



Published in final edited form as:

Am J Prev Med. 2017 September ; 53(3): 363–372. doi:10.1016/j.amepre.2017.05.010.

Patient Navigation for Colonoscopy Completion: Results of an RCT

Amy DeGroff, PhD, MPH¹, Paul C. Schroy III, MD, MPH², Kerry Grace Morrissey, MPH³, Beth Slotman, MS³, Elizabeth A. Rohan, PhD, MSW¹, James Bethel, PhD³, Jennifer Murillo, BA², Weijia Ren, PhD³, Shelley Niwa, MA³, Steven Leadbetter, MS¹, Djenaba Joseph, MD, MPH¹

¹Division of Cancer Prevention and Control, Centers for Disease Control and Prevention, Atlanta, Georgia;

²Boston Medical Center, Gastroenterology, Boston, Massachusetts;

³Westat, Rockville, Maryland

Abstract

Introduction: Colorectal cancer is a leading cause of cancer-related death in the U.S. Although screening reduces colorectal cancer incidence and mortality, screening rates among U.S. adults remain less than optimal, especially among disadvantaged populations. This study examined the efficacy of patient navigation to increase colonoscopy screening.

Study design: RCT.

Setting/participants: A total of 843 low-income adults, primarily Hispanic and non-Hispanic blacks, aged 50–75 years referred for colonoscopy at Boston Medical Center were randomized into the intervention ($n=429$) or control ($n=427$) groups. Participants were enrolled between September 2012 and December 2014, with analysis following through 2015.

Intervention: Two bilingual lay navigators provided individualized education and support to reduce patient barriers and facilitate colonoscopy completion. The intervention was delivered largely by telephone.

Main outcome measure: Colonoscopy completion within 6 months of study enrollment.

Results: Colonoscopy completion was significantly higher for navigated patients (61.1%) than control group patients receiving usual care (53.2%, $p=0.021$). Based on regression analysis, the odds of completing a colonoscopy for navigated patients was one and a half times greater than for controls (95% CI=1.12, 2.03, $p=0.007$). There were no differences between navigated and control groups in regard to adequacy of bowel preparation (95.3% vs 97.3%, respectively).

Conclusions: Navigation significantly improved colonoscopy screening completion among a racially diverse, low-income population. Results contribute to mounting evidence demonstrating the efficacy of patient navigation in increasing colorectal cancer screening. Screening can be

further enhanced when navigation is combined with other evidence-based practices implemented in healthcare systems and the community.

INTRODUCTION

In 2013, colorectal cancer (CRC) was diagnosed in 136,119 people and 51,813 people died of the disease in the U.S.¹ Screening reduces CRC incidence and mortality by detecting disease early, thus improving survival, and by preventing cancer through the removal of precancerous polyps through colonoscopy.² The U.S. Preventive Services Task Force recommends CRC screening for all average risk adults, aged 50–75 years, using colonoscopy every 10 years, high-sensitivity fecal occult blood testing (FOBT) or fecal immunochemical testing (FIT) annually, or sigmoidoscopy every 5 years with FOBT/FIT every 3 years.³ However, in 2014, only 65.7% of respondents reported they were up-to-date with screening.⁴ Screening rates were lower among those with lower incomes and education and people of Hispanic/Latino ethnicity.⁴

Among those up-to-date with CRC screening in 2014, colonoscopy was the most commonly used screening test (63.5%). However, significant barriers to colonoscopy limit screening, including individual and intrapersonal issues (lack of knowledge, embarrassment, fear); cultural concerns (language, distrust of the medical system, fatalistic attitudes about cancer); structural impediments (cost, lack of transportation, inability to secure time off of work); and health system challenges (access to bowel preparation materials, lack of an escort to and from the procedure).^{5–9}

Patient navigation (PN) is an intervention aimed at reducing barriers to cancer screening, diagnostic testing, treatment, and survivorship care. Developed in the early 1990s,¹⁰ PN has been applied to screening for multiple cancers including breast, cervical, colorectal, and prostate.¹¹ In 2009–2011, evaluators conducted a formative study including a literature review and environmental scan to examine the effects of PN on CRC screening. Evaluators identified a limited number of studies, several of which had significant limitations including small sample sizes, non-randomized designs, and single navigators.¹²

The purpose of this study is to conduct a rigorous evaluation of a PN intervention for colonoscopy screening to examine its impact on completion rates. Having established the need for further research, investigators conducted a randomized trial among low-income patients referred for colonoscopy screening at Boston Medical Center (BMC) in Massachusetts. Colonoscopy is the study focus given unique barriers to endoscopy and because BMC providers primarily refer patients in need of screening for colonoscopy. Researchers hypothesize that patients receiving the navigation intervention would have greater colonoscopy completion within 6 months of the study enrollment date than those in the control group.

METHODS

Study Sample

An RCT of PN was conducted at BMC's Section of Gastro-enterology (hereafter, BMC GI) in Boston, Massachusetts, from September 2012 through May 2015. As the largest safety net hospital in the northeast, BMC patients are largely a medically underserved population; approximately 70% are from racial and ethnic minority populations and 30% are non-English speakers. Participants were recruited from BMC's Section of General Internal Medicine and Family Medicine Department. In December 2013, recruitment was expanded to East Boston Neighborhood Health Center, a community health center serving a large Spanish-speaking population, to increase the number of Spanish speakers in the study. Inclusion criteria were as follows:

1. patient referral by a primary care provider to the BMC GI for colonoscopy screening;
2. speaking English or Spanish;
3. being aged 50–75 years;
4. no previous diagnosis of colon cancer or adenomatous polyps; and
5. no active substance abuse or acute psychiatric diagnosis as determined by medical records/primary care provider.

