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CLINICAL STUDY PROTOCOL

Colorectal cancer screening through proactive outreach and navigation in federally qualified health care center in Brooklyn

Principal Investigator
Aasma Shaukat

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Study Personnel

Principal Investigator	Aasma Shaukat NYU Langone Health & NYU Grossman School of Medicine Division of Gastroenterology & Hepatology Email: Aasma.Shaukat@nyulangone.org Address: 240 E 38th St, 23rd Floor, New York, NY 10016 Phone: 929-458-5502
Sub-Investigators	Oliver Stewart NYU Grossman School of Medicine Graduate Medical Education Email: Oliver.Stewart@nyulangone.org Address: 462 1st Ave, 4th Floor, New York, NY 10016 Phone: 561-847-1614
Research Coordinators	Jennifer Stromberg NYU Langone Health & NYU Grossman School of Medicine Division of Gastroenterology & Hepatology Email: Jennifer.Stromberg@nyulangone.org Address: 240 E 38th St, 23rd Floor, New York, NY 10016 Phone: 612-747-9205
	Jessica Rauch NYU Langone Health & NYU Grossman School of Medicine Division of Gastroenterology & Hepatology Email: Jessica.Rauch@nyulangone.org Address: 240 E 38th St, 23rd Floor, New York, NY 10016 Phone: 415-939-0214
	Ashley Augustin NYU Langone Health & NYU Grossman School of Medicine Division of Gastroenterology & Hepatology Email: Ashely.Augustin@nyulangone.org Address: 240 E 38th St, 23rd Floor, New York, NY 10016 Phone: 516-506-1608
Biostatistician	Chan Wang NYU Langone Health Population Health Email: Chan.Wang@nhyulangone.org Address: 180 Madison Ave, 2nd Floor, New York, NY 10016 Phone:

SYNOPSIS

Study Purpose The purpose of our study is to assess the effectiveness and acceptability of a proactive screening outreach program on colorectal cancer screening rates for eligible patients at the Flatbush Family Health Center.
Primary Objective The primary objective is to compare the effectiveness of a strategy of proactive invitation (eligibility assessment followed by a mailed invitation program and navigation) vs. standard-care colorectal cancer screening at the Flatbush Family Health Center.
Secondary Objectives The secondary objective is to identify potential barriers and facilitators to the implementation of a proactive outreach colorectal cancer screening program by performing quantitative surveys and qualitative interviews of randomly selected sample of providers and patients.
General Design Description Randomized, controlled, non-blinded study
Study Date Range and Duration The estimated duration for the study is approximately one year from the start of the intervention period (anticipated November 2022 – November 2023, depending on all approvals and other factors outside of the control of the study team).
Number of Study Sites There is 1 study site for this project: Flatbush Family Health Center at NYU Langone
Primary Outcome Variables The primary outcome variable is completion of initial fecal immunochemical test (FIT) or colonoscopy at 6 months.
Secondary and Exploratory Outcome Variables Secondary outcome variables include: 1) Completion of colonoscopy for individuals with a positive fecal immunochemical test at 6 months. 2) Determination of factors associated with non-adherence to initial fecal immunochemical testing or colonoscopy, and to completion of colonoscopy for those with positive FIT.

Study Population

The study population will be individuals aged 45-75 years old who receive medical care at a federally qualified health care center in Brooklyn, New York whom are either due or overdue for colorectal cancer screening.

Number of Participants

There will be a total of 100 participants in the study, 50 of whom will be randomized to receive proactive screening outreach and 50 of whom will be randomized to receive usual care.

Study Flow Chart

	QTR 1		QTR 2		QTR 3		QTR 4	QTR 5	QTR 6
Develop tailored invitation and other study letters; develop process for FIT mailings and returns; Work with FHC to establish process for training staff; IT support for obtaining list of screen eligible individuals and electronic data capture; Develop Protocol; Develop qualitative interview guides; Set up database for data entry in REDCap; IRB approvals	X	X							
Perform the screening program at FHC			X	X	X	X			
Study accuracy of organized screening program and logistical aspects						X	X		
Perform physician and patient qualitative interviews						X	X	X	
Collect data on screening rates and perform analyses as planned and dissemination								X	X

ABBREVIATIONS

Abbreviation	Explanation
CRC	Colorectal Cancer
EMR	Electronic Medical Records system
FHC	Family Health Center
FIT	Fecal immunochemical test

Table of Contents

1 - Statement of Compliance

1.1 Statement of Compliance

This document is a protocol for a human research study. The purpose of this protocol is to ensure that this study is to be conducted according to the Common Rule at 45CFR46 (human subjects) and other applicable government regulations and Institutional research policies and procedures.

