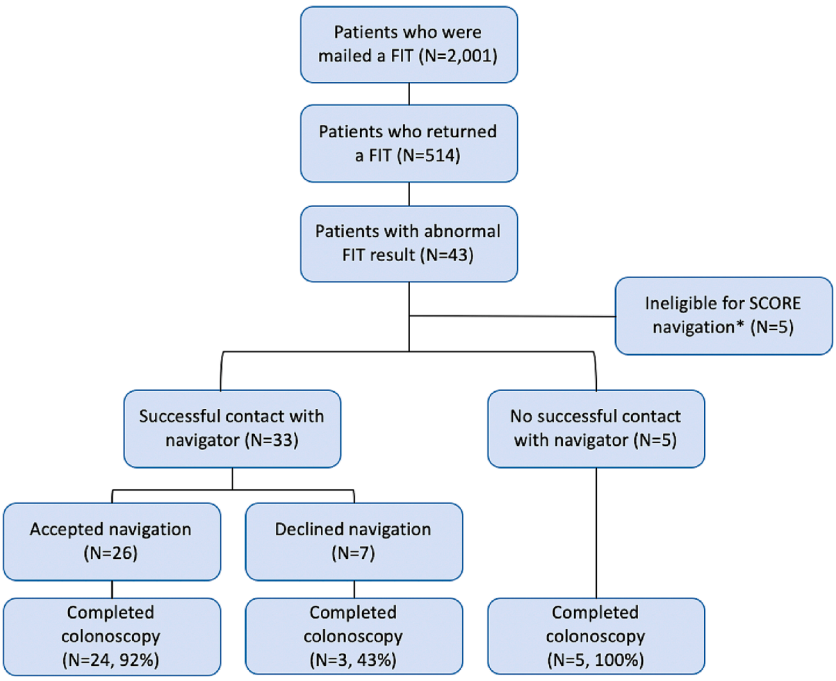

Fig. 2. Navigation Reach and Colonoscopy Completion Among SCORE Patients with an Abnormal FIT. This figure includes all patients offered the SCORE mailed FIT intervention, which was conducted in waves from June 2020-September 2021 in North Carolina; patients with an abnormal FIT were followed for nine months from the time of their abnormal result. *Patients were ineligible for SCORE patient navigation if they transferred care to a non-SCORE site (n = 3) or were not medically indicated for colonoscopy (n = 2). SCORE, Scaling Colorectal Cancer Screening Through Outreach, Referral, and Engagement.

3.1. Reach outcome domain

The majority of eligible patients with an abnormal FIT (26/38, 68%) were successfully contacted by phone and agreed to participate in the SCORE navigation program (i.e.,"reached"), while 18% were successfully contacted by phone but declined navigation, and 13% were unable to be contacted.

With respect to intervention reach by socio-demographic factors, patients who accepted navigation were majority female (58%), under 65 years of age (69%), non-Hispanic White (73%), and Medicare enrollees (38%) or self-pay patients (35%). Comparatively, of the 7 patients who declined navigation, most were 60 years of age or older (86%), male (57%), non-Hispanic Black (57%), and Medicaid (43%) or Medicare (43%) enrollees. No self-pay patients declined navigation (Table 2).

Navigation intensity, which included time spent and types of barriers addressed, varied considerably across those who accepted navigation (Figs. 3a and 3b; Appendix B). The navigator spent a median of 48.5 minutes (range: 24–277 min) total per navigated patient when accounting for both time spent preparing for calls (range: 12–173 min) and time on calls with or on behalf of the patient (range: 7–104 min). Among navigated self-pay patients, the median increased to 102.0 minutes (range: 32–277 min; Fig. 3a).

Of the types of barriers identified through navigation, most patients (81%) reported informational barriers (Fig. 3b), most commonly questions about whether medications for other health conditions needed to be stopped or altered. Additional questions included: why a colonoscopy is needed (including whether cancer had already been detected); whether leaving the stool sample out too long could cause a false positive; how sedation works; and how to interpret colonoscopy results. Over one-third (38%) of navigated patients reported financial barriers, 35% reported emotional barriers (often due to worries about sedation), 12% reported transportation barriers, and 42% reported at least two categories of barriers. Eighty percent of those reporting financial concerns were self-pay/uninsured patients.