Participants were enrolled between September 2012 and December 2014. Using BMC's electronic clinical data system, BMC's Data Coordinating Center produced a weekly list of prescreened patients meeting study inclusion criteria. A bilingual Research Coordinator (RC) made seven attempts via telephone to reach each patient, leaving up to two voicemails. Patients not reached by phone were mailed a letter inviting them to contact the RC to learn about the study.

For patients who were reached, the RC described the study in English or Spanish, as appropriate. If the patient verbally agreed, the RC performed a standardized screening assessment to confirm eligibility. All patients deemed eligible were invited to participate in the study, and the elements of informed consent were reviewed. Verbal informed consent was documented in the electronic study management system and the patient was enrolled in the study. The RC left the project in November 2013 and then navigators also served as recruiters.

The study protocol was approved by IRBs at BMC, the Centers for Disease Control and Prevention, and Westat. Informed consent was secured for all participants. The study was determined exempt from Office of Management and Budget review. A procedures manual was developed to document aspects of the study, including the intervention protocol.

Once enrolled, participants completed a pre-intervention survey administered by an interviewer using a computerized instrument. The 69-item survey included information on patient demographics, healthcare access, patient-provider communication, CRC screening history, CRC screening intentions, knowledge and attitudes about screening, self-efficacy,

social support, psychological distress, and logistic barriers to screening. Survey items were drawn from existing instruments including the Behavioral Risk Factor Surveillance Survey and the Health Information National Trends Survey. Participants received a \$25 gift card after completing the survey. The instrument is available from the corresponding author upon request. Following the survey, the recruiter randomly assigned participants to either navigation or usual care by applying a 1:1 ratio to a computer-generated randomization algorithm.

Figure 1 summarizes the trial sampling and randomized assignment. Of 3,798 patients assessed for eligibility, 22.5% (856/3,798) were successfully enrolled and randomized into the intervention ($n=429$) or control ($n=427$) groups. A total of 840 participants were included in the final analysis, after excluding 15 participants because seven were found ineligible and eight withdrew.

Intervention

The PN intervention was aimed at addressing multilevel, patient-defined barriers to CRC screening. The intervention incorporated several behavioral theories including the health belief model,¹³ theory of reasoned action,¹⁴ and social learning theories.¹⁵ Together, these purport that changes in knowledge, attitudes, beliefs, intentions, and self-efficacy precede individual-level behavior change. Additionally, the intervention was predicated on the theory that removing individual/intrapersonal (e.g., lack of knowledge); cultural (e.g., language challenges); structural (e.g., transportation); and healthcare system (e.g., patient-provider communication) barriers improves screening completion.

Two bilingual lay navigators familiar with the priority population, one man and one woman, delivered the intervention. One navigator had received PN training at the Outreach Worker Training Institute and motivational interviewing training from Cambridge Health Alliance. She also had significant experience working on a similar PN intervention trial for CRC screening. The second navigator was trained through a 2-day PN training at the Harold P. Freeman Patient Navigation Institute followed by mentorship provided by the experienced navigator. Both navigators received additional training in motivational interviewing from the Boston University School of Medicine.

Navigators primarily worked with participants via telephone, although some activities were conducted in person and by mail. Typical activities included assessing for barriers, informing and educating patients about the colonoscopy procedure and bowel preparation, addressing emotional concerns about the procedure, making appointments, and arranging for escorts and transportation services.¹⁶ Navigators assisted participants with obtaining bowel preparation materials by ensuring they received their prescription and picked up the medication along with the appropriate type of liquid to mix with the medication and, if needed, accompanying them to the pharmacy. Navigators called participants to remind them about bowel preparation and their screening appointment date and, following the procedure, ensure they received screening results. Additionally, navigators supported communication within the healthcare system confirming that the referring primary care provider received the endoscopy report on colonoscopy completion. Navigators documented participant barriers and service delivery in a navigator database that also facilitated participant tracking. On

average, navigators spent 44 minutes per patient working with the patient and conducting activities on behalf of the patient.¹⁶

For participants in the control group, usual care generally involved telephone contact by an administrative staff person in BMC GI to schedule an appointment after the referral was received electronically or by fax from their primary care physician. During this call, participants were also given brief verbal instructions about the bowel preparation and need for escorted transportation. Participants were sent a mailing with a prescription for bowel preparation materials and related instructions, instructions to arrange escorted transportation, and directions to the hospital. Participants who could not be contacted directly by phone after multiple attempts were sent non-negotiated appointment dates and times in the mail along with the other materials noted above. Participants were encouraged to call BMC GI with questions or problems (e.g., arranging escorted transportation, canceling and rescheduling appointments). Participants in the control group had no additional contact with BMC GI staff until a reminder call 3 days prior to the scheduled exam, at which time the bowel preparation instructions and need for escorted transportation were reviewed. Navigated patients did not receive usual care.