2 - Background

2.1 Background

Colorectal Cancer (CRC) is the third most common cancer in men and women and the second leading cause of cancer related death[7]. Screening for CRC reduces CRC incidence and mortality, and is recommended for average risk men and women between the ages of 45 and 75 by the US Preventive Services Task Force guidelines; which were updated recently to include 45-49 year olds, an additional 20 million individuals in the US[1]. In New York State, CRC screening rates are over 70%[2] but only 48-52% in Brooklyn family health centers (FHC) that provide free and subsidized health services to underrepresented minorities. Currently, invitations to screen are offered only when a patient is seen by his or her provider. Consequently, many eligible individuals, particularly 45-55 year olds who do not regularly access healthcare are under-screened.

3 - Rationale/Significance

3.1 Problem Statement

CRC screening rates are 72% in New York State[2] but 48-55% in the federally qualified health center where we anticipate performing the study. Hence, there is an unmet need to organize and implement CRC screening using multilevel interventions to improve screening rates.
The current model for CRC screening is far from optimal and poses many barriers at the patient, provider and systems level. At the patient level: the current model requires an in-person or telehealth visit, which poses barriers through difficulty accessing transportation, time commitments and financial barriers. Furthermore, men and women aged 45-55 (on the younger end of the screening spectrum) may not have a primary care provider or seek routine medical care. Many individuals may not know they are eligible for CRC screening or the benefits of CRC screening. At the provider level, barriers include lack of up to date information and a lack of time to address CRC screening in a short clinic visit with many pressing urgent medical needs. The alternative method of screening we are proposing, an organized program of proactive invitation, has two main components: 1) *identification* of screen eligible individuals using health records from the clinic; and 2) a *proactive invitation* program, with (a) mailed invitation, (b) a package of materials so patients can complete a fecal immunochemical test (FIT) from their homes (i.e., FIT kit), and (c) instructions on how to schedule colonoscopy if they prefer this to completing the FIT. From a public health perspective, an outreach screening program is more likely to reach all individuals eligible for screening.

Multiple trials have reported higher screening rates with proactive invitation through outreach efforts and programmatic approaches, compared to usual care[3,4]. Kaiser Permanente Northern and Southern California implemented proactive outreach screening in 2008, based primarily on annual FIT. Their reported rates of CRC screening are one of the highest in the country, at 81%[5,6]. In their recent publication, they reported that 323,349 health plan members were reached through the program. Completion rates for screening improved from 48% to 86% over 4 rounds of implementing the outreach screening process. The program detected 80% of patients diagnosed with stage I colon cancer within 1 year of screening[6].

3.2 Purpose of Study/Potential Impact

Disparities exist in the CRC screening rates in the Brooklyn family health centers compared to New York State at large, likely driven primarily by social determinants of health. The purpose of this study is to establish the effectiveness of a proactive CRC screening outreach approach on improving CRC screening rates in an underserved population. We will also gather data regarding patient and provider perception of feasibility and overall experience with the proactive outreach program in order to better inform future screening implementation efforts. Ultimately, the broader goal is to decrease patient morbidity and mortality from CRC through improved screening rates.

3.3 Potential Risks and Benefits

3.3.1 Potential Risks

Potential risks of the study include psychological harm associated with potential false-positive results on FIT screening or rare adverse reactions to routine colonoscopy screening which may include bleeding, bowel perforation, or adverse reactions to anesthesia during colonoscopy.

There is also a risk of loss of confidentiality. To protect participant confidentiality, the records from the study will be kept private. Any published reports will not include any information that can be used to identify individuals. Research records will be stored securely and only the study team will have access to the records. The recordings from interviews will only be accessible to the study team and a professional transcription service. The transcriptions of the recordings will have all identifying information removed. The recordings will be destroyed at the end of the study. De-identified information from the interviews will be provided to Flatbush FHC for the purpose of improving their colorectal cancer screening program.

