

A Culturally Tailored Navigator Program for Colorectal Cancer Screening in a Community Health Center: A Randomized, Controlled Trial

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BACKGROUND: Minority racial/ethnic groups have low colorectal cancer (CRC) screening rates.

OBJECTIVE: To evaluate a culturally tailored intervention to increase CRC screening, primarily using colonoscopy, among low income and non-English speaking patients.

DESIGN: Randomized controlled trial conducted from January to October of 2007.

SETTING: Single, urban community health center serving a low-income, ethnically diverse population.

PATIENTS: A total of 1,223 patients 52-79 years of age overdue for CRC screening, randomized to intervention (n=409) vs. usual care control (n=814) groups.

INTERVENTION: Intervention patients received an introductory letter with educational material followed by phone or in-person contact by a language-concordant "navigator." Navigators (n=5) were community health workers trained to identify and address patient-reported barriers to CRC screening. Individually tailored interventions included patient education, procedure scheduling, translation and explanation of bowel preparation, and help with transportation and insurance coverage. Rates of colorectal cancer screening were assessed for intervention and usual care control patients.

RESULTS: Over a 9-month period, intervention patients were more likely to undergo CRC screening than control patients (27% vs. 12% for any CRC screening, $p<0.001$; 21% vs. 10% for colonoscopy completion, $p<0.001$). The higher screening rate resulted in the identification of 10.5 polyps per 100 patients in the intervention group vs. 6.8 in the control group ($p=0.04$).

LIMITATIONS: Patients were from one health center. Some patients may have obtained CRC screening outside our system.

CONCLUSIONS: A culturally tailored, language-concordant navigator program designed to identify and overcome barriers to colorectal cancer screening can significantly improve colonoscopy rates for low income, ethnically and linguistically diverse patients.

ClinicalTrials.gov registration number: NCT00476970

KEY WORDS: colon cancer; screening; colonoscopy; patient navigation; randomized control trial.

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INTRODUCTION

Colorectal cancer (CRC) is the third most commonly diagnosed cancer and the second leading cause of cancer death in the US.¹ Although CRC-related morbidity and mortality can be reduced through early detection and treatment, almost two-thirds of patients are diagnosed with advanced stage disease.¹ Rates of CRC screening are lower than for other preventable cancers²⁻⁴ and are particularly low in ethnic minorities, non-English speakers, and low income individuals.⁵⁻⁹ When diagnosed with CRC, these individuals present with cancer in later stages and have higher mortality rates than white, English-speaking, and higher income patients.¹⁰⁻¹⁴

Barriers to CRC screening include lack of patient knowledge regarding the importance of screening and procedure-related patient concerns (e.g., regarding modesty, fear of pain, perceived risk).^{6,15-21} Factors particularly relevant for low income and limited English proficiency patients may include: insufficient time to effectively discuss CRC screening during clinic visits, difficulty contacting patients, financial strains associated with taking time off from work, lack of health insurance, difficulty obtaining transportation, and/or lack of interpreters at procedure sites.^{22,23} These unique barriers may contribute to observed disparities in care.²⁴⁻³¹

Strategies shown to modestly increase preventive cancer screening rates in low income and limited English proficiency populations have included both mailed reminders with educational information for patients and physician-directed efforts to increase recommendation rates.³²⁻³⁴ Recently, "navigator programs" specifically designed to overcome patients' perceived barriers to screening have been evaluated.³⁵⁻³⁹ These programs are oriented towards flexible problem solving rather than providing a predefined set of services and often employ bilingual individuals familiar with social and cultural nuances

of the patients they serve.⁴⁰ Two randomized trials have evaluated navigator programs designed specifically for CRC screening: one focused primarily on increasing fecal occult blood testing among ethnic Chinese patients,⁴¹ while a second study involved small numbers of patients receiving navigation services in an urban neighborhood health clinic.³⁵ To our knowledge, there have been no large-scale trials designed to increase overall rates of colonoscopy screening in low-income communities using a multilingual navigator program.