Measures

The primary outcome of the study was colonoscopy completion measured by the percentage of patients in each group completing the procedure within 6 months. Patients who failed to complete a colonoscopy within 6 months of study enrollment or after three appointment cancellations or no-shows were considered non-completers. Adequacy of bowel preparation, as determined by the performing endoscopist, was a secondary outcome. Using electronic health record system data, the BMC principal investigator, a gastroenterologist, transcribed data to an electronic patient colonoscopy outcome form within the data management system designed for the study. Information collection included test indication, procedure date, and test results.

Statistical Analysis

Data analysis followed the intent-to-treat principle; all subjects were analyzed in the group to which they were randomized. Chi-square tests and t-tests were used to compare demographic differences and other participant characteristics between navigation and control arms. Unadjusted logistic regression produced crude ORs that were used to evaluate independent predictors for colonoscopy completion. Besides the patient navigation intervention, other assessed predictors for completion were:

1. patient demographic characteristics (i.e., age, gender, race/ethnicity, marital status, education level, income, employment status, spoken language, foreign born);
2. health-relevant background (i.e., healthcare coverage, self-rated general health, smoking status, number of doctors, number of doctor visits, psychological distress levels);
3. previous CRC screening with a FOBT or FIT;

4. self-efficacy; and
5. barriers to colonoscopy completion and total number of barriers.

For categorical predictors, the ref category was chosen for purposes of facilitating interpretation.

Next, predictors with p -values ≥ 0.10 in the unadjusted models were included in the adjusted full model and assessed in a backward elimination procedure. Predictors with p -values ≤ 0.05 were identified as outcome factors in the final reduced model. Demographic predictors (age, gender, race/ethnicity), irrespective of their p -values, were retained in the final reduced model for adjustment purposes, which was assessed for adequacy and validity. All analyses were completed using SAS, version 9.3.

RESULTS

Overall, the sample included more women (57.1%); foreign born (55.7%); and people with a high school education or less (69.2%). Eighty percent of participants were either Hispanic (40.4%) or non-Hispanic black (40.4%). More than half (56.6%) of all participants reported household incomes $< \$20,000$. In total, 43.8% were employed, whereas 56.1% were out of work, not in the labor force, or unable to work. Participants provided an assessment of general health in the baseline survey and 73 (8.8%) reported having excellent health (Table 1). There was no racial or gender bias in the randomization of participants (data not shown).

Overall, 57.1% completed colonoscopy within 6 months, with the percentage significantly higher for the patient navigation group (61.1%) than the control group (53.2%, $p=0.021$). Table 2 summarizes the 16 significant predictor variables and their crude ORs.

Based on the final, adjusted model, identified colonoscopy completion factors included group assignment, race/ethnicity, self-rating of general health, scheduling assistance, and self-efficacy (Table 3). The odds of completing colonoscopy for navigated patients were 1.51 times greater (95% CI=1.12, 2.03) than the odds for control patients ($p=0.007$). The odds of Hispanics completing colonoscopy were 2.60 greater (95% CI=1.64, 4.13) than those for non-Hispanic whites ($p=0.001$). People who rated their general health as excellent had 3.50 times greater (95% CI=1.53, 8.00) odds of completing colonoscopy than those for individuals reporting poor health ($p=0.044$). Among participants not requiring assistance scheduling the colonoscopy appointment, the odds for completing colonoscopy were 1.51 times greater (95% CI=1.11, 2.04) than those among those needing assistance ($p=0.009$). And among individuals scoring higher on self-efficacy, the odds for completing colonoscopy were 1.74 greater (95% CI=1.14, 2.67) than others ($p=0.010$).

In regard to adequacy of bowel preparation, 96.2% of subjects completing colonoscopy were assessed by the endoscopist conducting the procedure to have adequate preparation with no significant difference between navigation and control groups (95.2% vs 97.3%, respectively). Because of the small number of subjects with inadequate preparation ($n=18$), no further analysis for this outcome was conducted.

DISCUSSION

In this randomized trial testing a lay navigator PN model, researchers found navigation resulted in significantly greater colonoscopy completion among a racially diverse, low-income, disadvantaged population. Navigated patients were one and a half times more likely to complete colonoscopy than patients receiving usual care. Results contribute to a mounting body of evidence based on RCTs^{17–19} and rigorous quasi-experimental designs^{20–22} supporting the efficacy of PN in increasing CRC screening. This research suggests that PN is an important strategy for reducing CRC incidence and death. Researchers did not demonstrate an effect of PN on the quality of bowel preparation, a secondary outcome; more than 95% of participants in both groups were assessed as having adequate preparation. These results might reflect strong patient education provided as part of usual care or institutional use of a split-dose bowel preparation regimen.²³

This study focused solely on colonoscopy, a complex clinical procedure requiring patients to devote significant time and effort, including taking time off from work for both bowel preparation and the procedure and managing varied logistics (e.g., escort, transportation).²⁴ In addition, patients in the study faced barriers including a lack of understanding about the procedure, language barriers, embarrassment, distrust of the medical system, and fear.¹⁶ Based on this study and others, PN represents an important public health intervention that supports patients to complete colonoscopy and contributes to increasing cancer screening rates nationally. PN is an important tool for increasing screening rates above the current level of 65.7%,⁴ especially among people experiencing disparities in screening.⁴ Use of evidence-based practices, like those recommended in *The Guide to Community Preventive Services* (Community Guide) (www.thecommunityguide.org/index.html), are strongly encouraged in government programs²⁵; therefore, the growing body of research supporting the effectiveness of PN reinforces the importance of its use in cancer screening programs among patients who otherwise would not complete screening.

