THOMAS JEFFERSON UNIVERSITY
Sidney Kimmel Cancer Center

Peer-Based Intervention for Genetic Evaluation for Prostate Cancer among African American Men: The Peer Genetic Study

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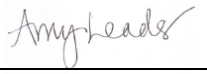
Signature Page

For multi-site studies, the protocol will be signed by the clinical site investigator who is responsible for the day to day study implementation at his/her specific clinical site. For a clinical trial involving an Investigational New Drug (IND), this is the individual who signs the Form FDA 1572 for a drug or the investigator agreement for a device.

The signature below constitutes the approval of this protocol and the attachments, and provides the necessary assurances that this trial will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable US federal regulations and ICH guidelines.

Principal Investigator:

Signed:  Date: 09/28/2022

Name: Amy E. Leader, DrPH, MPH

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Teaching Faculty, Public Health Program, College of Population Health

Statement of Compliance

This study will be conducted in accordance with the International Conference on Harmonisation guidelines for Good Clinical Practice (ICH E6), the Code of Federal Regulations on the Protection of Human Subjects (45 CFR Part 46), and Thomas Jefferson University research policies

List of Abbreviations

AA: African American

ASCO: American Society of Clinical Oncology

BRCA1, BRCA2, ATM, PALB2, CHEK2, NBN, the DNA mismatch repair genes: cancer risk genes

GEM: Genetic Evaluation of Men

GU: Genitourinary

MEE: Motivational, Educational, Entertainment Productions, Philadelphia, PA

NCCN: National Comprehensive Cancer Network

PARP: Poly ADP ribose polymerase

PCA: Prostate cancer

RESPOND: Research on Prostate Cancer in Men of African Ancestry

SURE: Decisional conflict scale

TPB: Theory of Planned Behavior

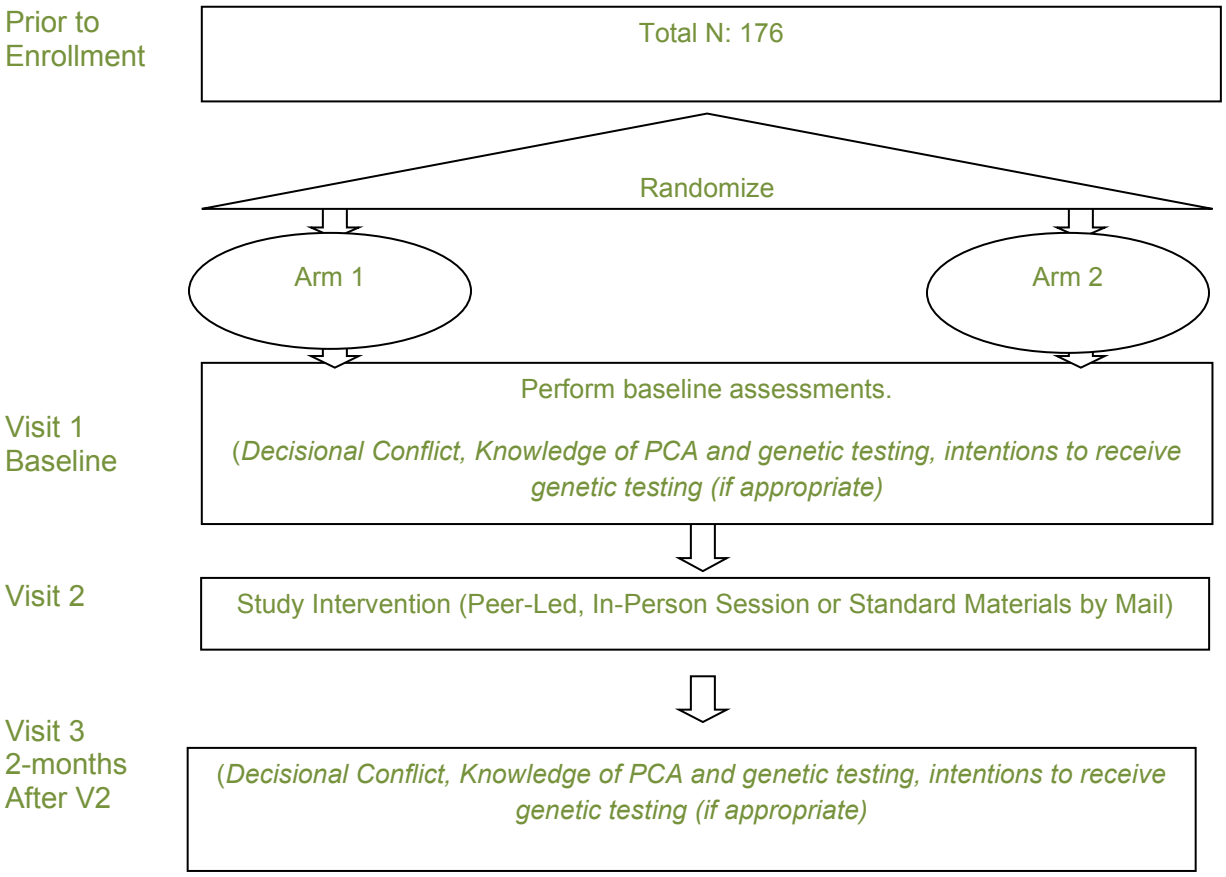
US: United States

Study Summary

Title:	***Peer-Based Intervention for Genetic Evaluation for Prostate Cancer among African American Men: The Peer Genetic Study***
Précis:	The study will evaluate the impact of a peer-educator led, clinic-based intervention to educate men about their risk of prostate cancer and facilitate genetic testing for prostate cancer risk assessment
Objectives:	Aim 1: Explore barriers to genetic testing and opportunities for intervention among AA males who live in low-resource communities through focus groups with AA men and interviews with key stakeholders. Aim 2: Implement a community-based peer health education intervention. AA male peer health educators will be trained in PCA genetics, and a randomized trial will be implemented for 176 AA males in the community of peer health education vs. mailed informational materials. Aim 3: Evaluate the impact of peer health education. The primary outcome will be decisional conflict regarding consideration of genetic testing. Exploratory outcomes will include rates of AA men meeting NCCN genetic testing guidelines and assessment of genetic counseling experience among AA men who opt for genetic testing.
Population:	176 men will be randomized to receive either: (1) a peer-led, clinic based educational intervention or (2) standard written materials about personal and family history of prostate cancer. Eligible men are between the ages of 35-69 and can speak and read English comfortably.
Phase:	N/A: Randomized controlled trial of a behavioral intervention
Number of Sites:	CityLife Neighborhood Clinic 1010 W. Lehigh Avenue Philadelphia, PA 19133 AND

