NYU Langone Health

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NYU School of Medicine
NYU LANGONE MEDICAL CENTER

RANDOMIZED TRIAL OF COMMUNITY HEALTH WORKER-LED DECISION COACHING TO PROMOTE SHARED DECISION MAKING FOR PROSTATE CANCER SCREENING AMONG BLACK MALE PATIENTS AND THEIR PROVIDERS.

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Statement of Compliance

This study will be conducted in accordance with the Code of Federal Regulations on the Protection of Human Subjects (45 CFR Part 46), any other applicable US government research regulations, and institutional research policies and procedures. The Principal Investigator will assure that no deviation from, or changes to the protocol will take place without prior agreement from the sponsor and documented approval from the Institutional Review Board (IRB), except where necessary to eliminate an immediate hazard(s) to the trial participants. All personnel involved in the conduct of this study have completed Human Subjects Protection Training.

Table of Contents

List of Abbreviations

AE	Adverse Event/Adverse Experience
CFR	Code of Federal Regulations
CHW	Community Health Worker
CRF	Case Report Form
CSOC	Clinical Study Oversight Committee
DCC	Data Coordinating Center
DHHS	Department of Health and Human Services
DSMB	Data and Safety Monitoring Board
FQHC	Federally Qualified Health Center
FFR	Federal Financial Report
FWA	Federalwide Assurance
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
ICF	Informed Consent Form
IRB	Institutional Review Board
ISM	Independent Safety Monitor
MOP	Manual of Procedures
N	Number (typically refers to participants)
NIH	National Institutes of Health
OHRP	Office for Human Research Protections
OHSR	Office of Human Subjects Research
PI	Principal Investigator
PSA	Prostate Specific Antigen
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event/Serious Adverse Experience
SDM	Shared Decision-Making
SOP	Standard Operating Procedure
US	United States

Protocol Summary

Title	RANDOMIZED TRIAL OF COMMUNITY HEALTH WORKER-LED DECISION COACHING TO PROMOTE SHARED DECISION MAKING FOR PROSTATE CANCER SCREENING AMONG BLACK MALE PATIENTS AND THEIR PROVIDERS.
Brief Summary	Black men are disproportionately affected by prostate cancer, the most common non-cutaneous malignancy among men in the U.S. The USPSTF encourages prostate-specific antigen (PSA) testing decisions to be based on shared decision-making, clinician professional judgment, and patient preferences. The purpose of this study is to evaluate the efficacy of a Community Health Worker-led decision-coaching program to facilitate SDM and PSA screening among Black men concerning decision quality, the decision-making process, patient-provider communication and PSA utilization for Black men in the primary care setting. A randomized trial assessing the effect of community health worker decision coaching sessions on the quality of decision-making in PSA screening for Black men aged 40-69. The study aims to enroll around 228 patients and 7 providers. Patients will spend 6-9 months participating in the intervention; providers will spend approximately 4 years participating in the intervention.
Intervention	Behavioral
Objectives	Our study primarily aims to assess 1) the effectiveness of a CHW as decision coach to improve decisions among Black men considering PSA screening, and 2) whether CHW decision coaching will improve providers' experience with PSA counseling to test whether a CHW-led decision coaching program affects decision quality, the decision making process, patient-provider communication and PSA utilization for Black men in the primary care setting.
Methodology	Randomized trial
Study Endpoints/Outcomes	Primary outcomes: decision quality, knowledge, and PSA screening rates
Study Duration	5 years
Participant Duration	Patients: 6-9 months; Providers: 3-4 years
Duration of behavioral intervention	~3-4 years, until target patient enrollment is reached
Population	Black men 40-69 years old visiting the Federally Qualified Health Center (FQHC) study site for primary care visit; providers that treat patient subjects.
Study Sites	Flatbush Family Health Center at NYU Langone, part of NYU Lutheran Family Health Center (FHC) network
Number of participants	Approximately 228 patients, up to 15 providers, 2 administrative staff

Description of Study Intervention/Procedure	Patients will be randomized to receive 1) a decision aid along with decision coaching on PSA screening from a CHW or 2) a decision aid along with CHW interaction on dietary and lifestyle modification to serve as an attention control. The intervention group will receive an educational counseling session from an extensively- trained CHW Coach to facilitate the decision making process in a 1:1 setting for potential PSA screening. The Coach will offer patients in the control arm general health coaching using an educational tool focused on dietary and lifestyle modification to reduce the risk of cardiovascular disease.
Key Procedures	Patients: 4 surveys, decision coaching (behavioral intervention) or attention (health discussion, control), subset sample for 1 interview Providers: 2 one-time surveys, 1 survey after each appointment with enrolled patient, 1 interview
Statistical Analysis	We will use linear mixed models (for continuous outcomes), logistic generalized linear mixed models (for binary outcomes), and random effects multinomial models (for outcomes with more than 2 levels, such as adherence). In all models, time (2 dummy variables) and intervention will be included as fixed effect; provider will be a random effect. The intervention effect of interest is the treatment X time interaction.

1 Key Roles

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2 Introduction, Background Information and Scientific Rationale

2.1 Background Information and Relevant Literature

Prostate cancer is the most common non-cutaneous malignancy among men in the United States and affects Black men disproportionately. Experts agree prostate-specific antigen (PSA)–based prostate cancer screening is a preference-sensitive decision and recommend Shared Decision Making (SDM), an approach where clinicians and patients discuss the best evidence and patients are supported to achieve informed decisions.

The US Preventative Services Task Force (USPSTF) recently proposed a revision of their Prostate Cancer Screening Statement, now encouraging that screening decisions happen within a SDM framework based on professional judgment and patient preference. USPSTF has also recognized SDM is underutilized in practice, especially among Black men, and has emphasized the need for research to understand how best to implement and adapt SDM programs within diverse populations. We seek to optimize, evaluate and disseminate a program to help Black men understand their increased risk of prostate cancer and receive guidance sensitive to their values and preferences when deciding about PSA screening. Our intervention is entitled: Randomized trial of community health worker-led decision coaching to promote shared decision making for prostate cancer screening among Black male patients and their providers.

2.2 Rationale

Based on the best available evidence, the United States Preventive Services Task Force (USPSTF) recently recommended “that clinicians inform men ages 55 to 69 years about the potential benefits and

harms of prostate-specific antigen (PSA)–based screening for prostate cancer."[1] The Task Force acknowledged the higher risk of prostate cancer death in Black men and decision models that suggest a mortality benefit to screening Black men earlier than age 55. As a result, the Task Force proposed clinicians inform Black men "about their increased risk of developing and dying of prostate cancer as well as the potential benefits and harms of screening so they can make an informed, personal decision about whether to be screened."[1] USPSTF now recommends an informed decision making approach to PSA screening for Black men that necessarily involves the clinician in the process, i.e. a "shared decision making" approach.

Few studies have explored decision coaching in PSA screening. Myers et al[2] conducted a randomized trial to test the effect of a decision coaching among Black men. However, the study endpoint was PSA screening rate, not the decision process.

In summary: SDM is underutilized in PSA screening; there is a local need for a balanced discussion about screening among Black men in primary care practices in New York City, and a CHW-led decision coaching intervention is feasible, and potentially as effective as a physician-led discussion for increasing prostate cancer knowledge and decreasing decisional conflict.

2.3 Potential Risks & Benefits

2.3.1 Known Potential Risks

We expect the level of risk due to this intervention to be minimal as no invasive measures or procedures are proposed. Providers will administer and patients will receive usual care during their clinical appointment. There is a potential risk to the participant of breach of confidentiality as the study team will be accessing medical records and interview and survey responses as well as audio recording of clinical encounter will be used as a source of data. Multiple safeguards will be in place to ensure information security.

2.3.2 Known Potential Benefits

The proposed study may directly benefit the participants because the intervention provides resources to patients that will help them to make an informed, value-concordant decision regarding PSA-screening for prostate cancer. The intervention group will receive an educational counseling session from an extensively- trained CHW to facilitate the decision making process in a 1:1 setting. The control group will also receive hard copies of the decision aid. The provider participants will have clinical visits with patients who are presumably more informed regarding this subject matter than they would have been if they did not participate in the intervention. This could possibly enable a shorter, less demanding clinical visit on behalf of the provider.

Moreover, this study will also allow us to have a better understanding of how a community based CHW-led intervention can benefit this population. This may contribute to indirect benefits through extrapolation of the intervention beyond this site to other community settings and populations.

3 Objectives and Purpose

3.1 Primary Objective

Aim 1: To test whether a CHW-led decision coaching program affects decision quality, the decision making process, patient-provider communication and PSA utilization for Black men in the primary care setting. Secondary Objectives (if applicable)

Aim 2: Test whether a CHW-led decision coaching program improves provider experience with counseling Black men considering PSA screening

Aim 3: To determine the cost and cost impact of a CHW-led decision coaching program for PSA screening.

Aim 4: To assess participant behaviors and norms around PSA screening and assess perceptions of the feasibility, acceptability and sustainability of CHW-led decision coaching in the primary care setting.

4 Study Design and Endpoints/Outcomes

4.1 Description of Study Design

We propose a CHW-led decision-coaching program to facilitate SDM for prostate cancer screening discussions in Black men at a primary care FQHC. This study will enroll Black men who are patients at the participating clinical site (aged 40-69 years) and the providers who care for them (up to 15). Patients will be randomized to receive 1) a decision aid along with decision coaching on PSA screening from a CHW or 2) a decision aid along with CHW interaction on dietary and lifestyle modification to serve as an attention control. The independent randomization process will be implemented within each provider and we will control for age by dividing patients into two strata: 40-54 years and 55-69 years. All study staff and providers will be blinded to the randomization groups. Conservatively assuming a 20% drop out, we will recruit 228 participants (114/group) to achieve a final sample of 182 (91/group) patients. This sample size will allow us to be sufficiently powered to detect differences in our primary study outcomes: knowledge, indicative of decision quality, and differences in PSA screening rates.

Among providers, we will assess perceptions of intervention acceptability and feasibility. We will explore communication in both groups. We will also conduct a cost analysis to measure program cost. Our results will enhance understanding of the efficacy, cost-effectiveness, and sustainability of CHW intervention in a community clinic setting. Findings will inform the subsequent design of a scalable intervention to promote adoption and integration of SDM across contexts and empower high-risk, vulnerable populations.

Due to the COVID19 crisis, we will be conducting the study both remotely and in person at the study site following the safety measures of social distancing, open spaces, and wearing PPE at all times implemented at the FQHC by their administration. Participants who are scheduled for in-office appointments who are interested in participating in our study in- person will be contacted to arrange the intervention as prior to clinical research changes. Participants who prefer to participate in our study through a WebEx video conference or a phone call will be consented to as preferred via a HIPAA-compliant platform, REDCap. Only essential research personnel like our Community Health Workers who are needed for in-person research interactions will be attending the FQHC when scheduled for patient intervention. Our CHWs will undergo NP swab for SARS-CoV-2 PCR testing and will be screened for illness and Covid-19 related symptoms daily prior to entrance to an NYU Langone facility, via pre-arrival self-screen reporting or direct screen at facility entrances. CHWs will maintain 6 feet of separation when possible in waiting rooms or public areas within the site.

