

SUPPORTING STATEMENT B:

Critical Thinking and Cultural Affirmation (CTCA): Evaluation of a Locally Developed

HIV Prevention Intervention

New OMB Application

OMB No. 0920-NEW

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B. Statistical Methods

1. Respondent Universe and Sampling Methods

Respondent Universe

The respondents providing the information for the proposed project are African American MSM (AAMSM) ages 18 to 55 years, residing in Chicago, IL. Estimates of the respondent universe of AAMSM, ages 18 to 55 years, residing in Chicago range between 8,000 and 14,000. The number of eligible participants we expect to enroll (n=438) thus represents 3-5% of all potentially eligible men making up the respondent universe in Chicago.

Overview of Sampling Method

During the enrollment period, CTCA recruiters/study staff will use convenience sampling methods to recruit potential participants for the randomized control trial (RCT) through a variety of community venues, using both active (i.e., venue outreach) and passive (i.e., referral, flyers/handcards) recruitment techniques.

Through our venue- and referral-based sampling method (described below), the study will target the African American MSM (AAMSM) populations that are demographically, geographically, and behaviorally diverse and those men at high risk of contracting or transmitting HIV/AIDS. Particular emphasis will be given to recruiting males engaging in homosexual and bisexual activity who do not identify as homosexual or bisexual, or who identify as heterosexual; males who engage in sex in public places, exchange sex for drugs or shelter; and males who have been incarcerated. However, men with these characteristics will not be specifically targeted. They are simply characteristics that we expect will describe some of the men enrolled in the study. The study will include AAMSMs who are either HIV positive, negative, or unknown, based on self-reports. The mix of transmission modes not only poses great risks of HIV infection for the target groups but also, through the many secondary infection channels (heterosexual transmission, prostitution) to the community at large.

The sample size will be 438, with 219 men to be randomly assigned to the CTCA treatment group and 219 into a waitlist-control group, which will not receive the intervention, only the basic men's health and wellness messaging. The men in the treatment group will be exposed to the CTCA intervention, while men in the treatment and control group will both receive men's health and wellness promotion messages twice monthly by the participants' preferred method of contact (text, voicemail, and/or Facebook, etc.). Following the 6-month follow-up assessment, men randomly assigned to the control group will be offered CTCA through the Black Men's Xchange agency.

We plan to complete approximately 20 clusters with, on average, 22 people in each cluster. Each cluster includes one intervention group and one comparison group with a median of 9 men randomized into each arm. The minimal intervention group size per cluster will be 8 and the maximum will be 15.

1. Randomization will occur at the consent and ACASI visit and will be in groups of 16. Once men have gone through consent and ACASI, they will be randomized, during the same visit, using the following procedure.

2. The numbers 1-16 will be placed on 16 different envelopes.

3. We will use Research Randomizer (<http://www.randomizer.org/form.htm>) to randomly select 8 sets of 2 numbers per set. 8 sets of 2 persons per set means that we will assign 16 persons in total, 8 to cluster A1 and 8 to B1 (This is why I said we will randomize in groups of 16). The “1” subscripts on the letters refer to the first group of sixteen men. Other groups of sixteen men will also have a subscript assigned to their clusters (e.g., A2 and B2, A3 and B3, etc., depending on when they were randomized). Since Research Randomizer assigns numbers not letters, if it assigns a “1” to a man, this will correspond to cluster A_n and a “2” will correspond to cluster B_n (Here “n” refers to the randomization group, that is the first sixteen men, the second sixteen, or whatever). The output from Research Randomizer will be 8 blocks of numbers. The first block will contain p₁ and p₂, the second p₃ and p₄, the third p₅ and p₆, and each subsequent block will contain p_n and p_{n+1} up to the final block which will contain p₁₅ and p₁₆. Each of the “p” numbers in a given block will have had either a 1 (cluster A_n) or 2 (cluster B_n) assigned to it by Research Randomizer. For example, the first block might have p₁ = 1 and p₂ = 2, the second block p₃ = 2 and p₄ = 1, the third p₅ = 2 and p₆ = 1, etc. The cluster assigned to p₁ will be placed in the envelope with the number 1 on it, the cluster assigned to p₂ will be placed in the envelope with the number 2 on it, etc. Once this is done, the envelopes will be placed in numerical order from 1 to 16. This means we will have 16 envelopes alternating between cluster A_n or cluster B_n assignment. Men will be given a numbered envelope that corresponds to the order in which they arrived. Once this is done, 8 men will have been assigned to cluster A_n and 8 to cluster B_n.

