Implementing a small media intervention to increase colorectal cancer screening in primary care clinics

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Abstract

Colorectal cancer (CRC) is one of the most common cancers in the USA. In 2017, an estimated 135,420 people were diagnosed with CRC and 50,260 people died from CRC. Several screening modalities are recommended by the United States Preventive Services Task Force (USPSTF), including annual stool tests that are usually completed at home and under-used compared with colonoscopy despite stated patient preferences for an alternative to colonoscopy. The *Community Preventive Services Task Force* recommends use of small media interventions (SMIs) to increase CRC screening and calls for a greater understanding of its independent impact on screening participation. This study tested whether a SMI increased the likelihood of participant return of a USPSTF recommended Fecal Immunochemical Test (FIT). In total, 804 individuals participated in a two-group, prospective randomized controlled trial. Descriptive statistics with chi-square tests compared differences in participant characteristics and return rates. Multivariable log-binomial modeling estimated combined effects of patient characteristics with FIT return rates. No differences in return rates were observed overall or by participant characteristics other than the year of enrollment. A multivariable model controlling for all covariates, found gender, insurance type, and regular place for healthcare to be significantly associated with return rates. Receipt of the SMI did not independently increase overall return rates but it may have improved the ease of completing the FIT by some participants, particularly women, those with insurance, and those with a regular place for healthcare.

Keywords

Small media intervention; Colorectal cancer screening; Primary care; Screening barrier

INTRODUCTION

Colorectal cancer (CRC) is one of the most common cancers in the USA. In 2017, it is estimated that 135,420 people will be diagnosed with CRC, and 50,260 people will die from it. CRC is disproportionately burdensome for African-Americans (AAs) who experience 25% greater incidence and nearly 50% greater mortality compared with Caucasians [2]. This disparity is particularly striking given the substantial improvements in CRC incidence and declines in mortality overall in the past 25 years, which are largely attributed to improvements in screening [1–3].

As this study was in its planning phase in 2008, the United States Preventive Services Task Force (USPSTF) released its third set of screening

Implications

Practice: The use of small media interventions may help patients overcome individual, health-care system, and other barriers to participation in colorectal cancer screening programs and encourage their use and return of home-based stool tests.

Policy: Low colorectal cancer screening rates among vulnerable populations may be improved by programs and services, including small media interventions that increase individual awareness of effective, cost efficient, home-based stool testing.

Research: Research to increase the participation of vulnerable populations in colorectal cancer screening should focus on multilevel, multimodal approaches to refine and promote the use of small media in combination with other proven approaches (e.g., use of patient navigators/community health educators) along with a choice of screening options, including newly developed, more sensitive/specific, and easier to use home-based stool tests.

recommendations: colonoscopy every 10 years, annual Fecal Immunochemical Tests (FIT), annual high-sensitivity Fecal Occult Blood Tests (FOBT), or flexible sigmoidoscopy every 5 years combined with high-sensitivity FOBT every 3 years [4]. Each modality was found to have functionally equivalent effectiveness for early detection of CRC when used according to guidelines [4]. A new set of recommendations was published in 2016 [5–7].

Use of effective screening modalities has been hindered by many factors, including differential perceptions of the invasiveness, discomfort, convenience, privacy, and cost of each modality, as well as differential awareness of CRC risk and the benefits of screening [6, 8–11]. In addition to being the least costly and thus presenting the lowest financial barrier, several studies have shown that home-based stool tests (FIT,

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FOBT) are preferred by patients for their perceived convenience and minimal invasiveness and discomfort, among other factors [10, 12–14]. However, the use of available home-based stool tests for CRC has been hampered by a lack of awareness of test availability and effectiveness, as well as low completion rates, especially in groups with low health literacy or cultural health beliefs that do not emphasize prevention [10, 15–17].

Several approaches are recommended by the Community Preventive Services Task Force (Task Force) to increase participation in CRC screening [18, 19]. One approach is the use of small media interventions (SMI) that may include videos and printed materials such as letters, brochures, and newsletters to inform and motivate people to be screened for cancer. SMI can also provide information tailored to specific individuals or groups and may be distributed either directly or through community or health-care settings [18]. The Task Force supports the use of SMI to increase screening and calls for research to examine the utility of small media to address structural and other barriers among specific populations, such as those who have never been screened or who may be difficult to reach regarding screening [20, 21]. This study responds to the Task Force call for additional small media research as a means to address “other barriers” faced by minority and underserved populations and tests whether participants receiving a SMI are more likely to return a FIT than those not receiving the SMI.

