

PROTOCOL

Project Title: Barbershop Talk: HIV Prevention for African American Heterosexual Men

NCT Number: NCT01980771

Date of document: 8/16/18

Project title:

Barbershop Talk: HIV Prevention for African American Heterosexual Men

Sponsor:

National Institute on Minority Health and Health Disparities (#P20 MD 006875)

Key Investigators:

<u>Name</u>	<u>Affiliation</u>	<u>Role</u>
Tracey E. Wilson, PhD	Department of Community Health Sciences	Principal Investigator
Michael Joseph, PhD	Department of Biostatistics and Epidemiology	Co-Investigator
Michael Szarek, PhD	Department of Biostatistics and Epidemiology	Co-Investigator
Yolene Gousse, DrPH	STAR Program, Department of Medicine	Project Coordinator
Marilyn White, MD	Arthur Ashe Institute for Urban Health, Inc.	Co-Investigator

Investigators for the project at SUNY Downstate include Drs. Tracey Wilson, Michael Szarek, and Michael Joseph. Dr. Wilson will serve as the Principal Investigator; she is a Professor in the Department of Community Health Sciences, School of Public Health at Downstate. She has many years of experience in the design, implementation and evaluation of HIV prevention research projects. In the current proposal, Dr. Wilson will have primary responsibility for the general management and direction of the project. Dr. Joseph will serve as a co-investigator on the project. Dr. Joseph is an Associate Professor in the Department of Biostatistics and Epidemiology; he will work with Dr. Wilson on implementation of the intervention, and analysis and dissemination of the results. Ms. Yolene Gousse will serve as the overall Project Coordinator, and Dr. Michael Szarek will serve as the biostatistician. Investigators from AAIUH include Dr. Marilyn White. Dr. White is the Chief Executive Officer at the Arthur Ashe Institute, and will co-direct the project; this includes oversight of staff and operations for the project at her site as well as working with Dr. Wilson on all aspects of program planning, implementation, evaluation, and dissemination

Project summary:

The HIV epidemic has reached a crisis state among Blacks in the United States. Blacks or African Americans account for approximately half of new HIV diagnoses annually, and the rate of new HIV infections among Black men is about six times that of white men (CDC 2011). The Centers for Disease Control and Prevention estimates that one in sixteen Black men will be diagnosed with HIV in their lifetime (MMWR 2010); this is reflected in the fact that black males have the highest HIV diagnosis rate across all race and sex categorizations (MMWR 2011). Further, among men diagnosed with HIV infection from 2005-2008, 71% of heterosexual transmissions occurred among those identifying as Black, and nearly one quarter of HIV transmissions in Black men are classified as being accounted for by heterosexual contact (MMWR 2011). Although a number of interventions have been developed to address Black priority populations such as youth, heterosexual women, and targeted populations such as drug users and serodiscordant couples, a large gap exists between the HIV prevention needs of adult heterosexual Black men and community-based programs that have been demonstrated as effective in meeting these needs.

Investigators at SUNY Downstate Medical Center and the Arthur Ashe Institute for Urban Health, Inc. have over ten years experience working together on local community based health education initiatives, behavioral interventions, and action oriented projects. More recently, the investigative team involved in this partnership has utilized community-engaged research methods to develop an intervention that seeks to reduce sexual risk behavior among Black adult heterosexual men who do not inject drugs, and which seeks to address contextual-level factors that impacts community risk. The structure for the intervention is theoretically-based, with content informed by our community advisory group, formative data collection, and feedback derived from pilot testing. The goal of this proposal is to test the efficacy of this HIV prevention program among 875 adult, heterosexual Black men. *A cluster randomized trial design will be utilized, with men recruited from barbershops in Brooklyn, NY; therefore barbershops, and not individual men, will be randomized to be a site for intervention activities, or a control site.* These barbershops are located in neighborhoods with high prevalence of HIV infection. Men will complete audio computer assisted structured interviewers (ACASI) at baseline and at three and six months following receipt of our HIV prevention program. The intervention is

consistent with the FY 2011 Trans-NIH Plan for HIV-Related Research, which has as a priority the reduction of HIV-related disparities in racial and ethnic populations, and addresses the needs of a population who bear a disproportionate burden of HIV/AIDS in the U.S., and for whom there are few effective approaches available. A critically important public health challenge is to design acceptable, sustainable HIV prevention programs that can effectively reach and serve high-risk adult heterosexual Black; the results of this study will lay the groundwork toward implementation of effective HIV prevention in this group, and will contribute to our understanding of factors that can support approaches toward behavior change and maintenance in this population.