The Massachusetts General Hospital (MGH) Practice-based Research Network consists of 12 affiliated primary care practices that share a common electronic medical record. Within this network, the MGH Chelsea HealthCare Center serves a low income, predominantly Latino and immigrant population. Analysis of preventive cancer care identified lower rates of CRC screening in this clinic relative to the network average. We therefore chose this practice to implement a multilingual navigator program for CRC screening. We hypothesized that this intervention would increase screening rates, particularly colonoscopy, for all patients regardless of their race, ethnicity, language spoken, or insurance status.

METHODS

Study Setting

MGH Chelsea HealthCare Center is the largest provider of care for the residents of Chelsea, MA, a city of 35,080 (US Census 2000) people that has been a gateway for refugees and immigrants for more than a century. Recent immigrants have come from Bosnia, Somalia, Afghanistan, Northern and Western Africa, and Central America. Latinos account for more than 48% of Chelsea's population. More than 58% of residents speak languages other than English, and nearly 44% speak only Spanish. Poverty levels are more than twice the statewide average: More than 27% of households earn less than \$15,000 annually and 43% live below 200% of national poverty thresholds.

Study Population and Randomization

Patients were identified using a previously validated algorithm that assigns all patients seen in the MGH primary care network to either a specific primary care physician or to the primary care practice where they receive most of their care.⁴² Patients were eligible if they were between 52-79 years of age⁴³ and had not undergone colorectal cancer screening (defined as a colonoscopy in the last 10 years, sigmoidoscopy/barium enema in the past 5 years, or home fecal occult blood testing in the past year).⁴⁴ Patients were excluded if they were acutely ill, or had dementia, metastatic cancer, schizophrenia, or any end stage disease.⁴⁵

Eligible patients were randomized into intervention and control groups in a 1:2 ratio. Patients in the usual care control group received navigator services after completion of the 9-month intervention. All study activities were approved by the MGH Institutional Review Board.

Navigator Program Intervention

Navigator training. Five health center outreach workers and interpreters were recruited to serve as patient navigators for

the study. Each was college educated, and one, a bilingual Spanish/English speaker, worked full-time on the CRC screening project and contacted all English and Spanish speaking patients. The other four navigators spoke a combined six other languages and were assigned depending on patient language needs. All navigators participated in a 6-h training course run by the study PI (SPL) and the center's community health director (SO). Training addressed multiple aspects of patient navigation and CRC screening including: performing an initial interview with patients to identify and explore barriers, working with patients to overcome barriers, educating patients about CRC screening, motivating and coaching patients, and scheduling and accompanying patients to colonoscopy testing. Each navigator was supervised by the study PI and the community health director throughout the study period. The cost of the initial training and subsequent study-specific navigator activities was approximately \$70,000 for the 9-month study period. The ongoing cost of the established CRC screening program is approximately \$75,000 per year.

Study protocol. An eligible patient list was imported into a navigator database to track patient visits to the health center and the gastroenterology unit. The navigator sent all intervention patients an introductory letter in their native language explaining the project and educational materials related to CRC screening. Subsequently she/he recruited the patients during visits to the health center or over the phone. During the initial contact, the navigator educated the patient about CRC screening and explored the patient's barriers to screening. Further interventions were tailored to each individual patient with the intention of overcoming personal, cultural, and systemic barriers to successfully complete screening. The navigator specifically educated patients about CRC screening, reviewed all available methods, helped schedule the appointments, reminded the patient about the appointments, reviewed and translated the required bowel preparation, organized transportation, and accompanied patients without available family members. The navigator updated the patient's medical record with the CRC screening results. Navigators encouraged patients to undergo colonoscopy, which is the preferred CRC screening method at MGH and is covered by most insurance including MGH 'Free Care' (MGH provides Free Care to eligible low income patients who do not qualify for Medicaid. It covers most medical care at the hospital, including medications and all types of CRC screening except CT colonography). However, if patients preferred another CRC screening method, the navigator also assisted them in getting screened via the alternate method.