METHODS

A two-group, prospective randomized controlled trial (RCT) was implemented in eight primary care clinics in collaboration with four health organizations in North Carolina (NC) and one in South Carolina (SC). Each clinical site serves or served (one NC clinic closed during the study) a broad population including AA and the uninsured and underinsured. Two clinics were in adjacent eastern NC counties (Edgecombe and Nash), a rural area of the state where approximately 50% of the 148,000 residents are AA. Other NC clinics were in Guilford County, a more urban county in central North Carolina where 34% of the 515,000 residents are AA. Charleston, in southeast South Carolina, is a city in which 25% of the 132,000 residents are AA. These clinics focus on providing a range of affordable, high-quality care to members of their local and regional communities and whose incomes may fall below 225% of the federal poverty level.

The principal investigator held in-person meetings with medical and administrative directors in each primary care clinic to present the opportunity to participate in the study and review the study aims and protocol. Once agreement to participate was reached, the PI worked with each clinic’s clinical leads to tailor the protocol to avoid disruptions

to patient flow and standard operating procedures. Research team members provided initial and ongoing training on how to implement the protocol, shared data on participant recruitment numbers each month, and met, as needed to resolve any observed problems with recruitment, data collection, or other issues.

The study protocol was submitted to and approved by the UNC Institutional Review Board (IRB) or the IRB at the Medical University of South Carolina.

Participants

Potential study participants were identified via medical record as English-speaking AA individuals over the age of 50 years and younger than 75 years seeking care at one of the study sites. Prospective participant recruitment occurred in one of three ways: (1) in-person with same-day enrollment; (2) in-person recruitment with delayed enrollment; or (3) in response to a mailed recruitment letter. Regardless of the recruitment method, each participant was interviewed by research staff using the Colorectal Cancer Risk Survey Profile (CRCRSP) to determine if they met study eligibility criteria: average risk of CRC (e.g., no personal or first-degree family history of CRC), having no symptoms of CRC (e.g., rectal bleeding), and not up-to-date on CRC screening per 2008 USPSTF recommendations (no FOBT or FIT CRC screening test in the past year, no sigmoidoscopy or barium enema in the past 5 years, and no colonoscopy in the past 10 years). All CRCRSP responses were entered directly into a REDCap database by a research team member and transferred to a secure server location at UNC via daily upload.

Eligibility for the RCT was determined in real time using an algorithm embedded in REDCap. Individuals reporting symptoms of CRC or family history of CRC were immediately referred to their primary care provider for usual care follow-up. Eligible individuals willing to participate in the study provided written informed consent prior to enrollment. A computer algorithm randomly assigned eligible, consented participants to an intervention group. Across all sites, 2402 patients were screened, 914 patients (38%) were eligible for the trial, and 804 (88%) eligible patients were consented, enrolled, and randomized into two intervention groups (FIT-SMI ($n = 419$, 52%) and FIT ($n = 385$, 48%)). The summarized cohort assembly is presented in Fig. 1.

Around month 20 of the enrollment period, a notable lag in enrollment was examined using the results of CRCRSP data from sites participating at the time ($n = 2$). A review of accrual data for each site showed that a higher percentage of potential participants reported being up-to-date on CRC screening in this study (67%) compared with those in the pilot study conducted between 2008 and 2010 (34%). Other eligibility categories (family history, etc.) did not differ.

Fig 1 | CONSORT flow diagram: participant enrollment and follow-up, small-media CRC screening trial, all sites, 2011–2016.

Investigators reported these data and their concerns about being able to meet target enrollment to the funding agency. Investigators were advised to open additional study sites and relax eligibility criteria to allow all under or uninsured participants. Beginning in month 23, both recommended approaches were implemented as the study was initiated in two additional clinics and “patients other than AA race” was no longer an exclusion for eligibility.

INTERVENTION

The small-media intervention was developed from input received from two consecutive focus groups with AA women and men aged 50 years and older from communities that reflected the target patient population [22]. The goal of the first focus group was to elicit knowledge of and opinions about CRC and screening options in the AA community, information on individual, healthcare and other systems barriers to participation in CRC screening, and attributes of effective messaging. The participants also reviewed and offered comments on the existing CRC screening tests available to them.