4.2 Study Endpoints/Outcomes

4.2.1 Primary Study Outcomes

The following are primary study outcomes:

- Decision quality: Measure of informed choice to evaluate screening decision and attitudes towards the screening test
- Patient knowledge: Patient knowledge of prostate cancer and PSA screening
- PSA screening rates: PSA rates collected through patient self-reported PSA testing and EHR data on PSA test utilization

4.2.2 Secondary Study Outcomes

Secondary study outcomes are:

- Perception of quality of care: Patient perception of quality of care assessed through domains of communication, decisional self-efficacy, self-efficacy in communicating with their provider, satisfaction and decisional conflict
- Experience with decision coaching program: Provider experience with decision coaching program measured through encounter satisfaction, difficulty, and communication

4.2.3 Exploratory Outcomes

- Net cost of CHW-led decision coaching program for PSA screening: cost of CHW-led decision coaching program and its effect on prostate cancer screening costs by measuring CHW program costs and healthcare utilization costs
- Behaviors and norms around PSA screening and perceptions of feasibility and acceptability of CHW led decision coaching: Qualitative evaluation of patient and provider perceptions through in-depth, semi-structured interviews and other qualitative data; triangulation of mixed methods data sets from patients and provider interviews, clinical encounters, and surveys to better understand implementation.

5 Study Enrollment and Withdrawal

5.1 Inclusion Criteria

In order to be eligible to participate in this study, an individual must meet all of the following criteria:
Patients:

1. Age 40-69 years old
2. Black
3. Male
4. Attending FQHC for routine primary care appointment

Providers:

1. Provider at Flatbush Family Health Center Federally Qualified Health Center (FQHC)
2. Caring for patients that fit inclusion criteria

5.2 Exclusion Criteria

An individual who meets any of the following criteria will be excluded from participation in this study:
Patients:

1. Patients seen within 9 months of other PSA tests
2. Patients seen within 180 days after primary diagnosis of urinary obstruction, prostatitis, hematuria, other disorder of prostate, unexplained weight loss, or lumbar back pain
3. Patients with a prior diagnosis of prostate cancer (ICD-10-CM C61)
4. Patients visiting their provider for any indication other than a well-visit appointment

Providers:

1. Providers who do not treat adult male patients (e.g. OB/Gyns, pediatricians)

5.3 Vulnerable Subjects

N/A

5.4 Strategies for Recruitment and Retention

Study staff will review weekly Epic EHR reports of men in the target demographic with upcoming clinic appointments at the Flatbush Family Health Center. We will request a Waiver of Authorization to screen for eligible patients. Research coordinators will send a mailer to eligible patients that will include a detailed study information sheet and sample informed consent form, along with study staff contact information. A flyer will be distributed to eligible patients at the participating clinic. Study staff will also call patients by telephone and/or meet in-person at the clinic to confirm enrollment criteria, and if eligible,

follow an IRB-approved recruitment script. Study staff will explain that the patient is being contacted for research purposes in regards to one or more recent and upcoming clinical visits to the Flatbush Family Health Center. The research coordinators will also explicitly state that participation is voluntary, will not affect clinical care, and responses will be de-identified and reported as aggregate. If agreeable, the patient will be enrolled in the study and asked to come to the clinic one hour prior to his scheduled appointment. In light of the COVID19 pandemic, the patient may meet with the CHW remotely, if preferred, using a HIPAA compliant method. The CHW will also review consent materials with the patients prior to commencing study activities and data collection. Upon enrollment, the patient will be randomized to the CHW intervention or the control arm of the study. Men in the intervention group will be mailed and/or SendSafe Secure emailed a copy of the prostate cancer decision aid to review prior to their office visit, and men in the control group will be mailed an educational tool focused on dietary and lifestyle modification, unrelated to prostate cancer. Men randomized to either group will receive an additional copy of study information and consent materials. If a study staff member is unable to reach the patient by phone, further attempts to call the patients may continue once per week for up to three weeks. Following three unsuccessful phone call attempts per appointment, recruitment efforts will cease. Recruitment efforts will be ongoing until the team has successfully recruited sufficient patients into the two study arms.

All eligible providers at Flatbush Family Health Center will be recruited with lists obtained from administrative leadership. Clinical and administrative leaders have already committed for the clinic to participate in the study. Providers will be recruited to participate in all components of the study at time of enrollment, including participation in the coaching program, surveys, and interviews. The Research Coordinators will notify eligible providers by email with study information. Providers will have the opportunity to respond to express interest in the study or to follow-up with further questions by phone or e-mail. The Research Coordinators may also reach out to eligible providers by phone, e-mail, or in-person to discuss the study further following the primary e-mail. During these exchanges, the study team may set up a brief meeting to review details related to informed consent. These meetings will occur in private offices to ensure confidentiality. Study staff will remind providers that participation is voluntary and all responses and study outcomes will be de-identified, reported as aggregate and identifying data or responses will not be shared with institutional leadership. Following three e-mails and three unsuccessful phone call attempts, recruitment efforts will cease.

We estimate that we will be able to meet recruitment goals of 228 patients, 5 healthcare providers and 2 clinical administrators during the study period.

To enhance retention in follow-up procedures, we will use several methods that have yielded us long-term success including:
1. We will reimburse both patient and provider participants for their time participating in the program and completing follow-up assessments. Clinician incentives are intended to compensate for the supplemental time that providers devote to each intervention participant appointment that is lost from regular clinical time. This will encourage providers to participate thoroughly in all elements of the intervention. The incentive will be $75 per individual patient participant seen during clinical appointments. Patients will receive payment of up to $80 to compensate for the coaching session and completing assessments. Receipts for each paid participant will be collected for record keeping and stored under lock and key. Our team has extensive experience enrolling patient participants in community settings as well as enrolling providers to participate in clinical research studies. Therefore, we believe we have developed an incentive plan that is consistent with our previous efforts and will reduce the risk of coercion.
2. We will ask providers to complete a detailed contact information sheet at the time of enrollment that lists all phone numbers, addresses, and email addresses that we may use to contact them for the follow-up assessments. The Local Clinical Champions will also be able to follow up with respective local staff. We will ask patients to verify that their contact information found in EHR is up to date and will confirm preferences for methods of follow-up.
3. Participating providers will be engaged throughout the study and engaged with the investigator team through the Local Clinical Champions. Providers will receive encouragement from clinical and administrative leadership to continue participation in the study. The overarching goal of the study, to optimize clinical care for Black men within the community, will be reinforced during clinic staff meetings.
4. Study staff will call or email participants to schedule follow-up assessments (surveys and interviews)

making multiple attempts at different times of day to reach participants. Study staff will conduct multiple contact attempts for participants who do not complete scheduled.

5.4.1 Use of DataCore/Epic Information for Recruitment Purposes

This study will utilize EPIC to identify subjects. DataCore will request a report of eligible patients for research coordinator review. The data will be used to identify subjects and for contact information (phone numbers). The research coordinators will have access to Epic search results. Research coordinators will use Epic to verify gender, age (DOB), race, dates of prior PSA tests and record results, dates of prior malignancies, and confirmation of no prostate cancer diagnosis. The search will encompass Black male patients with an upcoming primary care appointment at Flatbush Family Health Center who do not have a prostate cancer diagnosis and are between 40-69 years old. Data will be discarded when all follow-up assessment have been complete for an enrolled patient or if a patient refuses enrollment. The coordinators will search Epic once for recruitment purposes, then again following the clinical appointment (post 6 months) to determine if a PSA test was done during the encounter results will be collected for analysis, up to 3 instances for verification.
Once potential subjects have been identified, the study team will notify the treating physician (TP) that they have patients eligible to participate by email as follows: TP has been notified that the study team will contact potential subjects directly, by letter, phone, email, or the MyChart portal etc. Patients will be contacted directly by phone or in-person at the clinic. Any recruitment information sent by email will utilize Send Safe email.

Once contact is made, approved recruitment language will be used to communicate the reason they are being contacted and subjects will be asked if they are interested in participating in this specific study. Should the potential subjects agree, the study team will provide the subjects with information regarding the next steps for participation.

If a subject requests information regarding opting out of further recruitment for all research, subjects will be directed to contact research-contact-optout@nyumc.org or 1-855-777-7858.

5.5 Duration of Study Participation

Enrolled patients will be participating in the study for approximately 6 months. Providers will participate for about 3-4 years, until target enrollment of patients is reached and all follow-up assessments are complete. The study will run for about 5 total years.

5.6 Total Number of Participants and Sites

We aim to enroll 228 participants (Black men eligible for PSA screening) and 5 (up to 15) providers, 2 senior administrative staff members.

Recruitment will end when approximately _228_participants are enrolled. It is expected that approximately _228_ participants will be enrolled in order to produce _182_evaluable participants.

5.7 Participant Withdrawal or Termination

5.7.1 Reasons for Withdrawal or Termination

Participants are free to withdraw from participation in the study at any time upon request. An investigator may terminate participation in the study if:

- Any clinical adverse event (AE), laboratory abnormality, or other medical condition or situation occurs such that continued participation in the study would not be in the best interest of the participant
- The participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation.

5.7.2 Handling of Participant Withdrawals or Termination

As part of the informed consent process, all patients and providers will be reminded that their responses are confidential and that they may refuse to participate in the project or withdraw at any time, and further, that such an action will in no way affect their future interactions with their healthcare providers or employment at the FQHC.

The clinical providers will be conducting any clinical evaluations that occur during the study visit and will administer usual care. The PIs and Co-Investigators will meet biannually to review adverse event reports, participant complaints, and dropout rates.

5.7.3 Premature Termination or Suspension of Study

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. The suspending or terminating party will provide written notification, documenting the reason for study suspension or termination, to Danil V. Makarov, Joseph E. Ravenell, and the National Institutes of Health. If the study is prematurely terminated or suspended, the PI will promptly inform the IRB and will provide the reason(s) for the termination or suspension.
Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Demonstration of efficacy that would warrant stopping
- Insufficient compliance to protocol requirements
- Data that are not sufficiently complete and/or evaluable
- Determination of futility

Study may resume once concerns about safety, protocol compliance, data quality are addressed and satisfy the sponsor and/or IRB.

6 Behavioral Intervention

6.1 Study Behavioral Intervention(s) Description

Decision coaches provide non-directive support to help patients consider options, prepare for provider discussions, and implement their decisions. The decision coaching intervention will include the following components: 1) a structured interview with the patient that focuses on determining his understanding of his prostate cancer risk, his screening options, and his goals and values related to their decision making, 2) role playing exercises to improve shared decision making skills, and 3) the coach accompanying the patient to his appointment and taking notes.

Intervention Arm: At the office visit, patients in the intervention arm will review the content of the mailed and/or emailed decision aid, including the values clarification exercise, with the Decision Coach. The Coach will then conduct a structured decision counseling session about prostate cancer screening. Decision coaching will include the following components: 1) a structured interview with the patient that focuses on determining his understanding of his prostate cancer risk, his screening options, and his goals and values related to their decision making, 2) role playing exercises to improve shared decision making skills, and 3) the Coach accompanying the patient to his appointment and taking notes.

The coaching session will begin by asking the patient about his values and goals of screening. The Coach will ask the patient what questions he has and what information he needs to make his decision. The Coach will ascertain knowledge and ask the patient to think through the questions he would like to ask his provider.

Finally, the Coach will talk to the patient about any concerns. The patient will have the opportunity to participate in role-playing exercises, allowing him to practice talking with his provider about treatment

values, goals, and preferences. Our coaching strategy is based on the Belkora consultation planning program and pilot tested with men at risk for prostate cancer. We will further pilot test and revise the questionnaire in our study population.