Study Outcomes

The primary outcome was the percentage of eligible patients in intervention vs. control groups who received CRC screening, defined as colonoscopy, sigmoidoscopy, barium enema, or home fecal occult blood testing, during the study period. As a secondary outcome, we also specifically examined between-group differences in the percentage of colonoscopy exams completed. To evaluate the impact of our intervention on prevention of colorectal cancer, we compared the number of polyps and cancers per 100 patients in the intervention vs.

control group by reviewing all colonoscopies and related biopsy results. The pathologic findings were classified as either polyps (hyperplastic polyps and adenomas) or carcinomas.

Statistical Methods

The primary analysis was intention-to-treat and involved all randomly assigned patients. We calculated that a sample size of 408 patients in each group would be needed to demonstrate a minimum clinically significant improvement in CRC screening of 10%, a power of 80% with a 0.05 two-sided significance level. There were 1,223 patients meeting eligibility criteria, and we estimated that the maximum number of patients the navigator could contact during the study period would be 400. Because we had access to all study outcomes using our validated electronic patient registry, we chose a 1:2 randomization scheme rather than 1:1 to increase the power of our study. We randomized 409 patients to the intervention group and 814 patients to the usual care group.

We used chi-square tests to compare proportions between groups and univariate logistic regression models to calculate odds ratios and confidence intervals. We also examined our results stratified by demographic characteristics: gender, age, race/ethnicity, English language proficiency, and insurance status. Two-sided significance tests with P-values less than 0.05 were considered statistically significant. All statistical analyses were performed using a commercial software package (Statistical Analysis System; SAS Institute, Cary, NC).

Table 1. Baseline Demographic Characteristics of Participants by Study Group

Variable, N (%)	Intervention group (n=409)	Usual care group (n=814)	P-value
Gender, female	237 (58.0)	497 (61.0)	0.29
Mean age (SD)	63.1 (7.7)	62.9 (7.8)	0.75
Primary language			
English	241 (58.9)	455 (55.9)	0.43
Spanish	139 (34.0)	279 (34.3)	
Other navigator language*	21 (5.1)	56 (6.9)	
Other/unknown	8 (2.0)	24 (3.0)	
Race			
White	191 (46.7)	387 (47.5)	0.54
Latino	164 (40.1)	327 (40.2)	
Black	26 (6.4)	41 (5.0)	
Asian	6 (1.5)	22 (2.7)	
Other/unknown	22 (5.4)	37 (4.6)	
Insurance			
Private	220 (53.8)	436 (53.6)	0.86
Government	118 (28.8)	248 (30.5)	
Free Care	56 (13.7)	106 (13.0)	
No insurance	15 (3.7)	24 (3.0)	
Months since last primary care physician visit, mean (SD)	10.3 (6.1)	9.9 (5.9)	0.20
Number of practice visits in past 3 years, mean (SD)	8.2 (6.5)	8.8 (7.2)	0.09

*Other navigator languages include: Arabic, Farsi, Portuguese, Russian, Serbo-Croatian, and Somali

RESULTS

Study Participants

Figure 1 displays the number of patients accrued, randomized, and assessed for the primary outcome. After randomization, intervention patients were contacted over a 9-month period starting January 8, 2007. A chart review prior to sending the introductory letter to intervention patients identified 27 patients who had completed screening elsewhere and four patients who had died. During the study period, CRC screening navigators contacted 302 (74%) intervention patients. Navigators were unable to reach 37 participants after sending two letters and calling four times over a 3-month period. An additional 39 patients were unreachable (returned letter or disconnected phone). Patients not contacted had fewer practice visits in the prior 3 years, went a longer period since their last PCP visit, and were more likely to be Latino and Spanish speaking (data not shown).