Based on feedback from focus group participants, the study team prepared two SMI prototypes with educational messages and materials designed to promote the benefit of early and periodic CRC screening as recommended by the USPSTF and to address information and logistical needs associated with completing a stool test at home. Each SMI contained items recommended by the first focus group: a large water-resistant envelope (“to keep everything in one place”) with colorful health messaging (“to remind me of why I need to do this test”), a frequently asked

questions (FAQ) sheet with a toll-free number to call for help, a set of specific instructions with photographs of how to obtain a fecal sample, use of a large font (“so I don’t have to put on my glasses”), a stamped, self-addressed envelope to return the test cards (“so I don’t have to pay postage or go to the post office”), and a drying envelope to protect stool samples from contamination and/or prevent contact by others as the cards dried (“my grands get into everything”) [22]. Participants in the second focus group offered comments on the SMI prototypes and chose the SMI shown in Fig. 2 (FIT-SMI).

In each setting, providers were notified of participant eligibility for the study and asked to remind all eligible patients (i.e., those between ages of 50 and 74, at low risk for CRC and not up-to-date on CRC screening) during their clinic visit that they were due for CRC screening and that options for screening were available to them (options varied by site, e.g., hospital sites were able to do colonoscopy on site vs. free standing clinics which did not offer colonoscopy on site). Scripting beyond this advice for providers was not provided as part of this study, in part to not unduly influence an individual’s decision to participate in a home-based stool test study.

Study participants received either the FIT (control) or the FIT-SMI (intervention). Participants in the FIT group received three stool collection cards, tissue paper and scoops for stool collection, and a stamped self-addressed envelope for returning the stool collection cards. In addition to these items, the FIT-SMI group received the SMI which included a water-resistant envelope with colorful, large-font health messaging, a FAQ with toll-free

Kit contents:

- Day 1 stool collection page with card for stool collection, tissue paper, and stick
- Day 2 stool collection page with card for stool collection, tissue paper, and stick
- Day 3 stool collection page with card for stool collection, tissue paper, and stick
- Drying envelope
- Mailing envelope
- Frequently Asked Questions sheet with a phone number you can call for more information

Take care of your health!

**If you are 50 or older,
you are at risk for getting colon cancer.
Colon cancer starts with no symptoms.
You need this test, now.
Take this test even if you feel fine.**

Preventable, Treatable, and Beatable

Things you need to know before you start:

- If you have **hemorrhoids or blood in your urine**, if you **strained during your bowel movement**, or if you have **open cuts on your hands** — **do not** collect stool samples from that bowel movement.
- If you are a woman who is still having periods, wait until **3 days after bleeding has stopped** before starting this test.
- Keep collection cards **away from heat, light, and chemicals**.

What else do I need?

- 1 sheet of newspaper or 2 feet of plastic wrap

1 Fill out the card

- ▶ Take the page called Day 1 from the envelope. Write your name, your health care provider's name, and the date on the stool collection card with a pen.

2 Set up the toilet

- ▶ Try to empty your bladder **before** your bowel movement.
- ▶ Lift the toilet seat. Put 1 sheet of newspaper or plastic wrap over the **back half** of the toilet bowl. Let the middle of the newspaper hang just above the water.
- ▶ Put 1 sheet of the provided tissue paper on top of the newspaper. Lower the seat.
- ▶ Have a bowel movement. But, **do not** flush yet.

3 Collect stool

- ▶ Open the front flap of the card. Use the stick to collect a pea-sized bit of stool. Spread it on the **top half** of the circle, **above** the line.
- ▶ Use the same stick to collect another pea-sized bit from a **different** area of the stool. Spread it on the **bottom half** of the circle, **below** the line.
- ▶ Use the stick to mix the top and bottom samples together.

Do not collect a sample from stool that has fallen into the toilet water.

Fig 2 | FIT-SMI contents, small-media CRC screening trial.

number to call for help, specific instructions and photos to inform stool collection, and a drying envelope.

Study participants in both intervention groups received all materials free of charge (test cards and return envelopes donated by Beckman Coulter) and were not charged a lab-processing fee. Follow-up expenses associated with a positive test were covered for all participants via the patient's insurance and/or pro bono provision of services by hospitals affiliated with each clinic or by UNC Health Care system providers. Patients without insurance coverage were also referred to appropriate local services and resources for enrollment in available services, including Medicare and/or Medicaid. Coverage of financial costs for those without insurance was negotiated with local and state health providers prior to the start of the trial. Participants could either mail or return the FIT in person to the clinic.