The patient will be encouraged to make a final decision about screening use in consultation with his provider. The Coach will accompany the patient to his appointment to take notes. At the conclusion of coaching, the patient and provider will receive a document with data collected that reflects the content of the interview and prioritizes questions, values, and goals.

Control Arm: Patients in the control arm will receive the decision aid in the mail and/ or Send Safe Secure email prior to the office visit. However, patients in the control arm will not review the decision aid with the Decision Coach. In order to ensure consistent interactions between and among patients in the intervention and control groups, the Coach will offer to patients in the control arm general health coaching using an educational tool focused on dietary and lifestyle modification to reduce the risk of cardiovascular disease. Specifically, the Coach will use the American Heart Association's "Life's Simple 7" educational tool, as described above. Health coaching in the control arm will focus on improving the four modifiable health behaviors, including nonsmoking, healthy diet, physical activity, and body mass index (BMI), and the three modifiable biological factors, including blood pressure (BP), total cholesterol, and fasting glucose described in the control educational tool. It is crucial that the control group has some form of interaction with the Coach for an amount of time similar to the intervention group, albeit with a different focus, to ensure a sufficient attention control between study arms. Without such an interaction, it would be difficult to determine whether the study results were due to the content of the coaching or an extraneous experimental effect (e.g., extra time and attention). The Coach will accompany control arm patients to their appointments to take notes. The CHW's performance will be evaluated to ensure consistency and uniformity. The visits (both intervention and control) will be audio recorded to determine whether the quality or content of the discussion differed due to coaching.

6.1.1 Administration of Intervention

The intervention will be administered in-person with a CHW-led decision coaching session (1-hour minutes). Patient surveys will be administered at 4 different time points: pre-coaching session, post-coaching session, post clinical appointment, and 3 months follow-up. Providers will complete surveys pre- and post- study period, and they will complete post-clinical encounter surveys for each patient participant seen. A subsample of patients will be invited to participate in in-depth interviews during the follow-up period in an ongoing manner; all provider participants and administrative staff will participate in in-depth interviews once patient target enrollment has been reached (study completion).

6.1.2 Procedures for Training Interventionalists and Monitoring Intervention Fidelity

The Community Health Worker Network of New York will have certified a Community Health Worker Decision Coach after having completed the requisite 35-hour training course. Regardless of educational background, the coach must be able to communicate with patients from vulnerable populations. In our experience, these qualities do not correlate with educational attainment, thus there will not be an educational minimum. The coach will demonstrate empathetic and interpersonal skills as determined by his response to crafted scenarios. He will receive extensive training beginning with a 2-day training led by Dr. Ravenell based on Belkora's decision coaching protocols.[4] On Day 1, a model of neutral, non-directive interviewing designed to elicit and document patient questions and concerns will be presented.[4] The learning objectives include practice with: low-inference paraphrasing and summarizing; neutral, non-directive prompting to stimulate patients to elaborate on initial questions and concerns; a general prompt sheet to stimulate an expanded range of patient questions; collaboratively triaging patient issues into strategic, tactical, and logistical categories; and documenting patient questions and concerns into predefined categories to be presented in a consistent format. Drs. Ravenell and Makarov, will observe the practice sessions and provide feedback in real-time (e.g. stop the session and explain what did not go well and how the Coach could have better handled the situation). Finally, there will be weekly and then monthly meetings between the Coach and Dr. Ravenell to discuss any issues. A key component of training is our emphasis that the Coach's role is not to explain medical evidence or give medical advice.

In fact, doing so could result in the Coach's removal from the project (if it recurs and does not stop after retraining). Rather, his responsibility is to help patients prepare for talking with their provider by determining what the patient does not understand and helping formulate questions for him to take to the appointment. The Coach will also help patients determine what their values are in relation to the decision and their values and goals for screening.

To ensure quality control in the CHW's performance, uniformity of experience for the control group participants will be highlighted in the CHW curriculum and emphasized during CHW training sessions. Additionally, all coaching sessions will be audio recorded for analysis and so that the study team can review them for quality and uniformity using the "Coaching Fidelity and Supervision Checklist", used previously by Dr. Fagerlin's group. We will evaluate the first 10 sessions the CHW conducts in the intervention and control groups and 20% of subsequent coaching sessions. The CHW's performance will be evaluated to ensure consistency and uniformity. If analysis of the audio recordings reveals significant variation or sub-par performance, the CHW will be retrained and tested before further interaction with patients.

Lastly, the Coach will collect and record data using the coaching report instrument for the patient to reference during the appointment

6.1.3 Assessment of Subject Compliance with Study Intervention

All participants will be included in the data analysis in the arm to which they were randomized, regardless of compliance, intervention received, or deviation from protocol. Data from participants who withdraw will be used to the extent permitted by human subjects and privacy considerations.

7 Baseline Assessment Study Procedures and Schedule

7.1 Baseline Study Procedures/Evaluations

Baseline Data Collection

Prior to beginning recruitment for the sample size of 228 participants (114/group), we will be adapting certain methods from the primary randomized control trial to collect baseline data from clinical visits to the Flatbush Family Health Center. The purpose of this model is to determine what measures and procedures are currently being implemented at the clinic in regards to prostate cancer screening, prostate cancer risk, and any goals and values related to the patient's decision-making. This model will enroll 20 male patients who will be scheduled at the clinic for a routine visit. Inclusion and exclusion criteria's will remain the same as greater study intervention.

We will prompt patients and providers to discuss Prostate Specific Antigen Screening for the appointment section of the encounter. Patients will be prompted about PSA in the context of their primary care visit. Providers will be handed a document with a prompt to identify the patient is part of the study and that PSA should be discussed in the session. Prompt states the following: "This patient is enrolled into our study. Please engage him in conversation about PSA testing for prostate cancer screening."

Audio recording of clinical encounter will remain as a source of data. Consent forms describing this model in detail will be provided to the participant and written documentation of informed consent is required prior to starting baseline data collection. New informed consent forms were created for the patients in regards to this encounter. Patients enrolled in this portion of the study will not be randomized later on/ participating in either of the main intervention/control arm. We will only reimburse the **patients** for their participation and for completing follow-up assessments for this baseline. The incentive amounts will remain the same as greater study.

Baseline Data Collection Specific Procedures

Patients:

- Will not receive Decision Aid booklet in the mail.

- Patients will not engage in decision coaching session for PSA screening.
- All patients will be asked to arrive at their regularly scheduled primary care clinical appointment about one hour early to meet with the Decision Coach.
- Verify inclusion/exclusion criteria.
- Obtain demographic information, medical history.
- Obtain informed consent of potential participant verified by signature on study informed consent form.
- Patients will be asked to complete surveys only at **three** times: pre-coaching session, post-clinical appointment, and 6-months follow-up from your appointment.
- The decision coach will not accompany patient participants to the clinic appointment but will arrange for audio recording of the encounter.

Providers:

- Providers will consent for both baseline and greater study intervention on the same informed consent form.
- Obtain basic demographic information
- Providers will not be asked to participate in any survey encounters for this portion of the study.

Study Procedures and Schedule

Study Procedures/Evaluations

7.1.1 Study Specific Procedures

Patients:

- Upon enrollment, patients will be randomized to the control or intervention group. Patients will not be informed explicitly which group they are in.
- All patients will be asked to arrive at your regularly scheduled primary care clinical appointment about one hour early to meet with the Decision Coach or via a HIPAA-compliant platform prior to the appointment if the patient prefers to meet remotely. All participants will receive a decision aid and educational materials in the mail and/or by Send Safe Secured email before the scheduled clinical appointment.
- Patients will be asked to complete surveys at 4 time periods: pre-coaching session, post-coaching session, post-clinical appointment, and 3-months follow-up from your appointment.
- Patients randomized to the intervention arm will engage in decision coaching session for PSA screening, including a values clarification exercise. Men in the control group will receive an educational tool on diet and lifestyle to discuss with the Decision Coach.
- The Decision Coach will accompany all patient participants to the clinic appointment and audio record the encounter
- A random sub-sample of patient participants will be invited to complete qualitative in-depth interviews throughout the study period during follow-up.

Providers:

- Providers will be asked to complete 2 one-time surveys: one before the study starts and once after we reach target enrollment of patient subjects.
- Providers will be asked to complete a post-encounter survey following the clinical appointment of each enrolled patient subject that you treat during the study period. Providers will be blinded to randomized group of patient subject.

- Providers will be asked to allow the Decision Coach to accompany enrolled patients to the clinical appointment and audio record your encounter with your patients.
- All participating providers will be asked to complete an in-depth interview (approximately one hour) following study completion.

7.1.2 Standard of Care Study Procedures

Providers will administer and patients will receive usual care during their primary care clinical appointment.

7.2 Study Schedule

7.2.1 Screening

Screening Call (Day -180 to -1)

- Review medical history to determine eligibility based on inclusion/exclusion criteria.
- Review medications history to determine eligibility based on inclusion/exclusion criteria.
- Study staff will review weekly Epic EHR reports of men in the target demographic with upcoming clinic appointments.
- Study staff will reach out to the patient by telephone and/or in-person at the clinic to confirm he fits enrollment criteria and, if so, will attempt to recruit the patient into the study.
- After the telephone call, the patient will be randomized to the CHW intervention or the control arm of the study.
- Men in both groups will be mailed and/or Send Safe Secure emailed a copy of the prostate cancer decision aid to review prior to their office visit.

7.2.2 Enrollment

Enrollment Visit (Day 0)

- Obtain informed consent of potential participant verified by signature on study informed consent form.
- Verify inclusion/exclusion criteria.
- Obtain demographic information, medical history (Patients)
- Obtain basic demographic information (Providers)
- At the office visit, patients in both arms will review the decision aid, including a values clarification exercise, with the Coach.
- For the Intervention group, the Coach will review the content of the mailed and/or emailed decision aid and conduct a structured decision counseling session about prostate cancer screening.
- Intervention group: The patient will be encouraged to make a final decision about PSA screening use in consultation with his provider. The Coach will accompany the patient to his appointment to take notes. At the conclusion of coaching, the patient and provider will receive a document with data collected that reflects the content of the interview and prioritizes questions, values, and goals.
- Control group: the Coach will offer to patients in the control arm general health coaching using an educational tool focused on dietary and lifestyle modification to reduce the risk of cardiovascular disease.
- (Providers) Measures will be collected via brief survey after each patient encounter (the provider will be blinded as to whether the patient was in the control or intervention arm).

7.2.3 Intermediate Visits

N/A

7.2.4 Final Study Visit

Survey Administration/Qualitative Interview (Day 180 – 225)

- (Patients) Time 4 measures are collected 3 months post-clinic visit by phone. If participants do not complete the survey within 3 weeks, a second attempt will be made.
- If after 6 weeks they still have not returned a survey, the Coach will call the patient and conduct it by phone.
- A subset of patients will be recruited to complete a qualitative interview at 3 months post-clinic visit.
- (Providers) A final survey will be completed at study completion immediately before the semi-structured qualitative interview.

7.2.5 Withdrawal Visit

As part of the informed consent process, all patients and providers will be reminded that their responses are confidential and that they may refuse to participate in the project or withdraw at any time, and further, that such an action will in no way affect their future interactions with their healthcare providers or employment at the FQHC.