	Community and Church based organizations in and around Philadelphia, PA
Description of Intervention:	Men in the intervention group (n=88) will attend a peer-led education session about PCA genetic testing while men in the control group (n=88) will receive mailed informational materials about PCA genetic testing. Men in either group who wish to pursue genetic testing will be referred to the Clinical Cancer Genetics Program at SKCC. The cost of genetic testing will be covered for all men.
Study Duration:	4 years: July 1, 2019- June 30, 2024
Participant Participation Duration:	Estimated time is 1-3 months
Estimated Time to Complete Enrollment:	3.5 years (April 2020-October 2023)

Schematic of Study Design:



1 Introduction

1.1 Background Information

African American (AA) males have some of the highest rates of prostate cancer (PCA) incidence and death in the US.[1] Indeed, AA males have over twice the rate of mortality from PCA compared to any other race group.[1] While the causes of this disparity in PCA mortality for AA men likely include a combination of biologic, behavioral, and environmental factors, a deep understanding of the interplay of these factors lending to PCA-related death remain largely unknown. In fact, a major study as part of the Cancer Moonshot led by the National Cancer Institute, National Institute of Minority Health and Health Disparities, and Prostate Cancer Foundation (RESPOND - Research on Prostate Cancer in Men of African Ancestry) is now underway to gain greater understanding of PCA aggressiveness among AA men.[2] Thus, reducing PCA disparities for AA men is now taking major national priority. To maximize the impact of such studies will require novel groundwork in community settings.

Meanwhile, genetic testing is revolutionizing PCA care. Over the last 2-3 years, research studies have provided ground-breaking insights into high rates of germline (inherited) mutations (12-15%) among men with metastatic PCA.[3,4] Our research group extended the scope of insights into inherited genetic mutations, reporting rates of 5-7% among men with earlier stage PCA particularly with strong family cancer history.[5] Mutations in multiple genes have been reported in these prior studies including *BRCA1, BRCA2, ATM*, DNA mismatch repair genes, *NBN,* and *CHEK2*.[3-5] Furthermore, men with PCA and specific genetic mutations have been shown to have improved responses to targeted therapy with PARP inhibitors,[6] leading the FDA to grant "Breakthrough Therapy" designation for olaparib (a PARP inhibitor) for men with *BRCA1*, *BRCA2*, or *ATM* mutations. These landmark insights led our institution to host and publish the first international consensus conference on the "Role of Genetic Testing for Inherited Prostate Cancer Risk" to set forth a comprehensive framework for genetic testing for men with PCA.[7] Subsequently, the National Comprehensive Cancer Network (NCCN) rapidly expanded genetic testing guidelines to encompass testing multiple genes including *BRCA1, BRCA2, ATM, PALB2, FANCA*, and DNA mismatch repair genes in all men with metastatic PCA, men with earlier stage disease who have strong family cancer history, or men unaffected with PCA who are making screening decisions and have a strong family cancer history.[8-10] Thus, genetic results are now informing precision treatment for metastatic PCA, management for early-stage disease, and PCA screening discussions among men unaffected with PCA.[8-10]

A major concern is that expansion of genetic testing for PCA will increase PCA disparities for AA men. In fact, genetic information in AA men is a major gap in knowledge due to low representation in prior genetic studies.[3-5] Patients from ethnic minority groups participate less frequently in genetic testing due to lack of awareness or understanding, cultural beliefs, financial limitations, fear of discrimination, and mistrust in the healthcare system.[11] This is of particular concern in the Philadelphia region, where African Americans account for up to 44% of our catchment area, and PCA mortality exceeds the national average.[12]Addressing awareness, barriers to consideration of genetic evaluations, and engagement in informed decision-making for genetic testing for PCA among AA men is therefore imperative, since testing is increasingly informing screening strategies for unaffected men and treatment for men with PCA.[8-10]

Peer health education has been used to access 'hard to reach' groups with the participation of those who are of a similar age, background or interest.[13] Typically, there are four essential elements of peers: (1) they share specific characteristics, experiences, or circumstances and are selected because they are from the same community or belong to a specified subgroup; (2) their shared qualities increase the effectiveness of the services they provide; (3) they lack professional training or status in the scope of their work, but are trained to deliver a specific intervention; and (4) they function intentionally based on standardized protocols, and therefore their interactions extend beyond their existing social network.[13] Peer-led dialogue groups have the potential to increase families' and communities' uptake of recommended health practices.[14,15] Facilitated discussions allow group members to actively participate in the learning process and share their experiences and knowledge with other group members, as well as engage in group problem-solving.[16] Hearing what group members know, think, and do can lead other members to positively change their attitudes and behaviors.[17] The use of peer interventions has been demonstrated as effective, regardless of the health behavior, the population or demographics of individuals who are the target audience, although most have been related to HIV testing, alcohol and substance abuse, physical activity, heart disease, and diabetes.[18]

1.2 Rationale for the Proposed Study

As an increasing number of people seek information about cancer genetics, there is a growing need for competent and culturally relevant dissemination of information. It is well documented that low-income, low-literacy individuals are less likely to participate in genetic counseling and genetics research,[19] which only continues to perpetuate health disparities. Previous research indicates that individuals with reduced health literacy often report feeling overwhelmed during a genetic counseling session due to too much information, the complexity of the information, unintentional inhibition of patient engagement and interaction, and vague discussions about screening and testing resources.[20] Peer-led programs are uniquely suited to fill part of this gap by educating individuals about basic cancer genetics in a way that is understandable and relatable for those involved.