Baseline demographic characteristics of intervention and usual care groups are shown in Table 1. Women represented 60% of the population, and the mean age was 63.0 years. More than 40% of participants were Latino, while 47% were white, 5% black, and 2% Asian. Approximately 5% were registered as other or unknown race. Over 40% of participants identified themselves as non-English speakers, including 34% who self-identified as Spanish speaking. Serbo-Croatian, Somali, Portuguese, and Arabic were other spoken languages. Over 45% of patients did not have private insurance: 27% had Medicare, 3% had Medicaid, 3% were uninsured, and 13% were eligible for 'Free Care' coverage provided by MGH. There were no statistically significant differences in baseline characteristics between intervention and usual care groups.

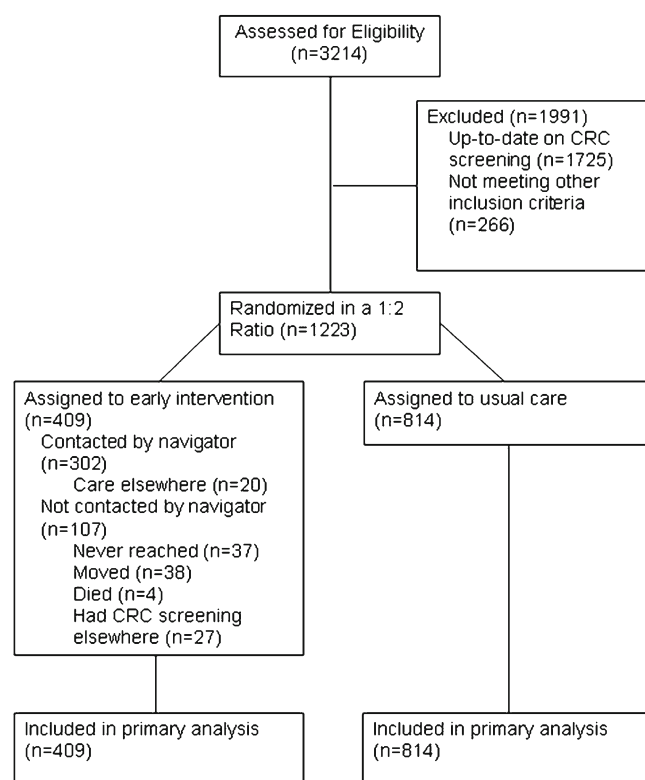


Figure 1. Flow diagram of study participants through recruitment, eligibility assessment, randomization, intervention, and outcome analysis. CRC = Colorectal cancer.

Colorectal Cancer Screening Rates at Study Completion

The incidence of CRC screening was more than double in intervention patients vs. usual care controls (27.4% and 11.9%, respectively, $p < 0.001$) during the 9-month study period (Fig. 2). Colonoscopy was performed in 20.8% of intervention participants vs. 9.6% in the usual care group ($P < 0.001$). This higher screening rate corresponded to 10.5 polyps and 0.24 cancers detected per 100 patients among intervention patients compared to 6.8 polyps and 0.12 cancers detected per 100 patients among controls (polyps: $p = 0.04$, cancers: $p = 1.0$).

Stratified analyses demonstrated that the navigator program was beneficial for each subgroup examined when comparing intervention vs. usual care patients. The navigator program showed a relatively larger effect in females, older patients, non-Latinos, English speakers, and those without private insurance (Fig. 3). This relative difference in demographic subgroups is explained in part by the higher rates of screening in control patients among Latinos (15.3% vs. 9.7% for non-Latinos, $p = 0.01$) and non-English speakers (15.3% vs. 9.2% for English speakers, $p = 0.01$) (Fig. 4). Nonetheless, Latino and non-English speaking patients had significantly higher CRC screening rates in the intervention group compared to the usual care group ($p < 0.001$). The overall rates of screening (intervention plus control) were higher among Latinos (20.8% vs. 14.6% for non-Latinos, $p = 0.01$) and non-English speakers (19.5% vs. 15.2% for English speakers, $p = 0.05$).