3.3.2 Potential Benefits

Potential benefits to subjects include improved access to CRC screening, earlier detection of CRC, and decreased morbidity and mortality associated with CRC. On a larger scale, potential benefits to society at large include further proof of concept of the efficacy of proactive outreach programs for increasing CRC screening rates amongst underserved populations. CRC is the third most common cancer in men and women as well as the second leading cause of cancer related death[7]. Given that CRC screening is associated with decreased morbidity and mortality, the benefits of improving screening rates far outweigh any potential risks associated with our study.

4 - Study Objectives

4.1 Hypothesis

We hypothesize that CRC screening rates will improve in underserved populations with the implementation of a proactive approach that incorporates a mailed *outreach invitation* to screen with fecal immunochemical testing (FIT), followed by active assistance to colonoscopy completion if preferred or indicated by FIT test result.

4.2 Primary Objective

The primary objective is to compare the effectiveness of a strategy of proactive invitation (eligibility assessment followed by a mailed invitation program and navigation) vs. standard-care CRC screening at Flatbush Family Health.

4.3 Secondary Objectives

The secondary objective is to identify potential barriers and facilitators to the implementation of a proactive outreach CRC screening program by performing quantitative surveys and qualitative interviews of a randomly selected sample of providers and patients. These data can be used to inform further tailoring of an ongoing program of proactive CRC screening at this clinic, if shown to be feasible and effective.

5 - Study Design

5.1 General Design Description

Our study is a single-site randomized, compared effectiveness study. Patients randomized to the proactive outreach group will be blind to the presence of an alternative group assignment. Patients randomized to the usual care group will be blind to the presence of group assignment altogether. Group allocation will be concealed because all patients will be randomized at a single time point. To accurately assess whether this proactive approach is effective, real-world, unbiased behavior by the patients involved is vital. Intervention group patients will be informed that their data will be used for this research project via a study information sheet included with the initial FIT kit mailing. This sheet will clearly indicate that the CRC screening itself is standard of care screening for which they are due and not a research test. We are seeking a waiver of HIPAA authorization, a complete waiver of consent for the usual care group, and a waiver of documentation of written consent for the intervention group, including the subset of intervention patients who complete the post-intervention interview. This subset will be verbally consented via telephone prior to completing the interview.

The study team will operate mainly in the background, to facilitate mailings and reminders. All materials will be sent on behalf of the clinic, using the clinic's usual stationery, and containing the electronic signature of the patient's primary care physician, when applicable. The study team will be tracking the cost and effort involved to help the clinic determine the feasibility of long-term implementation of a proactive screening program for CRC.

5.1.1 Study Date Range and Duration

The estimated duration for the study is approximately one year from the start of the intervention period (anticipated November 2022 – November 2023, depending on all approvals and other factors outside of the control of the study team).

5.1.2 Number of Study Sites

There is 1 study site for this project (Flatbush Family Health Center at NYU Langone).

5.2 Outcome Variables

Please see the following primary and secondary outcome variables below.

5.2.1 Primary Outcome Variables

The primary outcome variable is completion of initial fecal immunochemical test (FIT) or colonoscopy at 6 months.

5.2.2 Secondary and Exploratory Outcome Variables

1) Completion of colonoscopy for individuals with a positive fecal immunochemical test at 6 months.

2) Determination of factors associated with non-adherence to initial fecal immunochemical testing or colonoscopy, and to completion of colonoscopy for those with positive FIT.

5.3 Study Population

Our study population includes men and women aged 45-75 who are patients in the Flatbush Family Health Center medical practice and are due or overdue for CRC screening. The patient population in the Flatbush FHC medical practice is an underserved population that currently has lower CRC screening rates compared to the average screening rate in New York State. Assessing the effectiveness of a proactive outreach CRC screening program is pivotal to develop strategies to increase CRC screening rate in underserved populations.

5.3.1 Number of Participants

There will be a total of 100 participants in the study, 50 of whom will be randomized to receive proactive screening outreach and 50 of whom will be randomized to receive usual care. Approximately 7 patients from the intervention group are expected to complete a follow-up interview about their experience with the proactive program.