7.2.6 Unscheduled Visit

N/A

7.3 Concomitant Medications, Treatments, and Procedures

N/A

7.4 Justification for Sensitive Procedures

N/A

7.4.1 Precautionary Medications, Treatments, and Procedures

N/A

7.5 Prohibited Medications, Treatments, and Procedures

N/A

7.6 Participant Access to Study Intervention at Study Closure

N/A

8 Assessment of Safety

8.1 Specification of Safety Parameters

The Community Health Worker Decision Coach and/or research coordinator staff will give the patient oral and written descriptions of the research protocol and will answer any questions the patient may have. The CHW Decision Coach will also be instructed to offer to read any related study materials to the patients if difficulty exists due to low literacy levels or poor vision. As part of the informed consent process, all patients and providers will be reminded that their responses are confidential and that they may refuse to participate in the project or withdraw at any time, and further, that such an action will in no way affect their future interactions with their healthcare providers or employment at the FQHC. After reading and understanding the consent and the procedures, those who choose to participate will sign and date the consent form. All research staff and study personnel will have completed and passed IRB, HIPAA, and extensive human subjects training and will be thoroughly trained in appropriate consent procedures and the precaution to maintain strict confidentiality.

The clinical care of any given participant will be handled entirely by the participant's primary care provider, and study participants will be made aware of this during enrollment. Similarly, any medical problem that arises during study visits will be referred to the participant's primary care provider.

In compliance with HIPAA, individual participant confidentiality is assured through the use of ID codes, assigned by the statistician. These ID numbers will not contain any protected health information (PHI). Data collection forms will be identified only with IDs; relating of ID code to names will require protected information supervised by a designated high-level staff member. None of the analyses will permit individual identification.

Hard copy data will be kept in a locked storage area in a locked office and building. Electronic data will be password-protected, stored only on a secure server, and backed up frequently. Only designated members of the study team will have access to Protected Health Information (PHI) and a variety of precautions will be taken to ensure the security of participant data.

8.1.1 Definition of Adverse Events (AE)

An ***adverse event*** (AE) is any symptom, sign, illness or experience that develops or worsens in severity during the course of the study. Intercurrent illnesses or injuries should be regarded as adverse events. Abnormal results of diagnostic procedures are considered to be adverse events if the abnormality:

- results in study withdrawal
- is associated with a serious adverse event
- is associated with clinical signs or symptoms
- leads to additional treatment or to further diagnostic tests
- is considered by the investigator to be of clinical significance

8.1.2 Definition of Serious Adverse Events (SAE)

Serious Adverse Event
Adverse events are classified as serious or non-serious. A ***serious adverse event*** is any AE that is:

- fatal
- life-threatening
- requires or prolongs hospital stay
- results in persistent or significant disability or incapacity
- a congenital anomaly or birth defect
- an important medical event

Important medical events are those that may not be immediately life threatening, but are clearly of major clinical significance. They may jeopardize the subject, and may require intervention to prevent one of the other serious outcomes noted above. For example, drug overdose or abuse, a seizure that did not result in in-patient hospitalization, or intensive treatment of bronchospasm in an emergency department would typically be considered serious.

All adverse events that do not meet any of the criteria for serious should be regarded as ***non-serious adverse events***.

8.1.3 Definition of Unanticipated Problems (UP)

Unanticipated Problems Involving Risk to Subjects or Others
Any incident, experience, or outcome that meets <u>all</u> of the following criteria:

- <u>Unexpected in nature, severity, or frequency</u> (i.e. not described in study-related documents such as the IRB-approved protocol or consent form, the investigators brochure, etc.)

- Related or possibly related to participation in the research (i.e. possibly related means there is a reasonable possibility that the incident experience, or outcome may have been caused by the procedures involved in the research)
- Suggests that the research places subjects or others at greater risk of harm (including physical, psychological, economic, or social harm).

8.2 Classification of an Adverse Event

8.2.1 Severity of Event

The Principal Investigators are responsible for reporting adverse events to the NYU IRB, the entity granting IRB approval. Adverse events (AEs) and serious adverse events (SAEs) that are severe in nature and could potentially affect the well-being of study participants will be reported to IRB immediately

For AEs not included in the protocol defined grading system, the following guidelines will be used to describe severity.

- **Mild** – Events require minimal or no treatment and do not interfere with the participant's daily activities.
- **Moderate** – Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.
- **Severe** – Events interrupt a participant's usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating.

8.2.2 Relationship to Study Intervention

For all collected AEs, the clinician who examines and evaluates the participant will determine the AE's causality based on temporal relationship and his/her clinical judgment. The degree of certainty about causality will be graded using the categories below.

- **Definitely Related** – There is clear evidence to suggest a causal relationship, and other possible contributing factors can be ruled out. The clinical event, including an abnormal laboratory test result, occurs in a plausible time relationship to intervention administration and cannot be explained by concurrent disease or other drugs or chemicals. The response to withdrawal of the intervention (dechallenge) should be clinically plausible.
- **Probably Related** – There is evidence to suggest a causal relationship, and the influence of other factors is unlikely. The clinical event, including an abnormal laboratory test result, occurs within a reasonable time after administration of the intervention, is unlikely to be attributed to concurrent disease or other drugs or chemicals, and follows a clinically reasonable response on withdrawal (dechallenge). Rechallenge information is not required to fulfill this definition.
- **Possibly Related** – There is some evidence to suggest a causal relationship (e.g., the event occurred within a reasonable time after administration of the trial intervention). However, other factors may have contributed to the event (e.g., the participant's clinical condition, other concomitant events). Although an AE may rate only as "possibly related" soon after discovery, it can be flagged as requiring more information and later be upgraded to "probably related" or "definitely related," as appropriate.
- **Unlikely to be related** – A clinical event, including an abnormal laboratory test result, whose temporal relationship to intervention administration makes a causal relationship improbable (e.g., the event did not occur within a reasonable time after administration of the trial intervention) and in which other drugs or chemicals or underlying disease provides plausible explanations (e.g., the participant's clinical condition, other concomitant treatments).
- **Not Related** – The AE is completely independent of study intervention administration, and/or evidence exists that the event is definitely related to another etiology. There must be an alternative, definitive etiology documented by the clinician.

8.2.3 Expectedness

Danil V. Makarov will be responsible for determining whether an AE is expected or unexpected. An AE will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the study intervention.

8.3 Time Period and Frequency for Event Assessment and Follow-Up

The occurrence of an AE or SAE may come to the attention of study personnel during study visits and interviews of a study participant presenting for medical care, or upon review by a study monitor. All AEs including local and systemic reactions not meeting the criteria for SAEs will be captured on the appropriate RF. Information to be collected includes event description, time of onset, clinician's assessment of severity, relationship to study intervention (assessed only by those with the training and authority to make a diagnosis), and time of resolution/stabilization of the event. All AEs occurring while on study must be documented appropriately regardless of relationship. All AEs will be followed to adequate resolution.

Any medical condition that is present at the time that the participant is screened will be considered as baseline and not reported as an AE. However, if the study participant's condition deteriorates at any time during the study, it will be recorded as an AE. UPs will be recorded in the data collection system throughout the study.

Changes in the severity of an AE will be documented to allow an assessment of the duration of the event at each level of severity to be performed. AEs characterized as intermittent require documentation of onset and duration of each episode.

The PI will record all reportable events with start dates occurring any time after informed consent is obtained until 7 (for non-serious AEs) or 30 days (for SAEs) after the last day of study participation. At each study visit, the investigator will inquire about the occurrence of AE/SAEs since the last visit. Events will be followed for outcome information until resolution or stabilization.

All unresolved adverse events should be followed by the investigator until the events are resolved, the subject is lost to follow-up, or the adverse event is otherwise explained. At the last scheduled visit, the investigator should instruct each subject to report any subsequent event(s) that the subject, or the subject's personal physician, believes might reasonably be related to participation in this study. The investigator should notify the study sponsor of any death or adverse event occurring at any time after a subject has discontinued or terminated study participation that may reasonably be related to this study.

8.4 Reporting Procedures – Notifying the IRB

8.4.1 Adverse Event Reporting

The Principal Investigators are responsible for reporting adverse events to the NYU IRB, the entity granting IRB approval. Adverse events (AEs) and serious adverse events (SAEs) that are severe in nature and could potentially affect the well-being of study participants will be reported to IRB immediately. The contact-PI (Dr. Makarov) will summarize AEs and SAEs in annual continuation reports. The PIs will create a detailed plan to address serious events that may occur during the study period. The clinical providers will be conducting any clinical evaluations that occur during the study visit and will administer usual care.
.. The PIs and Co-Investigators will meet biannually to review adverse event reports, participant complaints, and dropout rates.

8.4.2 Serious Adverse Event Reporting-

The Principal Investigators are responsible for reporting adverse events to the NYU IRB, the entity granting IRB approval. Adverse events (AEs) and serious adverse events (SAEs) that are severe in nature and could potentially affect the well-being of study participants will be reported to IRB immediately.

We expect the level of risk due to this intervention to be minimal as no invasive measures or procedures are proposed. Providers will administer and patients will receive usual care during their clinical appointment.

8.4.3 Unanticipated Problem Reporting

Incidents or events that meet the OHRP criteria for UPs require the creation and completion of an UP report form. It is the site investigator's responsibility to report UPs to their IRB and to the DCC/study sponsor. The UP report will include the following information:

- Protocol identifying information: protocol title and number, PI's name, and the IRB project number;
- A detailed description of the event, incident, experience, or outcome;
- An explanation of the basis for determining that the event, incident, experience, or outcome represents an UP;
- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the UP.

To satisfy the requirement for prompt reporting, UPs will be reported using the following timeline:

- UPs that are SAEs will be reported to the IRB and to the DCC/study sponsor within 48 hours of the investigator becoming aware of the event.
- Any other UP will be reported to the IRB and to the DCC/study sponsor within 1 week of the investigator becoming aware of the problem.
- All UPs should be reported to appropriate institutional officials (as required by an institution's written reporting procedures), the supporting agency head (or designee), and OHRP within 1 wee of the the IR's receipt of the report of the problem from the investigator.

8.5 Reporting Procedures – Notifying the Study Sponsor

The study clinician will complete a SAE Form within the following timelines:

- All deaths and immediately life-threatening events, whether related or unrelated, will be recorded on the SAE Form and submitted to the DCC/study sponsor within 24 hours of site awareness. See Section 1, Key Roles for contact information.
- Other SAEs regardless of relationship will be submitted to the DCC/study sponsor within 72 hours of site awareness.

All SAEs will be followed until satisfactory resolution or until the site investigator deems the event to be chronic or the adherence to be stable. Other supporting documentation of the event may be requested by the DCC/study sponsor and should be provided as soon as possible.

As a follow-up to the initial report, within the following 48 hours of awareness of the event, the investigator shall provide further information, as applicable, on the unanticipated event or the unanticipated problem in the form of a written narrative. This should include a copy of the completed Unanticipated Problem form, and any other diagnostic information that will assist the understanding of the event. Significant new information on ongoing unanticipated adverse effects shall be provided promptly to the study sponsor.

8.6 Study Halting Rules

If the study is prematurely terminated or suspended, the PI will promptly inform the IRB and will provide the reason(s) for the termination or suspension.

Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Demonstration of efficacy that would warrant stopping
- Insufficient compliance to protocol requirements
- Data that are not sufficiently complete and/or evaluable
- Determination of futility

8.7 Safety Oversight

It is the responsibility of the Principal Investigator to oversee the safety of the study at his site. This safety monitoring will include careful assessment and appropriate reporting of adverse events as noted above, as well as the construction and implementation of a site data and safety-monitoring plan. Medical monitoring will include a regular assessment of the number and type of serious adverse events.

