Colonoscopy Outreach for Rural Communities (CORC) Aim 2

ClinicalTrials.gov: NCT05453630

Funding: National Cancer Institute, R01CA254515

IRB protocol #: STUDY00014807

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STUDY SYNOPSIS

Title	Colonoscopy Outreach for Rural Communities (CORC)
Study Design	Type 1 hybrid implementation-effectiveness study.
Study Sites	Six primary care organizations in ID, OR, WA
Study Objectives	The study aims to test the effectiveness of a patient navigation program for increasing colonoscopy completion for colorectal cancer screening among rural populations. The study will be implemented in partnership with a community based organization and will engage up to 6 rural or rural-serving primary care organizations.
Participants	480 - 600

ACRONYMS

Acronym	Full Name
CORC	Colonoscopy Outreach for Rural Communities
CBO	Community based organization
CRC	Colorectal cancer
FQHC	Federally Qualified Health Center
FIT	Fecal Immunochemical Test
FOBT	Fecal Occult Blood test
PN	Patient Navigation
RC	Research Coordinator
RS	Research Scientist
PI	Principal Investigator
UW	University of Washington

I. Details

1.1 Funding

National Institutes of Health, National Cancer Institute
Funded award project title: Rural Community Support for Colonoscopy (R01CA254515)

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The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health. The funding sources and support had no role in the design of this study and will not have any role during its execution, analyses, interpretation of the data, or decision to submit results.

1.2 Trial Registration

ClinicalTrials.gov: NCT05453630, https://clinicaltrials.gov/study/NCT05453630

1.3. IRB

University of Washington Institutional Review Board Protocol number: STUDY00014807

II. Study Period

3/8/2021 – 2/28/2026 (5 years)

III. Background

Colorectal cancer (CRC) is the second leading cause of cancer death in the United States[1] and its burden is greater in rural communities, with higher incidence and mortality rates in rural counties.[2,3] The U.S. Preventive Services Task Force recommends that adults aged 45-75 complete screening for CRC using one of several tests including fecal immunochemical test (FIT) or guaiac-based fecal occult blood test (gFOBT) annually, a stool DNA test (FIT-DNA) every 1-3 years, flexible sigmoidoscopy every 5 years, or colonoscopy every 10 years.[4]

Colonoscopy is the most widely used method for CRC screening in the United States,[5–7] either as primary screening, or diagnostic follow-up after a positive stool-based test.[4] There is increasing evidence of decreased risk of CRC and mortality associated with completing screening colonoscopy.[4,8–11] Additionally, for patients referred after a positive stool-based test, delay in completed colonoscopy procedures is associated with increased risk of finding cancer at a more advanced stage,[12] and with increased incidence and mortality of CRC.[13] However, as few as half of patients referred for colonoscopy for CRC screening eventually complete the procedure.[14–16]

Adherence to colonoscopy and CRC screening overall is lower in rural than in urban areas.[17–20] Rural populations experience geographic barriers to accessing colonoscopy due to longer travel times[21,22]and fewer local providers[23,24] than urban residents. Furthermore, rural communities have higher rates of poverty[17] and people living without insurance[25] than urban areas, which are associated with lower colonoscopy adherence.[17,26] Low-income populations experience barriers to colonoscopy completion, including difficulty scheduling, cost concerns, lack transportation, as well as lack of knowledge about the procedure and fear of the procedure and of CRC.[27,28]

Patient navigation is an evidence-based approach to increasing colonoscopy completion[29,30] that uses one-on-one education, motivational interviewing, care coordination, and barriers resolution to support to patients in preparing for and completing colonoscopy.[31–33] However, staffing challenges in rural primary care settings[23,34] in addition to other resource constraints may make it difficult to implement patient navigation programs in these settings.[35]

A centralized patient navigation program delivered through a community-clinical partnership that brings together a community-based organization and rural primary care organizations has the potential to overcome the aforementioned challenges and facilitate implementation of patient navigation programs to support colonoscopy completion in rural settings.