The proposed study titled "Peer-Based Intervention for Genetic Evaluation for Prostate Cancer among African American Men: The Peer Genetic Study" will identify and address barriers and beliefs regarding genetic testing for PCA among AA men in the Philadelphia region. The study will build upon strong community partnerships supported by prior DOD funding and link to a first-in-field genetic counseling and genetic testing program. Leveraging an invested cadre of AA male peer health educators, the study will train them in the principles and practice of genetic testing, to implement a peer education intervention in a community clinic setting. We aim to study the impact of peer education, compared to the standard approach of printed educational materials, in reducing decisional conflict about genetic testing. Results of the study will inform health system approaches and health policy, regarding peer education. We expect the results to ultimately reduce PCA disparities for AA men by promoting responsible engagement in informed decision-making for genetic testing to guide PCA screening and treatment. Therefore, the study will create a community-based sustainable pipeline to address the overarching challenge of engaging AA males in cancer genetics research to define the biology of lethal prostate cancer, namely germline genetics of AA men. Results of the study will ultimately inform PCA screening and identification of novel targeted agents for population-specific precision treatment of PCA to reduce death among AA men.

1.3 Previous Research

The current proposal leverages expertise in clinical cancer genetics, PCA risk assessment, PCA treatment, community-based health interventions, and population science towards the goal of developing, implementing, and assessing a novel peer-based PCA genetic education program for AA males in community health clinics. Limited genetic data has hindered tailored PCA screening and the development of targeted therapies to improve PCA outcomes in AA men, necessitating novel approaches to genetic evaluation for AA men as proposed here.

Leadership in prostate cancer genetic testing. Dr. Veda Giri is a medical oncologist with specialization in clinical cancer genetics. She has been a thought leader in conducting multigene testing for inherited PCA through the Genetic Evaluation of Men (GEM) study (Partially funded by PA Department of Health grant).[5] Dr. Giri started the first Men's Genetic Risk Clinic in the US in 2014 focused on genetic evaluation of inherited PCA.[21] Dr. Giri also co-chaired an international consensus conference that published a comprehensive framework for genetic evaluation of PCA, which noted that genetic testing among AA males is a high priority due to lack of genetic data in this population.[7] Dr. Giri's work has contributed novel insights into the germline spectrum of inherited PCA from multigene testing.[5] Furthermore, Dr. Giri and Dr. Leader collaborated on a project of understanding of genetic test results among men and co-authored the publication.[22]

Forefront of community-based PCA education for African Americans. Dr. Amy Leader is a population scientist and a current recipient and Co-PI of a Synergistic IDEA Award (#PC140667) (Title: *A Neighborhood Based Intervention to Reduce PCA Disparities*) (Funded 10/15-9/18). Dr. Giri is a Co-Investigator on the funded study. Specific Aims for the funded study were to:**(1)** identify neighborhoods with disproportionately high rates of advanced PCA and describe patient- and neighborhood-level risk factors associated with the high-risk neighborhoods; **(2)** develop, using a mixed methods approach, a peer-led educational intervention about PCA for men who live in high risk neighborhoods; **(3)** test the impact of the intervention on levels of knowledge, anxiety, and informed decision making about PCA screening; **(4)** observe rates of PCA screening in the intervention and control groups. The research team successfully enrolled 240 AA males into this study, demonstrating its ability to engage and collaborate with the AA communities of Philadelphia.

Collaboration of successful prior research and expertise for the current proposal. The PI (Dr. Giri) and Co-PI (Dr. Leader) will now leverage their successful experience with genetic education and counseling, genetic testing, and community-based research toward addressing barriers and developing implementation of genetic evaluation for PCA for AA males from community health clinics in underserved communities in the Philadelphia area, which has some of this highest burden of lethal PCA in the US.[12] The specific aims of the current proposal are designed to gain information on challenges and barriers to uptake of genetic assessment for PCA among AA males, develop a peer education intervention for community health clinics with predominantly AA population, and assess the value of peer education in decisional conflict to seek genetic testing. Knowledge gained from implementing Study # PC140667 will ensure the likelihood of success of the proposed study in the following ways: (1) We have engaged a diverse group of community partners to form a network of grass-roots and professional organizations which will form the foundation of community engagement and outreach crucial for its success; (2) We developed a specialized curriculum for training peer health educators, which will serve as the foundation for training the peer health educators in PCA genetic assessment for the proposed study; (3) Five peer health educators from # PC140667 will be readily trained and engaged in the proposed study. Thus, the current proposal will make major strides to addressing barriers to awareness and implementation of genetic evaluation for AA males to ultimately reduce death from PCA.

1.4 Potential Risks and Benefits

1.4.1 Potential Risks

There are very few risks expected with this educational intervention. Participants may experience anxiety when talking or thinking about their personal or family risk of cancer. There may be a loss of confidentiality when discussing your medical history with a peer health educator. All efforts to reduce these risks, whether psychosocial or privacy-related, will be taken.

1.4.2 Benefits

Potential benefits to patients include learning more about PCA and how one's personal or family history of disease may increase one's risk of PCA. Also, having access to genetic testing may benefit some participants.

2 Study Objectives

2.1 Study Aims

Aim 1: Explore barriers to genetic testing and opportunities for intervention among AA males who live in low-resource communities through focus groups with AA men and stakeholders.

Aim 2: Implement a PCA genetics education and testing program for AA men who live in low-resource communities. Eligible men will be randomized to either the intervention group (peer-led health education sessions) or the control group (mailed materials).

Aim 3: Evaluate the impact of the intervention. The primary outcome is decisional conflict regarding consideration of genetic testing. Exploratory outcomes include rates of AA men meeting NCCN genetic testing guidelines and assessment of genetic counseling experience among AA men.

2.2 Endpoints/Outcome Measures

Aim 1: Focus groups will uncover knowledge and awareness of prostate cancer; understanding of genetic testing; perceptions of genetic testing; risks and benefits of testing

Aim 2: Outcome will be the design of a feasible intervention to employ in a community-practice setting.