A reminder was sent to each study participant by the USA mail if the FIT was not returned within 2 weeks of distribution. FITs returned after 6 weeks from the date of receipt were counted as "not returned."

OUTCOME MEASURE

The primary outcome of the study was the FIT return rate: the number of FITs returned by study participants compared with the number of FITs distributed to study participants.

STATISTICAL ANALYSIS

Using the O'Brien-Fleming method that allows for early stopping of the trial if a larger or smaller than expected difference in return rates was observed after half of the total sample was enrolled, it was estimated that a maximum total sample size of 1,564 (782 per group) was needed to detect a 7% difference in return rates (60% vs. 67%) with a two-sided test statistic, a significance level of 0.05, and 80% power. Study enrollment began November 7, 2011 and was suspended when the enrollment target ($N = 792$) was surpassed ($N = 804$) on February 29, 2016. Descriptive statistics are provided for patient characteristics, and return rates are compared between groups using chi-square tests. A multivariable log-binomial model was estimated to examine the combined association of patient characteristics with return rates, while accounting

Table 1 | Demographic and survey characteristics of participants, small-media colorectal cancer screening trial, all sites, 2011–2016, *n* = 804

Characteristics	Total sample		Control group		Intervention group		<i>p</i> value
	<i>N</i>	(%)	<i>N</i>	(%)	<i>N</i>	(%)	
Overall	804	100.0%	385	47.9%	419	52.1%	—
Race							
African-American	672	85.4%	322	85.0%	350	85.8%	0.7437
Caucasian	115	14.6%	57	15.0%	58	14.2%	
Ethnicity							
Hispanic	12	1.5%	5	1.3%	7	1.7%	0.6639
Non-Hispanic	792	98.5%	380	98.7%	412	98.3%	
Age							
49–54	318	39.6%	150	39.1%	168	40.1%	0.6941
55–59	239	29.8%	115	29.9%	124	29.6%	
60–64	152	18.9%	69	18.0%	83	19.8%	
65–69	71	8.8%	36	9.4%	35	8.4%	
70–74	23	2.9%	14	3.6%	9	2.1%	
Gender							
Male	341	42.4%	159	41.3%	182	43.4%	0.5400
Female	463	57.6%	226	58.7%	237	56.6%	
Marital status							
Married	197	24.6%	94	24.5%	103	24.6%	0.9897
Not married	605	75.4%	289	75.5%	316	75.4%	
Education level							
<High school	253	31.5%	116	30.1%	137	32.9%	0.2260
High school grad	372	46.4%	174	45.2%	198	47.5%	
Any college	177	22.1%	95	24.7%	82	19.7%	
Health insurance							
None	300	37.4%	133	34.6%	167	39.9%	0.2671
Private	104	13.0%	51	13.3%	53	12.6%	
Medicare	102	12.7%	56	14.6%	46	11.0%	
Medicaid	118	14.7%	64	16.7%	54	12.9%	
Medicare+Medicaid	50	6.2%	21	5.5%	29	6.9%	
Other	129	16.1%	59	15.4%	70	16.7%	
Annual household income							
<\$5,000	137	18.7%	64	18.1%	73	19.3%	0.3621
\$5,000–\$14,999	260	35.6%	126	35.7%	134	35.4%	
\$15,000–\$24,999	226	30.9%	119	33.7%	107	28.3%	
\$25,000–\$34,999	62	8.5%	25	7.1%	37	9.8%	
>\$35,000	46	6.3%	19	5.4%	27	7.1%	
Employment status							
Employed	256	31.9%	114	29.6%	142	34.0%	0.1852
Not employed	547	68.1%	271	70.4%	276	66.0%	
Year of enrollment							
2011	10	1.2%	4	1.0%	6	1.4%	0.0123
2012	142	17.7%	66	17.1%	76	18.1%	
2013	24	3.0%	16	4.2%	8	1.9%	
2014	341	42.4%	157	40.8%	184	43.9%	
2015	256	31.8%	135	35.1%	121	28.9%	
2016	31	3.9%	7	1.8%	24	5.7%	
Regular source of care							
Yes	699	87.5%	331	86.6%	368	88.2%	0.4947
No	100	12.5%	51	13.4%	49	11.8%	

(Continued)