IV. Study Objective and Significance

The study aims to test the effectiveness of a patient navigation program for increasing colonoscopy completion for colorectal cancer screening among rural populations. The study will be implemented in partnership with a community based organization and will engage up to 6 rural or rural-serving primary care organizations.

Promoting timely colonoscopy for CRC screening is a key opportunity to reduce CRC mortality. This project is critical in advancing our knowledge of the effectiveness of patient navigation for increasing colonoscopy in this patient population as well as for understanding factors that can support long term implementation and sustainability of effective interventions.

V. Study Aims

Aim 1: Collaboratively adapt a patient navigation (PN) program to enhance the acceptability and feasibility of the program for rural communities, through a collaborative process with community and clinical partners.

Aim 2: Test the effectiveness of the adapted CORC patient navigation program while gathering data on implementation. We will conduct a randomized controlled trial with 480 - 600 participants in up to six primary care clinical organizations located in rural (Rural-Urban Continuum Code (RUCC) 4 or above) or rural-serving (RUCC 3) communities. We will use patient-level randomization, stratified by clinical organization, to compare the effectiveness of the adapted patient navigation program versus a comparison condition (i.e., an educational brochure) for increasing colonoscopy completion rates for colorectal cancer screening and follow-up among rural and rural-adjacent patients.

Aim 3: Assess implementation and sustainability of the adapted CORC PN program.

VI. Study Design

6.1 Design Overview

Randomized controlled trial to evaluate the effectiveness of the CORC Patient Navigation (PN) program for increasing colonoscopy completion for colorectal cancer screening among rural populations.

6.2 Study Arms

Arm 1: Patient Navigation Intervention (experimental arm). Patients randomized to this arm will receive language-concordant patient navigation from a trained navigator, over the phone and via text and email, to assist patients to complete colonoscopy to screen for colorectal cancer.

Arm 2: Usual Care Control (other). Participants randomized to this arm will receive an educational brochure about the importance of completing colonoscopy to screen for colorectal cancer.

6.3 Partners

Community-based organization (CBO): A CBO will employ the patient navigator who will deliver the CORC Patient Navigation program.

Clinical partners: Six primary care organizations in rural or rural-servings areas will partner with the research team on this study.

6.4 Advisors

The research team will convene a group of stakeholders including representatives from the CBO, clinical partners, and individuals from the Washington State Department of Health who focus on rural populations and cancer prevention, respectively. This stakeholder group, the Rural Health Council (CORC advisory group), will assist with adapting and finalizing the CORC patient navigation program. The advisory group may also advise on the overall successful implementation of the CORC study and dissemination of results to study partners.

6.5 Participants

Adults aged 45-75, who receive care at a primary care clinic located in a rural or rural-serving community (defined as a Rural Urban Continuum Code $\geq$ 3 or as a Federal Office of Rural Health Policy (FORHP)-defined rural area).

6.6 Inclusion and Exclusion Criteria

Clinical Partner organizations	Partnership criteria: 1) Located in areas serving rural populations, defined as a county with a Rural-Urban Continuum Code (RUCC) of 3 or above (3=rural-serving, ≥4 = rural) 2) Federally qualified health center or have a majority of patients with Medicaid or Medicare insurance 3) Have at least 100 patients per year referred to colonoscopy for CRC screening or follow-up 4) Have an estimated completion rate of less than 80% for CRC-related colonoscopy.

Participants	Inclusion criteria: • Aged 45-76.25 on the date of their referral for colonoscopy • In the last 3 months, referred for colonoscopy after an abnormal stool screening test (FIT/FOBT/Cologuard), OR • Referred for colonoscopy as a primary screening test for colorectal cancer, after the clinical organization's study start date, and within the last 3 months. Exclusion criteria: • Deceased • Colonoscopy procedure since colonoscopy referral • Colonoscopy procedure scheduled less than or equal to 7 days from study enrollment date* • Colonoscopy procedure scheduled more than 9 months from colonoscopy referral date (if known at enrollment) ** • Have diagnosis or past history of total colectomy or colorectal cancer (malignant neoplasm) at any time • Has hospice • Aged 66 and older living long-term in an institution for more than 90 consecutive days during the year prior to the query *Effective 2/17/23 ** Effective 4/7/23