Aims and Hypotheses:

Aim 1: To assess the impact of a linguistically and culturally tailored HIV prevention program on the HIV risk of heterosexual, African American adult men.

Hypothesis 1: Compared to men assigned to an attention control condition, those exposed to the intervention will have lower levels of sexual risk behavior at a 3 and 6 month follow-up.

Hypothesis 2: Compared to men assigned to an attention control condition, those exposed to the intervention will have improved outcomes at 3 and 6 months, on theoretically derived mediators of sexual risk behavior, including interpersonal factors such as attitudes, self-efficacy, communication skills and perceived norms around safer behavior, as well as on factors such as increased individual and community empowerment and decreased HIV-related stigma.

Aim 2: To examine individual and contextual-level factors that explain variation in the efficacy of the intervention.

Hypothesis 3: Intervention impact will be moderated by individual and contextual level-factors such as higher perceived basic needs and housing instability, incarceration and substance use history, higher perceived racism, and traditional gender role norms and attitudes, such that intervention effects will be reduced among men with these risk factors.

Project Rationale:

Blacks accounted for half (50.3%) of the HIV diagnoses in adolescents and adults in 37 states during 2005—2008 (MMWR 2011). During this time, 56.1% of HIV diagnoses were among persons aged 25-44 years; in this age group, blacks accounted for 46.4% of HIV diagnoses (MMWR 2011). In 2008, among males and females of all racial/ethnic populations, black males had the highest HIV diagnosis rate (131.9 per 100,000) (CDC 2011), and it is expected that 1 in 16 Black men will be diagnosed with HIV in their lifetime (MMWR 2010). Further, while trends in HIV diagnoses reveal relatively stable rates of HIV diagnoses by racial/ethnic and sex group, these rates continue to increase among Black men (MMWR 2011). Nearly a quarter (23%) of HIV transmissions in black males are classified as being accounted for by heterosexual contact (MMWR 2011). There have been significant contributions to our understanding of the predictors of HIV risk among African Americans as it relates to populations of injection drug users and men who have sex with men. There have also been impressive inroads made into understanding factors related to Black women's heterosexual risk behavior and the behaviors of youth. Significantly less is known, however, about how to address the risk behaviors of heterosexual African American adult men and about the individual and contextual factors that put these men at risk for HIV infection. As such, there is a large and unacceptable gap between the prevention needs of these men and the number and quality of prevention programs demonstrated to meet these needs. Despite the need for effective risk reduction approaches, few resources exist to help reduce HIV/AIDS risk among African-American heterosexual men who do not inject drugs and who are at risk primarily due to unprotected sex with multiple or concurrent sex partners of the opposite sex. In response to this need, our investigative team has spent the last several years conducting community-based, formative research in the service of intervention development with and for heterosexually-active African-American men recruited from barbershops located in urban, low-income areas with high HIV morbidity and mortality. In this proposal, we seek to examine the effectiveness of this program, *Barbershop Talk*.

Methods

The *Barbershop Talk* intervention program.