Aim 3: Analysis of intervention data will determine: extent of decisional conflict; knowledge of prostate cancer and genetic testing for prostate cancer risk; individual assessment of prostate cancer risk; intentions to seek genetic testing (if appropriate)

3 Study Design

3.1 Characteristics

Aim 1: Two focus groups consisting of men who are current patients of CityLife Neighborhood Clinic or who live in the surrounding neighborhood

Aim 2/3: Design and implementation of an educational intervention to increase knowledge about PCA, the role of personal and family history as risk factors for PCA, and the purpose of genetic testing for PCA risk, if appropriate.

3.2 Number of Participants

Aim 1: 2 focus groups, each with 8-10 men

Aim 2/3: 176 men

3.3 Duration of Study Intervention

Aim 1: Each focus group will last approximately 1.5 hours

Aim 2/3: Each participant will be in the study for approximately 2 months

Treatment Assignment Procedures

3.3.1 Randomization Procedures

Aim 2/3: At the time of consent and enrollment into the study, each participant will be randomly assigned to participate in the intervention arm or the control arm. A randomization scheme will be provided by the study biostatistician.

3.4 Study Timeline

	Year 1				Year 2				Year 3			
Convene Advisory Board	x	x	x	x	x	x	x	x	x	x	x	x

IRB Approval of Study	x											
Conduct Focus Groups and Stakeholder Interviews		x										
Recruit and Train Peer Health Educators			x									
Develop Intervention Materials			x									
Implement Intervention; Refer to Genetic Testing				x	x	x	x	x	x			
Data Cleaning and Analysis									x	x		
Disseminate Study Results											x	x

4 Study Enrollment and Withdrawal

4.1 Eligibility Criteria

4.1.1 Inclusion Criteria

Aim 1: Men will be eligible to participate in a focus group if they are between the ages of 35 and 69 and are able to read and speak English comfortably. Men with or without a personal or family history of PCA are eligible to participate in a focus group. Men do not need to be an established patient at CityLife Neighborhood Clinic in order to participate in a focus group.

Aim 2/3: Men will be eligible to participate in the intervention if they are between the ages of 35 and 69 and are able to read and speak English comfortably. Men with or without a personal or family history of PCA are eligible to participate. Men do not need to be an established patient at CityLife Neighborhood Clinic in order to participate.

4.1.2 Exclusion Criteria

Aim 1: Men who are not between the ages of 35 and 69, or who do not read or speak English comfortably will not be able to participate in a focus group.

Aim 2/3: Men who are not between the ages of 35 and 69, or who do not read or speak English comfortably will not be able to participate in the intervention. Additionally, men who participated in a focus group will be excluded from participating in the intervention.

4.2 Gender/Minority/Pediatric Inclusion for Research

Given that CityLife Neighborhood Clinic is located in a diverse neighborhood and has a diverse patient population, we expect that a large proportion of the study population will be African American and Hispanic males. Women are not eligible to participate in the study as they are not at risk for PCA. Children are excluded from participating, as their risk of PCA is non-existent.

4.3 Strategies for Recruitment and Retention

4.4 Participant Withdrawal

4.4.1 Reasons for Withdrawal

Participants are free to withdraw from participation in the study at any time upon request.

An investigator may terminate a study participant's 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.

4.5 Premature Termination or Suspension of Study

This study may be suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party. If the study is prematurely terminated or suspended, the principal investigator will promptly inform the IRB and will provide the reason(s) for the termination or suspension.

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

- Determination of unexpected, significant, or unacceptable risk to participants.
- Insufficient adherence to protocol requirements.
- Data that is not sufficiently complete and/or evaluable.
- Determination of futility.

5 Study Intervention

5.1 Study Behavioral or Social Intervention(s) Description

The goal of Aim 1 is to conduct 2 focus groups to identify gaps in awareness, cultural beliefs, and barriers to considering genetic counseling and genetic testing for PCA. Key themes identified during the focus groups will inform the development of the behavioral intervention in Aim 2. The goal of Aim 3 is to evaluate the impact of the intervention, focusing on outcomes related to decisional conflict about genetic testing and knowledge of PCA.

6 Study Procedures and Evaluations

Aim 1: Focus Groups

We will conduct two focus groups of approximately 8 AA men each, recruited from the patient population at CityLife Clinic or the surrounding neighborhood. MEE Productions, Inc. will coordinate and moderate both of the focus groups. MEE Productions, Inc. is a nationally recognized communications, market research and social-marketing firm with roots in Philadelphia that specializes in developing cost-effective, cutting-edge and culturally relevant messages for hard-to-reach, low-income and underserved audiences. The study team has significant experience in working with MEE Productions, Inc. on a prior research study [DOD Synergistic IDEA Award (#PC140667)]. The goal of the focus groups will be to gather information on awareness, understanding, attitudes, and challenges to considering genetic testing for PCA. Factors such as knowledge of family cancer history, relevance of genetic testing in health, and competing risks and pressures will also be explored.

Prior to the start of each focus group, each participant will provide informed consent. Focus group discussions will be audio recorded and transcribed by a professional transcription company. The transcriptions will be verified for accuracy by a member of the research team who attended each focus group. Transcripts will be analyzed by iterative rounds of coding by at least two members of the research team, where specific themes and trends will be identified within each transcript and discussed by the research team until final consensus is reached. Themes will be identified as topics that consistently occur across transcripts, as well as similarities and differences between transcripts.[23] NVivo software will be used to perform thematic content analysis. Participants will be compensated $25 for attending a focus group.