6.7 Sample size and sampling

400-600 patients

6.8 Study outcomes

Primary outcome:

- Percentage of patients who complete colonoscopy within 12 months of the colonoscopy referral

2) Secondary outcomes:

- Percentage of patients who complete colonoscopy within 6 months of the colonoscopy referral
- Percentage of patients who complete colonoscopy within 9 months of the colonoscopy referral
- Time to completion of colonoscopy after the colonoscopy referral
- Percentage of completed colonoscopies with adequate patient preparation
- Percentage of completed colonoscopies with cecal intubation

VII. Study Procedures

7.1 Remote procedures

There will be **no face-to-face interaction** between study research staff and participants. Enrollment, data collection, and delivery of the intervention will occur via remote interaction.

7.2 Recruitment and Enrollment of Patients

a) Patient Identification

Potentially eligible patients will be identified by the partner clinical organizations. The clinical organizations will identify patients who have been referred for a colonoscopy to screen for colorectal cancer either for primary screening or as a follow-up to an abnormal stool screening test. Patients may be identified via query of the electronic health record (EHR) or care management registry, or other methods such as documentation from a referral coordinator. Whenever possible, if desired by the clinical partner, the clinical organization will notify patients that they will be contacted by the research team about the study. This means that at the time that clinic personnel tell a patient they are being referred to colonoscopy, personnel may tell the patient that they might be contacted about participating in a research study. At some clinical organizations, clinic personnel (such as an MA, health worker, or navigator) will contact patients identified as potentially eligible for the study and ask for explicit permission to share their contact information with the research team. Clinical personnel speaking with patients about the study will only share general information about the study such its name, affiliation, and a brief description. The clinical organization will share contact information for potentially eligible patients with the research team via secure, HIPAA compliant, electronic transfer.

Timeline: At the beginning of the study recruitment period, clinical organizations will identify potentially eligible patients who have been referred for a colonoscopy after a positive screening test in the last 3 months. Then they will identify eligible patients on a rolling, ongoing basis (e.g., every 1 week), as additional patients are referred for screening colonoscopy after a positive screening test or as a primary screening test for the duration of the 18-24 month recruitment period, until the study meets target enrollment goals.

b) Patient Recruitment, Enrollment, and Informed Consent

The research team will enroll 480 - 600 patients from clinical partner organizations in the clinical trial. The Research Coordinator (RC) will be fluent in Spanish in order to facilitate recruitment of Spanish speaking patients. The RC will use interpreter services to reach patients with limited English proficiency who do not speak Spanish. All recruitment materials will be translated and available in Spanish.

Recruitment

1) The RC will mail approach letters to identified eligible patients, signed by a representative from the partner clinical organization and the study principal investigator. The mailing will include an Information Statement containing the full study information needed for informed consent.
2) The RC will call all potential participants who do not opt-out, within 5-14 days from the date of the mailing, to assess their interest in participating in the study. This includes calling patients whose mailing is returned to the study team. The RC will make up to 10 attempts to reach these patients via phone, text, or email, leaving no more than 3 voicemail messages. For patients lacking phone numbers, we will send a follow-up letter or email asking them to call us directly about the study.

Enrollment and Informed Consent

3) If patients are interested, the RC will verbally administer an eligibility screen and then verbally consent eligible patients. The eligibility screen will include questions to ensure that patients who enroll in the study have not already completed their colonoscopy and if their procedure is already scheduled, there is reasonable amount of time prior to that date to be able to receive the intervention if they are assigned to the experimental arm of the study. At the beginning of the verbal consent process, the RC will ask patients if they received the recruitment mailing with the Information Statement. If they do not remember receiving the approach letter, the RC will go

through the consent talking points in greater detail. The RC will also obtain verbal documentation of HIPAA authorization unless written medical record release/HIPAA authorization is required by the partner clinical organization.