The purpose of this study is to test the efficacy of the *Barbershop Talk* program. Clients who are eligible and who consent to participating in the intervention and corresponding evaluation will engage in the program, which takes approximately up to two hours to complete. The session is broken down into three parts, which are called “wake up”, “gear up”, and “stand up”. In the “wake up” module, participants are oriented to the program objectives and ground rules for the program, and discuss the theme of the module, which is to wake up to the “fire” of local community health problems; this metaphor seeks to demonstrate to men how their natural inclination to take care of others (i.e., how they would react if they witnessed a fire on their block) can be applied in the service of other, less visible problems. During this module, participants engage in discussions of how they see health and what it means to be a healthy man in our society, and an exploration of how definitions and conceptualizations of masculinity impact men’s health behaviors. Discussions of health also focus on social health and networks, and how men can comfortably work within their networks to improve community health. The overall purpose of this first module is to promote community engagement and motivation to engaging in health promotion with men and women in the participant’s social network. During this module we discuss input that we received from our formative work regarding men’s ability and motivation to address health, and discuss a movement in Brooklyn toward control of our own health. The “gear up” module introduces another “fire” – that of HIV. This module utilizes methodologies that have been shown to be standard components of effective HIV interventions, but that are grounded in our formative research and which speak specifically to local concerns and beliefs surrounding condom use, HIV testing, and HIV transmission. These methodologies including educational information, and attitudinal arguments meant to promote positive attitudes toward safer sex and HIV testing, and behavioral skills surrounding condom use (Albarracin, Gillette et al. 2005). This module addresses the local epidemiology of HIV/AIDS, highlighting the burden of heterosexually transmitted infection in the area, includes a discussion about the role of community stigma as a barrier to effectively battling HIV/AIDS, involves a discussion and demonstration surrounding which types of condoms to use and how to use them properly, and includes a myths and truths discussion, in which we address population specific beliefs that came up during the formative work (e.g., anal sex between men and women does not convey risk of HIV transmission; all heterosexual transmissions are the result of men lying about their actual drug use or same sex behavior; a ‘quickie’ without a condom does not put you at risk for HIV, women have physical characteristics that allow you to ‘see’ their HIV status). As part of this module, and congruent with social cognitive theory, men are asked to develop and commit to a step toward behavioral change that they could take to reduce their risk of HIV or that could help reduce risk for someone they know. The third module, “gear up” is about preparing to take what was learned in the intervention and sharing it with sexual partners and others in the participant’s social network. This component of the intervention focuses on developing skills in communicating effectively with sexual partners and with others in the community about HIV risk and protection and the development of a social action plan by which to assist others in learning the information conveyed in the intervention. The majority of the time spent in this last module focuses on developing ‘conversation skills’ around HIV, in which we provide feedback and exercises on ways to communicate effectively. This component spends most of its time working through a number of role play scenarios, which were based on stories of risk that were presented during our formative work. These involve varied physical and emotional contexts of risk, including sexual risk as a function of emotional motivations (anger, loneliness), high risk interactions (sexual pressures from female partners to not use condoms, a theme which came up frequently in our formative work), and high risk settings (when there is limited perceived ‘time’ or ‘opportunity’ to have sex, in clubs, etc.). Participants will be provided \$20 to complete the *Barbershop Talk* program; the program takes about two hours to complete.

Study design and sample size:

The *Barbershop Talk* program will recruit from barbershops, and seeks to leverage the naturally occurring social bonds and networks within barbershops to effect change in HIV-related risk behavior. Although the unit of analysis for the program evaluation is at the individual level, the focus on social relationships and empowerment approaches to building community capacity in the intervention make randomization at the individual level challenging. The nature of our program is such that we seek for participants to reach out within networks to discuss HIV, and barbershop-linked networks of friends and neighbors would be a naturally occurring social network. There exists, therefore, a risk for contamination between intervention and control participants who are recruited within individual barbershops. In order to minimize this risk, we have chosen to use barbershops as the unit of randomization. Program staff will conduct observations of shops and interviews

with staff in order to assess these conditions. Participating barbershops will know in advance of agreeing to work with us that clients will be eligible to receive some form of health education, but that the process of deciding which intervention takes place in the shop is determined via a process of random assignment. We will work with shops to develop a memorandum of agreement in order to establish clear expectations of what will happen in each shop. Shops will be randomized after our list of eligible barbershops is compiled.

The sample size calculation is based on the expected percent of men engaging in high risk behavior after 6 months of follow-up, accounting for the intraclass correlation coefficient (ICC) and estimates of unprotected sex estimated from our pilot dataset of 105 participants from four barbershops. Unprotected sex, defined in this example as two or more sexual partners in the past three months plus at least one episode of unprotected vaginal or anal sex, was reported by 42% of our sample in a previous pilot study of the program. Assuming that 42% of the participants in the control group would engage in high risk behavior, an ICC of 0.03, and a minimum of 23 participants from each barbershop, the study has 80% power to detect an absolute reduction of 12% (relative reduction of 29%) in rates between the two groups with alpha=0.05, two-tailed and 15 barbershops for each intervention group (i.e., 30 clusters and 690 total participants). In order to achieve a sample size of 690 at the six-month follow-up, we estimate that we will need to recruit 875 men in order to account for a loss to follow-up as high as 20%.