Barriers to Colorectal Cancer Screening Identified among Intervention Patients

Table 2 lists barriers identified during navigator interviews for the 302 intervention patients contacted during the study period. Patients had an average of 3.1 contacts with the navigator (median=3.0, range: 1-11). Although initial navigator contact was often over the phone, 117 patients (39%) met the navigator in person at least once. Among patients contacted by the navigator, those who met the navigator in person were somewhat more likely to complete CRC screening than those contacted by other methods (42.7% vs. 33.0%, $p = 0.09$).

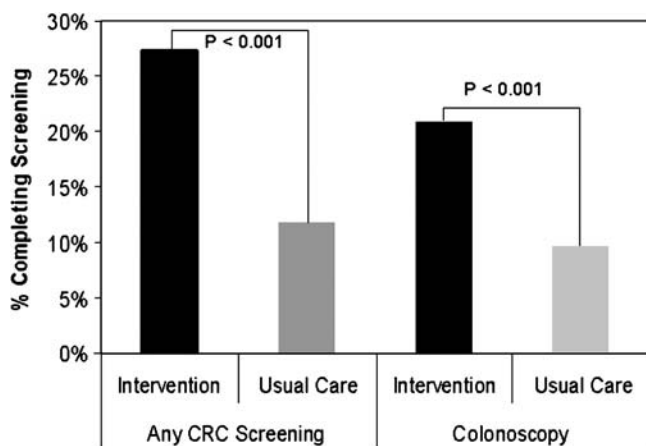


Figure 2. Colorectal cancer screening rates, intervention vs. usual care groups. Percentage of patients completing: (1) any colorectal cancer screening and (2) colonoscopy.

Colonoscopy was performed in 35.0% of patients contacted in person vs. 23.2% of patients contacted by other methods ($p = 0.03$). Almost all patients had at least one barrier identified, and most had several (mean=4.4, median=4.0). Barriers were broadly categorized as patient-related ($n = 301$, 99.7%) or logistical/system-level ($n = 178$, 58.9%). In most cases navigators performed an intervention for each barrier identified. Specific interventions were performed for 96% of patient-related barriers and for 64% of logistical/system-level barriers.

DISCUSSION

We designed and implemented a culturally tailored, language-concordant navigator program to identify and overcome barriers to colorectal cancer screening among an ethnically diverse group of low-income patients attending a community health center. The program more than doubled colorectal cancer screening rates among intervention patients compared to control patients randomly assigned to usual care. The intervention specifically increased colonoscopy screening rates, considered the most sensitive and specific of available CRC screening tests⁴⁶, and it was effective in all patient subgroups regardless of gender, language spoken, race/ethnicity, or insurance status.

Prior studies have demonstrated the benefits of navigator programs for cancer prevention in general and for CRC screening in particular.^{35-40,47-49} Tu et al.'s health educator study among US ethnic Chinese patients focused on FOBT rather than colonoscopy screening and showed a 5.98 increased odds for FOBT screening among intervention patients over the 6-month study.⁴¹ A study using centralized telephone case management among low-income women increased rates of CRC screening by 13% (95% CI 7-20%) in intervention compared to usual care patients.³⁷ However, most of the CRC screening was FOBT, and they found no difference in colonoscopy rates.³⁷ Another telephone outreach program among predominately African-Americans in metropolitan New York also showed benefit.⁵⁰ However, the study population was limited to patients with current employment and health insurance, and is thus less generalizable to low income populations such as the patients in our study. In addition, our study showed that patients with in-person contact with the navigator were more likely to have CRC screening, especially colonoscopy, than patients with only phone contact.