3.2. Effectiveness outcome domain

Among patients with abnormal FIT who were eligible for navigation, 84% completed a colonoscopy, all within 9 months of the lab processing their FIT. While some differences were found across sites, time to colonoscopy overall ranged from 14 to 265 days (median: 45 days). Median time to colonoscopy differed by insurance status (49 days or less for commercial and Medicare vs. 59 days or more for self-pay and Medicaid). When assessing colonoscopy completion by navigation reach, 92% of those who accepted navigation, 43% of those who declined navigation, and 100% of those unable to be contacted for navigation completed the exam within 9 months, and the median number of days from the lab result to the exam was 45 days, 33 days, and 88 days in these groups, respectively.

Ninety-one percent of all patients with an abnormal FIT who completed a follow-up colonoscopy had adequate bowel prep. The exam was still completed for the three patients with inadequate prep. Differences were found by insurance status with 100% of self-pay patients and Medicaid enrollees, 92% of Medicare enrollees, and 67% of commercially-insured patients having adequate bowel prep. By reach status, 23 (96%) of those who accepted navigation, 2 (67%) who declined navigation, and 4 (80%) who were unable to be contacted for navigation had adequate bowel prep.

4. Discussion

Our study found that a centralized navigation program for patients with an abnormal FIT within a safety-net population in North Carolina was successful at reaching, and navigating, patients for follow-up colonoscopy. Nearly seventy percent of patients with an abnormal FIT accepted navigation, and the vast majority (92%) of these navigated patients completed a timely colonoscopy, typically within just two months of the FIT result. We found evidence that those who accepted navigation were more likely to complete a follow-up colonoscopy than those who declined navigation.

We demonstrated that our centralized approach was successful at navigating patients to their follow-up colonoscopy. In the SCORE program, despite not being physically located at the FQHC sites, the

Table 1
Characteristics of SCORE Patients with Abnormal FITs and Their Navigation Reach and Colonoscopy Completion by Site.

Characteristic	Site 1 (N = 25)	Site 2 (N = 18)	Both Sites (N = 43)
Age, mean (SD)	59.3 (7.9)	62.1 (7.1)	60.5 (7.6)
Age Category			
50–54 years	10 (40%)	4 (22%)	14 (33%)
55–59 years	4 (16%)	2 (11%)	6 (14%)
60–64 years	4 (16%)	6 (33%)	10 (23%)
65–69 years	3 (12%)	4 (22%)	7 (16%)
70–74 years	4 (16%)	2 (11%)	6 (14%)
Sex			
Female	14 (56%)	11 (61%)	25 (58%)
Male	11 (44%)	7 (39%)	18 (42%)
Race/Ethnicity			
Non-Hispanic White	20 (80%)	7 (39%)	27 (63%)
Non-Hispanic Black	1 (4%)	10 (56%)	11 (26%)
Other/Unknown	4 (16%)	1 (6%)	5 (12%)
Insurance Type			
Commercial	7 (28%)	3 (17%)	10 (23%)
Medicaid	7 (28%)	2 (11%)	9 (21%)
Medicare	7 (28%)	8 (44%)	15 (35%)
Self-pay/uninsured	4 (16%)	5 (28%)	9 (21%)
Primary Language*+			
English	24 (96%)	18 (100%)	42 (98%)
Spanish	1 (4%)	0	1 (2%)
Navigation Reach			
Accepted navigation	14 (56%)	12 (67%)	26 (60%)
Declined navigation	3 (12%)	4 (22%)	7 (16%)
Unable to be contacted	3 (12%)	2 (11%)	5 (12%)
Ineligible	5 (20%)	0	5 (12%)
Colonoscopy Completed	N = 20	N = 18	N = 38
Yes	16 (80%)	16 (89%)	32 (84%)
No	4 (20%)	2 (11%)	6 (16%)
Adequacy of Bowel Prep	N = 16	N = 16	N = 32
Adequate	15 (94%)	14 (88%)	29 (91%)
Inadequate but completed	1 (6%)	2 (13%)	3 (9%)
Time to colonoscopy, median (range), in days	71.5 (14–265)	33.5 (21–245)	45 (14–265)