7.3 Randomization

The research team includes Research Coordinators (RC), two Research Scientists (RS), the patient navigator (PN), and a biostatistician. One RS and the biostatistician will be blinded to participant study arm; the RC and other RS will not be blinded. To ensure participants with similar characteristics are equivalently assigned to the 2 groups, we will use 1:1 randomization to randomize enrolled participants in equal numbers into one of the two study arms. Unblinded research staff (RS or RC) will randomize participants via REDCap, using a randomized allocation sequence generated by the study biostatistician. Randomization is stratified by clinical organization and insurance status (yes, no, don't know) and generated in blocks of random sizes of 4 or 8 within each stratum.

7.4 Notifying Patient Navigator of Intervention Participants

The unblinded RS will notify the patient navigator about participants assigned to the intervention arm.

7.5 Welcome Letter

Participants will receive a welcome letter via mail or email, as preferred, informing them about whether they are in the intervention or control condition. If applicable, a HIPAA authorization form and pre-paid return envelope will be included with the welcome letter mailing, which will be sent by postal mail. If participants do not remember receiving the information statement with the initial approach letter, a copy will be included in this mailing.

7.6 Description of the Intervention and Control Arms

a) Usual Care Control Arm: Colonoscopy Educational materials

Participants randomized to the usual care control arm receive a welcome letter with an educational brochure about colonoscopy to screen for colorectal cancer. The brochure is available in English or Spanish. If a brochure is needed in another language, whenever possible, it will be translated and sent to the participant

b) Intervention Arm: CORC Patient Navigation program

Participants randomized to the intervention arm receive a welcome letter with a flyer introducing the patient navigator and what to expect from the CORC PN program

Patient Navigator

The CORC PN program is a 4-topic, remote (phone, video call, email, text) program to support participants in the intervention arm to complete their colonoscopy. The centralized and remote approach of the CORC PN program allows it to be offered to patients across all six geographically disparate clinical partner organizations. The CORC PN program is based on the New Hampshire Colorectal Cancer Screening Program[36] with adaptations based on previously conducted research[37] and the Aim 1 needs assessment process, to further adapt the program to the settings of CORC partners.

A lay patient navigator, employed by the CBO, will deliver the program. The patient navigator will be fluent in Spanish and will use interpreter services to reach patients with limited English proficiency who do not speak Spanish. All PN materials provided to participants are available in English or Spanish, and translated into other languages when possible, as needed.