This study identified other independent predictors of colonoscopy completion including being Hispanic, reporting excellent general health, not needing help scheduling an appointment, and self-efficacy. Analysis of Center for Disease Control and Prevention's Behavioral Risk Factor Surveillance Survey data show that screening rates are greater among those who are married, employed, insured, have a usual source of care, and who have greater incomes and education and lower among Hispanics.⁴ Perhaps Hispanics recruited from the East Boston Neighborhood Health Center had strong peer and institutional support for colonoscopy screening. Other PN studies have used regression analysis to identify predictive factors. Consistent with results presented here, in a randomized trial led by Jandorf et al.,²⁶ self-efficacy was found to predict colonoscopy completion among a population of African Americans at Mt. Sinai in New York. Somewhat surprisingly, income >\$10,000 was not found to be a predictor of screening completion in this study in contrast to two previous PN studies.^{26,27} These predictors might be useful in helping to identify or triage persons most in need of PN.

In this study, screening rates for both groups might have been improved if participants had been given the opportunity to choose among U.S. Preventive Services Task Force-

recommended tests (i.e., FOBT/FIT, sigmoidoscopy, and colonoscopy).²⁸ Other PN studies have included multiple CRC tests.^{17,19,29} In practice and in future research, navigators should be trained to counsel and support patients to select a CRC screening test that is best for them. Even though colonoscopy is used most often for CRC screening³⁰ and providers recommend it more than other tests,³¹ screening uptake would likely be improved and disparities reduced if patients were educated about the different test types and given the opportunity to choose a test consistent with their preferences within the context of shared decision making.³²

Further research is needed in several areas. First, there is fairly little known about what models of PN might be most effective. Most PN research has been based on lay navigator models; far fewer studies have involved professional health educators^{21,26} or nurses as navigators.^{20,34} Given the clinical complexity of colonoscopy, culturally competent nurses might be especially effective navigators either alone or in combination with lay navigators. The patient-centered medical home, an important transformation within primary care, provides another opportunity to examine the effects of a model where navigators are incorporated into a care team focused on delivery of coordinated health care, including preventive services.³⁵ Lay health workers who link unscreened, hard to reach people to clinical care, could be incorporated into these models.

Additionally, little is known about the effects of intervention dose or intensity of navigation on outcomes. Researchers have not typically reported information about PN implementation in manuscripts, including patient barriers, number of navigator contacts, navigator delivery time, and caseload. More-intensive PN interventions might prove more effective. A recent study by Rice and colleagues²⁰ examined a PN model using registered nurse navigators and a strict, six-call intervention protocol. Intervention fidelity was found to be high (82% of patients received six calls), and patients received an average of 133 minutes of navigation over the six calls.²⁰ More than 96% of navigated patients completed colonoscopy compared with 69% of controls ($p<0.001$), the highest documented completion rate identified in the literature. Because aspects of implementation (e.g., dose, fidelity, reach, and quality) contribute to improved health outcomes,³⁶ future studies should consider incorporating related metrics.

Finally, increasing CRC screening will likely be further enhanced when PN is combined with other evidence-based practices implemented as system-level changes within primary care including patient and provider reminders, provider assessment and feedback, reducing structural barriers, and small media (Community Guide). Together, these strategies contribute toward the development of an organized screening program necessary to improve screening rates across the U.S.

Limitations

The current study has several limitations. First, results might not be generalizable to other areas given that all participants had a primary care provider, a referral for colonoscopy, and a payment source for colonoscopy. Second, colonoscopy completion was assessed based on a 6-month time frame, which is in contrast to other studies using longer periods (e.g., 12 months). Some researchers have observed positive effects of PN only after 90 days³³

or after 6 months.¹¹ In these studies, no colonoscopy completion rate differences were found between navigated and non-navigated patients within either 90 days or 6 months, respectively, suggesting that this study might have observed more pronounced effects had the follow-up period been extended to 9 or 12 months. Finally, this analysis excluded incomplete records from the final adjusted model, which might introduce bias in the model results if covariate data from the excluded records are not missing completely at random. The assessment of potential bias compared records with complete versus incomplete covariate data and found no significant model bias resulting from excluding records with missing data.

CONCLUSIONS

As CRC is one of the few preventable cancers, increasing screening rates among age-eligible adults is paramount. These results contribute to a growing body of literature demonstrating the effectiveness of PN in improving colonoscopy completion among disadvantaged populations. Although this study focused solely on colonoscopy screening, screening completion among study participants might have been greater had patients had the opportunity to select a screening test consistent with their personal preferences. As a public health strategy, PN, especially in combination with other evidence-based interventions, can contribute to increasing population-level screening rates. Future research should examine the comparative effectiveness of unique navigation models differing in regard to staffing characteristics and intervention dose.

ACKNOWLEDGMENTS

Westat received funding from the Centers for Disease Control and Prevention to support this research (Contract #200200827600-0009).

The findings and conclusions in this manuscript are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

No financial disclosures were reported by the authors of this paper.