Available evidence does not support choosing one CRC screening test over another, none is ideal but all save lives.^{51,52} Our study sought to emphasize colonoscopy since it is the most sensitive and specific method⁴⁶ and is widely recommended as the preferred CRC screening test.^{44,53,54} Our data demonstrated that colonoscopy was a broadly achievable goal for an underserved population with a high prevalence of procedure-related barriers. Jandorf et al.³⁵ reported on a randomized trial of a patient navigator in an urban health clinic that increased colonoscopy as the CRC screening test. However, their study included only 78 patients of whom 49% received navigation services. After 6 months, nine (23.7%) patients in the intervention group had colonoscopy compared with two patients (5%) in the control group ($p = 0.019$). Our study population included 1,223 patients with 409 patients in the intervention group. Over the 9-month study period, 163 colonoscopies were performed including 85 in the intervention group.

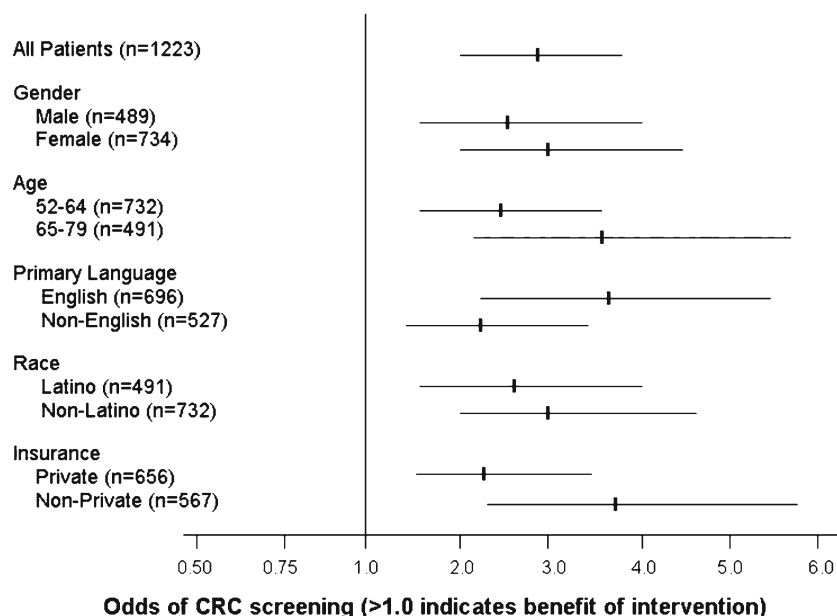


Figure 3. Odds ratios for colorectal cancer screening, intervention vs. usual care by demographic subgroups.

Race and ethnic disparities in colorectal cancer screening, diagnosis, treatment, and survival are well documented in the literature.^{6-8,10-14,55-58} We designed our intervention to be generalizable across a range of cultural, language, and racial/ethnic differences among patients served by the community health center. We trained a group of outreach workers and interpreters to identify and address each patient's unique social or culturally based concerns and barriers to screening. Reflecting this tailored and adaptable approach, the intervention improved CRC screening in all intervention subgroups. While the odds ratios in Fig. 3 suggest that the program had somewhat greater relative benefit for English-speaking patients, further analysis (Fig. 4) revealed that this was due to the higher screening rates for non-English speaking patients in the usual care group. We believe, after discussion with the navigators, that the higher rate in our controls may

have been due to "intervention contamination" among non English-speaking control patients, many of whom had interaction with navigators (study-trained HC outreach workers) or became interested in CRC screening through family or friends who interacted with navigators.