5.3.2 Inclusion Criteria

- Men and women aged 45-75
- Receiving medical care at Flatbush FHC
- Due or overdue for CRC screening

5.3.3 Exclusion Criteria

- Age younger than 45 years old or greater than 75 years old
- Up-to-date with colorectal cancer screening (FIT within 1 year or colonoscopy within 10 years)
- History of colorectal cancer, inflammatory bowel disease or colorectal polyps
- No address or phone number on file
- FIT test ordered within 6 months

5.3.4 Vulnerable Populations

We do not intend to target recruitment/enrollment of vulnerable subjects as defined by federal regulations or institutional policies.

6 – Methods

6.1 Intervention

6.1.1 Description of Intervention

Our proposed intervention involves proactive outreach for CRC screening for patients receiving care at Flatbush FHC. More specifically, patients randomized to the proactive outreach group will receive a letter from their clinic (mailed by the study team) explaining colorectal cancer screening options (FIT vs colonoscopy) including a FIT kit with completion and return instructions. The letter will also include information for navigation to a screening colonoscopy instead of FIT testing, if deemed to be the patient's preference. A study information sheet will be included to inform the patient that their data will be used for this research study and explain that the screening by FIT is not a research procedure, but a standard of care screening test for which they are due or overdue.

Approximately 10-14 days after mailing the FIT kit, patients who have not completed screening will receive a telephone call (with voice message left) and text message, querying whether the FIT kit was received and reminding the patient to complete the test or request a new kit, if needed.

Finally, if the FIT kit has not been submitted after about two weeks from the reminder call/text message, the study team will mail a final letter to the patient on behalf of the clinic, reminding them to complete and return the FIT kit.

If no FIT kit is returned after an additional three weeks, there will be a final note uploaded to the patient's chart alerting the patient's primary care physician to complete further action regarding CRC screening as indicated.

Those patients with a positive FIT test result will be receive assistance with navigation to scheduling a colonoscopy by the study coordinator or appropriate clinic staff. Screening and diagnostic colonoscopy completion will be facilitated through phone calls to triage whether a colonoscopy can be scheduled over the phone or requires an in-person pre-colonoscopy visit. In addition, it will be facilitated through ensuring that bowel prep is mailed to the patient with instructions or is available for pick-up in clinic. Finally, bowel preparation instructions and appointment reminders will be performed via phone call, text or mail 5-7 days prior to colonoscopy.

After the intervention period is over, patients in the intervention group will be invited to complete a qualitative interview with a trained member of the study staff, during which they will be asked about their personal experience with the proactive outreach screening program. An invitation letter will be mailed and non-responders will receive a follow-up phone call or text message to gauge interest in participating. Those who agree will be verbally consented over the phone prior to the interview.

Patients need not have completed the at-home screening to take part in the interview. Interviews will be audio recorded and professionally transcribed, with all identifiers scrubbed from the transcription.

6.1.2 Method of Assignment/Randomization

The study biostatistician will randomize 50 eligible patients to proactive outreach and 50 eligible patients to usual care, stratified by age and biological sex. Proactive outreach patients will be blind to the presence of an alternative group assignment and "usual care" patients will be unaware of group assignment altogether.

6.1.3 Selection of Instruments/Outcome Measures

The primary outcome measure is completion of initial fecal immunochemical test (FIT) or colonoscopy at 6 months. Both colonoscopy and fecal immunochemical tests are well-validated screening modalities for colorectal cancer that have been extensively studied throughout the years.

6.1.4 Intervention Administration

Please note: all days listed beyond day 0 have a +5 day tolerance window.

Day 0: Patients randomized to the proactive outreach group will be mailed letters explaining CRC screening options and a FIT kit with detailed instructions for collection and submission.

Day 10-14: In the proactive outreach group, if a FIT kit has not been submitted by this time point, the patient will receive a call or voice message from our research team to ensure FIT kit was received and reminding the patient to complete and return it or request a new kit, if necessary.

Day 28: If the FIT kit has not been submitted, the patient will receive a final letter reminding the patient to complete and return the FIT kit.

Day 56: For patients who have still not submitted a FIT kit or requested screening via colonoscopy, there will be a final note in the chart alerting the patient's primary care physician to complete further action regarding CRC screening as indicated.