Table 1 | Continued

Characteristics	Total sample		Control group		Intervention group		<i>p</i> value
	<i>N</i>	(%)	<i>N</i>	(%)	<i>N</i>	(%)	
Enrollment site							
Clinic 1	5	0.6%	3	0.8%	2	0.5%	
Clinic 2	80	10.0%	36	9.4%	44	10.5%	
Clinic 3	41	5.1%	21	5.5%	20	4.8%	
Clinic 4	223	27.7%	112	29.1%	111	26.5%	
Clinic 5	433	53.9%	204	53.0%	229	54.7%	
Clinic 6	22	2.7%	9	2.3%	13	3.1%	

for correlation within site. Relative risks, along with 95% confidence intervals are reported. All analyses were conducted using SAS Statistical Software v9.4 (Cary, NC).

RESULTS

Sample characteristics

Overall, a significant difference between intervention and control groups was observed only for the year of enrollment ($p = .01$); no significant differences were found for other participant characteristics of race, ethnicity, age, gender, marital status, education level, annual household income, employment status, and enrollment site (Table 1).

Intervention outcome: return rates

Overall, 39.6% of study participants ($N = 318$) returned the FIT. The return rate did not differ between the intervention (FIT-SMI) and control group (FIT) (39.1% vs. 40.0%, $p = .8$) (Table 2). For the entire cohort, no differences in return rates were observed by participant characteristics of: age, race, marital status, education level, annual household income, employment status, and year of enrollment. Significant differences in return rates were observed based on health insurance coverage and type ($p = .01$) with a significantly higher rate among participants with no insurance compared with those with any insurance ($p = .01$). Participants with a regular source of care had significantly higher return rates than those who did not (41.2% vs. 29%, $p = .02$). Within the control group, significantly higher return rates were seen for AA versus Caucasian participants (42.9% vs. 24.6%, $p = .01$) and among those with health insurance compared with those without health insurance ($p = .01$). In the intervention group, no significant differences were observed in test return based on patient characteristics. Among AA participants, there was no difference in test return rate between the intervention and control group ($p = .26$); however, the observed difference in test return in the Caucasian group (39.7% in the intervention group, compared with 24.6% in the control group) approached significance at $p = .08$.

Factors associated with return rates

In a multivariable model controlling for all covariates, gender, insurance type, and regular place for healthcare were significantly associated with return rates (Table 3). Females were more likely to return the kit than males (RR = 1.17, $p = .03$). Patients with private, Medicaid, or Medicare and Medicaid insurance were all significantly more likely to return their kits compared with patients with no insurance (all $p < .02$). Patients with Medicare or Other insurance did not have significantly different return rates compared with those with no insurance. Participants who had a regular place for healthcare were more likely to return their FIT compared with those without a regular place for healthcare (RR = 1.22, $p = 0.01$).

DISCUSSION

This study examined the use of a participant designed, FIT-SMI as a means of improving participation in CRC screening among a population of predominantly AA patients seen in primary care clinics. In our prior study, we found that a large percentage of patients were not up-to-date on CRC screening and preferred an alternative to the usual recommendation of their clinicians for CRC screening via colonoscopy (P. Godley, unpublished, July 20, 2010). Patients in subsequent focus groups indicated their preference for a test that was not invasive and/or likely to result in complications, did not require time away from work or for another person to accompany them for an inpatient procedure, did not require a change in diet or a “cleanse” prior to the test, and was less expensive.

We found that a home-based stool test was widely accepted by eligible patient participants who were at average risk for CRC and not up-to-date on CRC screening. Eighty-eight percent of eligible individuals ($n = 914$) agreed to participate ($n = 804$), although FIT was the only CRC screening option available through the study. Participant acceptance of the FIT screening test may have been more in line with their stated preferences than other screening modalities [22] and may have presented fewer barriers to participation such as time away from work, the need for another person to accompany them to

Table 2 | Differences in return rates of small-media colorectal cancer screening trial: overall and by patient characteristics, $n = 804$