Aim 2/3: Behavioral Intervention

Recruitment and training of peer health educators. The study team has built strong AA community relationships from work on a prior funded DOD grant [Synergistic IDEA Award (#PC140667)]. Peer educators from this prior grant will be re-contacted to participate in the Peer Genetic Study. A total of five peer educators will be recruited. If prior peer educators are not available to commit to the study, additional avenues to recruit peer health educators will be through CityLife Clinics or MEE Productions, Inc. Men need not have previous heath care experience to be trained as a peer educator. Dr. Giri or Dr. Leader will lead the educator training sessions. Culturally relevant issues will be addressed throughout the 9 training sessions, as they pertain to each of the training modules. Questions and concerns from peer health educators will also be addressed throughout the training. Peer educators will also complete human subjects training to be able to collect participant subject data during the intervention. Peer educators will attend training sessions in person, typically over the dinner meal, and will be compensated $20/hour of training time.

Development of genetic training materials. Content of the training materials for peer educators will be adapted from ASCO's Practice Guideline Genetics Toolkit.[24] The toolkit modules will be adapted as follows: (1) understanding hereditary cancer, (2) assessing hereditary cancer risk, (3) considerations of genetic testing and results, (4) management PCA and PCA screening based on genetic test results, (5) financial and ethical considerations of genetic testing, (6) cultural issues to address regarding genetic testing among AA males, (7) PCA risk and lifestyle modifications, (8) implications of genetic testing on family members, and (9) case scenarios. Based on input from the study team, MEE Productions, Inc. will develop print materials for the training sessions covering the aforementioned content.

Assessment of competency. To assess peer educator competency prior to the start of the intervention, we will adapt evaluation materials from the International Society of Nurses in Genetics 2011 Consensus Panel and survey on knowledge and understanding of PCA genetics and genetic results.[22,25] Example true/false assessment questions will include: (1) Factors such as personal behavior (diet, exercise) and environmental conditions (exposures) can raise the risk of getting prostate cancer; (2) Men with a family history of prostate cancer should also consider other factors that could raise the risk of getting prostate cancer, such as diet or exposures; (3) A family history of prostate cancer can raise the risk of getting prostate cancer; (4) Family history of additional cancers, such as breast cancer, can raise the risk of getting prostate cancer; (5) Having a history of prostate cancer on his mother's side of the family, can raise the risk of a man getting prostate cancer; (6) A genetic test can tell if someone will definitely get prostate cancer in the future; (7) Genetic testing may still be important even if a man has prostate cancer; (8) Patients with one cancer can be at risk for getting other cancers if the patient has a genetic mutation.

Additional multiple-choice questions will include: (1) What types of genetic test results can you get from genetic testing? (2) How can genetic testing be used in treatment of prostate

cancer? (3) How can genetic testing be used in prostate cancer screening discussions? (4) What should a man know about genetic discrimination laws before proceeding with genetic testing? (5) What additional cancer risks might be learned from genetic testing for prostate cancer? Peer health educators will be expected to score correctly on 80% or more of the questions to proceed with the intervention in Aim 3. Any areas of deficiency in understanding will be addressed by the study team in a group format or one-on-one with a peer health educator.

Participant Recruitment and Study Enrollment. MEE Productions, Inc. will develop culturally-tailored recruitment materials including flyers, posters and email blasts for CityLife Clinics to send to their AA male patients. The goal is to enroll 176 men in the study. We are anticipating a roughly 15% attrition rate over the course of the intervention, producing a final sample size for analysis of 150 men. We anticipate, based on our previous experience in community-based research, that we will have to screen about 10 times that number, or about 2000 men, to reach our study recruitment goal of 176 men. The research team will work with CityLife Clinic to mail a study recruitment letter to eligible males at their clinic, inviting them to participate. A toll-free, local telephone number will be included in the letter for men to opt-out of the study. After two weeks, any male who has not opted out will receive a telephone call from a member of the research team to screen for study eligibility. We will supplement our recruitment at CityLife Clinic by grassroots outreach in the neighborhood surrounding the clinic, to invite men not associated with the clinic to participate. We will promote the study at community recreation centers, public libraries, housing complexes and apartments, local non-profit organizations, barbershops, and employment agencies. Men who see the flyers or a member of the study team in the community can also call the toll-free, local number to screen for eligibility and participate. This is a similar approach that the study team was successful in using for the previously funded DOD study.

Study eligibility. Men who call the telephone number associated with the study or are who approached in the community will be screened for eligibility by the study research manager. Any AA male with or without prostate cancer between the ages of 35-69 will be eligible for the study. Men must speak and read English comfortably, as all study materials will be in English. Men do not need to be established patients at CityLife Clinics to participate.

Study Randomization and Informed Consent. Those who are eligible to participate will be randomized to either the intervention or the control arm. Men randomized to the intervention arm will be scheduled to attend a health education session hosted at CityLife Clinic or virtually, while men who are randomized to the control arm will receive educational materials about PCA genetic testing in the mail or in person. All men who agree to participate will be read a consent statement over the phone or in person and will verbally agree to consent to participate. A copy of the consent statement will be provided to them for their records.

Baseline Survey. All participants will complete a brief baseline questionnaire over the telephone or in person with the study manager. Items to be assessed at baseline include knowledge about prostate cancer, their personal family cancer history, knowledge of genetic testing and screening, attitudes towards genetic testing, subjective norms about genetic testing, decisional conflict about genetic testing, and intentions to seek genetic counseling. Knowledge about PCA genetics and genetic testing will be measured using a 14-item scale, recently published by the study team in a population of men undergoing genetic testing.[22] The measure for decisional conflict will be the SURE Decisional Conflict Scale, a low-literacy validated measure to screen for decisional conflict.[26] The four questions encompass the following with Yes/No responses: (1) Do you feel sure about the best choice for you? (2) Do you know the benefits and risks of your options? (3) Are you clear about which benefits and risks matter most to you? (4) Do you have enough support and advice to make a choice? Demographic data related to age, race/ethnicity, family history of prostate or other cancer, and other pertinent health information will be collected.

Study Intervention.

Intervention Arm: Men who are randomized to the intervention arm will be invited to a peer health education session, either in-person or virtually. Eighty-eight of the 176 men will be randomized to this group, and we will host sessions that attract roughly 6-8 men at a session. Our previous experience conducting peer health education sessions found that 6-8 men was an ideal attendance level, as it allowed for interaction and discussion but did not feel overwhelming. Each session will be facilitated by two peer educators, who can share responsibilities and interact with each other. We expect to offer 12-15 sessions, or roughly 1-2 sessions per month. Sessions will be scheduled at various times of the day and days of the week, to accommodate men with varying schedules and commitments. Each peer educator will be compensated for 2 hours of time to run a session from start to finish, being compensated at $20/hour.

