

COMPARING THE EFFECTIVENESS OF TWO MAILED OUTREACH INTERVENTIONS TO INCREASE COLORECTAL CANCER SCREENING IN COMMUNITY HEALTH CENTERS

Authors: Folasade P. May, MD PhD MPhil^{1,2,3,4}, Jessica J. Tuan MPH⁴, Suzanne Brodney PhD MS⁵, Beth Glenn PhD^{4,6}, Yixuan Zhou⁷, Adjoa Anyane-Yeboah MD MPH^{8,9}, Nicolette J. Rodriguez MD MPH^{10,11,12}, Caylin Marotta MPH⁵, Susan Regan PhD⁵, Sapna Syngal MD MPH^{10,11,12}, Andrew T. Chan MD MPH^{8,9,13,14,15}, Catherine Jeffries¹⁶, Kelley Le Beaux MA¹⁶, Samantha Kuney MA¹¹, Kimberly Schoolcraft¹⁷, Anjelica Q. Davis MPPA¹⁷, Chinedu Ukaegbu MBBS MPH^{11,12}, Erica T. Warner ScD MPH^{8,18}, Beverly Moy MD MPH¹⁹, David A. Drew PhD^{8,9}, Gina Johnson¹⁶, Yuchiao Chang PhD^{5,12}, Jennifer S. Haas, MD MSc^{5,18}

Affiliations:

1. Department of Medicine, David Geffen School of Medicine, UCLA Ronald Reagan Medical Center, University of California Los Angeles, 757 Westwood Plaza, Los Angeles, CA, 90095, USA
2. Vatche and Tamar Manoukian Division of Digestive Diseases, Department of Medicine, David Geffen School of Medicine, University of California Los Angeles, 650 S. Charles E Young Drive, Center for Health Sciences, Suite A2-125, Los Angeles, CA, 90095-6900, USA
3. Greater Los Angeles Veterans Affairs Healthcare System, Los Angeles, CA, USA
4. UCLA Kaiser Permanente Center for Health Equity, Jonsson Comprehensive Cancer Center, 650 S. Charles E Young Drive, Center for Health Sciences, Suite A2-125, Los Angeles, CA, 90095-6900, USA
5. Division of General Internal Medicine, Massachusetts General Hospital, Boston, MA, USA
6. Department of Health Policy and Management, UCLA Fielding School of Public Health
7. Department of Biostatistics, UCLA Fielding School of Public Health, UCLA, Los Angeles, CA, USA
8. Clinical and Translational Epidemiology Unit, Massachusetts General Hospital and Harvard Medical School, Boston, Massachusetts
9. Division of Gastroenterology, Massachusetts General Hospital, Boston, Massachusetts
10. Division of Gastroenterology, Brigham and Women's Hospital, Boston, Massachusetts, USA
11. Population Sciences and Cancer Genetics and Prevention Divisions, Dana Farber Cancer Institute, Boston, Massachusetts, USA
12. Harvard Medical School, Boston, Massachusetts, USA
13. Broad Institute of Massachusetts Institute of Technology and Harvard, Cambridge, Massachusetts
14. Channing Division of Network Medicine, Department of Medicine, Brigham and Women's Hospital, and Harvard Medical School, Boston, Massachusetts
15. Department of Immunology and Infectious Diseases, Harvard T.H. Chan School of Public Health, Boston, Massachusetts
16. Health Promotion Disease Prevention Programs, Great Plains Tribal Leaders Health Board, Rapid City, South Dakota, USA
17. Fight Colorectal Cancer, 134 Park Central Sq. Ste 210, Springfield, MO, 65806, USA
18. Mongan Institute, Massachusetts General Hospital and Harvard Medical School, Boston, MA, USA
19. Division of Hematology/Oncology, Massachusetts General Hospital, Harvard Medical School, Boston, MA, USA

Introduction: Community health centers (CHCs) in the United States (US) provide primary care services to over 31 million low-income and uninsured individuals. In CHCs, stool-based colorectal cancer (CRC) screening modalities are common; however, screening rates and colonoscopic follow-up after abnormal screening are below the national average. This 2-arm pragmatic trial aims to increase CRC screening and follow-up after abnormal screening in CHCs in 2 US regions.

Methods: We included 4 CHCs in Boston and 4 CHCs in Los Angeles (LA). We identified patients ages 45 to 75 in each CHC with a recent primary care visit and English or Spanish language preference. Clinics were matched by region and size and then randomized to either (1) mailed fecal immunochemical test (FIT) outreach, or (2) mailed FIT-DNA outreach. In the FIT outreach arm (2 Boston and 2 LA clinics), patients were mailed a FIT kit with instructions and received 3 text message reminders from study personnel over 35 days. In the FIT-DNA outreach arm (2 Boston and 2 LA clinics), patients were mailed a FIT-DNA kit with instructions and received outreach from Exact Sciences per their standard protocol (texts messages, letters, telephone calls). All participants with an abnormal FIT or FIT-DNA result were offered language-concordant navigation from study personnel to colonoscopy completion (up to 3 telephone calls over 180 days). We calculated the preliminary screening rate in each study arm and by region at 60 days from kit mailing; final results at 180 days are pending.