Days 7-180: Patients with a positive FIT test result will receive assistance with navigation to scheduling a follow-up colonoscopy. If patients indicated that they prefer colonoscopy to FIT testing, they will also receive assistance with navigation to scheduling a colonoscopy. Assistance to scheduling a colonoscopy will include an initial phone call performed by our research coordinator or appropriate clinic staff to triage whether a colonoscopy can be scheduled over the phone or requires an in-person pre-colonoscopy visit. In addition, study staff will ensure bowel prep will either be mailed to the patient with instructions or made available to pick-up in clinic, depending on patient preference. Finally, bowel preparation instructions and appointment

reminders will be performed via phone call, text or mail 5-7 days prior to scheduled colonoscopy.

6.1.5 Reaction Management

Patients will be made aware in their testing instructions that the presence of a positive FIT test result does not confirm the presence of colorectal cancer. The patient will be able to follow-up with appropriate clinic staff, as well as with a gastroenterologist at the time of their colonoscopy in order to further answer any questions.

6.2 Assessments

6.2.1 Efficacy

We will assess the efficacy of our intervention through a statistical analysis comparing the rates of completion of a FIT test or colonoscopy in the proactive outreach group compared to the usual care group. In addition, we will perform a statistical analysis comparing the rates of completion of a colonoscopy for individuals with a positive fecal immunochemical test at 6 months in the proactive outreach group compared to the usual care group.

6.2.2 Adverse Events Definition and Reporting

There are no anticipated adverse events with our proposed intervention.

6.3 Study Procedures

6.3.1 Study Schedule

See section 6.1.4 for intervention schedule. Data on control group CRC screening rates will be collected from clinic's electronic medical records system (EMR) after the intervention period is over and prior to beginning data analysis.

6.3.2 Informed Consent

We are seeking a full waiver of informed consent and HIPAA authorization for the purpose of determining eligibility and group assignment. We are seeking a waiver of written documentation of consent for the intervention group and a full waiver of informed consent for the usual care group for the duration of the study. This research is minimal risk and involves the promotion of a recommended, standard-of-care, preventative health screening for which patients are due or overdue to undergo. By foregoing informed consent prior to mailing the FIT kit, we will avoid selection bias of enrolling individuals whom are particularly interested in receiving CRC screening or research, thus improving our study's external validity and more accurately measuring the potential efficacy of our intervention on the population at large. In short, the traditional consenting process would negatively impact the reliability of study outcomes.

Additionally, providing information about the study prior to offering the proactive CRC screening to intervention patients may interfere with decision-making and the clinical care

process. The possible perception that CRC screening is research may negatively impact an individual's behavior, attitudes towards such screening, or their willingness to undergo any type of screening in general, due to fear or other stigma associated with research.

Providing information about the study to the standard-care (control) group could also influence decision-making regarding CRC screening and interfere with the clinical care process for these patients.

The waiver of documentation of consent for the intervention group will include the subset of intervention patients who complete the qualitative interview. Information about the interview is included in the Study Information Sheet provided to all intervention patients in the initial FIT kit mailing. The study coordinators will verbally consent those patients who opt-in for the interview, using a study-specific NYU telephone consent script.

6.3.3 Screening

Screening for participant eligibility will be performed through the research team accessing patient charts through the Flatbush FHC's EMR (Epic) and applying the inclusion and exclusion criteria previously stated.

6.3.4 Recruitment, Enrollment and Retention

Patients will be identified for inclusion in the study via accessing the Flatbush FHC EMR (Epic) and applying the inclusion and exclusion criteria previously mentioned. We will work with DataCore to obtain an initial list of eligible patients once, at the beginning of the study. The PI and study coordinators will be the only research staff with access to the list. The list will contain the following information about the eligible patients: MRN, full name, date of birth (or age), address, phone number(s), email addresses, biological sex, race, ethnicity, height/weight (or BMI), smoking status, and primary care physician's name. Data for the patients that will not be included in the study will be deleted from the electronic list provided by DataCore at the end of the study. No information will be retained about these patients.

After the mailed intervention process is complete, data regarding colorectal cancer screening will be obtained for the control group patients. This will include whether colonoscopy, FIT, or other screening tests for colorectal cancer were completed during the study period. Approved waiver of consent and HIPAA authorization for this patient group will allow this information to be collected directly from Epic by the study team.