Safety oversight will be under the direction of a DSMB composed of individuals with the appropriate expertise, including statistician (distinct from the project statistician) and two pedagogical experts (distinct from study personnel. The DSMB will meet annually to assess safety and efficacy data on each arm of the study. The DMSB will operate under the rules of an approved charter that will be written and reviewed at the organizational meeting of the DSMB. At this time, each data element that the DSMB needs to assess will be clearly defined. The DSMB will provide its input to NIH.

9 Clinical Monitoring

Clinical site monitoring is conducted to ensure that the rights and well-being of human subjects are protected, that the reported trial data are accurate, complete, and verifiable, and that the conduct of the trial is in compliance with the currently approved protocol/amendment(s), with GCP, and with applicable regulatory requirement(s).

- The clinical providers will be conducting any clinical evaluations that occur during the study visit and will administer usual care. However, in the event that the Research Coordinator finds a high PSA result during time of post 6 month follow-up (defined as PSA>4, which is indicative of potential risk for prostate cancer), the RC will check to see if the patient has since followed up with his provider; if not: the study team will contact the provider immediately via Epic messaging (In Basket) and urge the provider to have a consultation with the patient.

10 Statistical Considerations

10.1 Statistical and Analytical Plans

An "intent-to-treat" (ITT) approach will be used to assess the hypotheses. All participants will be included in the data analysis in the arm to which they were randomized, regardless of compliance, intervention received, or deviation from protocol. Data from participants who withdraw will be used to the extent permitted by human subjects and privacy considerations.

A descriptive analysis of all data collected will be performed using graphical and numerical exploratory data techniques. These preliminary analyses will be used to: (1) assess data quality and completeness; (2) describe univariate and bivariate distributions at each time point; and (3) identify associations between variables. We will identify features of the data that may necessitate special methods (e.g. excess zeroes, missing data, departures from distributional assumptions). During preliminary analysis we will examine: (1) comparability of study arms at baseline (based on Chi-squared statistics or t-tests, as appropriate), (2)

relationships between the response variables and potential covariates, and (3) predictors of missing data/drop-out.

We will use linear mixed models (for continuous outcomes), logistic generalized linear mixed models (for binary outcomes), and random effects multinomial models (for outcomes with more than two levels, such as adherence). In all models, time (2 dummy variables) and intervention will be included as fixed effects; provider will be a random effect. The intervention effect of interest is the treatment X time interaction. Identified predictors of missing data will be included as covariates in this random effects framework, to provide unbiased estimates of the intervention effect under an assumption of missing at random (i.e. missingness depends only on observed - not on unobserved - covariates). We will conduct sensitivity analyses to assess plausible departures from this assumption. Other demographic and clinical covariates will be included as necessary in adjusted analyses. Model assessment will be conducted using appropriate regression diagnostics. The primary and secondary analyses will be done using Stata and SAS, and MPlus will be used in the mediation analyses.

10.2 Patient Survey Outcome Variables: Patient Demographics, Clinical Features and Preferences:

Demographics: We will collect baseline information known to be associated with utilization of PSA screening including age, race, marital status, highest education level, yearly income, and insurance status.

Clinical Features: The International Prostate Symptom Score[22] (IPSS) is an 8-item scale to assess the severity of prostate-related symptoms and quality of life. IPSS has high internal consistency (Cronbach's α = 0.86) and excellent test-retest reliability (r = 0.92). Patient overall health will be self-assessed on a 0-5 scale ranging from “very poor” to “excellent”. These survey data will be supplemented by EHR clinical data.

Literacy and Numeracy: We will measure literacy using the REALM[23], a word recognition task that measures reading level and classifies patients as having adequate or inadequate literacy. To assess patients’ numerical skills we will use the 8-item Subjective Numeracy Scale,[24,25] a scale correlated with objective numeracy.

Trust: The Trust in Physicians Scale (TIPS) has 11-items that quantify a patient’s interpersonal trust in his physician.26 This scale is valid and reliable (Cronbach’s α =0.85). The Health Care System Distrust Scale is 10 items including 4 measuring honesty, 2 measuring confidentiality, 2 measuring competency, and 2 measuring fidelity.[27] These items are designed to encapsulate patient distrust of the health care system. It is valid and reliable (Cronbach’s α =0.75).

Preference for shared decision-making: We will measure patients’ desire to participate in SDM using an adaptation of Degner & Sloan's commonly used Control Preference Scale, which asks patients whether they want to make the decision alone, with their provider, or have their provider make it.[28]

Experience with Decision Coaching Program: A survey developed by our group will be utilized to assess the patient’s overall experience with the decision-coaching program. The survey consists of 13 items measuring the usefulness as well as the impact of the CHW intervention on the patient and the appointment.

10.3 Statistical Hypotheses

Decision Quality (Hypothesis 1.1): We will use an objective measure of decision quality consisting of two components as defined by Sepucha et al.: 1) being informed (e.g. accurate understanding about screening and its risks and benefits) and 2) making preference-concordant decisions (i.e. treatment consistent with patient preferences as determined by responses to survey questions).[7]

Knowledge: We will use a survey developed by our group that assesses understanding of prostate cancer and PSA screening (Appendix F).[8] The survey was piloted among Black men recruited from churches in Harlem, New York enrolled in a study to help determine whether PSA screening was right for them.

Informed Choice: The Measure of Informed Choice evaluates the screening decision. It assesses knowledge, it is consistent with the decision-maker's values, and it is behaviorally implemented. The measure consists of 8 items assessing knowledge, 4 assessing attitudes towards the screening test and a record of test uptake.[29] A Decisional Balance Scale will assess the patient's attitudes towards PSA testing. The scale consists of a six item pros scale (alpha = 0.87) and six item cons scale (alpha = 0.82) scored on a 5-point Likert scale (strongly agree to strongly disagree).[30]

Perception of Quality of Care (Hypothesis 1.2): Patient perception of quality of care will be assessed along the domains of communication, decisional self-efficacy, and self-efficacy in communicating with their provider, satisfaction and decisional conflict. These domains represent some benefits for patients engaging in SDM.[9]

Communication: Combined Outcome Measure for Risk communication And treatment Decision-making Effectiveness (COMRADE) is a 20-item measure validated for clinical encounters.[10] Its sub-scales are 1) satisfaction with physician communication and 2) patient confidence in the decision. The scale has excellent internal consistency (Cronbach's α =0.92). Additionally, the Questionnaire Concerning the Doctor-Patient Communication Skills will be used.[11] This validated 19 item scale captures process (greeting, listening) and content (explanations and next steps) aspects of the visit from the provider's and patient's perspectives.

Self-efficacy: The Decision Self-Efficacy Scale is an 11-item scale measuring self-efficacy to perform informed decision-making (e.g., getting needed information, asking questions, expressing opinions, and asking for advice).[31] The Perceived Efficacy in Patient-Physician Interactions is a 10-item scale measuring self-efficacy for provider communication.[12] The scale is reliable (Cronbach's α=0.91) and valid in older adults.

Satisfaction with Decision: The SWD is a 6-item measure assessing patient satisfaction with their decision and decision-making process. The scale has been used in several hundred studies and has good internal consistency (Cronbach's α=0.87).[13] The Decisional Regret Scale is a validated, 5-item scale measuring regret or remorse following a health care decision.[14] It has good internal consistency (Cronbach's α=0.81 to 0.92).

Difficulty and Decisional Conflict: The Decisional Conflict Scale will measure patients' perceptions of 1) uncertainty in choosing options, 2) feelings of having adequate knowledge and clear values, and 3) effective decision-making.[32] It is reliable (α ranged from 0.78 to 0.92) and its test-retest reliability coefficient is 0.81.

Measurement of Impact on PSA Screening (Hypothesis 1.3): Three months post-intervention, we will collect patient survey data, including self-reported PSA testing. After six months post-intervention, we will also extract patient-level EHR data on PSA test utilization. We will then test the association between PSA utilization and intervention exposure.

Provider Survey Variables: Demographics and Preferences
Demographics: We will collect age, gender, race/ethnicity, year of medical school graduation, years since completion of residency, and fraction of time spent in direct patient care.

Preferences: We will assess providers' practice style through the Evidence-Based Practice Attitude Scale.[33] This 5-domain, 15-item scale assesses providers' feelings toward adopting new practices with good internal consistency (Cronbach's α = 0.90-0.59.)

Provider Experience (Hypothesis 2.1):
Satisfaction: The Physician Satisfaction Scale designed for encounter-specific situations measures satisfaction.[34] The survey has 2 dimensions and 16 items measuring understanding of the patient's problem, perceiving patient comprehension, and affective reactions. Internal consistency is good (Cronbach α=0.85).

Difficulty: The Mental Work-Load Instrument assesses difficulty with the subjective experience or cost incurred by a physician in performing patient care.[35] The survey has 5 dimensions and 6 items addressing mental effort, physical effort, difficulty, performance and stress. Internal consistency is good (Cronbach α=0.80).

Communication: We reuse Questionnaire Concerning the Doctor-Patient Communication Skills from C8.2.[11]

10.4 Analysis Datasets

An "intent-to-treat" (ITT) approach will be used to assess the hypotheses posited in the Aims. All participants will be included in the data analysis in the arm to which they were randomized, regardless of compliance, intervention received, or deviation from protocol. Data from participants who withdraw will be used to the extent permitted by human subjects and privacy considerations.

10.5 Description of Statistical Methods

10.5.1 General Approach

Statistical Analysis Plan: An "intent-to-treat" (ITT) approach will be used to assess the hypotheses posited in the Aims section. All participants will be included in the data analysis in the arm to which they were randomized, regardless of compliance, intervention received, or deviation from protocol. Data from participants who withdraw will be used to the extent permitted by human subjects and privacy considerations.

A descriptive analysis of all data collected will be performed using graphical and numerical exploratory data techniques. These preliminary analyses will be used to: (1) assess data quality and completeness; (2) describe univariate and bivariate distributions at each time point; and (3) identify associations between variables. We will identify features of the data that may necessitate special methods (e.g. excess zeroes, missing data, departures from distributional assumptions). During preliminary analysis we will examine: (1) comparability of study arms at baseline (based on Chi-squared statistics or t-tests, as appropriate), (2) relationships between the response variables and potential covariates, and (3) predictors of missing data/drop-out.

We will use linear mixed models (for continuous outcomes), logistic generalized linear mixed models (for binary outcomes), and random effects multinomial models (for outcomes with more than 2 levels, such as adherence). In all models, time (2 dummy variables) and intervention will be included as fixed effects; provider will be a random effect. The intervention effect of interest is the treatment X time interaction. Identified predictors of missing data will be included as covariates in this random effects framework, to provide unbiased estimates of the intervention effect under an assumption of missing at random (i.e. missingness depends only on observed - not on unobserved - covariates). We will conduct sensitivity analyses to assess plausible departures from this assumption. Other demographic and clinical covariates will be included as necessary in adjusted analyses. Model assessment will be conducted using appropriate regression diagnostics. The primary and secondary analyses will be done using Stata and SAS, and MPlus will be used in the mediation analyses.

10.5.2 Analysis of the Primary Endpoint(s)

Our primary outcomes of interest are knowledge and PSA screening rates. Knowledge will be measured once after decision coaching. This approach prevents patients from preferentially learning the questions from the knowledge pre-test. For other measures in hypotheses 1.1 and 1.3 pertaining to knowledge, decision quality and PSA screening rate, the outcomes measure change in those domains at post coaching and whether those changes are sustained at Times 3 and 4. A random effects (generalized) linear regression model will be used to test absolute and time-specific differences attributable to the intervention. In additional analyses, we will adjust for other covariates which may be unbalanced between the intervention arms at baseline at p=0.10. For hypothesis pertaining to patients' perception of care quality,

we will model satisfaction with provider communication, self-efficacy, and difficulty and decisional conflict in separate analyses of control and Intervention groups to examine possible associations between those measurements and outcomes.