Participants:

Inclusion criteria include men age 18 or older who report two or more partners in the past six months, unprotected sex with a woman in the past six months, and identify as Black or African American. Exclusion criteria for participation include (1) having been in an HIV prevention research study in the last six months, (2) reporting a history in the past five years of injection drug use, (3) reporting a history in the past five years of having sex with other men, (4) reporting an HIV-positive serostatus, or (5) inability to understand spoken English. In order to ensure that our program meets the needs of a unique and understudied population, we have chosen to exclude men with an injection drug use history or who report same sex behavior, given that interventions have been developed for these populations and that the behavioral risk and determinants of risk are unique to these subpopulations. However, it is recognized that the very nature of being on the 'down low' would necessitate that some men who engage in same-sex relationships may not report this behavior and be included in the sample. Similarly, the stigmatized nature of injection drug use may be linked to underreporting during our screening and evaluation procedures. The risk in this scenario is that inclusion of men who for whom intervention messages are not tailored could dilute differences between the experimental and control group, but would not cause harm. We note that although we focus on men who identify as Black, some men will also report Latino ethnicity; these men will not be excluded from the study, as reflected in our planned enrollment table. However, given that our program is being completed in barbershops serving African American men, the vast majority of potential enrollees will be English-speaking. During a pilot test of the Barbershop Talk program, we found that of over 100 men who completed a screener, all were able to understand English. While this does not negate the fact that some non-English speaking men may have been less likely to agree to screener, it does speak to the project team's view that translation of all intervention sessions and evaluation measures would not be a worthwhile use of funds given that we are unlikely to be able to have a large enough number of non-English speakers in the sample to be able to draw conclusions about effectiveness in these sub-groups, and that the program was not tailored to what are likely the unique needs of men who are non-English speaking.

Recruitment procedures:

Recruitment will take place in barbershops. Customers will be introduced to study staff by their barber and asked whether they would be willing to meet with our research assistant to complete screening for the study. Given that we will be attempting to enroll all eligible customers within a recruitment period, we anticipate that enrollment at each barbershop will be approximately proportional to the size of that venue's total client pool. The research assistant will describe the study, and assess eligibility via an ACASI screening form with a privacy screen attached. All eligible participants who are interested in participating will provide individual, written, informed consent written at a level appropriate to our priority population. After receiving the information on the Consent Form appropriate for the barbershop condition, the potential participant can direct any additional questions or clarifications to the research assistant. Those who agree to join the study will sign the consent form and will be given a copy for their records, and will complete a locator form. Following the consent

procedure the participant will complete an ACASI administered baseline assessment, and will be provided study activities congruent with the experimental arm assigned at that barbershop. To reduce self-report bias, project staff responsible for recruiting and administering evaluation assessments do not administer intervention activities, and staff administering intervention activities do not administer assessments to those clients. The consent form is written at a Flesch-Kincaid grade level below 8.0.

Program Evaluation:

Audio Computer-Assisted Self-Interview (ACASI) will be utilized to collect self-reported data at baseline (pre-intervention) and also at 3- and 6-month follow-up from the date of completion of the *Barbershop Talk* program. Respondents will listen to headphones and questions will be provided by a recorded voice stored in computer memory. The responses will be entered by pressing on the computer's touchscreen. A privacy screen will be utilized so that other barbershop customers cannot view responses, and headphones with disposable covers will be used so that respondents can listen to questions and answer options. Prior to baseline questions being administered, participants will complete a series of 'warm up' practice items. During our formative work, we piloted the recruitment, screening, consent and baseline procedures described in this project on 78 men and have found them to be feasible to implement, acceptable to barbershop personnel and clients, and a sound method for maintaining privacy and confidentiality. Additionally, at the 6-month interview participants will be asked to complete an additional set of questions to help identify the need for future programs. These final questions will be administered by a study staff in an interviewer led format. Questions 1-3 of the questionnaire pertain to existing knowledge about PrEP, and interest to receive more information about PrEP. In conjunction with these questions, study participants will be offered a PrEP brochure to increase their knowledge about HIV prevention. For question #4 of the interview a response card will be handed to study participants to facilitate the selection of their answers to that question. Participants will be reimbursed at \$20 for the baseline interview, \$30 for the three month follow-up assessment, and \$40 for the six month follow-up assessment, which is reasonable considering the length of the interview, and is in line with typical reimbursement levels for other HIV prevention program evaluations. The evaluation instruments will take approximately forty minutes to complete. All measures described in the following section have been selected based on their established reliability and validity in published HIV prevention studies and with adult African American populations.

