J Community Health (2015) 40:975–983
DOI 10.1007/s10900-015-0021-5

ORIGINAL PAPER

A Randomized Trial to Compare Alternative Educational Interventions to Increase Colorectal Cancer Screening in a Hard-to-Reach Urban Minority Population with Health Insurance

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Published online: 8 April 2015

Abstract This randomized controlled trial assessed different educational approaches for increasing colorectal cancer screening uptake in a sample of primarily non-US born urban minority individuals, over aged 50, with health insurance, and out of compliance with screening guidelines. In one group, participants were mailed printed educational material (n = 180); in a second, participants' primary care physicians received academic detailing to improve screening referral and follow-up practices (n = 185); in a third, physicians received academic detailing and participants received tailored telephone education (n = 199). Overall, 21.5 % of participants (n = 121) received appropriate screening within one year of randomization. There were no statistically significant pairwise differences between groups in screening rate. Among those 60 years of age or older, however, the detailing plus telephone education group had a higher screening rate than the print group (27.3 vs. 7.7 %, $p = .02$). Different kinds of interventions will be required to increase colorectal cancer screening among the increasingly small population segment that remains unscreened. ClinicalTrials.gov Identifier: NCT02392143.

Keywords Colorectal cancer · Screening · Education

Introduction

Early detection and treatment remain the primary strategies for reducing colorectal cancer (CRC) incidence and mortality [1], both of which have declined in recent decades [2]. From 2002 to 2010, the CRC screening rate in the United States among 50–75 year olds increased from 52.3 to 65.4 % [3]. Despite this progress, 136,830 new cases of CRC are estimated to have developed in 2014 (representing 8.2 % of all cancer cases) and causing 50,310 deaths (8.6 % of all cancer deaths) [4]. Nationwide, considerable disparities persist between blacks and whites in CRC screening [5], and in incidence, stage of diagnosis, and mortality [6].

A variety of approaches to increase CRC screening have yielded promising results: telephone outreach and education directed to patients [7–9], patient navigation [10, 11], and academic detailing (AD) directed to primary care physicians (PCPs) [12–14]. In prior work, between 2000 and 2003, we conducted a 2-group randomized clinical trial (RCT) in a predominantly black urban population, all with health insurance, and drawn from the same sampling frame as the current study. Compared with those who received printed educational material by mail, those who received tailored telephone education (TTE) were 4.4 times more likely to receive CRC screening within a 6-month follow up period (6.1 % vs. 27.0 %) [8]. Additional investigation suggested the possible benefit of intervening with PCPs regarding their CRC screening referral and follow up

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practices [8]. We, therefore, designed and conducted a 3-group RCT comparison of printed educational material, academic detailing, and tailored telephone education.

Methods

Design

Between 2011 and 2013, we enrolled and randomized 564 individuals. In one group, participants received printed educational materials (PEM) sent by first class mail (n = 180). In a second group, participants' PCPs received AD to improve CRC screening referral and follow-up practices (n = 185). In a third group, PCPs received AD, as above, and participants received TTE (n = 199). The Institutional Review Boards at Teachers College and the Columbia University Medical Center approved this study. Informed consent was obtained from all individuals.

Participants

The trial was conducted in the New York City (NYC) metropolitan area among the membership of a union-based, self-administered and self-insured benefit fund. The fund's health plan provides first-dollar coverage for all medically necessary services, including CRC screening. A total of 564 participants were enrolled, almost all residing in the five NYC boroughs. Table 1 presents demographic data by group. Most participants (69.3 %) were female, all were over 50 years of age, and 69.7 % were between 50 and 59 years of age. Almost half (48.9 %) self-identified as black and 79.1 % as non-Hispanic. Half (49.5 %) reported education beyond high school, 47.1 % reported an annual household income of $\leq$$50,000, including 12.2 % <$30,000. More than half (61.9 %) described themselves as non-US-born, emigrating from a wide variety of countries. Overall, 78.4 % of the sample had resided in the US for at least 20 years. Self-reported health problems included "heart problem" (10.1 %), "high blood pressure" (44.3 %), "high cholesterol" (34.4 %), diabetes (17.2 %), and "being overweight" (38.1 %). Randomization was successful in avoiding imbalances between groups on demographic and health characteristics.