SCORE mailed FIT outreach was conducted in North Carolina in waves from June 2020-September 2021, and patients with an abnormal result were followed for nine months from the time of their abnormal result. This table includes all patients who completed a mailed FIT or clinic-provided FIT during the intervention period and had an abnormal result (n = 43). *Patient navigation was offered in English and Spanish, and translation services were available for patients who spoke other languages. +In cases where language was missing in EMR records, primary language was determined based on language used during interactions with the navigator. SCORE, Scaling Colorectal Cancer Screening Through Outreach, Referral, and Engagement.

navigator had access to their EMR systems and communicated through the EMR and by phone with FQHC staff, endoscopy providers, and other entities as needed. Thus, while navigation was provided by a source external to the health system, it operated in close partnership with the FQHC, and presented the navigator to patients as another member of their primary care clinical team. This centralized design highlights future opportunities to provide similar assistance to patients facing barriers to colonoscopy without placing additional burdens on on-site clinic staff and providers.

Although the numbers are relatively small, insurance status

Table 2
Navigation Reach and Effectiveness by Insurance Status, Among Eligible SCORE Patients with a Positive FIT.

	Commercial (N = 7)	Medicaid (N = 8)	Medicare (N = 14)	Self-Pay/Uninsured (N = 9)	All Insurance Types (N = 38)
Navigation Reach					
Accepted navigation	4 (57%)	3 (38%)	10 (71%)	9 (100%)	26 (68%)
Declined navigation	1 (14%)	3 (38%)	3 (21%)	0	7 (18%)
Unable to be contacted	2 (29%)	2 (25%)	1 (7%)	0	5 (13%)
Colonoscopy Completed					
Yes	6 (86%)	5 (63%)	12 (86%)	9 (100%)	32 (84%)
No	1 (14%)	3 (38%)	2 (14%)	0	6 (16%)
Adequacy of Bowel Prep	N = 6	N = 5	N = 12	N = 9	N = 32
Adequate	4 (67%)	5 (100%)	11 (92%)	9 (100%)	29 (91%)
Inadequate but complete	2 (33%)	0	1 (8%)	0	3 (9%)
Time to Colonoscopy, median (range), in days	49 (14 – 245)	88 (31 – 265)	39 (14 – 153)	59 (27 – 133)	45 (14 – 265)

SCORE mailed FIT outreach was conducted in North Carolina in waves from June 2020-September 2021, and patients with an abnormal result were followed for nine months from the time of their abnormal result. This table includes all patients who completed a mailed FIT or clinic-provided FIT during the intervention period, had an abnormal result, and were eligible to receive patient navigation to their follow-up colonoscopy through SCORE (n = 38). SCORE, Scaling Colorectal Cancer Screening Through Outreach, Referral, and Engagement.