Characteristics	Total sample (N = 804)				Control group (N = 385)				Intervention group (N = 419)				p value ^d (intervention group returned vs. control group returned)			
	Returned FIT Kit	Did not return FIT Kit	p value ^a (re- turn rate by characteristics)		Returned FIT Kit	Did not return FIT Kit	p value ^b (re- turn rate by characteristics)		Returned FIT Kit	Did not return FIT Kit	p value ^c (returned vs. not returned)					
	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)				
Overall FIT Kit returns																
	318	39.6%	486	60.4%	NA	154	40.0%	231	60.0%	NA	164	39.1%	255	60.9%	NA	0.80
Race																
African-American	273	40.6%	399	59.4%	0.09	138	42.9%	184	57.1%	0.01	135	38.6%	215	61.4%	0.88	0.26
Caucasian	37	32.2%	78	67.8%		184	24.6%	43	75.4%		23	39.7%	35	60.3%		0.08
Ethnicity																
Hispanic	5	41.7%	7	58.3%	0.88	4	80.0%	1	20.0%	0.07	1	14.3%	6	85.7%	0.17	0.02
Non-Hispanic	313	39.5%	479	60.5%		150	39.5%	230	60.5%		163	39.6%	249	60.4%		0.98
Age																
50–54	109	34.3%	209	65.7%	0.06	51	34.0%	99	66.0%	0.30	58	34.5%	110	65.5%	0.34	0.92
55–59	110	46.0%	129	54.0%		53	46.1%	62	53.9%		57	46.0%	67	54.0%		0.99
60–64	58	38.2%	94	61.8%		28	40.6%	41	59.4%		30	36.1%	53	63.9%		0.58
65–69	32	45.1%	39	54.9%		17	47.2%	19	52.8%		15	42.9%	20	57.1%		0.71
70–75	9	39.1%	14	60.9%		5	35.7%	9	64.3%		4	44.0%	5	55.6%		0.68
Gender																
Male	125	36.7%	216	63.3%	0.15	60	37.7%	99	62.3%	0.45	65	35.7%	117	64.3%	0.21	0.70
Female	193	41.7%	270	58.3%		94	41.6%	132	58.4%		99	41.8%	138	58.2%		0.97
Marital status																
Married	72	36.5%	125	63.5%	0.33	32	34.0%	62	66.0%	0.18	40	38.8%	63	61.2%	0.94	0.49
Not married	245	40.5%	360	59.5%		121	41.9%	168	58.1%		124	39.2%	192	60.8%		0.51
Education level																
<High school	102	40.3%	151	59.7%	0.91	49	42.2%	67	57.8%	0.61	53	38.7%	84	61.3%	0.43	0.57
High school grad	144	38.7%	228	61.3%		71	40.8%	103	59.2%		73	36.9%	125	63.1%		0.44
Any college	71	40.1%	106	59.9%		34	35.8%	61	64.2%		37	45.1%	45	54.9%		0.21

(Continued)

Table 2 | Continued

Characteristics	Total sample (N = 804)				Control group (N = 385)				Intervention group (N = 419)				p value ^d (intervention group returned vs. control group returned)			
	Returned FIT Kit		Did not return FIT Kit		p value ^a (re- turn rate by characteristics)	Returned FIT Kit		Did not return FIT Kit		p value ^b (re- turn rate by characteristics)	Returned FIT Kit			Did not return FIT Kit		p value ^c (returned vs. not returned)
	N	(%)	N	(%)		N	(%)	N	(%)		N	(%)		N	(%)	
Health insurance																
Private	32	30.8%	72	69.2%	0.01	12	23.5%	39	76.5%	0.01	20	37.7%	33	62.3%	0.22	0.12
Medicare	47	46.1%	55	53.9%		24	42.9%	32	57.1%		23	50.0%	23	50.0%		0.47
Medicaid	45	38.1%	73	61.9%		28	43.8%	36	56.3%		17	31.5%	37	68.5%		0.17
Medicare + Medicaid	11	22.0%	39	78.0%		3	14.3%	18	85.7%		8	27.6%	21	72.4%		0.26
Other	50	38.8%	79	61.2%	0.59	26	44.1%	33	55.9%	0.31	24	34.3%	46	65.7%	0.26	
None	133	44.3%	167	55.7%		61	45.9%	72	54.1%		72	43.1%	95	56.9%	0.63	
Annual household income																
<\$5,000	57	41.6%	80	58.4%	0.59	22	34.4%	42	65.6%	0.31	35	47.9%	38	52.1%	0.48	0.11
\$5,000–\$14,999	105	40.4%	155	59.6%		56	44.4%	70	55.6%		49	36.6%	85	63.4%		0.20
\$15,000–\$24,999	88	38.9%	138	61.1%		49	41.2%	70	58.8%		39	36.4%	68	63.6%		0.47
\$25,000–\$34,999	24	38.7%	38	63.0%		10	40.0%	15	60.0%		14	37.8%	23	62.2%		0.86
>\$35,000	13	28.3%	33	71.7%	0.60	4	21.1%	15	78.9%	0.55	9	33.3%	18	66.7%	0.88	0.36
Employment status																
Employed	98	38.3%	158	61.7%	0.60	43	37.7%	71	62.3%	0.87	55	38.7%	87	61.3%	0.23	0.87
Unemployed	220	40.2%	327	59.8%		111	41.0%	160	59.0%		109	39.5%	167	60.5%		0.73
Year of enrollment																
2011	6	60.0%	4	40.0%	0.23	2	50.0%	2	50.0%	0.87	4	66.7%	2	33.3%	0.88	0.60
2012	61	43.0%	81	57.0%		28	42.4%	38	57.6%		33	43.4%	43	56.6%		0.90
2013	13	54.2%	11	45.8%		8	50.0%	8	50.0%		5	62.5%	3	37.5%		0.56
2014	129	37.8%	212	62.2%		64	40.8%	93	59.2%		65	35.3%	119	64.7%		0.30
2015	94	36.7%	162	63.3%		49	36.3%	86	63.7%		45	37.2%	76	62.8%		0.88
2016	15	48.4%	16	51.6%		3	42.9%	4	57.1%		12	50.0%	12	50.0%		0.74