Eligibility and Exclusion Criteria

To be eligible for the RCT, participants had to be out of compliance with recommended CRC screening. Non-eligibility on grounds of previous CRC screening was defined as colonoscopy in the past 10 years, flexible sigmoidoscopy, barium enema or CT colonography in the past 5 years, stool test for DNA in the past 3 years, or 3-day fecal occult blood test (FOBT) or fecal immunochemical test (FIT) within the past year. Eligibility also required having a "regular doctor" (which for women could be their gynecologist), a stated intention to remain in the benefit fund for at least 1 year, age 50–75 years, reachable by telephone, able to communicate in English, and ability to grant informed consent. Exclusions included a history of colorectal polyps, inflammatory bowel disease, irritable bowel syndrome, Crohn's disease, ulcerative colitis, or current treatment for any type of cancer. All participants were eligible for CRC screening, including colonoscopy, without copay or deductible.

Enrollment

Over 33,000 individuals, 50 years of age or older, and not screened appropriately for CRC to the extent determinable from the benefit fund's past 5 years of medical claims records, were informed about the study via first class mail and offered the opportunity to opt out of further contact. The letter promised a $20 payment to those completing the study. Between February 2011 and December 2012, 8792 prospective participants were reached by telephone to assess eligibility and interest; 8228 of these were ineligible or excluded. The main reasons for ineligibility were self-reported receipt of timely recommended CRC screening (n = 4862, 55.3 %), language barrier (n = 702, 8.0 %), and current lack of insurance (n = 507, 5.8 %); 1643 (18.7 %) declined to participate (see Fig. 1).

Randomization

To ensure equal assignment among groups, randomization was within sets of three. In cases where a new enrollee named as her PCP a doctor associated with a previous enrollment, that new enrollee was assigned to the same group as the earlier enrollee. Thus, the participant was the unit of sampling and analysis (n = 564), but the PCP was the unit of assignment (n = 459). Most PCPs represented a single participant (n = 382, 83.2 %). Of those with multiple patients enrolled in the study, 70.1 % (54 of 77) represented two patients and 24.7 % represented three.

Educational Interventions

The educational intervention approaches were informed by our earlier 2-group RCT in this same population, which aimed to help participants make an informed choice about screening [8, 15–17]. The CRC print education material (PEM) described CRC risk factors and the importance of early detection and prevention, and of talking to one's doctor about CRC screening. The PEM highlighted colonoscopy as being the only test that can identify and prevent CRC and described how to prepare for a colonoscopy beginning 7 days prior to the test [18]. The PEM also described other

Table 1 Baseline demographics and select health characteristics of study sample (N = 564)