10.5.3 Analysis of the Secondary Endpoint(s)

We will evaluate the effect of intervention assignment on provider experience using a random effects (generalized) linear regression model as in Aim 1. Provider will be the random effect. We will also investigate the specific provider experience with each patient group separately and compare the experience across all the participating providers. A qualitative analyst, trained on using the "Observing patient involvement in decision making" ("OPTION") scoring method (Appendix E) will assign ratings to transcripts of the physician-patient encounter. A second researcher will independently assign ratings, and reliability will be assessed based on the Kappa agreement statistic. When ratings achieve a Kappa >0.80, the analyst will continue to rate the encounters. The 2nd rater will continue to rate 5% of the remaining encounters to ensure continued reliability. We will test the hypothesis that patient conversational involvement (determined by patient OPTION) and physician facility with discussing screening (determined by physician OPTION) is associated with the patient decision quality.

10.5.4 Safety Analyses

Adverse events (AEs) and serious adverse events (SAEs) that are severe in nature and could potentially affect the well-being of study participants will be reported to IRB immediately. In addition, the contact-PI (Dr. Makarov) will summarize AEs and SAEs in annual continuation reports. The PIs will create a detailed plan to address serious events that may occur during the study period. The clinical providers will be conducting any clinical evaluations that occur during the study visit and will administer usual care.
The PIs and Co-Investigators will meet biannually to review adverse event reports, participant complaints, and dropout rates.

10.5.5 Adherence and Retention Analyses

The PIs and Co-Investigators will meet biannually to review adverse event reports, participant complaints, and dropout rates.

10.5.6 Baseline Descriptive Statistics

We will collect baseline information known to be associated with utilization of PSA screening including age, race, marital status, highest education level, yearly income, and insurance status.

During preliminary analysis we will examine: (1) comparability of study arms at baseline (based on Chi-squared statistics or t-tests, as appropriate), (2) relationships between the response variables and potential covariates, and (3) predictors of missing data/drop-out.

10.5.7 Planned Interim Analysis

N/A

10.5.7.1 Safety Review- N/A

10.5.7.2 Efficacy Review

N/A

10.5.8 Additional Sub-Group Analyses

Identified predictors of missing data will be included as covariates in this random effects framework, to provide unbiased estimates of the intervention effect under an assumption of missing at random (i.e. missingness depends only on observed - not on unobserved - covariates). We will conduct sensitivity

analyses to assess plausible departures from this assumption. Other demographic and clinical covariates will be included as necessary in adjusted analyses.

10.5.9 Multiple Comparison/Multiplicity

N/A

10.5.10 Tabulation of Individual Response Data

N/A

10.5.11 Exploratory Analyses

Cost: We will determine the cost of a CHW-led decision coaching program and its effect on prostate cancer screening costs. According to theoretical models for dissemination and implementation, understanding cost is critical to future implementation. The costs of research-related activities will not be included in estimates of intervention costs. All costs will be summarized and confidence intervals calculated.

Program Costs: We will estimate the cost of implementing CHW-led decision coaching using methods described by Liu et al. in their paper documenting organizational costs for implementing a depression care quality improvement intervention into primary care practices. These methods allow for the documentation of organizational costs associated with the program itself, not just the costs associated with changes in patient care, whose calculation we describe below. We will collect data on participant hours and intervention-related activities directly related to the program's implementation. Implementation costs are related to travel, clinical informatics, provider training sessions, conference calls, development of training materials, email communication, and any other activities spent counseling, training, or supporting personnel at the study site. Participants will include any individual (provider, CHW, study staff, administrator) participating in the program. Data sources used for estimating CHW program costs are described in Section

Healthcare Utilization Costs: We will summarize costs for select screening procedures directly related to prostate cancer screening based on identification in diagnosis and procedure codes, as described by Drs. Gold and Makarov. Screening care activities will be ascertained beginning with the initial clinic visit and any related care received up to one year later. We will tally costs for PSA screening and downstream procedures. PSA-based screening will be determined using specific Healthcare Common Procedure Coding System (HCPCS) codes: G0103, 84152, 84153, and 84154. Biopsies will be restricted to prostate biopsies that were done within 180 days after a PSA test. For each prostate biopsy, we will record the result and count the number of specimen jars containing tissue cores using HCPCS code 88305 because patients could have different numbers of specimens taken and Medicare payment is based on the number of specimens.99 Hospitalizations due to biopsy complications are defined as those that occurred within 30 days of prostate biopsies and have ICD-9 primary diagnosis codes consistent with complications. Data sources for estimating healthcare utilization costs include Medicare payments, a good proxy for true economic cost.

Qualitative Aim: We will use qualitative methods to identify and describe attitudes and perceptions of Black men and their providers relating to PSA testing, the CHW-led decision coaching intervention, and SDM. We will conduct in-depth, semi structured interviews with both groups. Interviews will be audio recorded and transcribed for thematic analysis. The study population will be patients from the intervention group, their providers, and two administrative leaders at the study site. Patients will be enrolled in the qualitative portion of the study throughout the study period. We will enroll all site providers who care for adult men and participated in the intervention (n=5) and administrative leadership (n=2). Providers (5) include two full-time Family Nurse Practitioners (FNPs), one full time medical/pediatric provider (MD), and two family medicine providers (MD). We will exclude providers who do not care for adult men, since our focus is prostate cancer. At study initiation, investigators will interview each of the participating providers and administrators to document and analyze attitudes towards and perceptions of the intervention. These interviews will then be

conducted every 6 months thereafter. During these interviews, the investigators will take detailed field notes to document responses as an additional source of qualitative data

10.6 Sample Size

Sample Size Justification: In determining the recruitment target, we considered the 1) detectable group differences in patient knowledge and decision quality based on pilot study data, 2) differences in PSA screening rates between the control and intervention groups, and 3) expected drop out. In our PSA pilot study, the group means of knowledge change are 2.6 (SD=2.81) and 5.1 (SD=3.19) in the control and intervention groups respectively. Using the proposed sample size and the above listed group standard deviations and assuming our control and CHW group have no knowledge difference at baseline, we are able to detect a 1.26 post-intervention group difference in knowledge based on the two sample t-test with 80% power and 5% significant level. Comparing to the observed knowledge improvement group difference (2.6 in the pilot study) we would have excellent power for this goal. Conservatively assuming a 20% drop out, we will recruit 228 participants (114/group) to achieve a final sample of 182 (91/group). Based on current clinic screening rates provided by our clinical partners, we assume the post-intervention PSA screening rate will be 30% (unchanged from baseline) in the control group and 50% (consistent with current general screening rates among Medicare beneficiaries) in the intervention group.66 Using a two-sided Z-test for two proportions, a total group of 182 subjects with 91 subjects in each group can achieve 80% power to detect a 20% difference in the post-intervention PSA screening rate between control and CHW groups with 5% significance level.

10.7 Measures to Minimize Bias

10.7.1 Enrollment/Randomization/Masking Procedures

Randomization Scheme: The independent randomization process will be implemented within each provider. To further consider the possible confounding effect of age, we will divide the participants from each provider into two strata: 40-54 years and 55-69 years. Within each stratum, patients (4 person blocks) will be randomized with a computer-generated permuted block random number to control or intervention upon enrollment. Healthcare providers, the statistician and research staff who assess study outcomes will be blinded with regard to whether a participant was randomized to the intervention or to the control group

10.7.2 Evaluation of Success of Blinding

It may not be possible to blind providers completely, especially with the CHW Decision Coach's presence at the clinic visit. Discussion between coach and patient may reveal their previous interaction. Providers may thus be prompted to engage in greater SDM than they would outside of the study. Providers will be handed a document with a prompt to identify the patient is part of the study and that PSA should be discussed in the session. Prompt states the following: "This patient has been enrolled into our study. Please engage him in conversation about PSA testing for prostate cancer screening."
" However, if this occurs it would bias us toward the null and make a Type I error less likely.

10.7.3 Breaking the Study Blind/Participant Code

In the event that the Research Coordinator finds a critical PSA result during time of post 6 month follow-up (defined as PSA>4, which is indicative of potential risk of prostate cancer), the RC will check to see if the patient has since followed up with his provider; if not: the study team will contact the provider immediately and urge the provider to have a consultation with the patient.

11 Source Documents and Access to Source Data/Documents

Source data is all information, original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents. Examples of these original documents, and data records include: hospital records,

clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trial.

The study case report form (CRF) is the primary data collection instrument for the study. All data requested on the CRF must be recorded. All missing data must be explained. If a space on the CRF is left blank because the procedure was not done or the question was not asked, write "N/D". If the item is not applicable to the individual case, write "N/A". All entries should be printed legibly in black ink. If any entry error has been made, to correct such an error, draw a single straight line through the incorrect entry and enter the correct data above it. All such changes must be initialed and dated. DO NOT ERASE OR WHITE OUT ERRORS. For clarification of illegible or uncertain entries, print the clarification above the item, then initial and date it.

Study information will be entered into REDCap survey forms. All data fields will be entered using free text and multiple-choice entries with reminders to ensure fields are entered appropriately. REDCap has data auditing to ensure any changes to data are recorded and justified.

Access to study records will be limited to IRB-approved members of the study team. The investigator will permit study-related monitoring, audits, and inspections by the IRB/EC, the sponsor, government regulatory bodies, and University compliance and quality assurance groups of all study related documents (e.g. source documents, regulatory documents, data collection instruments, study data etc.). The investigator will ensure the capability for inspections of applicable study-related facilities (e.g. pharmacy, diagnostic laboratory, etc.).

Participation as an investigator in this study implies acceptance of potential inspection by government regulatory authorities and applicable University compliance and quality assurance offices.

12 Quality Assurance and Quality Control

QC procedures will be implemented beginning with the data entry system and data QC checks that will be run on the database will be generated. Any missing data or data anomalies will be communicated to the site(s) for clarification/resolution.

Following written SOPs, the monitors will verify that the clinical trial is conducted and data are generated, documented (recorded), and reported in compliance with the protocol, GCP, and the applicable regulatory requirements (e.g., Good Laboratory Practices (GLP), Good Manufacturing Practices (GMP)).

The investigational site will provide direct access to all trial related sites, source data/documents, and reports for the purpose of monitoring and auditing by the sponsor, and inspection by local and regulatory authorities.

13 Ethics/Protection of Human Subjects

13.1 Ethical Standard

The investigator will ensure that this study is conducted in full conformity with Regulations for the Protection of Human Subjects of Research codified in 45 CFR Part 46.

13.2 Institutional Review Board

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form must be obtained before any participant is enrolled. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form will be IRB approved; a determination will be made regarding whether previously consented participants need to be re-consented.

13.3 Informed Consent Process.

13.3.1 Consent/Assent and Other Informational Documents Provided to Participants

Consent forms describing in detail the study intervention, study procedures, and risks are given to the participant and written documentation of informed consent is required prior to starting intervention. The following informed consent form is submitted with this protocol, for both patients and providers.