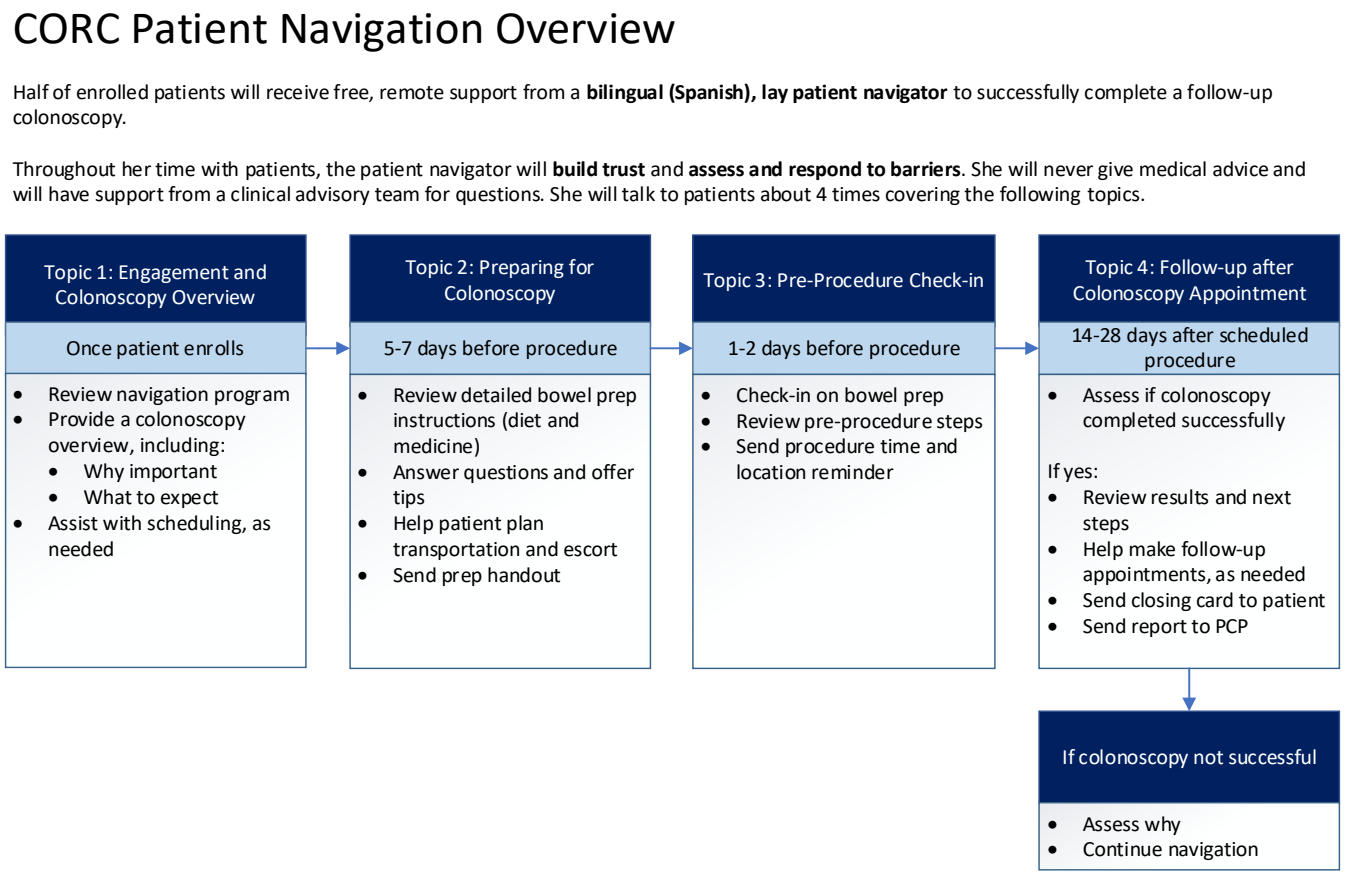
The patient navigator will receive extensive training in patient navigation skills, motivational interviewing, colorectal cancer screening, basics of health care, the CORC Patient Navigation program itself, and required evaluation and reporting. Quality assurance and supervision of the patient navigator will be provided by their supervisor at the CBO, and includes listening to navigation calls and meeting weekly with the navigator. No identifiable patient health information will be shared with the CBO supervisor.

The patient navigator may share information about individual participants with the participants' clinical organization for continuity of care and quality improvement purposes. Information shared with the partner organization may include dates of scheduled colonoscopy, information about barriers to colonoscopy or refusal to schedule, and a summary of topics discussed during the patient navigation program.

CORC Patient Navigation (CORC PN) Program

The CORC PN program consists of four contacts and is outlined in graphic 1. The navigator will work with the participant for up to one year from referral to colonoscopy. Throughout their time working with the participant, they build trust and assess and address barriers to colonoscopy completion. The navigator has the flexibility to adapt the timing of delivering the topics based on the needs of the participant (e.g., delivering topics 2 and 3 at the same time if appropriate).

The intervention is discontinued if a participant 1) withdraws from the study, 2) requests to discontinue the PN program, 3) completed their colonoscopy before the navigator reached them, 4) is told by their provider that they do not need to have a colonoscopy, or 5) does not respond to outreach for more than two months.



Patient Navigation Database and Documenting Implementation of the Intervention

The patient navigator will keep call logs and field notes about what content was discussed for each Topic. The patient navigator will enter this information including topics covered, barriers identified and addressed, types of medical questions raised, types of education provided, and information about contact attempts, into a HIPAA compliant REDCap study database. The patient navigator and their supervisor will meet at least monthly with unblinded members of the research team to ensure quality of data documentation. Members of the research team will keep field notes about the implementation of the intervention, including documenting what quality improvement efforts are undertaken, fidelity to the CORC PN program, and the navigation experience overall.