	PEM only N (%)	AD only N (%)	AD&TTE N (%)	Total N (%)	χ^2	p
Age						
< 60 years	128 (71.1)	121 (65.4)	144 (72.4)	393 (69.7)		
≥ 60 years	52 (28.9)	64 (34.6)	55 (27.6)	171 (30.3)	2.4	.30
Gender						
Female	133 (73.9)	122 (65.9)	136 (68.3)	391 (69.3)		
Male	47 (26.1)	63 (34.1)	63 (31.7)	173 (30.7)	2.9	.24
Self-reported race						
Black	89 (49.4)	84 (45.4)	103 (51.8)	276 (48.9)		
White	32 (17.8)	36 (19.5)	31 (15.6)	99 (17.6)		
Other	24 (13.3)	35 (18.9)	39 (19.6)	98 (17.4)		
Missing/refused	35 (19.4)	30 (16.2)	26 (13.1)	91 (16.1)	6.5	.35
Hispanic						
No	136 (75.6)	142 (76.8)	168 (84.4)	446 (79.1)		
Yes	29 (16.1)	29 (15.7)	20 (10.1)	78 (13.8)		
Missing/refused	15 (8.3)	14 (7.6)	11 (5.5)	40 (7.1)	5.4	.24
Education						
<High school	18 (10.0)	18 (9.7)	15 (7.5)	51 (9.0)		
High school or equivalent	61 (33.9)	61 (33.0)	72 (36.2)	194 (34.4)		
Beyond high school	86 (47.8)	93 (50.3)	100 (50.3)	279 (49.5)		
Missing/refused	15 (8.3)	13 (7.0)	12 (6.0)	40 (7.1)	2.0	.92
Income						
<$30 K	23 (12.8)	20 (10.8)	26 (13.1)	69 (12.2)		
$30 K–$50 K	68 (37.8)	67 (36.2)	62 (31.2)	197 (34.9)		
>$50 K	63 (35.0)	68 (36.8)	78 (39.2)	209 (37.1)		
Missing/refused	26 (14.4)	30 (16.2)	33 (16.6)	89 (15.8)	2.6	.86
Birthplace						
U.S.	63 (35.0)	63 (34.1)	45 (22.6)	171 (30.3)		
Jamaica	22 (12.2)	19 (10.3)	23 (11.6)	64 (11.3)		
Guyana	13 (7.2)	13 (7.0)	15 (7.5)	41 (7.3)		
Haiti	12 (6.7)	8 (4.3)	14 (7.0)	34 (6.0)		
India/Pakistan/Sri Lanka	6 (3.3)	9 (4.9)	17 (8.5)	32 (5.7)		
Antilles	7 (3.9)	7 (3.8)	17 (8.5)	31 (5.5)		
Europe	6 (3.3)	9 (4.9)	12 (6.0)	27 (4.8)		
Trinidad/Tobago	9 (5.0)	11 (5.9)	6 (3.0)	26 (4.6)		
Africa	8 (4.4)	4 (2.2)	12 (6.0)	24 (4.3)		
Puerto Rico	5 (2.8)	8 (4.3)	5 (2.5)	18 (3.2)		
Dominican Republic	0 (0.0)	5 (2.7)	7 (3.5)	12 (2.1)		
Central America	3 (1.7)	3 (1.6)	5 (2.5)	11 (2.0)		
South America	4 (2.2)	5 (2.7)	2 (1.0)	11 (2.0)		
Philippines	3 (1.7)	2 (1.1)	5 (2.5)	10 (1.8)		
Other	2 (1.1)	4 (2.2)	2 (1.0)	8 (1.4)		
Missing/refused	17 (9.4)	15 (8.1)	12 (6.0)	44 (7.8)	37.2	.17
Living in the U.S. 20+ years						
No	18 (10.0)	17 (9.2)	29 (14.6)	64 (11.3)		
Yes	144 (80.0)	149 (80.5)	149 (74.9)	442 (78.4)		
Missing/refused	18 (10.0)	19 (10.3)	21 (10.6)	58 (10.3)	3.4	.50

Table 1 continued

	PEM only N (%)	AD only N (%)	AD&TTE N (%)	Total N (%)	χ^2	p
Continuously insured +						
No	23 (12.8)	23 (12.4)	24 (12.1)	70 (12.4)		
Yes	157 (87.2)	162 (87.6)	175 (87.9)	494 (87.9)	.05	.98
Self-reported heart problem						
No	150 (83.3)	146 (78.9)	172 (86.4)	468 (83.0)		
Yes	16 (8.9)	25 (13.5)	16 (8.0)	57(10.1)		
Missing	14 (7.8)	14 (7.6)	11 (5.5)	39 (6.9)	4.7	.31
Self-reported high BP						
No	76 (42.2)	94 (50.8)	105 (52.8)	275 (48.8)		
Yes	90 (50.0)	77 (41.6)	83 (41.7)	250 (44.3)		
Missing	14 (7.8)	14 (7.6)	11 (5.5)	39 (6.9)	5.2	.27
Self-reported high cholesterol						
No	102 (56.7)	104 (56.2)	125 (62.8)	331 (58.7)		
Yes	64 (35.6)	67 (36.2)	63 (31.7)	194 (34.4)		
Missing	14 (7.8)	14 (7.6)	11 (5.5)	39 (6.9)	2.5	.65
Self-reported diabetes						
No	133 (73.9)	138 (74.6)	157 (78.9)	428 (75.9)		
Yes	33 (18.3)	33 (17.8)	31 (15.6)	97 (17.2)		
Missing	14 (7.8)	14 (7.6)	11 (5.5)	39 (6.9)	1.8	.78
Self-reported overweight						
No	97 (53.9)	97 (52.4)	115 (57.8)	309 (54.8)		
Yes	69 (38.3)	70 (40.0)	72 (36.2)	215 (38.1)		
Missing	14 (7.8)	14 (7.6)	12 (6.0)	40 (7.1)	1.4	.84
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	F	p
Age (years)	57.6 (4.9)	58.0 (4.6)	57.9 (5.2)	57.8 (4.9)	.30	.74
Body mass index (kg/m^2) ++	29.3 (6.1)	29.0 (5.4)	28.9 (7.0)	29.1 (6.2)	.18	.84