(continued)

Table 2 | Continued

Characteristics	Total sample (N = 804)				Control group (N = 385)				Intervention group (N = 419)				p value ^d (intervention group returned vs. control group returned)
	Returned FIT Kit	Did not return FIT Kit	N	(%)	Returned FIT Kit	Did not return FIT Kit	N	(%)	Returned FIT Kit	Did not return FIT Kit	N	(%)	p value ^c (returned vs. not returned)
Regular source of care													
Yes	288	41.2%	411	58.8%	138	41.7%	193	58.3%	150	40.8%	218	59.2%	0.11
No	29	29.0%	71	71.0%	15	29.4%	36	70.6%	14	28.6%	35	71.4%	0.93
Enrollment site													
Clinic 1	2	40.0%	3	60.0%	1	33.3%	2	66.7%	1	50.0%	1	50.0%	-
Clinic 2	36	45.0%	44	55.0%	18	50.0%	18	50.0%	18	40.9%	26	59.1%	0.42
Clinic 3	25	61.0%	16	39.0%	13	61.9%	8	38.1%	12	60.0%	8	40.0%	0.90
Clinic 4	56	25.1%	167	74.9%	25	22.3%	87	77.7%	31	27.9%	80	72.1%	0.33
Clinic 5	195	45.0%	238	55.0%	96	47.1%	108	52.9%	99	43.2%	130	56.8%	0.42
Clinic 6	4	18.2%	18	81.8%	1	11.1%	8	88.9%	3	23.1%	10	76.9%	0.47

^aFor the entire sample, differences in return rates by patient characteristic. ^bFor the control group, differences in return rates by patient characteristic. ^cFor the intervention group, differences in return rates by patient characteristic. ^dWithin each patient characteristic, differences in return rate by control/intervention group.

Table 3 | Relative risk and 95% confidence intervals of the difference in return rates of small-media colorectal cancer screening trial: overall and by patient characteristics, *n* = 804 (Multivariable Model)

Characteristics	Relative risk	95% CI	<i>p</i> value
Group			
Intervention vs. control	0.96	(0.79,1.16)	0.66
Age			
Each 5 year increase	1.05	(0.96,1.14)	0.28
Race			
African-American vs. Caucasian	1.11	(0.86, 1.43)	0.42
Gender			
Female vs. male	1.17	(1.01,1.36)	0.03
Marital status			
Married vs. not married	0.85	(0.69,1.04)	0.11
Education level			
≥High school vs. <high school	0.98	(0.78,1.23)	0.86
Health insurance			
Private vs. none	0.86	(0.77,0.96)	0.01
Medicare vs. none	1.03	(0.94,1.12)	0.55
Medicaid vs. none	0.80	(0.66,0.97)	0.02
Medicare + Medicaid vs. none	0.37	(0.18,0.73)	0.01
Other vs. none	0.83	(0.61,1.14)	0.25
Annual household income			
>\$35,000 vs. <\$35,000	0.91	(0.69,1.21)	0.51
Employment status			
Employed vs. unemployed	0.92	(0.71,1.20)	0.54
Regular place for healthcare			
Yes vs. No	1.22	(1.05,1.41)	0.01
Year of enrollment			
Each 1 year increase	0.93	(0.84,1.03)	0.15

a colonoscopy, and higher relative cost of other tests compared with the FIT.