4. Once men have received their envelopes with their cluster assignments, we will inform them regarding whether they have been assigned to the treatment or control arm. This latter assignment will be done in the following way. Before the men arrive, we will have used the statistical package R to assign men in cluster A_n to either the treatment or control arm. R will be programmed to generate a random integer between the integers 1 and 10 inclusive. If this integer is even, men in cluster A_n will be assigned to the treatment arm. If this integer is odd, men in cluster A_n will be assigned to the control arm. Men in cluster B_n will be assigned to the arm opposite that to which those in cluster A_n have been assigned. For each man we will record both his cluster and arm assignment.

5. Steps 1-5 will be repeated 28 times until we have attained an overall sample size of 438 men.

Sample Size Justification

The aim of the study is to determine the preliminary efficacy of the CTCA intervention. The design and sample sizes reflect this consideration. The sample size for each study is based on statistical power calculations. Further detail about statistical power is presented below.

Response Rates

We expect to approach and prescreen over 1,000 black men to determine their eligibility for the study. We expect between 45-50% of those approached to not be eligible or not be interested in participating in the study. Based on this assumption, we have estimated the eligibility and participation rate of those who complete full screening for this study to be approximately 85%. Thus, we will complete full-screening at least 515 men to achieve a sample size of 438. Recruitment of 438 participants will allow for a ~20% attrition rate resulting in a total of 350 participants to be included in the RCT's outcome analyses for a six-month follow-up measurement.

Sample Size Calculations

We used the Fisher's Exact Test to assess proportional differences between groups in rate of reduction for any unprotected anal intercourse (UAI, regardless of insertive/receptive or primary/casual partners) with another man. Assuming a background prevalence rate for any UAI among MSM of 45% (the reference proportion of .45 is based on a previous study of AAMSM in New York City; (Wheeler, Lauby, Liu, Van Sluytman, & Murrill, 2008), this study requires a sample size of 175 participants for both the treatment arm and the comparison arm for a total of 350 participants at follow-up. With 350 participants at follow-up we should expect to have adequate power ($\geq 80\%$) at a 95% confidence level to detect differences across groups if the intervention group achieves at least a 15% proportional difference in any UAI compared to the control group at follow-up (based on effect size of previous study assessing any UAI among AAMSM; (Wilton, Herbst, et al., 2009). Assuming a 20% attrition rate, we will need a total sample size of 438, and will randomly assign 219 of the 438 men into the CTCA treatment group and 219 into a standard of care control group.

2. Procedures for the Collection of Information

Training for Study Personnel

All study personnel will receive appropriate training to conduct RCT research activities, including instruction in facilitating CTCA group sessions, fidelity/quality assurance, participant recruitment, informed consent, randomization procedures, and outcome data collection (i.e., baseline and follow-up ACASI administration). Master trainers who are involved in quality assurance activities will complete a 5 day training course, and at the conclusion, they must successfully complete a comprehensive written final exam, complete all in class exercises and successfully conduct an assigned CTCA presentation class. CTCA recruiters/study staff who conduct recruitment activities in both physical (community) and virtual (Internet) venues will be specifically trained to screen potential participants for eligibility and to provide information about the purpose, procedures, risks and benefits of the CTCA project. Topics covered in study-related trainings will be included in an Operations Manual to describe details of study procedures. All project staff will keep personal information confidential, including self-reported HIV status. Confidentiality and scientific ethics will be covered during staff training to emphasize the importance of the issue. All staff will complete NIH human subject protection training. The Co-PIs will have the responsibility for ensuring all study personnel are trained to implement properly the IRB-approved study protocols.