The primary care physicians at Flatbush FHC have been notified that their intervention group patients will be contacted directly by the study team regarding this mailed CRC screening effort. All letters from the FHC (initial and final) will contain their electronic signature. These patients will receive the Study Information Sheet as part of the initial FIT kit mailing (first contact). If they decide to opt out, only de-identified data will be retained in REDCap for audits, summaries, and reporting purposes.

Subjects in the usual care group will not be approached or notified of their enrollment in the study.

6.3.5 Study Visits

There are no study visits associated with this protocol. Colonoscopy is also considered standard-of-care CRC screening and is not a study procedure. The only potential visits, possibly facilitated by the study team, would be for patients opting to be screened via colonoscopy or navigating to diagnostic colonoscopy following a positive FIT test result. These non-study visits are detailed below.

In person pre-colonoscopy screening visit (if applicable and if required, days 7-180): Patient will receive instruction from a certified R.N. or M.D. regarding colonoscopy preparation instructions, if not already provided by the colonoscopy provider. Estimated length of visit: 10-20 minutes

Colonoscopy procedure visit (if applicable, days 7-180): Patient will have colonoscopy performed by certified gastroenterologist at the Brooklyn Family Health Center facility or another facility at which they have access for this procedure.

6.3.6 End of Study and Follow Up

Following the completion of the intervention period of the study, we will administer interviews to a subset of patients randomized to the proactive screening arm regarding barriers to completion of colorectal screening, perceived effectiveness of the proactive outreach screening program, and any unexpected adverse effects that the patient may have experienced. Patients receiving the intervention can participate in an interview regardless of whether or not they completed CRC screening.

The interviews will be conducted by a member of the NYULH research staff trained in qualitative interviewing techniques and will occur either over the telephone or through HIPAA-compliant WebEx sessions. The interviews will be audio recorded and transcribed, with any identifiers to be removed from the transcription records. The interviews will take about 15 minutes to complete. Recording is required for participation.

6.3.7 Removal of Subjects

Given the nature of our proposed study and waiver of informed consent, participants in the usual care group will be unaware of their participation in this research study and thus will not actively withdraw from the study. Participants randomized to the intervention group may opt out of the screening program or refuse screening at any time. Instructions for how to opt out will be provided in the study information sheet included in the initial mailing. Once 50 of the eligible individuals are randomized to proactive screening and 50 to usual care, those selected to proactive screening will be mailed the FIT kit packet and this number will serve as our denominator for the remainder of the study.

At any point, if a patient initially randomized into the intervention group is found to no longer receive their medical care at Flatbush FHC or their address is deemed undeliverable by the United States Postal Service, they may be replaced at the discretion of the PI to ensure 50 eligible patients receive the proactive intervention. If this occurs, control group participants would be replaced based on the same criteria. Replacements would be determined by the study biostatistician.

6.4 Statistical Method

6.4.1 Statistical Design

The intent-to-screen principle will be utilized to analyze all participants for completion of the primary outcome variable of completion of colonoscopy or FIT testing screen at 6 months. The intent-to-screen principle will also be utilized to analyze all participants for completion of the secondary outcome variable of completion of colonoscopy in patients with a positive FIT test at 6 months. Analysis will be conducted utilizing an independent two sample t-test.

6.4.2 Sample Size Considerations

Sample size selection (n = 100) for this pilot study was based on feasibility.

6.4.3 Planned Analyses

The intent-to-screen principle will be utilized to analyze all participants for completion of the primary outcome variable of completion of colonoscopy or FIT testing screen at 6 months. The intent-to-screen principle will also be utilized to analyze all participants for completion of the secondary outcome variable of completion of colonoscopy in patients with a positive FIT test at 6 months. Analysis will be conducted utilizing an independent two sample t-test.

6.4.3.1 Primary Analyses

Analysis will be conducted utilizing an independent two sample t-test.

6.4.3.2 Secondary Objectives Analyses

Analysis will be conducted utilizing an independent two sample t-test.

6.4.3.3 Analysis of Subject Characteristics

We will summarize baseline and demographic characteristics utilizing standard descriptive summaries (means and standard deviations for continuous variables such as age and percentages for categorical variables gender).

7 – Study Administration

7.1 Ethical Considerations: Informed Consent and HIPAA Authorization

A waiver of informed consent (usual care group).

A waiver of written documentation of consent (intervention group) and HIPAA authorization (all participants) will be obtained for this study. Verbal consent via telephone will be obtained for intervention group participants who are willing to complete the post-intervention interview.