All measures included in the program evaluation have been selected based on their demonstrated reliability and validity in published research and in our own previous work in populations similar to the men in this study; we will pilot the instrument prior to administration. To examine hypothesis 1, our main outcome measure will be a composite measure of the proportion of respondents who report two or more partners in the last six months and report unprotected sex during this time. This outcome, which was reported by over 40% of our population in our formative work, is a more informative marker of risk than some other outcome measures used in HIV prevention trials (e.g., any unprotected vaginal or anal sex) in that it helps to differentiate persons engaging in unprotected sex in the context of a single monogamous partnership, versus those who are at higher risk for HIV infection. Other measures of risk will include (1) partner concurrency, (2) number of sexual partners, (3) condom use consistency, and HIV testing. Behaviors will be assessed over the previous three months. Of course, self-report measures of sexual risk behavior are prone to self-report bias as individuals are likely to inflate or deflate their responses based on factors such as gender norms around sexual behavior. However, we will engage in a number of activities to promote honesty in responses by (1) assuring men of the confidentiality of their responses and explain the system that will be used to ensure this, (2) stressing the importance of honest answers to the scientific integrity of the project and for informing community health, (3) and using ACASI. Responses on this measure will be correlated with measures such as sexual behavior and drug use to provide an estimate of the extent to which this bias contributes to scores. Often, clinic-based interventions are able to collect data on more 'hard' outcomes, such as STD rates. The ability to power these studies is based on the fact that participants at baseline typically have and are treated for STD, and that there are known and substantial risks for 'repeat' infections in the control group. In our study, however, it would neither be feasible to conduct STD testing, nor acceptable to do so in the context of a community-based study involving barbershops. As described in our second hypothesis, our intervention is designed to directly influence a set of theoretically derived variables, which in turn are expected to influence sexual risk. These mediating variables include intrapersonal variables such as condom use and HIV testing attitudes, self-efficacy, and subjective norms, as well as perceived skills in communication and negotiation skills around safer sex. These measures are typically ordinal in nature but analyzed as having interval level properties measures

(e.g., attitudes are assessed with a 7-point bipolar response formats anchored by extremely unfavorable to extremely favorable). We will follow a well-defined methodology for ensuring that relevant domains of these cognitive factors are assessed, and that the scales used with these items are psychometrically sound. In addition to these variables, we will also assess variables related to personal and community empowerment developed by Barbara Israel and colleagues (Israel, Checkoway et al. 1994), and we will assess HIV-related stigma using a widely implemented scale (Herek 2002; Herek, Capitanio et al. 2002; Darrow, Montanea et al. 2009). We will include an assessment of HIV transmission knowledge via the HIV-K-Q 18 (Carey and Schroder 2002), which will be supplemented with information about misconceptions related to HIV transmission derived from our formative work. Finally, we will assess the extent to which participants report speaking with anyone about HIV in the last 30 days. Those who respond yes will answer questions on who they spoke with, and about the specific topics covered and the frequency of conversations. There are a number of variables that we will also assess to determine generalizability of our study findings for adult heterosexual Black men. These moderator variables are 'in place' prior to program implementation and are not experimentally varied, and are the focus of our third hypothesis. In our intervention, potential moderators include drug use history, whether the respondent is U.S. born, gender role attitudes, substance use, incarceration history and housing stability, perceived racism, social support, and basic needs. Drug use severity will be assessed via the frequency of drug and alcohol use section of the Addiction Severity Index. These questions provide information on the specific type of drug use and the current/recent frequency of use, which is helpful for assessing severity and have been found to be valid and reliable indicators of severity of drug use (McLellan, Luborsky et al. 1985; McLellan, Kushner et al. 1992). Current frequency of depressive symptoms will be assessed via the PHQ-9. Lifetime history of criminal justice involvement will be assessed, as well as perceptions of unmet basic needs as an indicator of personal economic strain, perceived racism, and indices of male norms. The evaluation instrument is written at a Flesch-Kincaid grade level below 8.0. To help keep information about you confidential, we have obtained a Confidentiality Certificate from the U.S. Department of Health and Human Services (DHHS). This Certificate adds special protection for the research information about you.