First, the peer educator will introduce the topic of PCA, so that men understand the disease and how it relates to their health. The educator will lead a discussion regarding PCA risk, family history, PCA genetics, considerations of genetic testing, implications of genetic testing on family and self, and financial and ethical considerations. The discussion is meant to be interactive, with men sharing stories and experiences and peer educators answering questions and clarifying facts. All information will be delivered in a culturally appropriate manner by peer educators who are from the community they are serving. Immediately following the discussion, men will complete a post-survey to measure short-term changes knowledge about prostate cancer and genetic testing, thoughts about cancer, in decisional conflict about genetic testing, attitudes toward genetic testing, subjective norms about testing, and intentions to seek genetic testing. We will also get feedback on the peer-led session.

Control Arm: After providing informed consent and completing the baseline survey over the telephone or in-person, eighty-eight men will be randomized to this arm and each man will receive an educational booklet. It is expected that materials will be mailed within 24 hours of the

telephone call or provided to the participant in person. The information will cover PCA risk, family history, PCA genetics, considerations of genetic testing, implications of genetic testing on family, and financial and insurance considerations.

Endpoint Survey. All men, regardless of study arm, will complete an endpoint survey. A member of the study team will call each participant two months after either attending a peer education session (intervention arm) or being mailed the educational print materials (control arm). Previous research shows that two months is an adequate amount of time to digest the material and act upon it, if desired.[27] The majority of items on the baseline survey, except for the demographic information, will be repeated on the endpoint survey. Participants who are not reached by telephone will be contacted by mail and by email to attempt to retain the maximum number of participants over time.

Participant Compensation. Each man who participates in all study-related activities will receive $50 over the course of the study. Men in the intervention group will receive $25 for completing the baseline survey via the mail and $25 for completing the endpoint survey over the telephone at two-months post-intervention. Men in the control group will receive $25 in their mailed packet of materials after completion the baseline survey and an additional $25 for completing the endpoint survey over the telephone at two-months post-intervention.

Referral to Genetic Counseling. Men from both groups who decide they want to proceed with genetic counseling and genetic testing will be given the number to contact the Cancer Risk and Genetics Program at Sidney Kimmel Cancer Center at Jefferson, led by Dr. Giri (study PI). Once men contact the Genetics Program, an intake will be performed to determine if they meet personal or family history criteria for genetic testing. Current NCCN criteria for PCA genetic testing[8-10] include any of the following: (1) personal history of advanced or metastatic PCA, (2) family history of brother, father, or multiple family members diagnosed with PCA at age <60, (3) first-degree, second-degree, or third-degree relatives with cancers of the breast, ovary, prostate, pancreas, colon, or endometrium suggestive of a hereditary cancer syndrome. Men will then be scheduled for a genetic counseling visit to formally cover information regarding genetic testing such as how cancers can be inherited, types of genetic test results, and implications for the man and his family.[21,28,29] Once the man agrees to proceed with testing, a saliva sample will be collected and sent to Invitae, a CLIA-certified and experienced clinical genetic testing laboratory to perform multigene testing. Genes to be tested by sequencing and deletion/duplication testing will include *BRCA1, BRCA2, ATM, PALB2, CHEK2, NBN*, the DNA mismatch repair genes, and additional genes as needed. Invitae follows ACMGG guidelines for variant classification and all standard procedures for variant reclassification updates.[30] Since men in this study may be underinsured, the study will pay for the cost of genetic testing for all men who undergo genetic counseling. Once

results return, men will be called to come in for a results disclosure visit to discuss their results and answer any questions.

Assessment of genetic counseling experience. Since genetic testing of AA men is a novel field and is understudied, we will take the opportunity to survey men about their genetic counseling experience at the pre-test counseling visit and the post-test visit. We will use the Satisfaction with Genetic Counseling Scale,[31] a 6-item validated measure with responses entered on a Likert scale ranging from "Strongly Agree" to "Strongly Disagree". The questions include: (1) The provider or staff member seemed to understand the stresses I was facing; (2) The provider or staff member helped me to identify what I needed to know to make decisions about genetic testing; (3) I feel better about my health after meeting with this provider or staff member; (4) The session was about the right length of time I needed; (5) The provider or staff member was truly concerned about my well-being; and (6) The session was valuable to me.

At the post-test visit, we will also administer a survey developed regarding knowledge and understanding of genetic test results, which has previously been published by the study team in a male population undergoing genetic testing.[22] This survey includes questions about the man's genetic test results ("I was found to carry a genetic mutation" or "I was found to carry a variant of uncertain significance"), interpretation of the results ("I am at higher risk for PCA based on my genetic result" or "My children are recommended to be tested based upon my genetic result"), and sharing of genetic results with family and providers.

6.1 Specification of Safety Parameters

6.1.1 Unanticipated Problems

The research team has considerable experience in conducting behavioral interventions. A stakeholder advisory board will also provide expertise and guidance to the study team. Problems with meeting recruitment goals will be discussed among study team members, which include personnel from CityLife Neighborhood Clinic, to consider alternative approaches. A minority-owned health communication firm in Philadelphia, MEE Productions, Inc., will also be assisting the study team with recruitment and retention.

6.1.2 Adverse Events

We expect very few, if any, adverse events to occur with this protocol. Any psychosocial events that do

occur will be reviewed by the PI and addressed immediately. Corrective actions to the protocol, if warranted, will also be undertaken immediately,

6.2 Safety Reporting

6.2.1 Reporting to IRB

6.2.1.1 *Unanticipated Problems*

All incidents or events that meet criteria for unanticipated problems (UAPs) as defined in Section 6.1.1 Unanticipated Problems require the creation and completion of an unanticipated problem report form (OHR-20).