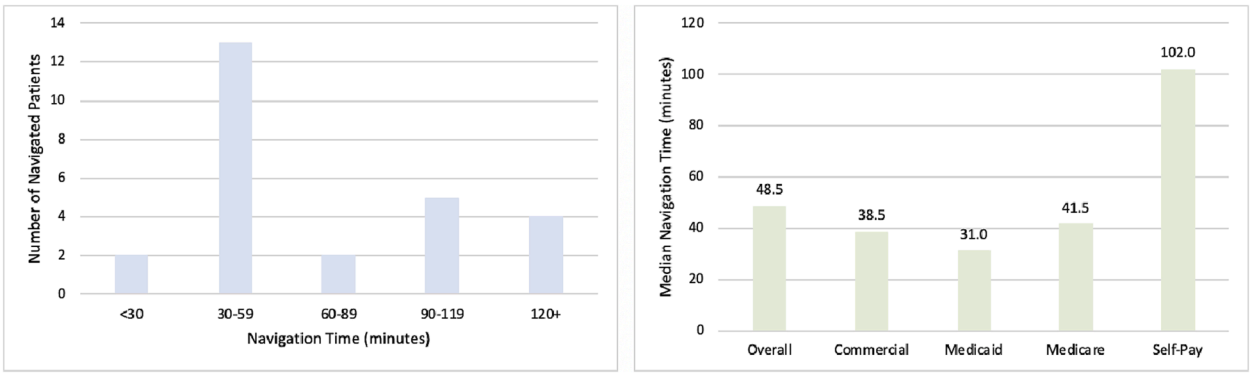

Fig. 3a. Total Navigation Time Per SCORE Navigated Patient, and Median Navigation Time by Insurance Status. SCORE mailed FIT outreach was conducted in North Carolina in waves from June 2020-September 2021, and patients with an abnormal result were followed for nine months from the time of their abnormal result. Data on total per-person navigation time, in minutes, is included for all patients with abnormal FITs who participated in SCORE patient navigation (n = 26). Total navigation time includes time spent preparing for and directly on calls with patients and on behalf of patients (i.e., case management activities). SCORE, Scaling Colorectal Cancer Screening Through Outreach, Referral, and Engagement.

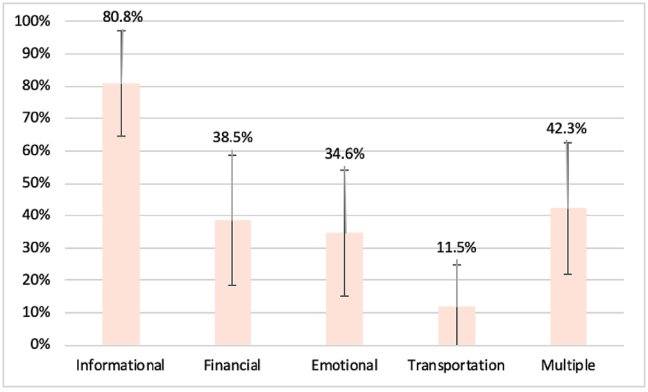

Fig. 3b. Percentage of SCORE Navigated Patients with Abnormal FITs (N = 26) Reporting Barriers to Colonoscopy Completion. SCORE mailed FIT outreach was conducted in North Carolina in waves from June 2020-September 2021, and patients with an abnormal result were followed for nine months from the time of their abnormal result. The categories of barriers to colonoscopy completion assessed during patient navigation are not mutually exclusive (i.e., a patient may have multiple types of barriers to colonoscopy). SCORE, Scaling Colorectal Cancer Screening Through Outreach, Referral, and Engagement.

appeared to influence the reach of our navigation program, with self-pay/uninsured and Medicare patients more commonly accepting navigation and requiring more intensive services. All uninsured patients with a positive FIT accepted navigation and, despite reporting high levels of financial need and information gaps, completed a timely colonoscopy with adequate bowel preparation. The navigator provided multiple services to support patients without insurance in overcoming financial barriers to colonoscopy completion. This included helping to coordinate the application process for patients applying for Charity Care (i.e., discounted or no-cost endoscopy services provided to low-income patients meeting eligibility criteria), as well as negotiating discounted colonoscopy rates with local endoscopy providers directly to cover both clinic check-in and procedures. The navigator also coordinated directly with endoscopy providers' financial services to ensure that patients' bills were paid in a timely manner and any billing issues or questions were resolved. In cases where no other options were available for patients without insurance, we used program funds to cover the cost of bowel prep at the patient's local FQHC pharmacy and any other out-of-pocket colonoscopy fees.