Intervention implementation:

Interventionists will be centrally trained using a standardized protocol developed by the principal investigator regarding appropriate techniques of group facilitation. At each barbershop, the intervention will begin with the training of barbershop staff and owners. Barbers will be paid \$40 for participation in the training, to compensate them for time spent away from clients. We recognize that all barbers may not be willing to participate in the training, and will monitor this as part of our evaluation procedures. Once barbers are trained, we will begin recruitment of participants. Intervention activities will take place at various locations central to and within sites of recruitment. Because the intervention involves personal information shared in a group format, we cannot hold program activities when other customers are in the barbershop. For these weekend sessions, we will hold activities in the AAIUH or SUNY Downstate, or we will rent space at a restaurant or other centrally located space. Trained study staff will implement the intervention; intervention staff will be independent from evaluators for the program. Participants will be provided with a nominal provision of \$20.00 USD for attendance at the program; this will be provided to both intervention recipients and those in the attention control group. The decision to provide this amount was based on discussions with our study team; who felt that participants are giving their time to participate in a study protocol with no guarantees of improving their health, and that if the program is effective, the amount may be low enough to make implementation feasible with some additional fiscal support. The scheduling and completion of intervention sessions and study interviews will be logged by date, visit number, and completion status; this information will be used to track monthly and cumulative accession and accrual rates.

Control group:

Although a classic randomized control trial involves comparison of persons who receive versus who do not receive an intervention, this conceptualization of a control group can be viewed as an unfair use of resources among population members who have been traditionally underserved in research and who distrust the research paradigm based on historical abuses. From the academic perspective, some scientists also believe that control groups should be similar in terms of the amount and nature of time spent with participants in intervention and control groups in order to improve the internal validity of conclusions. In response to these concerns and in consultation with our team, we are including a time and attention control group. All

participants assigned to the group will be scheduled to receive a curriculum focused on prostate cancer detection. This curriculum has several key advantages. This intervention was developed by the Arthur Ashe Institute in order to address racial/ethnic disparities in prostate cancer mortality, was constructed based on input from the communities that are the focus of the *Barbershop Talk* program, was demonstrated to be feasible and acceptable to implement, and produced changes in knowledge and attitudes among men with similar sociodemographic characteristics as those in our study sample (Fraser, Brown et al. 2009).

Data management:

Evaluation assessments will take place via ACASI, with all other data forms (e.g., locator, enrollment, contact logs, and final interview questions) completed manually. For the linked baseline, 3, and 6 month assessments, we will assign each study participant a unique study identification number and their name and study ID number will be linked on a Locator Form (which will provide detailed contact information for follow-up, and will help reduce the of participants enrolling more than once), on an Enrollment Log (which will provide date and location of enrollment and scheduled interviews), on a Contact Log (which will document contacts of the client with data collection staff) and in the local data management system. Locator Forms, Enrollment Logs, signed Consent Forms, and Contact Logs will be kept in locked file cabinets in a locked office in SUNY DMC. Data transmission will be tracked and monitored by the project coordinator. ACASI interview data will be encrypted during the ACASI interview as information is captured and saved on the computer's hard drive, which will be transmitted to the project coordinator daily. Computer programs will be developed to check data completeness and consistency. Each system file will have its own system dictionary containing variable names, labels, valid code values and labels and missing data definitions. The SUNY IS Division performs nightly automated backups on a Digital Linear Tape system. In addition, once each month a complete backup tape is made for offsite storage. All data stored on the servers are password protected and encrypted.

Data analysis:

Statistical analysis will be performed by SAS version 9.2 (SAS Institute, Cary, NC). The primary analysis method for study outcomes to test the main effect of the *Barbershop Talk* intervention will be generalized estimating equations (GEE) models, accounting for the cluster randomization. A logit link function will be specified for binary outcomes (including the primary outcome of engaging in high risk behavior after 6 months of follow-up) while a identity link function will be specified for continuous outcomes. The effects of mediating and moderating variables will be tested by appropriate modeling methods (Jaccard, Turrissi et al. 1990; Shrout and Bolger 2002; MacKinnon, Fairchild et al. 2007). Generalized mixed effects models, treating barbershop as a random effect, will also be fit as sensitivity analyses. All statistical tests will be at the 5% (two-tailed) significance level for main effects and at the 10% (two-tailed) significance level for interactions, with no adjustment for multiple testing.

Timeline:

This is a five year study. We will spend the first six months of the study working with our community advisory board on issues of protocol development, on development and production of high quality graphics for the program, on training of study staff, on securing of IRB approvals for the work and recruiting barbershops. Given our past experience in the barbershops, and our recruitment goal of 875 men, we anticipate that we will enroll participants at the rate of 20-25 per month over a forty-two month period. This would carry our follow-up period through to month six of year five. In the last six months of year five, we will engage in data cleaning and analysis, and dissemination of research findings.