Recruitment Procedures

During the enrollment period, we anticipate recruiting potential participants for the CTCA RCT through a variety of community venues, using both active (i.e., venue outreach) and passive (i.e., referral, flyers/handcards, internet) recruitment techniques.

Active Recruitment: This study will utilize venue-based and network referrals to recruit participants. Appropriate venues will be identified based on the experiences of project staff, suggestions by members of the Core Consulting Group and based on the research teams' assessment of "recruitable" venues identified through their community interactions. Venue-based recruitment will include health care facilities, public spaces (e.g., parks, recreational locations), local bars and/or social spaces, and community-based organizations. A primary recruitment strategy will be street outreach and the dissemination of palm cards at BMX, and placement of bus bench ads in ethnographically mapped and identified locations, such as churches and house parties convened by AAMSM. Each potential site other than public spaces will be approached to obtain permission to recruit on the premises. A brief description of the program will be provided both verbally and in written form before any recruitment is conducted on site. If permission is denied, recruitment will not occur in or outside any of these facilities. A list of the sites providing and denying recruitment permission will be maintained by the Project Coordinator. Staff will be supervised by the Project Coordinator regarding the sites' willingness to allow recruitment and to review the list of "recruitable" sites.

Social network recruitment will be based on referrals made to the project by participants or those screened and found ineligible for the study. Staff will provide participants with recruitment flyers that they may use to refer other men from their social networks. Men making referrals will not be compensated for making referrals and those they refer will be screened for eligibility before they proceed to the consenting or intake stages of the project. Note that internet-based social networking media such as Facebook will NOT be used by study staff for recruitment purposes, except for advertising space on the site, as described below.

Passive Recruitment: Passive recruitment will be conducted by leaving flyers and palm cards for potential participants to read at the same venues where active recruitment will occur (**see Attachments 17**). Additionally, advertising space may be purchased on websites identified as appropriate by suggestions of the Core Consulting Group and the research team's assessment of appropriate virtual spaces; this may include Facebook or other social networking websites. Limited gay-focused media will be used, as well as traditionally Black publications and radio. Note that advertising space would be in the form of banner ads; study staff will NOT send messages to anyone for recruitment purposes.

Prescreening for eligibility will be conducted during face-to-face encounters during active recruitment. During active recruitment, prescreening begins by asking the man if he is willing to speak with the staff member briefly about the project, and asked if he is comfortable answering a few questions in that location, given the level of privacy available. (For example, if recruitment is taking place at a park, the staff member will make every effort to interview the potential participant in a location that is out of earshot of anyone in the surrounding area.) If he agrees, or

when a potential participant calls to inquire about the project, the staff member will give a brief description of the project and ask if the study is something the man might be interested in.

If pre-screening occurs at venue-based recruitment, the man will be asked if he is willing to participate in a full screening now or at a later time. If he agrees to a full screening at that time, the staff member will continue with full screening. If he agrees to participate in a full screening at a later time, he will be given a project information card and asked to call for the full screening. Note that recruiters will use their best judgment to avoid obtaining verbal consent to screen from a person that is intoxicated, especially in the case of recruitment at a location that serves alcohol.

If at any point the man expresses that he does not want to continue the pre-screening conversation any further, the staff member will give him an information card that contains contact information for the project, and will tell him that he may call the project office for further information about the study. Potential participants will either call the project office or come to the office for the full screening. Each potential participant will be screened for eligibility using the full screening instrument (**Attachment 4**).

If the man is determined to be eligible, he will be asked if he would like to participate in the study. If he is in the study office, and he agrees to participate, he can move directly into the intake stage of participation (informed consent, record locator information, baseline ACASI, and randomization). If he agrees, but has been screened over the phone, or there is not enough time to do the intake procedures, he will be scheduled to come to the project office to complete the intake procedures.