REFERENCES

1. DHHS, CDC, National Cancer Institute. U.S. Cancer Statistics. <https://nccd.cdc.gov/uscs/>. Accessed July 1, 2016.
2. Whitlock EP, Lin JS, Liles E, Beil TL, Fu R. Screening for colorectal cancer: a targeted updated systematic review for the U.S. Preventive Services Task Force. *Ann Intern Med*. 2008;149(9):638–658. 10.7326/0003-4819-149-9-200811040-00245. [PubMed: 18838718]
3. U.S. Preventive Services Task Force. Final update summary: colorectal cancer: screening. www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/colorectal-cancer-screening. Published July 2015. Accessed January 27, 2016.
4. CDC. Behavioral Risk Factor Surveillance System Survey Data. Atlanta, GA: U.S. DHHS, CDC, 2014. www.cdc.gov/brfss/index.html. Accessed January 27, 2016.
5. Lasser KE, Ayanian JZ, Fletcher RH, Good MJ. Barriers to colorectal cancer screening in community health centers: a qualitative study. *BMC Fam Pract*. 2008;9:15. 10.1186/1471-2296-9-15. [PubMed: 18304342]
6. Sly JR, Edwards T, Shelton RC, Jandorf L. Identifying barriers to colonoscopy screening for nonadherent African American participants in a patient navigation intervention. *Health Educ Behav*. 2012;40 (4):449–457. 10.1177/1090198112459514. [PubMed: 23086556]

7. Hendren S, Chin N, Fisher S, et al. Patients' barriers to receipt of cancer care, and factors associated with needing more assistance from a patient navigator. *J Natl Med Assoc.* 2011;103(8):701–710. 10.1016/S0027-9684(15)30409-0. [PubMed: 22046847]
8. Guessous I, Dash C, Lapin P, et al. Colorectal cancer screenings barriers and facilitators in older persons. *Prev Med.* 2010;50(1–2):3–10. 10.1016/j.ypmed.2009.12.005. [PubMed: 20006644]
9. Jones R, Woolf S, Cunningham T, et al. Patient-reported barriers to colorectal cancer screening. *Am J Prev Med.* 2010;38(5):508–516. 10.1016/j.amepre.2010.01.021. [PubMed: 20409499]
10. Freeman HP, Rodriguez RL. History and principles of patient navigation. *Cancer.* 2011;117(suppl 15):3539–3542. 10.1002/cncr.26262. [PubMed: 21780088]
11. Paskett ED, Harrop JP, Wells KJ. Patient navigation: an update on the state of the science. *CA Cancer J Clin.* 2011;61(4):237–249. 10.3322/caac.20111. [PubMed: 21659419]
12. DeGroff A, Coa K, Morrissey KG, Rohan E, Slotman B. Key considerations in designing a patient navigation program for colorectal cancer screening. *Health Promot Pract.* 2013;15(4):483–495. 10.1177/1524839913513587. [PubMed: 24357862]
13. Becker MH. The health belief model and personal health behavior. *Health Educ Monogr.* 1974;2(4):324–508. 10.1177/109019817400200407.
14. Ajzen I, Fishbein M. *Understanding Attitudes and Predicting Social Behavior.* Englewood Cliffs, NJ: Prentice-Hall, 1980.
15. Bandura A *Social Learning Theory.* Englewood Cliffs, NJ: Prentice-Hall, 1977.
16. Rohan E, Slotman B, Morrissey KG, Murillo J, DeGroff A, Schroy P. Patient navigation: scope of practice as members of the oncology multi-disciplinary care team. July 31. Washington, DC: Paper presented at: 2015 World Congress of American Psychosocial Oncology Society, 2015.
17. Lasser KE, Murillo J, Lisboa S, et al. Colorectal cancer screening among ethnically diverse, low-income patients: a randomized controlled trial. *Arch Intern Med.* 2011;171(10):906–912. 10.1001/archinternmed.2011.201. [PubMed: 21606094]
18. Percac-Lima S, Grant RW, Green AR, et al. A culturally tailored navigator program for colorectal cancer screening in a community health center: a randomized, controlled trial. *J Gen Intern Med.* 2009;24 (2):211–217. 10.1007/s11606-008-0864-x. [PubMed: 19067085]
19. Jandorf L, Gutierrez Y, Lopez J, Christie J, Itzkowitz SH. Use of a patient navigator to increase colorectal cancer screening in an urban neighborhood health clinic. *J Urban Health.* 2005;82(2):216–224. 10.1093/jurban/jti046. [PubMed: 15888638]
20. Rice K, Butterly L, Gressard L, et al. An effective patient navigation intervention: results from a study of the New Hampshire colorectal cancer screening program. Paper presented at: 2015 APHA Annual Conference; November 2015; Chicago, IL.
21. Honeycutt S, Green R, Ballard D, et al. Evaluation of a patient navigation program to promote colorectal cancer screening in rural Georgia, USA. *Cancer.* 2013;119(16):3059–3066. 10.1002/cncr.28033. [PubMed: 23719894]
22. Lasser KE, Murillo J, Medlin E, et al. A multilevel intervention to promote colorectal cancer screening among community health center patients: results of a pilot study. *BMC Fam Pract.* 2009;10:37. 10.1186/1471-2296-10-37. [PubMed: 19480698]
23. ASGE Standards of Practice Committee, Saltzman JR, Cash BD, et al. Bowel preparation before colonoscopy. *Gastrointest Endosc.* 2015;81 (4):781–794. 10.1016/j.gie.2014.09.048. [PubMed: 25595062]
24. Rohan E, Boehm J, DeGroff A, Glover-Kudon R, Preissle J. Implementing the Center for Disease Control and Prevention's Colorectal Cancer Screening Demonstration Program: wisdom from the Field. *Cancer.* 2013;119(15):2870–2883. 10.1002/cncr.28162. [PubMed: 23868482]
25. Burkhardt JT, Schroter DC, Magura S, Means SN, Coryn CLS. An overview of evidence-based program registers for behavioral health. *Eval Program Plann.* 2015;48:92–99. 10.1016/j.evalproplan.2014.09.006. [PubMed: 25450777]
26. Jandorf L, Braschi C, Ernstoff E, et al. Culturally targeted patient navigation for increasing African Americans' adherence to screening colonoscopy. *Cancer Epidemiol Biomarkers Prev.* 2013;22(9):1577–1587. 10.1158/1055-9965.EPI-12-1275. [PubMed: 23753039]