+ continuously insured = 11+ months during the one-year post-randomization window

++ N = 516 due to missing data

CRC screening tests, including the FOBT, FIT, sigmoidoscopy, barium enema and virtual colonoscopy. Of 180 mailings, only one was returned (and resent to a corrected address).

Academic detailing (AD) involved an in-person visit from a member of the research team who attempted to communicate strategies for improving CRC screening uptake in the practice's patient panel. In cases where the PCP was unavailable, an office staff member was approached. A brief description of the RCT was followed by a semi-structured interview assessing usual practice regarding CRC screening referral and follow up. The direction of the discussion was guided by PCP responses. A variety of resources were provided: a binder with up-to-date scientific evidence about CRC screening recommendations and printed patient education materials [19–21], and order forms for refilling supplies. Specific directives were following up to make sure patients had made appointments with a gastroenterologist and offering a home stool test. The detailer attempted to elicit a verbal commitment to do at least one new thing to strengthen the probability that patients would be screened. Among 153 PCPs (representing 185 patients) in the AD group, 139 received some level of AD; 7 refused; and 7 engaged in no interpersonal interaction with the detailer but were left with AD materials. Among 153 PCPs (representing 199 patients) in the AD&TTE group, 144 received some level of AD; 2 refused; and 7 engaged in no interpersonal interaction with the detailer but were left with AD materials.

The TTE was based on our previously tested model and involved a semi-structured protocol in which the first goals were to build rapport and assess level of knowledge and readiness to be screened [8, 22]. In contrast to the earlier RCT, the current study's TTE clearly represented colonoscopy as the screening method of choice, though encouraging alternative screening methods as well. The emphasis on colonoscopy was consistent with goals of the NYC