Results: The study included 2435 patients in the FIT arm and 2693 in the FIT-DNA arm (5128 total). Mean age was 54.5 years (s.d.=8.1); 58.9% were female, 74.5% were Hispanic/Latino, 65.6% preferred Spanish language, and 49.6% were Medicaid insured, with notable demographic differences between the 2 regions (**Table**). At 60 days, screening participation was significantly higher in the FIT-DNA arm than in the FIT arm (23.2% v. 18.6%, $p<0.001$). Overall screening participation was 21.0% and significantly higher in Boston (23.2%) than in LA (19.4%) ($p<0.001$). Of note, FIT and FIT-DNA clinics had similar screening rates in Boston (24.1% v 22.6%, $p=0.43$) but not in LA (15.2% (FIT) v. 23.8% (FIT-DNA), $p<0.001$) (**Figure**). In Boston, there were 30 (5.8%) patients with an abnormal test result at 60 days. In LA, there were 44 (7.8%) patients with an abnormal result at 60 days. Colonoscopy navigation is ongoing.

Conclusion: In this pragmatic trial, CRC screening participation was significantly higher for mailed FIT-DNA than for mailed FIT in CHCs in 2 US regions. This is an early demonstration of how to implement FIT-DNA in underserved settings. Screening uptake was also higher in Boston CHCs than in LA CHCs, which may be attributable to differences in access, insurance, and patient populations (e.g., race/ethnicity, language) in Boston and LA.

Table: Study Population Demographics and Clinical Data by study arm, by CHC region, and overall.

Patient Characteristic	Boston n = 2208 (43.1%)			Los Angeles n = 2920 (56.9%)			Overall N = 5128		
	FIT n = 950	FIT-DNA n = 1258	Overall n = 2208	FIT n = 1485	FIT-DNA n = 1435	Overall n = 2920	FIT n = 2435	FIT-DNA n = 2693	Overall N = 5128
Age, years [mean (s.d.)]	53.2 (8.8)	52.5 (8.5)	52.8 (8.6)	55.9 (7.5)	55.8 (7.5)	55.8 (7.5)	54.8 (8.1)	54.3 (8.1)	54.5 (8.1)
Female sex, n (%)	569 (59.9)	727 (57.8)	1296 (58.7)	868 (58.5)	854 (59.5)	1722 (59.0)	1437 (59.0)	1581 (58.7)	3018 (58.9)
Race/ethnicity, n (%)									
Non-Hispanic American Indian	4 (0.4)	3 (0.2)	7 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.2)	3 (0.1)	7 (0.1)
Non-Hispanic White	431 (45.4)	279 (22.2)	710 (32.2)	25 (1.7)	28 (2.0)	53 (1.8)	456 (18.7)	307 (11.4)	763 (14.9)
Non-Hispanic Asian	18 (1.9)	22 (1.7)	40 (1.8)	5 (0.3)	2 (0.1)	7 (0.2)	23 (0.9)	24 (0.9)	47 (0.9)
Non-Hispanic Black	75 (7.9)	105 (8.3)	180 (8.2)	121 (8.1)	69 (4.8)	190 (6.5)	196 (8.0)	174 (6.5)	370 (7.2)
Hispanic	396 (41.7)	774 (61.5)	1170 (53.0)	1326 (89.3)	1322 (92.1)	2648 (90.7)	1722 (70.7)	2096 (77.8)	3818 (74.5)
Multiple	0 (0.0)	2 (0.2)	2 (0.1)	1 (0.1)	0 (0.0)	(0.0)	1 (0.0)	2 (0.1)	3 (0.1)
Unknown/Declined	26 (2.7)	73 (5.8)	99 (4.5)	7 (0.5)	13 (0.9)	20 (0.7)	33 (1.4)	86 (3.2)	119 (2.3)
Language Preference, n (%)									
English	673 (70.8)	654 (52.0)	1327 (60.1)	234 (15.8)	204 (14.2)	438 (15.0)	907 (37.2)	858 (31.9)	1765 (34.4)
Spanish	277 (29.2)	604 (48.0)	881 (39.9)	1251 (84.2)	1231 (85.8)	2482 (85.0)	1528 (62.8)	1835 (68.1)	3363 (65.6)
Insurance Type, n (%)									
Commercial/Private	612 (64.4)	756 (60.1)	1368 (62.0)	70 (4.7)	76 (5.3)	146 (5.0)	682 (28.0)	832 (30.9)	1514 (29.5)
Medicaid	183 (19.3)	292 (23.2)	475 (21.5)	1037 (69.8)	1029 (71.7)	2066 (70.8)	1220 (50.1)	1321 (49.1)	2541 (49.6)
Medicare	120 (12.6)	143 (11.4)	263 (11.9)	103 (6.9)	75 (5.2)	178 (6.1)	223 (9.2)	218 (8.1)	441 (8.6)
Uninsured/Self Pay	34 (3.6)	63 (5.0)	97 (4.4)	268 (18.0)	249 (17.4)	517 (17.7)	302 (12.4)	312 (11.6)	614 (12.0)
Other/Missing	1 (0.1)	4 (0.3)	5 (0.2)	7 (0.5)	6 (0.4)	13 (0.4)	8 (0.3)	10 (0.4)	18 (0.4)

Figure: Screening participation by study arm, by CHC region, and overall, at 60 days.