Human subjects considerations:

We are applying for a federal Certificate of Confidentiality for this study, and will submit an amendment when the Certificate is obtained. Some potential risks for studies involving reduction in HIV-transmission behaviors include possible mild psychological distress at reflecting upon and being asked questions related to sexual behavior and other potentially stigmatizing factors. This possible distress is likely to be experienced for only a brief duration, that is, during the interview or discussion. This risk is expected. To minimize the potential psychological risks for participants, we will ensure that a) study staff are fully trained to deal with emotional responses to difficult questions or issues that are brought up and b) that appropriate referrals for treatment with a social worker or some other mental health provider are available to the respondent should he or she require support following any phase of study participation. Interviewers will report to the Project Director and Principal

Investigator any instances in which participants experience psychological discomfort so that we can determine adverse event status. Additionally, there is some risk that during the brief risk assessment, other customers at the barbershop will be able to observe responses to the brief risk assessment that are being entered into the ACASI. To the extent possible, participants will complete the ACASI in a setting in which other customers will not be able to view these entries, and a privacy screen and headphones are used so that others cannot view information on the screen nor hear the questions being asked of the participant. If a private setting is not available at the time of the brief risk assessment, we will ask participants to sit with the computer screen away from other customers (e.g., in a corner). Another possible risk is that information discussed in the group setting of the intervention could be provided to others by another participant outside of the group session. If information is of a personal nature, then it could cause potential harm. We will work within groups to set parameters for participation, including the importance of keeping all group discussions confidential, and discussion of the fact that participants should not divulge information in group settings that could harm them if it was released outside of the study. Participants will be informed that they can refuse to discuss any issues that they feel uncomfortable discussing. If participants are injured by being in this study, emergency care will be available; however the participant's medical insurance will be billed. SUNY Downstate Medical Center and the Arthur Ashe Institute do not have a policy to pay participants if they are injured by being in the study.

All data will be collected specifically for research purposes, and no data collection will take place until all protocols are approved and while approval is active. All participants will be recruited within the barbershops identified and recruited by the program team. Individuals within barbershops who are eligible and who are willing to learn more about the study will meet with a member of the study staff who will review all aspects of the study goals, the extent of participation, risks and benefits, and will provide an explanation of how confidentiality will be ensured. To participate, clients must first provide informed consent for all aspects of study participation and sign an IRB-approved consent form. A signed copy of the IRB approved consent form will be provided to the participants. The risks and benefits of study participation will be fully explained. The consent form includes information on purposes and procedures, risks and benefits, confidentiality, participant rights for participation, refusal and withdrawal, contact information, and other relevant information as required by federal regulations and our local Institutional Review Board.

Following enrollment, each study participant will be assigned a unique study identification number and their name and study ID number will be linked on the participant's Enrollment form, and in the local data management system in an encrypted file. The link is necessary in order to schedule follow-up assessments following the baseline assessment. The Locator Form, Enrollment forms, signed Consent Forms, and Contact Logs are kept in locked file cabinets in a locked office in SUNY-DMC. While in the field, participants will keep all signed consent forms on their person in a shoulder bag until they are secured at Downstate. All study participant data will be identified only by study ID numbers. A study investigator will review all of these forms at the time of enrollment and throughout each participant's time in the study and will ensure that consent forms are signed and dated by the participant and the research assistant responsible for overseeing the consent process. Due to the sensitive nature of some of the questions asked in the interviews it is possible that any breach of confidentiality could result in stigma or damage to reputations. The investigators will take numerous steps to minimize the possibility of breaches of confidentiality. We will ensure that data collection efforts take place in as private an area as possible. For quantitative interviews, participants will listen to questions via headphones, and computer screens used with A-CASI will not be visible to other study personnel, participants, or bystanders. Each study participant will be assigned a unique study identification number and their name and study ID number will be linked on the participant's Locator Form, in the Enrollment form, and in the local data management system in an encrypted file. The Locator Form, Enrollment forms, signed Consent Forms, and Contact Logs are kept in locked file cabinets in a locked office in SUNY-DMC. All study participant data will be identified by study ID numbers only. For all phases of the study, a number of steps will be taken to ensure participant confidentiality. Specifically, we will: (1) keep all files in locked offices, (2) use only code numbers to identify this information and remove all identifiers on patient records, (3) keep the key that links numbers to names in a locked file, and (4) obtain informed consent from each study participant. All study procedures will adhere to federal guidelines regarding patient confidentiality. Study participants' Identifiable Health Information (IIHI) will be retained/available for reporting until January 2022; five years after the end of the study, and may be shared with the following persons or agencies for purposes related to the conduct of the research: 1) The

sponsor(s) of the study: The National Institute of Health (NIH); 2) The Institutional Review Board of SUNY Downstate Medical Center and the applicable DMC officials and staff who supervise the way research is done and run the business operations; 3) The research team for this study; and 4) The collaborating research agency, namely Arthur Ashe Institute for Urban Health.