27. Braschi CD, Sly JR, Singh S, Villagra C, Jandorf L. Increasing colonoscopy screening for Latino Americans through a patient navigation model: a randomized clinical trial. *J Immigr Minor Health*. 2014;16(5):934–940. 10.1007/s10903-013-9848-y. [PubMed: 23736964]
28. Inadomi JM, Sandeep V, Janz NK, et al. Adherence to colorectal cancer screening: a randomized clinical trial of competing strategies. *Arch Intern Med*. 2012;172(7):575–582. 10.1001/archinternmed.2012.332. [PubMed: 22493463]
29. Horne HN, Phelan-Emrick DF, Pollack CE, et al. Effect of patient navigation on colorectal cancer screening in a community-based randomized controlled trial of urban African American adults. *Cancer Cause Control*. 2015;26(2):239–246. 10.1007/s10552-014-0505-0.
30. CDC. Vital signs: colorectal cancer screening test use—United States, 2012. *MMWR Morb Mortal Wkly Rep*. 2013;62(44):881–888. www.cdc.gov/mmwr/preview/mmwrhtml/mm6244a4.htm?s_cid=mm6244a4_w. [PubMed: 24196665]
31. Klabunde CN, Lanier D, Nadel MR, McLeod C, Yuan G, Vernon SW. U.S. primary care physicians' colorectal cancer screening recommendations and practices, 2006–2007. *Am J Prev Med*. 2009;37(1):8–16. 10.1016/j.amepre.2009.03.008. [PubMed: 19442479]
32. Schroy P, Emmons K, Peters E, et al. Aid-assisted decision making and colorectal cancer screening: a randomized controlled trial. *Am J Prev Med*. 2012;43(6):573–583. 10.1016/j.amepre.2012.08.018. [PubMed: 23159252]
33. Freund KM, Battaglia TA, Calhoun E, et al. Impact of patient navigation on timely cancer care: the Patient Navigation Research Program. *J Natl Cancer Inst*. 2014;106(6):dju115. 10.1093/jnci/dju115. [PubMed: 24938303]
34. Green BB, Anderson ML, Wang CY, et al. Results of Nurse Navigator follow-up after positive colorectal cancer screening test: a randomized trial. *J Am Board Fam Med*. 2014;27(6):789–795. 10.3122/jabfm.2014.06.140125. [PubMed: 25381076]
35. Allen CL, Harris JR, Hannon PA, et al. Opportunities for improving cancer prevention at federally qualified health centers. *J Cancer Educ*. 2014;29(1):30–37. 10.1007/s13187-013-0535-4. [PubMed: 23996232]
36. Durlak JA, DuPre EP. Implementation matters: a review of research on the influence of implementation on program outcomes and the factors affecting implementation. *Am J Community Psychol*. 2008;41(3–4): 327–350. 10.1007/s10464-008-9165-0. [PubMed: 18322790]