Despite the absence of a comparison group, our study's colonoscopy completion rate of 92% overall among navigated patients (and 100% among the uninsured) compares favorably with published rates in non-navigated populations. Coronado, et al, found a 65% follow-up colonoscopy completion rate among non-navigated patients (versus 76% of those navigated) in insured patients in an integrated health system (Coronado et al., 2021). DeGroff and colleagues reported a 53% completion rate for non-navigated patients (compared to 61% for navigated patients) among low-income, non-white patients undergoing colonoscopy screening (DeGroff et al., 2017). In a large sample of safety-net patients with abnormal FIT, Idos, et al, reported colonoscopy completion rates of 41% and 46% for non-navigated and navigated patients, respectively (Idos et al., 2021). In an international survey of 35 CRC screening programs, Selby and colleagues found a mean colonoscopy completion rate after positive stool test of 79%, with an average increase of 11 percentage points for programs using patient navigation versus those that did not (Selby et al., 2021). The relatively high acceptability of navigation and colonoscopy completion by our safety-net population, especially the uninsured, suggests the need for resources to implement and sustain this type of intervention in similar contexts.

Nearly three-quarters (71%) of Medicare enrollees with an abnormal FIT accepted navigation. Informational gaps were their primary barrier to colonoscopy, though 30% also expressed emotional barriers, and most (86%) completed a colonoscopy once their questions and concerns were addressed. In contrast, just 38% of Medicaid enrollees accepted navigation. While surprising, since Medicaid enrollees often experience barriers to accessing care that could be addressed with navigation (Slater et al., 2018), this finding may be due to small sample sizes in our study. Medicaid enrollees in North Carolina may also not be representative of those in other states due to having stricter Medicaid eligibility criteria at the time of the study compared to non-expansion states. Previous research has also shown mixed evidence of Medicaid enrollees' navigation use and colonoscopy completion (Brenner et al., 2018; Breen et al., 2019; Green et al., 2020; Slater et al., 2018). We similarly found relatively low navigation reach (57% declined) among individuals who identified as Black, but 73% overall completed colonoscopy. Prior research has shown that navigation acceptance is associated with statistically significant increases in screening uptake and timeliness of diagnostic follow-up among Black individuals (Ko et al., 2016; Cole et al., 2017; Rogers et al., 2020). Further research is needed to understand how to improve navigation reach in the Black population as well as the Medicaid population, since later-stage CRC diagnoses in this population negatively affect state-level healthcare costs and outcomes (Andrew et al., 2018), and because navigation was originally developed to address inequities in cancer burden (Freeman and Rodriguez, 2011).

The timeliness of follow-up colonoscopy completion was another important finding. Median time to colonoscopy among navigated safety-net patients who completed colonoscopies in our study was less than two

months (45 days), a marked improvement over the 3–7 month time to follow-up previously documented in other safety-net populations (Escaron et al., 2022; Thamarasseril et al., 2017; Breen et al., 2019; Issaka et al., 2017; Idos et al., 2021). In another study of patient navigation, Idos and colleagues reported a median time to follow-up colonoscopy with navigation of more than three months (105 days) among Los Angeles safety-net patients, compared to 121 days without navigation (Idos et al., 2021).

While our navigation program typically included four structured calls, we allowed for tailoring to patients' individual needs and preferences. For example, some patients initially identified barriers to colonoscopy (e.g., financial, transportation), but later declined to receive related services since they had addressed these barriers on their own. This suggests that, while patients may have high perceived barriers to care, some concerns can be resolved through discussion and encouragement alone, without requiring additional services. Most patients had primarily informational barriers, minimizing the number of calls needed after addressing their questions. This is consistent with Cusumano and colleagues' finding that 38% of patients overdue for follow-up colonoscopy after abnormal FIT requested to schedule their exam after receiving brief patient education (Cusumano et al., 2020). PR campaigns and/or practice-level patient education tools are likely to be useful in the future, allowing navigation to be reserved for those who require additional services. While we anticipated that transportation would be a large barrier to care, as previously reported (Idos et al., 2021; Jetelina et al., 2019; Muthukrishnan et al., 2019; Schneider et al., 2020; Zoellner et al., 2021), just 12% of our population reported transportation barriers, possibly due to geographic or other contextual factors specific to our population.