Although our hypothesis that participants in the FIT-SMI intervention group would be significantly more likely to return the kit than participants in the control group was found to be null, we did observe other findings that could inform both additional research and program development. Specifically, the SMI may have helped some participants use the kit with greater ease due to the packaging that included health messages, illustrated instructions written at fifth grade level, and larger fonts. The provision of free FIT tests and the guarantee of follow-on screening and treatment may have removed structural barriers related to financial and insurance coverage for some participants. Overall, when offered, participants accepted FIT and returned it 40% of the time, a rate that is on the high end of those observed for return of home-based stool sample tests in other populations/studies [4]. Females and individuals with insurance and individuals with a regular source of care were significantly more likely to return the FIT.

The applicability and generalizability of these findings are limited by several factors. The study enrollment period spanned 52 months and was much longer

than planned, due in part to changes within participating healthcare organizations. Specifically, one health system closed during the study and another with several clinic sites in North Carolina initiated a provider awareness campaign in 2008–2010 regarding compliance with the Affordable Care Act requiring provision of cancer screening in line with USPSTF recommendations. This activity included making sure that age-eligible patients were screened for CRC. It is our understanding that the campaign did not directly address shared decision-making and CRC screening. A higher percentage of patients approached during this study reported being up-to-date on screening than patients participating in the pilot phase conducted in 2008–2010 (P. Godley, unpublished, July 20, 2010). This prolonged enrollment period may have resulted in more variation in participating healthcare systems and community responses to CRC screening and its benefits and/or temporal changes in sub-group characteristics and/or response to the intervention. Fortunately, the USPSTF recommendations remained the same during the study period, thus reducing the possibility of bias associated with any change in recommendations over the life of this study.

The initial study population was limited to AA individuals seeking care at primary care clinics in the study

area, presenting with no symptoms of CRC, at average risk of CRC, and not up-to-date on CRC screening. Although enrollment criteria were expanded to improve accrual by including eligible non-AA participants later in the study (month 23), the resulting sample is not representative of the general population of all healthcare patients in the regions served by these clinics, the broader community of individuals in need of CRC screening, or any other group experiencing a disparity in either CRC screening or CRC mortality or morbidity, including the AA population.

The FIT was the only recommended screening modality offered to study participants, a condition that may have biased participants in both the intervention and control arms in the direction of accepting and returning the test. Acceptance may have also been biased given the guarantee of referral of any participant, if needed, to available financial assistance associated with the participant's screening and other healthcare and to follow-on colonoscopy and treatment regardless of the ability to pay at each participating site. At a minimum, this provision removed a frequently cited structural barrier (e.g., cost of screening) to participation in CRC screening and any needed follow-on treatment.

The SMI was designed to meet expressed needs and characteristics of the AA population but not of other participants in either this study or the broader community. Although this design potentially could have biased the utility of the intervention for non-AA populations and/or participants with higher educational levels, we found the opposite. Within the Caucasian group, the return rate difference between intervention and control groups approached significance ($p = .08$) whereas no difference was observed for the AA group ($p = .26$). This finding should be explored in future studies that consider more carefully the impact of cultural context, participant motivation, health literacy, and other social determinants in message and material development.

CONCLUSIONS

We found that a home-based stool test was widely accepted by a predominantly AA patient population in collaborating primary care clinics who were at average risk for and not up-to-date on CRC screening. The FIT-SMI did not independently increase return rates, but it might have made the tests easier to use due to its larger font, colorful graphics, step-by-step instructions, and health messaging. Going forward, refining and implementing small media in combination with other proven approaches such as the use of patient navigators/community health educators along with a choice of screening strategies, such as newly developed more sensitive and specific and easier to use stool tests, could reduce participant burden to participate in CRC screening, a screening with substantial net benefit among average risk, asymptomatic adults aged 50 to 75 years.

This benefit could be especially important for groups facing ongoing disparities in care such as AA and/or lower income, uninsured individuals.

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Compliance with Ethical Standards

Conflict of Interest: No conflicts of interest are reported.

Ethical Approval: This study was reviewed, approved, and continuously overseen by Institutional Review Boards at both participating institutions. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This article does not contain any studies with animals performed by any of the authors.

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