Many barriers previously identified^{6,15-20,22,23} were also reported by patients in our study, particularly knowledge gaps, lack of motivation, and concerns about the colonoscopy procedure. Many patients needed help with scheduling their procedure. For our intervention, the MGH Gastrointestinal Department assigned a secretary whom our navigators could directly contact to schedule appointments. In addition, department policy waives all charges for a screening colonoscopy for patients with the MGH Free Care plan. This may explain

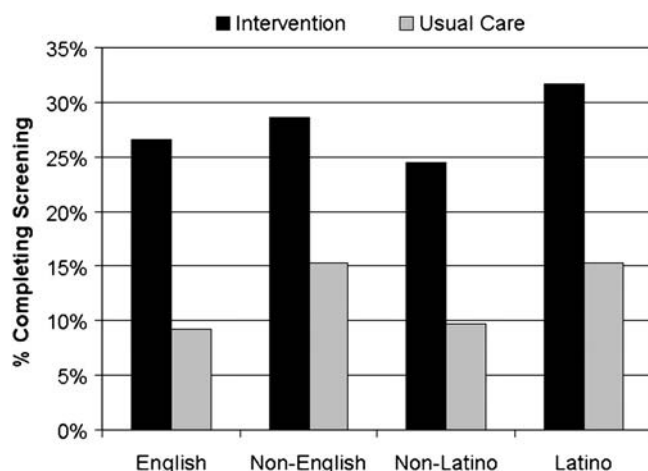


Figure 4. Percentage of patients with colorectal cancer screening, intervention vs. usual care by ethnicity and language status.

Table 2. Number of Patients Contacted by Navigator with Identified Colorectal Cancer Screening Barriers

Domain	N (%)
Patient-related barriers:	301 (99.7)
Patient's lack of knowledge about CRC screening	188 (62.3)
About colorectal cancer	179 (59.3)
About the screening process	176 (58.3)
Patient's level of motivation	130 (43.1)
Embarrassment by procedure	15 (5.0)
Forgotten appointments	120 (39.7)
Patient-reported concerns	134 (44.4)
Pain from the procedure	128 (42.4)
Complications from the procedure	101 (33.4)
Receiving a diagnosis of cancer	30 (9.9)
Logistical or system-level barriers:	178 (58.9)
Difficulty scheduling colonoscopy appointment	99 (32.8)
No interpreters available	94 (31.1)
Difficulty with the bowel preparation	100 (33.1)
Financial costs	31 (10.3)
Medication for bowel preparation	2 (0.7)
Lost time (wages) from work	21 (7.0)
Lack of insurance coverage for procedure	11 (3.6)
Lack of transportation to the colonoscopy site	90 (29.8)
Nobody to accompany patient after colonoscopy	80 (26.5)

the lack of difference in screening colonoscopies according to insurance status. Although study patients often reported lack of someone to accompany them as a reason they did not have a colonoscopy, only 18 patients had a navigator accompany them. Some patients may have used transportation as an excuse for other underlying reservations. Assistance with transportation was also provided via a free shuttle service directly to the main hospital, and in some cases, taxicab vouchers were provided to get home after the procedure.

Our results must be interpreted in the context of the study design. Although our intervention was relatively inexpensive to implement, results from a single urban community health center may not be generalizable to other clinical settings. Some patients may have had CRC screening outside of our clinical network, thereby underestimating our measured overall screening rate. However, it is unlikely that outside screening occurred more commonly in control patients. In addition, group allocation was not concealed, and the study design precluded blinding of intervention status. The higher rates of CRC screening among Latinos and other non-English speakers among control patients suggest that there may have been some cross-over contamination specifically in these patients. Such contamination would bias our results towards the null, and we nonetheless demonstrated a significant intervention impact even within this sub-group.

Using a large randomized clinical trial design, we definitively demonstrated that a culturally tailored, language-concordant navigator program designed to identify and overcome barriers to colorectal cancer screening can significantly improve colonoscopy rates in a wide spectrum of low income, ethnically and linguistically diverse patients. Future research should focus on integrating navigator programs into routine care, examining their cost effectiveness, and devising additional strategies to motivate the large number of residual patients who do not complete screening despite the navigator program. Given the beneficial impact of navigator programs on cancer screening and reduction of disparities, current payment structures may need to be revised to support these population-level approaches to delivering health care.

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Conflict of Interest: None disclosed.

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