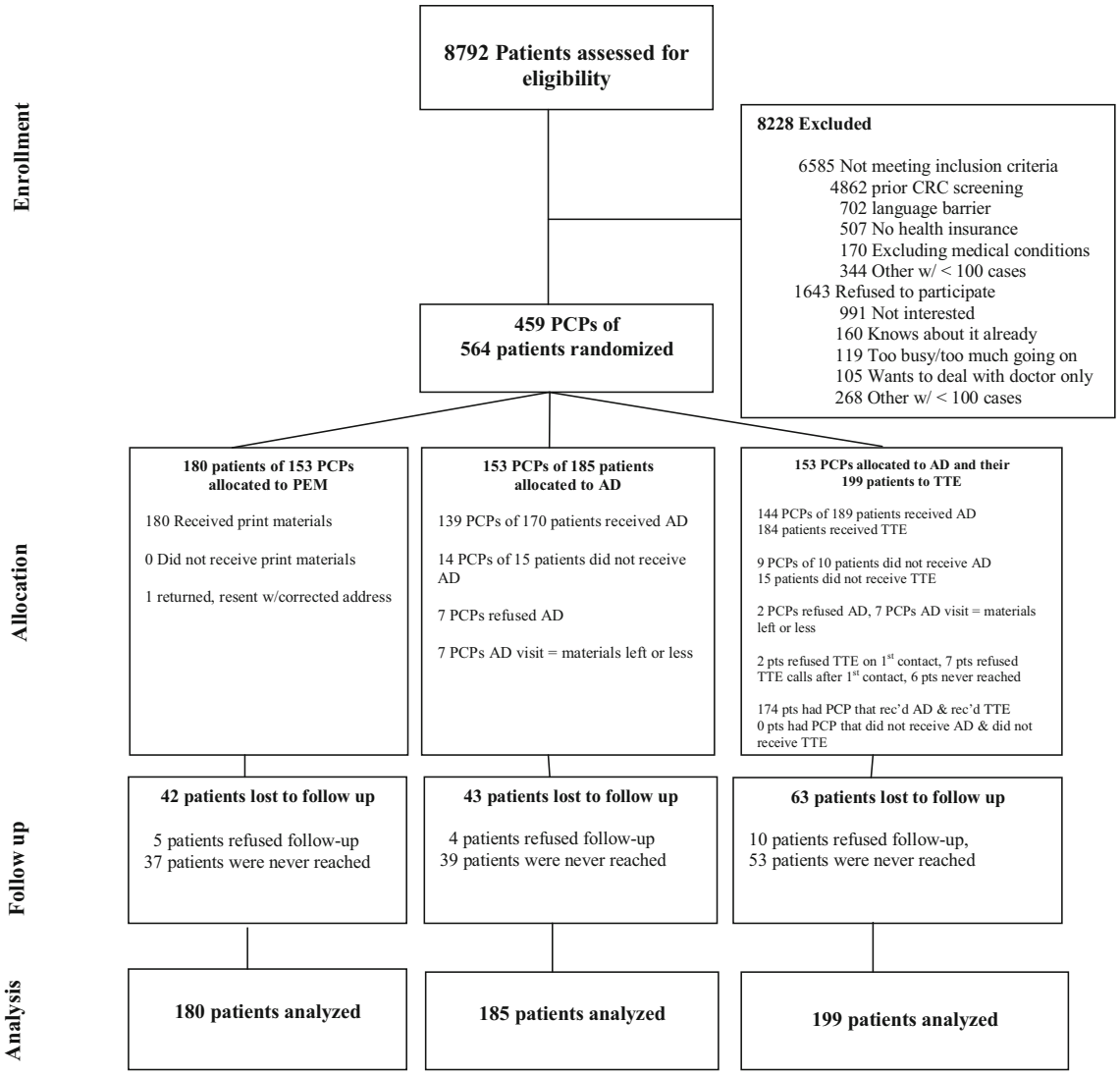

Fig. 1 Enrollment, allocation, follow-up and analysis

Department of Health and Mental Hygiene and the American Cancer Society at the time of the study [6, 23]. Rapport established, the TTE dialogue focused on identifying and addressing barriers that might impede receipt of screening. Verbal commitments were elicited: to speak with the PCP and make an appointment for a colonoscopy, or request a home stool test, as appropriate. Follow up calls assessed progress towards achieving goals. Among the 184 participants who received TTE, the number of calls ranged from one (8.2 %) to eleven (1.1 %); the median number of calls was five.

Measures

Three types of data were collected. Baseline survey data assessed eligibility and measured a variety of demographic and other variables. Implementation data monitored the extent to which the AD and TTE interventions had been conducted as planned. Outcome data were based on medical claims paid by the benefit fund. Receipt of CRC screening was pre-specified as colonoscopy (CPT codes 44388–44394, 44397, 45355, 45378–45387, 45391, 45392), flexible sigmoidoscopy (CPT codes 45330–45335, 45337–45342, 45345), and FOBT or FIT (CPT codes 82270, 82274). No occurrences of barium enema, CT colonography, or DNA stool tests were observed. The follow up period, which included an end-of-protocol survey, was one-year post-randomization.