13.3.2 Consent Procedures and Documentation

Informed consent is a process that is initiated prior to the individual's agreeing to participate in the study and continues throughout the individual's study participation. Extensive discussion of risks and possible benefits of participation will be provided to the participants and their families. Consent forms will be IRB-approved and the participant will be asked to read and review the document. The investigator will explain the research study to the participant and answer any questions that may arise. All participants will receive a verbal explanation in terms suited to their comprehension of the purposes, procedures, and potential risks of the study and of their rights as research participants. Participants will have the opportunity to carefully review the written consent form and ask questions prior to signing. The participants should have the opportunity to discuss the study with their surrogates or think about it prior to agreeing to participate.

Due to COVID-19 and to keep the safety of both our research team and research subjects, we will be collecting consent via telephone or WebEx. A trained Research Assistant will schedule a time with eligible interested participants to go over the written consent via telephone or WebEx. Research Assistants will email or mail a copy of the consent to participants in preparation for the telephone consent. After going over the written consent via telephone, research assistants will also send the consent via a RedCap link where the participant has the opportunity to read a copy of the written consent and sign electronically, confirming that they read and understood the consent. Research Assistants will also document on RedCap the time and date of the telephone consent and note that the consent process was done via telephone due to COVID-19. The completed ICF will be returned via REDCap. Upon receipt of the signed ICF, SC will schedule the coaching session by secure video (such as webex). Upon signing the consent form participants will be assigned a participant ID number that will be used to identify their interview and all other documents related to their participation. Additionally, they will be assigned a pseudonym for reporting purposes.

Consent forms will include the participant's name and are to be signed by the participant and the interviewer at the time of the consent appointment, prior to the collection of any data. For remotely conduced ICF appointments, the study staff obtaining consent will document having witnessed the consent by signing a hard copy of a progress note to be mailed to and stored at the site in the study records.

Remote interviews conducted and recorded by WebEx will be immediately saved to the NYU Shared drive server by use of the virtual desktop with all local files destroyed upon verification of upload.

The participant will sign the informed consent document prior to any procedures being done specifically for the study. Subjects will sign written full informed consent and audio consent form prior to enrollment in the study. These forms will be administered and hand written digital signatures will be collected with a study iPad or tablet, witnessed by a Community Health Worker. The participants may withdraw consent at any

time throughout the course of the trial. A copy of the signed informed consent document will be given to the participants for their records. The rights and welfare of the participants will be protected by emphasizing to them that the quality of their medical care will not be adversely affected if they decline to participate in this study.

A copy of the signed informed consent document will be stored in the subject's research record. The consent process, including the name of the individual obtaining consent, will be thoroughly documented in the subject's research record. Any alteration to the standard consent process (e.g. use of a translator, consent from a legally authorized representative, consent document presented orally, etc.) and the justification for such alteration will likewise be documented.

The iPad/tablet devices used in this research will have security features that are designed to protect the device and data while enforcing strict network and platform security. These are:

1. Device protection
   - Strong passwords
   - Passcode expiration
   - Passcode reuse history
   - Maximum failed attempts
   - Over-the-air passcode enforcement
   - Progressive device protection

2. Data protection
   - Remote and local wipe
   - Encrypted configuration profiles
   - Encrypted iTunes backup
   - Hardware encryption

3. Network Security
   - Cisco IPSec, L2TP, PPTP VPN protocols
   - SSL/TLS with X.509 certificates
   - WPA/WPA2 Enterprise with 802.1X
   - Certificate-based authentication
   - RSA SecurID, CRYPTOCard

4. Platform security
   - Runtime protection
   - Mandatory code signing
   - Keychain services
   - Common crypto APIs

   The extensive precautions available to iPads will minimize the risk involved with maintaining research databases on portable devices. Furthermore, the device is a conduit that passes data to the cloud storage site, so only information from the current records are locally stored until the web is accessed through the cellular network.

All research protocols will be reviewed and approved by the NYUSOM Institutional Review Board (IRB) prior to gaining access to personal health information (PHI) and participant recruitment. The Community Health Worker Decision Coach will give the patient oral and written descriptions of the research protocol and will answer any questions that the patient may have. The CHW Decision Coach will also be instructed to offer to read any related study materials to the patients if difficulty exists due to low literacy levels or poor vision. As part of the informed consent process, all patients and providers will be reminded that their responses are confidential and that they may refuse to participate in the project or withdraw at any time, and further, that such an action will in no way affect their future interactions with their healthcare providers or employment at the FQHC. After reading and understanding the consent and the procedures, those who choose to participate will sign and date the consent form. All research staff and study

personnel will have completed and passed IRB, HIPAA, and extensive human subjects training and will be thoroughly trained in appropriate consent procedures and the precaution to maintain strict confidentiality.

In order for research coordinators to review patient charts and abstract relevant clinical data to determine study eligibility, we will request a waiver of authorization prior to recruitment for screening purposes only. Informed consent will be obtained from each participant prior to enrollment in research study. Audio consent will also be obtained prior to enrollment in study to audio record clinical encounters and conduct qualitative interviews.

Providers: During recruitment communications, the study team may set up a brief in-person meeting to review details related to informed consent. These meetings will occur in private offices to ensure confidentiality. Study staff will remind providers that participation is voluntary and all responses and study outcomes will be de-identified, reported as aggregate and identifying data or responses will not be shared with institutional leadership. Providers will consent to the study in its entirety prior to recruitment of patients. Audio consent will also be obtained to audio record clinical encounters and conduct qualitative interviews.

13.4 Participant and Data Confidentiality

Information about study subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Those regulations require a signed subject authorization informing the subject of the following:

- What protected health information (PHI) will be collected from subjects in this study
- Who will have access to that information and why
- Who will use or disclose that information
- The rights of a research subject to revoke their authorization for use of their PHI.

In the event that a subject revokes authorization to collect or use PHI, the investigator, by regulation, retains the ability to use all information collected prior to the revocation of subject authorization. For subjects that have revoked authorization to collect or use PHI, attempts should be made to obtain permission to collect at least vital status (i.e. that the subject is alive) at the end of their scheduled study period.

Participant confidentiality is strictly held in trust by the participating investigators, their staff, and the sponsor(s) and their agents. This confidentiality is extended to cover testing of biological samples and genetic tests in addition to the clinical information relating to participants. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the sponsor.
The study monitor, other authorized representatives of the sponsor, or representatives of the IRB may inspect all documents and records required to be maintained by the investigator, including but not limited to, medical records (office, clinic, or hospital) and pharmacy records for the participants in this study. The clinical study site will permit access to such records.

The study participant's contact information will be securely stored at each clinical site for internal use during the study. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by local IRB and Institutional regulations.

Study participant research data, which is for purposes of statistical analysis and scientific reporting, will be transmitted to and stored at the NYU School of Medicine. This will not include the participant's contact or identifying information. Rather, individual participants and their research data will be identified by a unique study identification number. The study data entry and study management systems used by clinical sites and by NYU School of Medicine research staff will be secured and password protected. At the end of the study, all study databases will be de-identified and archived at the NYU School of Medicine.

To further protect the privacy of study participants, a Certificate of Confidentiality will be obtained from the NIH. This certificate protects identifiable research information from forced disclosure. It allows the investigator and others who have access to research records to refuse to disclose identifying information on research participation in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. By protecting researchers and institutions from being compelled to disclose information that would identify research participants, Certificates of Confidentiality help achieve the research objectives and promote participation in studies by helping assure confidentiality and privacy to participants.

13.4.1 Research Use of Stored Human Samples, Specimens, or Data

N/A

13.5 Future Use of Stored Specimens

N/A

14 Data Handling and Record Keeping

14.1 Data Collection and Management Responsibilities

Study personnel will access demographics, PSA use and Gleason score using Epic. Data will be stored locally and backed up on a secure server. Statistical analyses will be performed using SAS 9.3 (SAS Institute, Cary, NC), Stata Release 14 (StataCorp LLC, College Station, TX) and MPlus Version 7.4 (Muthén & Muthén, Los Angeles, CA).

Data collection is the responsibility of the clinical trial staff at the site under the supervision of the site PI. The investigator is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

All data will be inputted into a digital data collection system on a secure network provided by the NIH and NYU School of Medicine, REDCap. The data system includes password protection and internal quality checks, such as automatic range checks, to identify data that appear inconsistent, incomplete, or inaccurate A tablet computer will be used for data entry over secure Wi-Fi or 4gLTE data networks. There is no risk that if the iPad is lost that it will compromise study information. All data will be recorded on REDCap using secure data streaming with no local device storage. In addition, the iPad tablet devices used in this research will have security features that are designed to protect the device and data while enforcing strict network and platform security.
All source documents should be completed in a neat, legible manner to ensure accurate interpretation of data. Black ink is required to ensure clarity of reproduced copies. When making changes or corrections, cross out the original entry with a single line, and initial and date the change. DO NOT ERASE, OVERWRITE, OR USE CORRECTION FLUID OR TAPE ON THE ORIGINAL.

Copies of the electronic CRF (eCRF) will be provided for use as source documents and maintained for recording data for each participant enrolled in the study. Data reported in the eCRF derived from source documents should be consistent with the source documents or the discrepancies should be explained and captured in a progress note and maintained in the participant's official electronic study record.

Hard copy data will be kept in a locked storage area in a locked office and building. Electronic data will be password-protected, stored only on a secure server, and backed up frequently. Only designated members of the study team will have access to Protected Health Information (PHI) and a variety of precautions will be taken to ensure the security of participant data.

14.2 Study Records Retention

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.

14.3 Protocol Deviations

A protocol deviation is any noncompliance with the clinical trial protocol, GCP, or MOP requirements. The noncompliance may be on the part of either the participant, the investigator, or the study site staff. Because of deviations, corrective actions are to be developed by the site and implemented promptly.

These practices are consistent with ICH E6:

- 4.5 Compliance with Protocol, sections 4.5.1, 4.5.2, and 4.5.3
- 5.1 Quality Assurance and Quality Control, section 5.1.1
- 5.20 Noncompliance, sections 5.20.1, and 5.20.2.

It is the responsibility of the site to use continuous vigilance to identify and report deviations immediately after identification of the protocol deviation. All deviations must be addressed in study source documents, reported to the NIH NIMHD Program Official. Protocol deviations must be reported to the local IRB per their guidelines. The site PI/study staff is responsible for knowing and adhering to their IRB requirements. Further details about the handling of protocol deviations will be included in the MOP.

14.4 Publication and Data Sharing Policy

This study will comply with the NIH Public Access Policy, which ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication.

The International Committee of Medical Journal Editors (ICMJE) member journals have adopted a clinical trials registration policy as a condition for publication. The ICMJE defines a clinical trial as any research project that prospectively assigns human subjects to intervention or concurrent comparison or control groups to study the cause-and-effect relationship between a medical intervention and a health outcome. Medical interventions include drugs, surgical procedures, devices, behavioral treatments, process-of-care changes, and the like. Health outcomes include any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events. The ICMJE policy, and the Section 801 of the Food and Drug Administration Amendments Act of 2007, requires that all clinical trials be registered in a public trials registry such as ClinicalTrials.gov, which is sponsored by the National Library of Medicine. Other biomedical journals are considering adopting similar policies. For interventional clinical trials performed under NIH IC grants and cooperative agreements, it is the grantee's responsibility to register the trial in an acceptable registry, so the research results may be considered for publication in ICMJE member journals. The ICMJE does not review specific studies to determine whether registration is necessary; instead, the committee recommends that researchers who have questions about the need to register err on the side of registration or consult the editorial office of the journal in which they wish to publish.