The locator form, contact log, and enrollment form will be kept until the evaluation is completed, after which time they will be destroyed. At that time, we will also electronically shred the computer file linking the names and ID numbers. Laptop computers used to collect ACASI data will be protected during transport through the use of locked padded cases which will remain with the interviewers at all times. Data collection will occur in the barbershop; follow-up evaluations may also take place within a private space at SUNY Downstate. In summary, this is a low risk study, conducted in an area of elevated HIV risk. All participants, whether assigned to the intervention and control will receive some health education, but the question of the effectiveness of the intervention program on reducing sexual risk behavior is not known. Based on program elements, it is our hypothesis that the program will produce changes in skills and motivation for safer sex, in community and personal empowerment, and in interpersonal communication skills, but similarly this cannot be guaranteed.

References

Albarracin, D., J. C. Gillette, et al. (2005). "A test of major assumptions about behavior change: a comprehensive look at the effects of passive and active HIV-prevention interventions since the beginning of the epidemic." *Psychol Bull* **131**(6): 856-97.

Carey, M. P. and K. E. Schroder (2002). "Development and psychometric evaluation of the brief HIV Knowledge Questionnaire." *AIDS Educ Prev* **14**(2): 172-82.

CDC. (2011). "Diagnoses of HIV Infection and AIDS in the United States and Dependent Areas, 2009." *HIV/AIDS Surveillance Report, Volume 21* Retrieved March 21, 2011, from <http://www.cdc.gov/hiv/surveillance/resources/reports/2009report/>.

CDC. (2011). "HIV in the United States." Retrieved March 23, 2011, from <http://www.cdc.gov/hiv/resources/factsheets/us.htm>.

Darrow, W. W., J. E. Montanea, et al. (2009). "AIDS-related stigma among Black and Hispanic young adults." *AIDS Behav* **13**(6): 1178-88.

Fraser, M., H. Brown, et al. (2009). "Barbers as lay health advocates: Developing a prostate cancer curriculum." *Journal of the National Medical Association* **101**(7): 690-697.

Herek, G. M. (2002). "Thinking about AIDS and stigma: a psychologist's perspective." *J Law Med Ethics* **30**(4): 594-607.

Herek, G. M., J. P. Capitanio, et al. (2002). "HIV-related stigma and knowledge in the United States: prevalence and trends, 1991-1999." *Am J Public Health* **92**(3): 371-7.

Israel, B. A., B. Checkoway, et al. (1994). "Health education and community empowerment: conceptualizing and measuring perceptions of individual, organizational, and community control." *Health Educ Q* **21**(2): 149-70.

Jaccard, J., R. Turrisi, et al. (1990). *Interaction effects in multiple regression*. Newbury Park, CA, Sage.

MacKinnon, D. P., A. J. Fairchild, et al. (2007). "Mediation analysis." *Annu Rev Psychol* **58**: 593-614.

McLellan, A. T., H. Kushner, et al. (1992). "The Fifth Edition of the Addiction Severity Index." *J Subst Abuse Treat* **9**(3): 199-213.

McLellan, A. T., L. Luborsky, et al. (1985). "New data from the Addiction Severity Index. Reliability and validity in three centers." *J Nerv Ment Dis* **173**(7): 412-23.

MMWR (2010). "Estimated lifetime risk for diagnosis of HIV infection among Hispanics/Latinos --- 37 states and Puerto Rico, 2007." *MMWR Morb Mortal Wkly Rep* **59**(40): 1297-301.

MMWR (2011). "Disparities in diagnoses of HIV infection between blacks/African Americans and other racial/ethnic populations--37 states, 2005-2008." *MMWR Morb Mortal Wkly Rep* **60**(4): 93-8.

Paulhus, D. L. (1984). "Two-component models of socially desirable responding." *Journal of Personality and Social Psychology* **46**(3): 598-609.

Radloff, L. (1977). "The CES-D scale: A self-report depression scale for research in the general population." *Applied Psychological Measurement* **1**: 385-401.

Shrout, P. E. and N. Bolger (2002). "Mediation in experimental and nonexperimental studies: new procedures and recommendations." Psychol Methods 7(4): 422-45.