UAPs that pose risk to participants or others, and that are not AEs, will be submitted to the IRB on an OHR-20 form via the eazUP system within 10 working days of the investigator becoming aware of the event.

UAPs that do not pose risk to participants or others will be submitted to the IRB at the next continuing review.

6.2.1.2 *Adverse Events*

Grade 1 AEs will be reported to the IRB at continuing review.

Grade 2 AEs will be reported to the IRB at the time of continuing review.

6.2.1.3. *Serious Adverse Events*

SAEs will be reported to the IRB on OHR-10 forms via the electronic reporting system (eSAEy) according to the required time frames described below.

Grade 3-4 AEs that are unexpected and deemed to be at least possibly related to the study will be reported to the IRB within 2 working days of knowledge of the event.

Grade 3-4 AEs that are deemed unrelated to the study will be reported to the IRB within 5 working days.

Grade 5 AEs will be reported to the IRB within one working day of knowledge of the event.

All SAEs will be submitted to the IRB at continuing review, including those that were reported previously.

6.2.2 Reporting to SKCC DSMC

All AEs and SAEs, safety and toxicity data, and any corrective actions will be submitted to the DSMC per the frequency described in the SKCC DSMP. The report to the SKCC DSMC will also include any unanticipated problems that in the opinion of the PI should be reported to the DSMC.

Reporting to Funding Sponsor

Any adverse events will be reported to the sponsor of the study, the Department of Defense.

7 Study Oversight

In addition to the PI's responsibility for oversight, study oversight will be under the direction of the SKCC's Data and Safety Monitoring Committee (DSMC). The SKCC DSMC operates in compliance with a Data and Safety Monitoring Plan (DSMP) that is approved by the NCI.

8 Clinical Site Monitoring and Auditing

Clinical site monitoring and auditing is conducted to ensure that the rights of human participants are protected, that the study is implemented in accordance with the protocol and/or other operating procedures, and that the quality and integrity of study data and data collection methods are maintained. Monitoring and auditing for this study will be performed in accordance with the SKCC's Data and Safety Monitoring Plan (DSMP) developed by the SKCC Data and Safety Monitoring Committee (DSMC). The DSMP specifies the frequency of monitoring, monitoring procedures, the level of clinical site monitoring activities (e.g., the percentage of participant data to be reviewed), and the distribution of monitoring reports. Some monitoring activities may be performed remotely, while others will take place at the study site(s). Appropriate staff will conduct monitoring activities and provide reports of the findings and associated action items in accordance with the details described in the SKCC DSMP.

9 Statistical Considerations

9.1 Study Hypotheses

Men who are educated about PCA genetic testing by peer health educators will be less conflicted about their decision to seek genetic testing than men who receive traditional information by mail.

9.2 Analysis Plans

Decisional Conflict to Consider Genetic Testing. All study variables, such as demographics, PCA knowledge, and outcome responses, will be summarized in tables with descriptive statistics or graphically in data plots at each time they are assessed along with changes in responses over time. We will investigate imbalances in these data for potential confounding of primary and exploratory endpoint analyses and investigate disparities and intervention effect modification in various subgroups of subjects. The primary outcome is decisional conflict regarding genetic testing assessed by the 4-item SURE scale. To compute a summary decisional conflict score, the Likert-scaled responses will be averaged across the SURE item responses provided by a subject completing at least 2 of the 4 questions. The change in decisional conflict scores between baseline and endpoint at 2-months will be calculated and group means for these changes compared between subjects randomized to receive control materials vs. those randomized to receive the peer health education intervention (i.e., by intention to treat). The significance of the difference will be evaluated at the 0.05 level using a two-sided Student's t-test. The assumptions for this test will be carefully evaluated. If the changes are substantially skewed, they will be summarized with group medians and evaluated for significant differences by the nonparametric Wilcoxon's rank sum test. If concerns arise over potential confounding from imbalances in baseline covariates, we will conduct a sensitivity analysis by applying analysis of covariance (ANCOVA) to adjust the comparison for baseline imbalances, including baseline decisional conflict scores.

Descriptive and Exploratory Analyses. Exploratory analyses will include estimating the proportion of AA men meeting the NCCN guidelines for genetic testing[8,10] and computing a 95% confidence interval using the Clopper-Pearson exact method. Summary statistics and qualitative analyses will be used to assess the genetic counseling experience of those subjects accepting the offer for genetic counseling. Additional analyses will include estimating the intervention effect on genetic testing/counseling intentions and uptake, respectively, changes in attitudes toward genetic testing, and understanding of personal genetic test results using discrete variable tests, such as McNemar's test.

9.3 Sample Size Considerations

Sample Size Considerations and Missing Data Analysis. In a study conducted at Jefferson of 273 older AA subjects at risk of PCA, the SURE decisional conflict instrument showed good reliability (Cronbach's $\alpha = 0.76$) and the summary scores were 3.77±0.76, on average. A sample size of n=75 per group (N=150 total) is necessary in order to have at least 90% power to detect a difference of at least 0.40 Likert scale units (a moderate, but clinically important, relative effect size of about ½ standard deviation) in mean decision conflict between control and intervention by

a two-sided t-test with a 5% type I error rate. We plan to over-recruit to 176 men (88 men per arm) to account for ~15% expected attrition. Missing data patterns across all efficacy outcome variables over time will be evaluated and multiple imputation will be considered if the data appear likely to be missing at random. Sensitivity to missing data mechanism assumptions will be evaluated, with methods such as pattern mixture modeling, if more than 10% of data are missing for any outcome variable.

10 Source Documents and Access to Source Data/Documents

Study staff will maintain appropriate medical and research records for this study, in compliance with ICH E6, and regulatory and institutional requirements for the protection of confidentiality of participant information. Study staff will permit authorized representatives of SKCC and regulatory agencies to examine (and when required by applicable law, to copy) research records for the purposes of quality assurance reviews, audits, and evaluation of the study safety, progress and data validity.