7.2 Institutional Review Board (IRB) Review

The protocol and all participant materials will be submitted to the IRB for approval. Any amendment to the protocol will be sent to the IRB for approval before the changes are implemented to the study. The IRB will be made aware of any reportable events and unanticipated problems.

7.3 Subject Privacy, Confidentiality & Data Management

The collection of personal patient information will be limited to the amount necessary to achieve the aims of the research, so that no unneeded sensitive information is being collected. Only study personnel as listed on the IRB will have access to study data. Patient identifiers that will temporarily be accessed/reviewed include name, medical record number, date of birth, phone number, address, height, weight, smoking status, and CRC screening history. Electronic study data will be stored on a securely managed (MCIT) network drive and in REDCap, with password-protected access limited to trained, authorized study personnel. It is not expected that paper documents will be generated in association with this study, however, any hard copy documents will be kept in a locked cabinet in the PI's office. Electronic data will be exported into excel file format (password protected) and utilized for data analysis. De-identified data will be sent to a biostatistician for statistical analysis.

7.4 Deviations/Unanticipated Problems

Any unanticipated problems will be reported promptly to the IRB (within one business day of discovery for serious adverse events), within 7 business days of discovery for all other unanticipated problems.

7.5 Data Collection

Data will be collected at the beginning the study during the initial eligibility screening process as well as ongoing throughout the intervention period in order to ascertain FIT testing and/or colonoscopy completion results. Data will only be accessed by trained, authorized study personnel. Data will be retained for the next 10 years for use in future studies following the completion of this pilot study.

7.6 Data Quality Assurance

All research coordinators and study personnel will be trained by the primary investigator on both the intervention and data collection process. The study will be continuously monitored on a monthly basis by the study team. Standardized templates for proactive outreach letters will be utilized during the study. Statistical analysis will be performed by a professional biostatistician.

7.7 Study Records

Study records include subject medical records including FIT testing/colonoscopy results, outreach attempts and outcomes, and any survey results collected and interview transcripts.

7.8 Access to Source

Source documents will be obtained from the Flatbush Family Health Center's electronic medical record (NYU Langone Health's Epic system). All study personnel listed on the IRB will have access to the study documents.

7.9 Data Storage / Security

Electronic study data will be stored on a secure NYULH MCIT-managed network shared drive and in REDCap. All hard copy documents will be kept in a locked cabinet in the PI's office. Electronic data will be exported into excel file format (password protected) and utilized for data analysis. De-identified data will be sent to a biostatistician for statistical analysis.

7.10 Retention of Records

Study documents will be retained for the longer of 3 years after close out or 5 years after final reporting/publication. These documents should be retained for a longer period, however, if required by local regulations. No records will be destroyed without the written consent of the sponsor, if applicable. It is the responsibility of the sponsor to inform the investigator when these documents no longer need to be retained.

7.11 Future Use of Stored Data

Data will be maintained for 10 years following the pilot study in order to be utilized in future studies. Study data will be stored in REDCap and on a secure NYULH MCIT-managed network shared drive. Access to the dataset for any future research will require separate IRB approval. If any information is shared with external interested site(s), data set agreements with NYU LANGONE will be established.

Transcripts from the patient interview audio recordings will be de-identified and will be used to tailor and improve possible future proactive CRC screening efforts.
Study data may be used to inform future funding proposals. The purpose of other possible future research is unknown at this time.

7.12 Study Monitoring

The principal investigator will monitor the study to ensure that it is completed in accordance with the protocol and that the data are valid. In order to ensure this, the study will be reviewed on a monthly basis by the principal investigator and study team.

7.13 Data Monitoring Plan

Our study involves minimal risk and thus does not require a data monitoring plan.

7.13 Study Modification

The study protocol will be updated with any study modifications and submitted to the IRB for approval.

7.14 Study Discontinuation

Given the benign nature of the study intervention, we do not foresee the study being discontinued for any reason.

7.15 Study Completion

The anticipated completion date of the study will be approximately one year after commencement of the intervention period. We will notify the IRB upon completion of the study.

7.16 Conflict of Interest Management Plan

There are no actual or perceived conflicts of interest for our study.

7.17 Funding Source

The study is funded by NCI (p20 SPORe pilot grant).

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