Although successful, our navigation program was resource-intensive, typically requiring nearly one hour (median: 48.5 min) of navigation time per patient. Of this time, 15.5 minutes were spent directly talking with the patient and the patient's care team, with the remaining time spent by the navigator looking into the patient's questions and setting up required services. Through tracking each individual call with navigated patients, we determined that assisting patients in scheduling their colonoscopy appointments and providing financial navigation were large contributors to the amount of navigation time required. We anticipate that per-patient navigation time could be reduced in the future by identifying even more efficient protocols and resource use. For example, with experience, navigators likely develop more comprehensive lists of patient questions and how to address those questions. Another efficient approach could involve separate protocols for patients with informational barriers only versus those who need more intensive services, such as applying for a financial assistance program. A comprehensive cost analysis of the SCORE intervention, including navigation, will be reported separately and used to inform intervention sustainment and scale-up.

Our study coincided with the COVID-19 pandemic, which had myriad effects on healthcare, including the navigation process. The navigator addressed a range of pandemic-related logistical issues (e.g., endoscopy providers requiring in-person COVID-19 testing before colonoscopies, small delays in colonoscopy scheduling as demand increased following the decline in COVID-19 cases, etc.) and patient concerns about seeking care during the pandemic. Despite these challenges, we were able to obtain high rates of navigation acceptance and colonoscopy completion, likely due to our phone-based navigation approach and adapting the structure of navigation calls to include these COVID-19-related topics.

This study has limitations. Though our study represents a population of 2,001 patients offered mailed FIT outreach, the sample size of patients with a positive FIT evaluated in this study was small, especially when evaluating the results by patients' insurance status. For this reason, we report only descriptive statistics without testing differences by navigation reach or insurance status. Also, all patients with an abnormal FIT in the SCORE intervention arm were offered navigation, so we did not have a control group in this analysis. However, as prior studies previously established that navigation is an EBI, systematic exclusion of patients from a known-effective intervention would arguably be unethical. Additionally, some settings include some degree of navigation as part of usual care and, as such, implementing a centralized navigation program may not have the same impact that we found. Finally, our results may not be comparable to navigation programs utilizing other modes of communication, like text messaging, or located in contexts differing substantially from ours in North Carolina.

5. Conclusion

Our study demonstrated that diverse safety-net patients with relatively high barriers to follow-up colonoscopy are willing to participate in a centralized navigation program. Navigated patients completed a follow-up colonoscopy at a high rate, over twice that of patients who were not reached in our program. Because of these findings, we conclude that layering on this individualized assistance for patients with abnormal stool tests is a critical component of population-level FIT programs.

Disclosure of funding and conflicts of interest

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CRediT authorship contribution statement

Meghan C. O'Leary: Methodology, Software, Formal analysis, Data curation, Writing – original draft, Writing – review & editing, Visualization. **Daniel S. Reuland:** Conceptualization, Methodology, Writing – review & editing, Supervision, Funding acquisition. **Connor Randolph:** Methodology, Validation, Formal analysis, Investigation, Writing – review & editing, Project administration. **Renée M. Ferrari:** Conceptualization, Methodology, Investigation, Writing – review & editing, Supervision, Project administration. **Alison T. Brenner:** Conceptualization, Software, Resources, Data curation, Writing – review & editing, Supervision, Project administration, Funding acquisition. **Stephanie B. Wheeler:** Writing – review & editing, Funding acquisition. **Deeonna E. Farr:** Writing – review & editing. **Michael K. Newcomer:** Writing – review & editing. **Seth D. Crockett:** Conceptualization, Methodology, Writing – review & editing, Supervision, Funding acquisition.

Declaration of Competing Interest

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.

Data availability

Data are available at https://dataverse.unc.edu/dataverse/CCSI.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.pmedr.2023.102211.

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