FDAAA mandates that a "responsible party" (i.e., the sponsor or designated principal investigator) register and report results of certain "applicable clinical trials":

- Trials of Drugs and Biologics: Controlled, clinical investigations, other than Phase I investigations of a product subject to FDA regulation;

- Trials of Devices: Controlled trials with health outcomes of a product subject to FDA regulation (other than small feasibility studies) and pediatric postmarket surveillance studies.
- NIH grantees must take specific steps to ensure compliance with NIH implementation of FDAAA.

15 Study Finances

15.1 Funding Source

This study is financed through a grant from the US National Institutes of Health (NIH).

15.2 Costs to the Participant

The grant budgets for the cost of CHW in each visit. There will be no cost to the participant beyond regular costs incurred by clinical visit.

15.3 Participant Reimbursements or Payments

We have budgeted $17,100 for incentives for participating providers ($5,700 in Years 1, 2, 3). The incentives are intended to compensate for the supplemental time that providers devote to each intervention participant appointment that is lost from regular clinical time. This will encourage providers to participate thoroughly in all elements of the intervention. The incentive will be $75 per individual patient participant seen during clinical appointments.

We have budgeted $11,850 for incentives for participating patients ($3,800 in Years 1, 2, 3). We anticipate enrolling approximately 228 participants by completion of Year 3 to achieve adequate statistical power. The incentive will be a payment of up to $65 per individual participant in cash to compensate patients for the coaching session. A subset sample of individual participants (n=20-30) will receive an incentive payment of $15 for completing a qualitative in-depth interview.

16 Study Administration

16.1 Study Leadership

The Steering Committee will govern the conduct of the study. The Steering Committee will be composed of the Study Chairman, the co-PIs of the Coordinating Center, representatives of NIH, the PI of the clinical sites, and chairperson of the Study Coordinators subcommittee. The Steering Committee will meet in person at least annually.

17 Conflict of Interest Policy

The independence of this study from any actual or perceived influence, such as by the pharmaceutical industry, is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the trial. The study leadership in conjunction with the NIH NIMHD has established policies and procedures for all study group members to disclose all conflicts of interest and will establish a mechanism for the management of all reported dualities of interest.

Any investigator who has a conflict of interest with this study (patent ownership, royalties, or financial gain greater than the minimum allowable by their institution, etc.) must have the conflict reviewed by the NYU Langone Conflict of Interest Committee with a Committee-sanctioned conflict management plan that has been reviewed and approved by the study sponsor prior to participation in this study. All NYULMC investigators will follow the applicable conflict of interest policies.

18 References

1. Draft Recommendation Statement: Prostate Cancer: Screening. 2017; https://www.uspreventiveservicestaskforce.org/Page/Document/draft-recommendation-statement/prostate-cancer-screening1, 2017.
2. Myers RE, Daskalakis C, Cocroft J, et al. Preparing African-American men in community primary care practices to decide whether or not to have prostate cancer screening. *Journal of the National Medical Association.* 2005;97(8):1143-1154.
3. Myers RE, Daskalakis C, Kunkel EJ, et al. Mediated decision support in prostate cancer screening: a randomized controlled trial of decision counseling. *Patient education and counseling.* 2011;83(2):240-246.
4. Belkora J, Edlow B, Aviv C, Sepucha K, Esserman L. Training community resource center and clinic personnel to prompt patients in listing questions for doctors: follow-up interviews about barriers and facilitators to the implementation of consultation planning. *Implementation science : IS.* 2008;3:6.
5. Walter LC, Bertenthal D, Lindquist K, Konety BR. Psa screening among elderly men with limited life expectancies. *Jama.* 2006;296(19):2336-2342.
6. Stump TE, Dexter PR, Tierney WM, Wolinsky FD. Measuring patient satisfaction with physicians among older and diseased adults in a primary care municipal outpatient setting. An examination of three instruments. *Medical care.* 1995;33(9):958-972.
7. Sepucha K, Ozanne E, Silvia K, Partridge A, Mulley AG, Jr. An approach to measuring the quality of breast cancer decisions. *Patient education and counseling.* 2007;65(2):261-269.
8. Fenstermaker M, Hickman T, Gold H, et al. Abstract A15: How does doctor-patient communication about prostate cancer screening influence African-American patients' decisional conflict around screening decisions? *Cancer Epidemiology Biomarkers & Prevention.* 2016;25(3 Supplement):A15-A15.
9. Makarov DV, Chrouser K, Gore JL, et al. AUA White Paper on Implementation of Shared Decision Making into Urological Practice. *Urology Practice.* 2016;3(5):355-363.
10. Edwards A, Elwyn G, Hood K, et al. The development of COMRADE--a patient-based outcome measure to evaluate the effectiveness of risk communication and treatment decision making in consultations. *Patient education and counseling.* 2003;50(3):311-322.
11. Campbell C, Lockyer J, Laidlaw T, Macleod H. Assessment of a matched-pair instrument to examine doctor-patient communication skills in practising doctors. *Medical education.* 2007;41(2):123-129.
12. Maly RC, Frank JC, Marshall GN, DiMatteo MR, Reuben DB. Perceived efficacy in patient-physician interactions (PEPPI): validation of an instrument in older persons. *Journal of the American Geriatrics Society.* 1998;46(7):889-894.
13. Holmes-Rovner M, Kroll J, Schmitt N, et al. Patient satisfaction with health care decisions: the satisfaction with decision scale. *Medical decision making : an international journal of the Society for Medical Decision Making.* 1996;16(1):58-64.
14. Brehaut JC, O'Connor AM, Wood TJ, et al. Validation of a decision regret scale. *Medical decision making : an international journal of the Society for Medical Decision Making.* 2003;23(4):281-292.
15. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implementation science : IS.* 2009;4.
16. Liu CF, Rubenstein LV, Kirchner JE, et al. Organizational cost of quality improvement for depression care. *Health Serv Res.* 2009;44(1):225-244.
17. Ma X, Wang R, Long JB, et al. The cost implications of prostate cancer screening in the Medicare population. *Cancer.* 2014;120(1):96-102.
18. Lu-Yao G, Albertsen PC, Stanford JL, Stukel TA, Walker-Corkery ES, Barry MJ. Natural experiment examining impact of aggressive screening and treatment on prostate cancer mortality in two fixed cohorts from Seattle area and Connecticut. *BMJ.* 2002;325(7367):740.
19. Mitchell JM. Urologists' self-referral for pathology of biopsy specimens linked to increased use and lower prostate cancer detection. *Health affairs (Project Hope).* 2012;31(4):741-749.

20. Loeb S, Carter HB, Berndt SI, Ricker W, Schaeffer EM. Complications after prostate biopsy: data from SEER-Medicare. *The Journal of urology.* 2011;186(5):1830-1834.
21. Brown ML, Riley GF, Schussler N, Etzioni R. Estimating health care costs related to cancer treatment from SEER-Medicare data. *Medical care.* 2002;40(8 Suppl):Iv-104-117.
22. Barry MJ, et al. (1992). American Urological Association symptom index for benign prostatic hyperplasia. Journal of Urology, 148(5): 1549–1557.
23. Davis TC, Long SW, Jackson RH, et al. Rapid estimate of adult literacy in medicine: a shortened screening instrument. *Family Medicine.* 1993;25(6):391-395.
24. Fagerlin A, Zikmund-Fisher BJ, Ubel PA, Jankovic A, Derry HA, Smith DM. Measuring numeracy without a math test: Development of the subjective numeracy scale. *Medical Decision Making.* 2007;27(5):672-680.
25. Zikmund-Fisher BJ, Smith DM, Ubel PA, Fagerlin A. Validation of the subjective numeracy scale (SNS): Effects of low numeracy on comprehension of risk communications and utility elicitations. *Medical Decision Making.* 2007;27(5):663-671.
26 Anderson LA, Dedrick RF. Development of the Trust in Physician scale: a measure to assess interpersonal trust in patient-physician relationships. *Psychological Reports*. 1990;67(3):1091-1100.
27. Rose A, Peters N, Shea JA, Armstrong K. Development and testing of the health care system distrust scale. *J Gen Intern Med*. 2004;19(1):57–63.
28. Degner L., Sloan J., & Venkatesh P. The Control Preferences Scale. *Canadian Journal of Nursing Research Archive.* 1997;29(3):21-43.
29. Marteau TM, Dormandy E, Michie S. A measure of informed choice. *Health Expect*. 2001;4(2):99–108.
30. Watson E, Hewitson P, Brett J, Bukach C, Evans E, Edwards A, Elwyn G, Cargill A, Austoker J. Informed decision making and prostate specific antigen (PSA) testing for prostate cancer: A randomised controlled trial exploring the impact of a brief patient decision aid on men's knowledge, attitudes and intention to be tested. *Patient Education and Counseling*. 2006;63(3):367-379
31. O'Connor A. *Decision Self-Efficacy Scale.* 1995.
32. O'Connor AM. Validation of a decisional conflict scale. *Medical Decision Making.* 1995;15(1):25-30.
33. Aarons GA. Mental health provider attitudes toward adoption of evidence-based practice: The Evidence-Based Practice Attitude Scale (EBPAS). *Mental health services research.* 2004;6(2):61-74.
34. Shore BE, Franks P. Physician satisfaction with patient encounters: Reliability and validity of an encounter-specific questionnaire. *Medical care.* 1986;24(7):580-589.
35. Bertram DA, Opila DA, Brown JL, et al. Measuring physician mental workload: reliability and validity assessment of a brief instrument. *Medical care.* 1992;30(2):95-104.

19 Attachments

These documents are relevant to the protocol, but they are not considered part of the protocol. They are stored and modified separately. As such, modifications to these documents do not require protocol amendments.

Attachment A
Schedule

Table 3 -- Project Period : (7/1/2018– 6/30/2023)																			
Activity	Year 1				Year 2				Year 3				Year 4				Year 5		
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Updating of decision aid																				
Development of coaching protocol																				
Decision coach training																				
Recruitment (Time 1)																				
Time 2 and Time 3 data collection																				
Data collection: 6 month follow up																				
Data entry & cleaning																				
Coding of clinical encounter transcripts																				
Coding of interview transcripts																				
Quantitative & qualitative analysis																				
Manuscript and report writing																				

Attachment B
Data Collection Times

Table 1- Quantitative Patient Measures	Collection Time			
Measure	**Pre coaching**	**Post coaching**	**Post Appt**	**6 mos**
Demographics, Clinical Features and Preferences				
Demographics	X			
Literacy[72] and Numeracy[73,74]	X			
Trust[75,76]	X			
International Prostate Symptom Score	X			
Health Survey	X			
Preference for Shared Decision Making[63]	X	X	X	
Experience with decision coaching program			X	
Specific Aim 1				
Hypothesis 1.1				
Knowledge[65]		X	X	
Measure of Informed Choice		X	X	
Decision Quality[64,78]		X	X	
Hypothesis 1.2				
Communication[75,79]			X	
Decision Self-Efficacy Scale[80]	X	X	X	
Self-efficacy for communicating with provider[81]	X	X	X	
Decisional conflict scale[82]		X	X	X
Satisfaction with Decision Scale[83]			X	X
Decisional Regret[84]				X
Hypothesis 1.3				
Screening choice (Epic Query)			X	X

Table 2 – Quantitative Provider Measures			
Measure	**Initiation**	**Post encounter**	**Completion**
Demographics and Preferences			
Demographics	X		
Preference for EBM[76]	X		X
Specific Aim 2			
Hypothesis 2.1			
Satisfaction[85]		X	
Difficulty[86]		X	
Communication[75]		X	