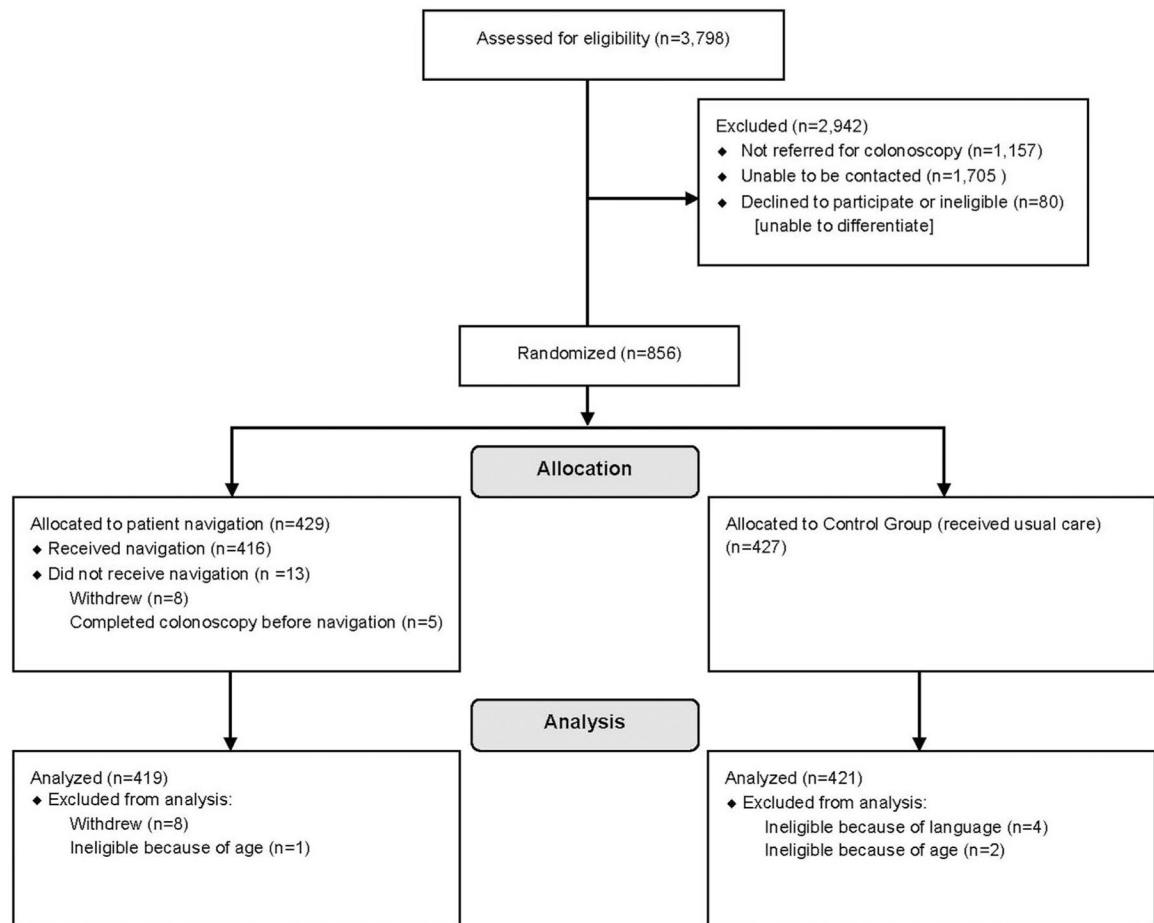


Figure 1.
Study participant referral, enrollment, and study group randomization.

Table 1.

Characteristics of Navigated and Control Group Participants

Participant characteristics	Navigation group characteristic (n=419 ^a)	Control group characteristic (n=421 ^b)
	n (%)	n (%)
Age, years	419	421
50–54	222 (53.0)	229 (54.4)
55–64	142 (33.9)	136 (32.3)
65–74	55 (13.1)	56 (13.3)
Gender	419	421
Male	187 (44.6)	173 (41.1)
Female	232 (55.4)	248 (58.9)
Race/ethnicity	418	420
Hispanic	164 (39.2)	175 (41.7)
Non-Hispanic black	170 (40.7)	169 (40.2)
Non-Hispanic white	63 (15.1)	56 (13.3)
Other	21 (5.0)	20 (4.8)
Marital status	417	420
Married or living together	151 (36.2)	156 (37.1)
Divorced or widowed	151 (36.2)	163 (38.8)
Never married	115 (27.6)	101 (24.1)
Education level	418	421
Less than high school	141 (33.7)	146 (34.8)
High school diploma or GED	146 (35.0)	147 (35.0)
Some college	73 (17.5)	67 (16.0)
College degree or higher	58 (13.9)	60 (14.3)
Income	419	421
\$0–\$9,999	132 (31.5)	143 (34.0)
\$10,000–\$19,999	111 (26.5)	89 (21.1)
\$20,000–\$34,999	63 (15.0)	60 (14.3)
\$35,000–\$49,999	30 (7.2)	44 (10.5)
\$50,000 or more	38 (9.1)	42 (10.0)
Not reported	45 (10.7)	43 (10.2)
Employment status	417	420
Employed	182 (43.6)	185 (44.0)
Out of work	58 (13.9)	61 (14.5)
Not in labor force (student, retired, housewife)	58 (13.9)	47 (11.2)
Unable to work	119 (28.5)	127 (30.2)
Language spoken at home	418	421
English	233 (55.7)	227 (53.9)
Language other than English	185 (44.3)	194 (46.1)
Foreign born	415	415
Yes	233 (56.1)	229 (55.2)

Participant characteristics	Navigation group characteristic (<i>n</i> =419 ^{<i>a</i>})	Control group characteristic (<i>n</i> =421 ^{<i>b</i>})
	<i>n</i> (%)	<i>n</i> (%)
No	182 (43.9)	186 (44.8)
Has healthcare coverage	417	418
Yes	407 (97.6)	412 (98.6)
No	10 (2.4)	6 (1.4)
Rating of general health	414	413
Excellent	39 (9.4)	34 (8.2)
Very good	73 (17.6)	70 (17.0)
Good	153 (37.0)	142 (34.4)
Fair	127 (30.7)	142 (34.4)
Poor	22 (5.3)	25 (6.1)
Smoking status	418	420
Never smoked	227 (54.3)	233 (55.5)
Not current smoker	91 (21.8)	112 (26.7)
Current smoker	100 (23.9)	75 (17.9)

Note: Percentages do not always sum to 100% because of rounding.

^{*a*}For navigation group, includes participants who were unable to be navigated prior to their colonoscopy (*n*=5), but excludes participants who withdrew (*n*=8) or were ineligible because of unknown age (*n*=1).

^{*b*}For the control group, excludes participants who were ineligible because of language barriers (*n*=4) or because of unknown age (*n*=2).

GED, general educational development test.