If desired by individual partner organizations, the patient navigator might access an enrolled intervention participant's electronic health record and directly view and edit records (when permissions are obtained by the partner clinical organization) in order to add documentation to the participant's medical record about services received from the study intervention, such as scheduled date of colonoscopy.

Clinical Advisory Team

A clinical advisory team will provide support to the patient navigator. The advisory team includes a Gastroenterologist who is a study co-investigator, and Allison Cole, MD, MPH, a primary care physician at UW Medicine and the study principal investigator. The advisory team will provide medical oversight and mentoring to the patient navigator related to colonoscopy in general, strategies to navigate colonoscopy barriers, and effective communication with participants. The Drs will meet with the patient navigator and correspond via email as needed to review and discuss medical questions that arise during the navigator's interactions with patients. The Drs will also be available to address urgent clinical questions. No identifiable patient information will be shared with the clinical advisory team; all medical issues will be discussed anonymously.

7.7. Assessments

a) Patient Baseline Enrollment Survey (intervention & control)

After consent is obtained, the RC will verbally administer an enrollment survey to participants. It is estimated to take 20-25 minutes to complete. For participants unable to complete the survey by phone, they will have the option to complete the survey online (i.e., the RC will send them a link to the survey via email or text) or on paper (i.e., mailed to consented participants and returned to the research team via pre-paid envelope). The RC will enter participant responses into the HIPAA compliant REDCap study database.

Incentives: Participants who complete the baseline survey will receive $20 as an electronic or mailed gift card. The incentive will be sent to participants within 2 weeks of completing the assessment.

b) Patient Outcomes Survey (intervention & control)

One year after referral to colonoscopy, only for enrolled participants who do not give either verbal or written HIPAA authorization to use their patient information for the research, the RC will attempt to contact participants to administer the outcomes survey. The survey will take approximately 5 minutes to complete. The RC will send a letter about the survey and a postage pre-paid return envelope. The letter will have a link for completing the survey online. If the HIPAA authorization form is not returned and the survey not completed online, the RC will make up to 10 attempts to contact participants (email, text, phone) to complete the survey. The RC will enter participant responses into the HIPAA compliant REDCap study database.

Incentives: Participants who complete the colonoscopy outcomes survey will receive $5 as an electronic or mailed gift card. The incentive will be sent to participants within 2 weeks of completing the assessment.

b) Patient Qualitative Interview or Survey (intervention only)

A sample of participants in the intervention arm who complete colonoscopy will be invited to participate in a remote one-on-one semi-structured interview with the unblinded RS to get feedback on topics including the general experience, effectiveness, and acceptability of the CORC PN program, as well as experience of and satisfaction with colonoscopy. If they are unable or uninterested in participating in the interview, we will invite them to participate in a short survey covering the same topics as the interview. We will conduct interviews and surveys until data saturation is reached, estimated to be a total of 5-15 participants per organization (60-90 total intervention participants).

Participants who complete a colonoscopy will be invited on a rolling basis throughout the study until there is data saturation. We will begin inviting participants after the first 15 participants, in order to allow for an expected "learning curve" for the patient navigator. Whenever possible, at the conclusion of the final CORC PN program call with the

participant, the patient navigator will inform them that a member of the research team will contact them about participating in an interview. The RS (or other unblinded member of the research team) will contact potential interview participants within 1 month of the participant's final session with the patient navigator. The RS will contact participants by mail, email, phone, or text, depending on what is the participant's preferred form of contact. The RS will make up to 10 attempts to reach these patients, leaving no more than 3 voicemail messages. The RS will schedule a time to conduct the interview. Before beginning the interview, the RS will obtain verbal consent. The interview will last 15-30 minutes. With permission from the participants, interviews will be audio-recorded and transcribed.

If the participant does not respond to the interview recruitment outreach or says they are unable to do the interview, the RS will invite them to do an online survey. The online survey is on a HIPAA compliant survey tool, REDCap, contains the elements of consent, and should take approximately 5-minutes to complete.