Analysis

Pairwise group differences in screening rate one-year post-randomization were compared using 2×2 χ^2 analyses (with continuity correction). Linear trend across groups

was also assessed (PEM to AD to AD&TTE). Associations between individual demographic variables and screening rates were assessed with χ^2 analyses in the total sample and in each group separately. Sub-analyses included stratification by gender and age group (<60 years of age versus ≥60). Since some PCPs represented multiple patients, associations were verified with logistic regressions that controlled for the random effect of PCP.

Since an AD effect could not be expected in participants who had not seen their PCPs, analyses were repeated in a sample restricted to those with medical claims indicating that they had, indeed, seen their PCPs in the one-year post-randomization period (visits that occurred after the AD had been delivered). Another refinement addressed discontinuities in coverage. At our request, benefit fund staff identified enrolled members who had gaps in coverage during their one-year follow-up window; 12.4 % of participants were found to have lacked continuous coverage.

Results

Overall, 21.5 % of participants (n = 121) received CRC screening during their one-year post-randomization window (Table 2). The majority of those screened received a colonoscopy (95/121 = 78.5 %). Nine had both colonoscopy and FOBT. In the pre-specified intention-to-treat analysis, there were no statistically significant differences between the AD and AD&TTE groups or between the PEM and AD groups (Table 2). A nearly significant positive linear trend in screening rates was in evidence across groups ($\chi^2 = 3.0$, $df = 1$, $p = .08$). The screening rate was almost 40 % higher in the AD&TTE group than in the PEM group (25.6 vs. 18.3 %), but that difference was not statistically significant ($\chi^2 = 2.5$, $df = 1$, $p = .11$). Among those participants 60 years of age or older, the difference between PEM and AD&TTE was significant (7.7 vs. 27.3 %; $\chi^2 = 5.7$ $df = 1$ $p = .02$). Receipt of screening was not associated with gender, race, Hispanic ethnicity, education or income, living in the US 20+ years or any of the self-reported health problems, in the total sample or within any of the three groups. Place of birth was associated with screening in the total sample and in the AD group. In both cases, Puerto Rican immigrants had relatively high rates of screening (10/18 = 55.6 % for the total sample), and Central American and European immigrants had relatively low rates of screening (0/11 = 0 % and 3/27 = 11.1 %, respectively, for the total sample). Being aged 60 years or older was associated with a lower rate of screening in the total sample and in the PEM group.

When the analysis was restricted to participants who had visited their PCPs within the one-year post-randomization window (68.8 %, n = 388), linear trends across groups were significant in the total sample, and for females, males, and those 60 years of age or older (Table 3). Compared with participants in the PEM group, those in the AD&TTE group were more than twice as likely to be screened (17.1 % vs. 36.2 %; $\chi^2 = 7.5$, $df = 1$, $p = .01$), with even greater differences among those 60 years of age or older (7.7 vs. 36.4 %; $\chi^2 = 7.3$, $df = 1$, $p = .01$). All comparisons between PEM and AD&TTE groups were verified with logistic regression analyses that included a term for the random effect of shared PCP.

Diagnostic codes in the medical claims data were used to determine the prevalence of relevant neoplasms. For the total sample (n = 564), 40 of the 121 (33.1 %) individuals screened within the one-year post-randomization window had a diagnosis (primary, 2nd, 3rd or 4th) of benign neoplasm of the colon (ICD-9 211.3) or rectum/anal (211.4). The likelihood of having one of these diagnoses was similar across the groups: PEM, 11/33 (33.3 %); AD, 11/37 (29.7 %); and AD&TTE 18/51 (35.3 %).