11 Quality Control and Quality Assurance

Prior to the start of the study, a manual of operating procedures will be created to describe all study-related tasks and procedures. The study PI will be responsible for ensuring that all study staff are trained on the manual and are competent in executing study procedures.

In addition to ensuring that all study staff are trained on study procedures, it is important that the peer health educators are familiar and competent in delivering the experimental arm of the study intervention. To assess peer educator competency prior to the start of the intervention, we will adapt evaluation materials from the International Society of Nurses in Genetics 2011 Consensus Panel and survey on knowledge and understanding of PCA genetics and genetic results.[22,25] Example true/false assessment questions will include: (1) Factors such as personal behavior (diet, exercise) and environmental conditions (exposures) can raise the risk of getting prostate cancer; (2) Men with a family history of prostate cancer should also consider other factors that could raise the risk of getting prostate cancer, such as diet or exposures; (3) A family history of prostate cancer can raise the risk of getting prostate cancer; (4) Family history of additional cancers, such as breast cancer, can raise the risk of getting prostate cancer; (5) Having a history of prostate cancer on his mother's side of the family, can raise the risk of a man getting prostate cancer; (6) A genetic test can tell if someone will definitely get prostate cancer in the future; (7) Genetic testing may still be important even if a man has prostate cancer; (8) Patients with one cancer can be at risk for getting other cancers if the patient has a genetic mutation.

Additional multiple-choice questions will include: (1) What types of genetic test results can you get from genetic testing? (2) How can genetic testing be used in treatment of prostate cancer? (3) How can genetic testing be used in prostate cancer screening discussions? (4) What should a man know about genetic discrimination laws before proceeding with genetic testing? (5) What additional cancer risks might be learned from genetic testing for prostate cancer? Peer health educators will be expected to score correctly on 80% or more of the questions to proceed with the intervention in Aim 3. Any areas of deficiency in understanding will be addressed by the study team in a group format or one-on-one with a peer health educator.

12 Ethics/Protection of Human Participants

12.1 Ethical Standard

The investigator will ensure that this study is conducted in full conformity with the principles set forth in The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, as drafted by the US National Commission for the Protection of Human

Subjects of Biomedical and Behavioral Research (April 18, 1979) and codified in 45 CFR Part 46 and/or the ICH E6.

12.2 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 in the study.

12.3 Informed Consent Process

Aim 1: Informed consent will be obtained from each participant prior to the start of a focus group. Men will be presented an informed consent statement that details the purpose of the study and the roles and responsibilities of both the research team and the participant. The moderator of the focus group will review the consent statement with the participants and answer any questions that may arise. Participants may take as long as needed to read the statement and provide consent.

Aim 2/3: A copy of the consent statement will be mailed to the participants. Yet, a copy of the document will be provided to them for their records.

12.4 Exclusion of Women, Minorities, and Children (Special Populations)

Because women and children are not a risk for PCA, they will be excluded from participating in this study. We expect that the majority of our participants will be African American or Hispanic males, due to the location of the recruiting clinical site and the nature of its surrounding community.

12.5 Participant Confidentiality

Participant confidentiality is strictly held in trust by the investigators, study staff, and the sponsor(s) and their agents. This confidentiality is extended to cover testing of biological samples and genetic tests in addition to any study information relating to participants. 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 or other authorized representatives of the sponsor may inspect all study documents and records required to be maintained by the investigator, including but not limited to, medical records (office, clinic, or hospital) for the study participants. The clinical study site will permit access to such records.

12.6 Future Use of Stored Specimens and Other Identifiable Data

All data will be de-identified for purposes of analysis. Data may be used for additional analyses after the study has ended, but only de-identified data will be used for these analyses.

13 Data Handling and Record Keeping

The investigators are responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported. All source documents must be completed in a neat, legible manner to ensure accurate interpretation of data. The investigators will maintain adequate case histories of study participants, including accurate case report forms (CRFs), and source documentation.

13.1 Data Management Responsibilities

Data collection and accurate documentation are the responsibility of the study staff under the supervision of the investigator. All source documents and laboratory reports must be reviewed by the study team and data entry staff, who will ensure that they are accurate and complete. Unanticipated problems and adverse events must be reviewed by the investigator or designee.

13.2 Data Capture Methods

Aim 1: Focus group discussions will be audio recorded and transcribed verbatim by a professional transcription company. Word document files will be returned to the study team ina de-identified format.

Aim 2: Survey data will be collected by paper-and-pencil methods and entered into RedCap by a member of the study team.

13.3 Study Records Retention

Study records will be maintained for at least three years from the date that the grant federal financial report (FFR) is submitted to the Department of Defense.

Study documents must be retained for a minimum of 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or until at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents will 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.

13.4 Protocol Deviations

A protocol deviation is any noncompliance with the clinical study protocol, Good Clinical Practice, or Manual of Procedures requirements. The noncompliance may be on the part of the participant, the investigator, or study staff. As a result of deviations, corrective actions are to be developed by the study staff and implemented promptly.

All deviations from the protocol will be addressed in study participant source documents and promptly reported to the IRB and other regulatory bodies according to their requirements.

14 Study Finances

14.1 Funding Source

The study is funded by the Department of Defense, Prostate Cancer Research Program.

14.2 Conflict 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.) will have the conflict reviewed by a properly constituted 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 Jefferson University Investigators will follow the TJU Conflicts of Interest Policy for Employees (107.03).

14.3 Participant Stipends or Payments

Aim 1: Participants will be compensated $25 for attending a focus group.

Aims 2/3: Each man who participates in all study-related activities will receive $50 over the course of the study. Men in the intervention group will receive $25 for completing the baseline survey at the time of the health education session and $25 for completing the endpoint survey over the telephone at two-months post-intervention. Men in the control group will receive $25 after completing the baseline survey and an additional $25 for completing the endpoint survey over the telephone at two-months post-intervention.

15 Publication and Data Sharing Policy

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 participants 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 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. 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.

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Appendices

Study materials (surveys, consent forms, educational brochures, and recruitment materials) will be created by the study team upon the receipt of study funds and will be amended to this protocol as they become available.