Overview of Data Collection Procedures

Our collaborative team will collect a variety of quantitative variables for both process and outcome evaluations of the CTCA RCT. To reduce interviewer bias in the collection of sensitive sexual behavior data (Ghanem, K.G., et al., 2005), we intend to use audio computer-assisted self-interviews (ACASI) for baseline and follow-up questionnaires.

Pre-screening/Full-screening- Prescreening for eligibility will be conducted during face-to-face encounters during active recruitment using the pre-screening form (**Attachment 3**). If pre-screening occurs at venue-based recruitment, the man will be asked if he is willing to participate in a full screening now or at a later time. If he agrees to a full screening at that time, the staff member will continue with full screening. If he agrees to participate in a full screening at a later time, he will be given a project information card and asked to call for the full screening. Potential participants will either call the project office or come to the office for the full screening. Each potential participant will be screened for eligibility using the full screening form (**Attachment 4**). For men meeting eligibility criteria, project staff will use the brief locator information form (**Attachment 5**) to collect contact information (e.g., name, email, telephone number). The brief locator information will be used to contact men to set up appointments to complete the informed consent process and Baseline Assessment via ACASI.

Enrollment - After potential participants have been identified and screened, study staff will confirm their willingness to participate and schedule a meeting to complete informed consent

procedures and baseline assessment. At the time of their pre-determined appointment, potential study participants will meet with study staff who will review the consent form with potential participants (**Attachment 13**). Potential participants will be able to read and/or have read to them the study procedures which will at minimum include, data collection steps, randomization procedures, study goals and purposes, means by which data are being protected, the extent and nature of confidentiality in the study, compensation for study participants, rights and limitations as a study participant and persons to contact for further information about the study and contact information for local and CDC IRB/Human Subjects Officers. After successfully completing written consenting procedures, the participant will complete a record locator form (**Attachment 7**) on a computer in a semi-private or private location.

Baseline and Follow-up Assessment- After completing the record locator form the participant will complete the baseline assessment in a semi-private or private location. Staff will be present to assist the participant in getting started on the computer. Staff will remain easily accessible to address any technical problems or to answer any questions participants may have. The baseline assessment consists of a 45-75 minute Audio Computer Assisted Self Interview (ACASI)-administered survey of self-reported demographic factors, recent sexual and drug use behavior, and a number of potential cofactors of sexual behavior, including attitudes, beliefs, knowledge, traits and other psychosocial factors (**Attachment 6**). The data elements collected on the Baseline Assessment are included in the 3-month Assessment (**Attachment 9**) and 6-month Assessment (**Attachment 10**) except certain items.

Participant Evaluation Form- Participants will be asked to complete 6 brief, pen-and-paper participant evaluation forms at the end of each session (**Attachment 8**). These data will assess participant satisfaction with specific sessions and other aspects of the groups. These surveys will be anonymous.

Exit Survey- The Exit Survey (**Attachment 11**) will be offered to all men [in the intervention arm] at the conclusion of their 6-month ACASI. The pen-and-paper survey obtains feedback from the participants on their experience as a CTCA study participant. It asks about participant's post-intervention HIV testing behavior and their thoughts on the usefulness of the CTCA intervention. The Exit Survey also asks if men are willing to be contacted for future follow-up purposes, which will be the Exit Interview.

Exit Interview- Exit Survey data will be assessed to identify potential men for the Exit Interview from men agreeing to be contacted for future follow-up at the time of the Exit Survey. Additionally, the Exit Survey data will be assessed to identify men who rated CTCA "more favorably" (agreeing and strongly agreeing with positive comments about the intervention) and "less favorably" (disagreeing and strongly disagreeing with positive comments about the intervention). Once we have 50 participants in each category, we will randomly select 15 participants from each group and invite them to participate in the exit interview. We anticipate that we will need to repeat these procedures and extend an invitation to at least 65 participants in order to reach and successfully interview 15 participants in each group.