Incentives: Participants who complete the interview will receive $25 as an electronic or mailed gift card. Participants who complete the survey will receive $5 as an electronic gift card. The incentive will be sent to participants within 2 weeks of completing the interview.

c) Electronic Health Record (EHR) Data Abstraction (intervention & control)

The research team will request electronic health record data from the clinical organizations for all enrolled patients (who granted HIPAA authorization) in order to review data related to the scheduled or completed colonoscopy. Clinical organizations may conduct chart reviews or provide access to their clinical systems to the CORC study team to obtain the requested data for enrolled patients. The EHR data will be requested at least one year after a participant's referral for colonoscopy screening for colorectal cancer, with the goal of waiting 13 months to receive the data to allow time for data to be updated in the EHR. Blinded research staff will abstract data from the colonoscopy report and other documentation from the EHR or note that the procedure was not completed. Data to be abstracted include primary and secondary outcomes, among others: Date of colonoscopy completion, adequacy of colonoscopy prep, colonoscopy quality, adenoma detection. Research staff will enter abstracted data into the HIPAA compliant REDCap study database.

Training: A blinded RS will train staff abstractors, using the chart abstraction manual as the official protocol for abstracting and entering data into the REDCap database. Training will include one-on-one meetings, review of example charts, and dual review of each staff abstractors' first 10 charts, as well as dual review of the first 5 charts abstracted from each clinical partner.

Quality review: The expert RS abstractor will perform data quality checks by randomly selecting 10% of participants for dual review, proportionally across clinical partners with at least 5% from the first half of participants for whom we receive data. Charts to review will be chosen using a random number generator. The expert abstractor and abstractor staff will review and resolve all discrepancies, under the supervision of the study PI (and gastroenterologist, if needed). Patterns of data errors will be discussed with the study team to maximize data quality.

VIII. Bias

To minimize the risk that missing data could create biases in our outcome analysis, our primary outcome of colonoscopy completion and secondary outcomes of colonoscopy quality and cancer detection rates will be obtained through medical record review, whenever possible, so that we will not have to rely on successfully reaching all patients for follow-up. Different staff roles will be blinded or "masked" to treatment allocation in order to avoid bias. The following roles will be blinded:

- Research scientist who oversees collection of outcomes data from clinical partners; trains chart abstractors to enter outcomes data; conducts quality reviews on entry of outcomes data.
- Any staff conducting chart abstraction/collecting and entering outcomes data.
- Research scientist and biostatistician conducting outcomes analyses.
- Principal investigator (PI) & CORC co-investigators

Ensuring blinding during participant enrollment and delivery of the patient navigation: The PI and gastroenterologist co-PI both serve as clinical advisors to the patient navigator. When a clinical question arises, the patient navigator gets feedback from clinical advisors via email or by monthly conference call. In these discussions, no patient names are used. The PI and co-PI's role is restricted to only providing clinical expertise, as needed, and do not participate in other navigation check-in discussions.

X. Human Subjects

10.1. Risks and Benefits to Participation

The study will be reviewed by the Institutional Review Board (IRB) at the University of Washington. All protocol modifications will be submitted for approval. Potential risks to participants as a result of study participation are expected to be minimal. There are no test articles (investigational new drugs, devices, or biologics) to be used in this study. Potential risks include the following:

Emotions. Participants may feel discomfort or embarrassment during the baseline survey administration, the outcomes survey, the participant interview and survey, or during the patient navigation intervention, as they discuss topics such as their health status, history of cancer, beliefs about colorectal cancer/screening, colonoscopy in general, and their experience with the patient navigation program.

Loss of Data Confidentiality. Risks include loss of confidentially about personal information, self-reported data, and medical records retrieved from partner clinical organizations.

The benefit of the study is that participants will receive either education or patient navigation to support colonoscopy completion.

10.2. Inclusion of Women and Minorities

We plan to recruit women and racial and ethnic minorities in proportion to those presented to us. We propose to recruit a sample that reflects the racial and ethnic make-up of the patient population of the partner clinical organizations. The RC and patient navigator will be fluent in Spanish in order to allow easier access to participation for Spanish speaking patients. We will monitor recruitment by creating and reviewing recruitment reports.