Table 2 N(%) screened for CRC by colonoscopy or FOBT within one-year post-randomization, by intervention group, gender and age group, total sample (n = 564)

	PEM only (N = 180)	AD only (N = 185)	AD&TTE (N = 199)	TOTAL (N = 564)	Linear trend		PEM versus AD		AD versus AD&TTE		PEM versus AD&TTE	
	N (%)	N (%)	N (%)	N (%)	χ^2	p	χ^2	p	χ^2	p	χ^2	p
Total (n = 564)	33 (18.3)	37 (20.0)	51 (25.6)	121 (21.5)	3.0	.08	0.1	.79	1.4	.23	2.5	.11
Female (n = 391)	24 (18.0)	27 (22.1)	34 (25.0)	85 (21.7)	1.9	.17	0.4	.51	0.2	.69	1.5	.21
Male (n = 173)	9 (19.1)	10 (15.9)	17 (27.0)	36 (20.8)	1.2	.27	0.0	.85	1.7	.19	0.5	.47
<60 years old (n = 393)	29 (22.7)	28 (23.1)	36 (25.0)	93 (23.7)	0.2	.65	0.0	1.00	0.0	.84	0.1	.76
≥60 years old (n = 171)	4 (7.7)	9 (14.1)	15 (27.3)	28 (16.4)	7.5	.01	0.6	.43	2.4	.12	5.7	.02

Table 3 N(%) screened for CRC by colonoscopy or FOBT within one-year post-randomization, by intervention group, gender and age group, with sample restricted to those with randomizing PCP visit within one-year post-randomization (n = 388)

	PEM Only (N = 129)	AD Only (N = 130)	AD&TTE (N = 129)	TOTAL (N = 388)	Linear trend		PEM versus AD		AD versus AD&TTE		PEM versus AD&TTE	
	N (%)	N (%)	N (%)	N (%)	χ^2	p	χ^2	p	χ^2	p	χ^2	p
Total (n = 388)	22 (17.1)	31 (23.8)	42 (36.2)	95 (24.5)	8.4	.00	1.4	.23	2.0	.16	7.5	.01
Female (n = 279)	18 (18.6)	22 (24.4)	29 (31.5)	69 (24.7)	4.2	.04	0.6	.42	0.8	.37	3.6	.06
Male (n = 109)	4 (12.5)	9 (22.5)	13 (35.1)	26 (23.9)	4.8	.03	0.6	.43	0.9	.33	3.6	.06
<60 years old (n = 274)	19 (21.1)	23 (26.1)	30 (31.3)	72 (26.3)	2.5	.12	0.4	.54	0.4	.55	2.0	.16
≥60 years old (n = 114)	3 (7.7)	8 (19.0)	12 (36.4)	23 (20.2)	9.0	.00	1.4	.24	2.0	.16	7.3	.01

Discussion

This study was a follow up to our 2003–2006 2-group RCT promoting CRC screening [8]. In that RCT, the TTE group had a higher CRC screening rate six-month post-randomization compared to PEM (27.0 vs. 6.1 %, $p < .01$). In the present 3-group RCT, for the total sample, there were no statistically significant pairwise differences between groups in one-year post-randomization CRC screening rates. TTE, effective in 2003–2006, failed to yield the same benefit in 2011–2014.

Screening rates in the two studies' TTE groups (27.0 % TTE alone earlier, 25.6 % TTE&AD now) were similar, but rates in the two PEM groups differed substantially (6.1 % earlier, 18.3 % now). We attempted to assess if the PEM group screening rate in the current study was the result of reactivity to the relatively lengthy baseline interview. At our request, the benefit fund generated the CRC screening rate within a mid-study, one-year window among non-enrolled, unscreened individuals on the original (33,000+) sampling list. That rate was 14.0 % (2227/15960), sufficiently high to rule out reactivity to the interview as an explanation.

We attribute the higher PEM CRC screening rate in the current study to secular trends in colonoscopy screening in NYC. New York State is one of 13 states with the highest rates of CRC screening in the nation [24], and CRC screening rates in NYC are particularly high. In 2010, 54.9 % of Americans aged 50-75 had had a colonoscopy in the prior 10 years [25]. In NYC, by 2007, 61.7 % had received colonoscopy screening and disparities among non-Hispanic whites, non-Hispanic blacks, and Hispanics were eliminated [26, 27]. Colonoscopy rates in NYC may have been affected by the NYC Department of Health and Mental Hygiene's multi-faceted collaboration with the Citywide Colon Cancer Control Coalition to increase colonoscopy rates and reduce socio-demographic disparities [27]. Thus the current context is one of increasing CRC screening uptake with minimal or no intervention and of a decreasing but sizeable group who remain highly resistant to screening. Reasonably, those who remain out of compliance now are harder to reach than those who were out of compliance a decade ago.