Table 2.
Significant Predictor Variables of Colonoscopy Completion Based on Bivariate Analysis

Predictor variables	n	Crude OR (95% CI)	p-value
Group	840		
Control	421	1.00	0.021
Navigation	419	1.38 (1.05, 1.82)	
Age, years	840		
50–54	451	1.00	0.033
55–64	278	0.76 (0.56, 1.03)	
65–74	111	0.61 (0.40, 0.92)	
Race/ethnicity	838		
Non-Hispanic white	119	1.00	< 0.001
Non-Hispanic black	339	1.21 (0.80, 1.84)	
Hispanic	339	2.30 (1.50, 3.51)	
Other	41	2.02 (0.97, 4.19)	
Marital status	837		
Never married	216	1.00	0.014
Divorced or widowed	314	1.09 (0.77, 1.54)	
Married or living together	307	1.61 (1.13, 2.29)	
Income	840		
\$0–\$9,999	275	1.00	0.026
\$10,000–\$19,999	200	1.11 (0.77, 1.59)	
\$20,000–\$34,999	123	2.09 (1.33, 3.31)	
\$35,000–\$49,999	74	0.98 (0.59, 1.64)	
\$50,000 or more	80	0.88 (0.53, 1.44)	
Not reported	88	0.96 (0.59, 1.55)	
Employment status	837		
Unable to work	246	1.00	0.003
Not in labor force (student, retired, housewife)	105	1.14 (0.72, 1.80)	
Out of work	119	1.38 (0.89, 2.14)	
Employed	367	1.82 (1.31, 2.52)	

Predictor variables	n	Crude OR (95% CI)	p-value
Language spoken at home	839		
English	460	1.00	< 0.001
Language other than English	379	1.84 (1.39, 2.43)	
Foreign born	830		
No	368	1.00	< 0.001
Yes	462	1.72 (1.31, 2.28)	
Self-reported general health	827		
Poor	47	1.00	0.019
Fair	269	1.47 (0.79, 2.74)	
Good	295	1.66 (0.89, 3.09)	
Very good	143	1.62 (0.83, 3.14)	
Excellent	73	3.52 (1.62, 7.65)	
Smoking status	838		
Current smoker	175	1.00	0.016
Never smoked	460	1.66 (1.17, 2.36)	
Not current smoker	203	1.33 (0.89, 1.99)	
Number of doctors	838		
Has more than one doctor	174	1.00	0.001
Has one doctor	651	1.89 (1.35, 2.65)	
Has no doctor	13	1.44 (0.46, 4.45)	
Need someone to translate the colonoscopy information	836		
English spoken at home	460	1.00	< 0.001
Yes	280	1.95 (1.43, 2.65)	
No	96	1.57 (1.00, 2.46)	
Need help to schedule the appointment	826		
Yes	331	1.00	0.006
No	495	1.48 (1.12, 1.97)	
Need unpaid work time off for a colonoscopy	815		
Not working	470	1.00	0.001
No	157	1.46 (1.01, 2.11)	
Yes	188	1.88 (1.32, 2.68)	

Predictor variables	<i>n</i>	Crude OR (95% CI)	<i>p</i> -value
Have ride home after colonoscopy	840		
No	165	1.00	0.024
Yes	560	1.58 (1.11, 2.24)	
Don't know	115	1.17 (0.73, 1.89)	
Self-efficacy ^a	817		
Not sure	113	1.00	0.011
Sure	704	1.68 (1.12, 2.50)	

^aMean self-efficacy scores were calculated based on five questions modified from a scale developed by M. Fernandez and colleagues for endoscopic CRC screening. The “Not sure” category includes “neither sure or unsure” responses. The instrument was obtained via personal communication, and original development was supported by Centers for Disease Control and Prevention Cooperative Agreements (CDC PRC SIP 2-02 U48 CCU60009653 and CDC PRC SIP 16-04U48 CCU6009653).

Table 3.Predictors of Colonoscopy Completion From Final Logistic Model, Adjusted for Demographics (*n*=787)

Factor	<i>n</i>	AOR (95% CI)	<i>p</i> -value
Group	787		
Control	395	1.00	0.007
Navigation	392	1.51 (1.12, 2.03)	
Race/ethnicity	787		
Non-Hispanic white	113	1.00	< 0.001
Non-Hispanic black	315	1.39 (0.89, 2.18)	
Hispanic	322	2.60 (1.64, 4.13)	
Other	37	2.27 (1.03, 5.03)	
Self-reported general health	787		
Poor	46	1.00	0.044
Fair	255	1.56 (0.81, 3.00)	
Good	280	1.82 (0.95, 3.48)	
Very good	138	1.76 (0.87, 3.55)	
Excellent	68	3.50 (1.53, 8.00)	
Need help to schedule the appointment	787		
Yes	301	1.00	0.009
No	486	1.51 (1.11, 2.04)	
Self-efficacy ^a	787		
Not sure	109	1.00	0.010
Sure	678	1.74 (1.14, 2.67)	

Note: Gender, age group, and marital status were retained in the final model for adjustment purposes. Most of the 53 records excluded from this analysis were because of “Don’t Know” or Refused responses.

^aMean self-efficacy scores were calculated based on five questions modified from a scale developed by M. Fernandez and colleagues for endoscopic CRC screening. The “Not sure” category includes “neither sure or unsure” responses. The instrument was obtained via personal communication, and original development was supported by Centers for Disease Control and Prevention Cooperative Agreements (CDC PRC SIP 2–02 U48 CCU60009653 and CDC PRC SIP 16–04U48 CCU6009653).