10.3. Inclusion of Children

We will not recruit children since this is a study of adults aged 45-75 who have completed initial colorectal cancer screening.

10.4. Discontinuation of Study Intervention or Control Arm

Participants are free to withdraw from participation in the study at any time upon request, or at the discretion of the Principal Investigator. If withdrawn by the PI, the PI will inform the participant by phone and via a written method (letter or email). All study withdrawals will be documented in the CORC REDCap Research Database. All outstanding incentives owed to the participant will be distributed. Research data will be retained for patients who withdraw, per UW record retention policies. No new data will be collected for patients who withdraw.

10.5. Data and Safety Monitoring Plan

Oversight of the trial is provided by the Principal Investigator (PI), Dr. Allison Cole. Dr. Cole and the two study Research Scientists will assure that informed consent is obtained prior to performing any research procedures, that all participants meet eligibility criteria, and that the study is conducted according to the IRB-approved research plan. Dr. Cole and the Research Scientists will train other research staff in procedures for maintaining participant confidentiality, securing data, and assessing and reporting adverse reactions among participants.

The RS will be responsible for submission and distribution of the final approved research protocol and any subsequent amended protocols to all partner clinical organizations. Partner clinical organizations will submit all local approvals to the RS and all protocol revisions will be submitted and approved at the UW IRB.

All members of the research team will be responsible for immediately reporting breaches of confidentiality or data security, or adverse reactions to Dr. Cole, who will be responsible for oversight of and reporting of this data. Reports of any adverse events, while unlikely, will be brought to the PI and shared with full investigator team immediately.

They will also be reviewed in aggregate on an annual basis. Dr. Cole and the RS will be responsible for timely submission of any necessary reports to the NIH, including reports of adverse events, revisions to the protocol that indicate a change in risk for participants, or actions taken by the IRB regarding the research.

Study data will be accessible at all times for the PI. Dr. Cole and the RS will monitor participant accrual and drop-outs on a monthly basis. A data processing timeline will be developed for each data component (e.g., intervention data must be transferred into the analytic database within 20 days of collection). Dr. Cole and the RS will monitor data entry and processing monthly, and conduct routine protocol compliance checks to ensure that procedures are followed.

Confidentiality will be protected by keeping patient identifiers separate from the research data, linked by a code. Survey data will be collected via a secure online survey platform. All data will be stored electronically, on a secure, HIPAA compliant server. Only study staff will have access to the research database, using UW approved password requirements. All study staff will be trained in the Ethics of Research in Humans Subjects. All data will be de-identified prior to analysis. Data published will be in aggregate form only, and will not identify any individual participants or partner clinical organizations. Audio-recordings will be deleted after they are transcribed; names will be replaced with pseudonyms in the transcripts.

Dr. Cole will be responsible for assessing external factors or relevant information (e.g., developments in the literature) that may impact the safety of participants or ethics of the research study. The University of Washington IRB reviews the study progress and safety information to assess continued acceptability of the risk-benefit ratio for human subjects. The trial will comply with the standard guidelines set forth by regulatory committees and other institutional, state, and federal guidelines.

XI. Data Management and Sharing Plan

The CORC study will generate quantitative data related to each of the study assessments: recruitment and enrollment data, participant characteristics and survey data, outcomes data related to receipt of colonoscopy and colonoscopy quality, process data related to delivering the patient navigation intervention. There will also be qualitative data: Interviews with participants in the patient navigation arm of the study who completed colonoscopy, interviews with staff from CORC's community and clinical partners, field notes and text from delivering the PN intervention. Final anonymized analysis datasets will be created and archived. Data will not be made publicly available.

XII. Dissemination

12.1. Dissemination Plan

Results will be shared on clinicaltrials.gov. A summary of results will be shared with each study partner. A summary of results will be shared with individual study participants by request only. The research team plans to disseminate findings via publication in peer-reviewed journals.

12.2. Authorship

We will use the ICMJE recommendations for defining authorship in study publications: (https://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html)

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
2. Drafting the work or reviewing it critically for important intellectual content; AND
3. Final approval of the version to be published; AND
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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