Rogers, in his seminal work [28], demonstrated that the adoption and use of any innovation that ultimately succeeds in attaining widespread use, whether in agriculture, technology or public health, follow predictable patterns. Different segments of the population adopt an innovation at different times. At first, only the most innovative (~2.5 %) change, followed by early adopters (~13.5 %), who tend to be influential and opinion leaders. Next, early majority adopters (~34 %) bring use rates to the tipping point. The remaining late majority (~34 %) and laggards (~16 %) are the slowest to change. Each of these population segments has been consistently shown to have different social and psychological characteristics. The current study sample is, by definition, "late majority" or "laggard".

Recent immigrants have been shown to be a particularly hard-to-reach group with respect to CRC screening [29, 30]. While over 60 % of study participants were non-US born, the majority were not recent immigrants; mean years in the US for the non-US born was 28.2 (median = 28.0). Furthermore, years in the US differed by country of origin. The great diversity in country of origin of the non-US born precluded both aggregating nationalities and examining them individually. Improved understanding about cultural beliefs between and within heterogeneous immigrant groups is needed to inform effective interventions.

A circumstance limiting the measured effectiveness of the interventions is that a non-trivial proportion of the sample experienced a gap in or cessation of health insurance coverage during the one-year follow-up period. Excluding those individuals from the analysis did not enhance group differences. A second limiting circumstance is that

more than 30 % (n = 176) did not see their self-identified PCPs during the follow-up period (although they may have seen other doctors). Yet, even among the participants who did see their PCPs, and were 60 or older—a group more likely to respond to the AD&TTE intervention—the majority remained un-screened.

Our AD and TTE interventions for this 3-group RCT emphasized colonoscopy in a way that our earlier intervention for the 2-group RCT did not [8]. Percentage screened who had completed a multiple-day home stool test was notably higher in the earlier study (41.3 % earlier; 28.9 % now). The benefits of colonoscopy are clear [31], but recent research indicates that tailoring interventions to individual's preference for alternative CRC screening tests can yield higher overall screening rates. Even then, the majority remained unscreened at 6- and 12-months post-randomization [32].

The perceived importance of PCP recommendation and follow-up for promoting CRC screening is clear from our earlier work [33, 34]. But AD interventions to PCPs to facilitate CRC screening have had mixed results [12, 14, 35–38], and these interventions can only benefit patients who see their PCPs. Over 30 % of our study participants did not have a claim for a visit to their self-identified PCPs within one-year post-randomization. These participants may have seen other internists and specialists (permitted by the benefit fund without referral), and possibly the restrictions of a tighter, gatekeeper-type system would have increased compliance. Further, the intention of the AD in this study was to influence practice-wide referral and follow up, as opposed to promoting screening specifically for study participants. Providing physicians with names of unscreened patients would likely have been more effective in getting those individuals screened and is a feasible strategy for agencies with access to protected health information [39]. The study was limited in its reliance, for the most part, on a single patient to represent a PCP's practice. It would have been preferable to assess the AD's effectiveness based on CRC screening rates among multiple patients or in the PCP's entire patient panel. Neither of these options was available.

Although we demonstrated a relatively large treatment effect among those who were at least 60 years old and had visited their PCPs, the majority of study participants did not receive CRC screening over the one-year follow-up period. The greater intervention effect among those aged 60 and over was primarily due to a lower rate of screening in the PEM group, suggesting that those in this age group are not being carried along with secular trends of increasing CRC screening uptake.

Improved understanding of CRC screening barriers, independent of direct medical cost, faced by the "late majority" and "laggard" populations, who remain out of compliance with CRC screening, is needed. The 18 % of individuals who declined to participate in our study and the 8 % who could not participate due to a language barrier may represent groups who are even harder to reach.

Acknowledgments This work was primarily supported by the American Cancer Society (Grant Number RSGT-09-012-01-CPPB).

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