Quality Control/Assurance

Data Collection-- ACASI technology will be used to minimize the potential discomfort since the

participants will not be interacting directly with another person. Staff will ask participants if they had any problems with ACASI immediately following completion of the survey. Staff will hold internal reviews and discussions about ACASI during the trial so that recommendations for assessment and procedural improvements can be made on an ongoing basis.

Data Management--Group facilitator summaries, summary report forms, and participant evaluation forms will be locked in a cabinet at the PI's LUC office with access only by trained study staff through the duration of the project and referred back to as needed. Study participant's information, including name, locator information and all data will be stored on secured and password-protected computers. Staff with access to these computers will have to log into and identify themselves to gain data entry or retrieval access. All participants' information will be codified using unique identifiers. All participant documents will be referenced using the unique identifiers. One document that cross references the client to the unique identifier will be maintained in hardcopy by the Principal Investigator. This document will be updated daily and stored in a secured Loyola University Chicago office in the PIs Office. The PI and Project Coordinator will have access to this information. ACASI interviews will be developed using QDS software. Each day, the ACASI interviews and Record Locator data will be backed-up and moved to the Data Manager's computer. The data manager will use a flash drive to transfer the data. Data will be deleted from the data collection computers and flash drive as soon as the data is successfully transferred to the Data Manager's computer. The data manager and computer will be physically located at the study site but in a room separate from all other study activities (i.e., ACASI, intervention implementation, consenting etc.) All data will be retained for 3 years after the study then hard copies destroyed.

Intervention delivery--The groups will be periodically observed, for purposes of facilitator supervision and content quality assurance. Two sessions will be randomly selected per every 3 clusters to be observed by 1-2 Master Trainers. Master Trainers will monitor fidelity to the intervention and will complete a brief summary report. This is done to examine the content and process of the sessions for purposes of facilitator supervision and to ensure the curricula are being implemented as intended. Additionally, participants are given the opportunity to complete evaluation forms after each session (**Attachment 8**). The facilitators will review these forms after each retreat. Feedback regarding session activity will be discussed among appropriate project staff to ensure adequate and appropriate delivery of intervention content and process; supplemental training of facilitators will be given as needed.

3. Methods to Maximize Response Rates and Deal with Nonresponse

Response Rates and Retention

We recognize it may be challenging to retain all 438 randomized participants for the intervention sessions and follow-up measurements. Several strategies will be implemented in order to reach the goal of at least 80% retention of both the intervention and control arms for follow-up. Participant locator and contact information will be collected and periodically updated in order to remind participants of their upcoming visits and enhance study retention (**Attachment 7**). The twice monthly electronic messaging delivered by the mechanism of the participant's choice will facilitate regular updating of the locator information with its built-in response incentive. The

messages will have a feature that allows the participants to confirm receipt of the message and/or change contact information if necessary. This confirmation response will make any participant who has completed the 3- or 6-months post-intervention assessments eligible to win one of six prizes to be given away during both data collection years (12 prizes total). Attachment 19 list example health messages that will be used. These messages were selected from the CDC factsheets website and include information regarding fruits and vegetables, hypertension, and smoking.

Contact information will be updated in a locator information database at the baseline visit and at the end of the intervention (for intervention participants), as well as periodically throughout the trial, as participants respond to the twice monthly messages. Participants will respond yes to “Received message” and yes to “Contact info is still the same”. If contact info has changed, respondents will be asked to call the office or to send a current telephone number. The anticipated burden is very minimal and if there is new information/up-date the staff will collect this from the participant and update the record locator form. Staff will update the database with the new locator information, but they will not share this information with any other person or organization.

Whenever the project staff uses this information to try to locate a participant, they will identify themselves as being from the organization conducting the study. If staff contact friends, family members, or another approved contact person, they will tell the contact person that the participant has provided written permission to contact this person or organization only to obtain locating information. Staff will not reveal to the contact person what the study is about (HIV prevention) or that the study involves MSM.

The database will hold all personal information for each participant, including contact information and scheduled and completed appointments (including appointment times and dates). These data will remain separate from the assessment data to protect participant confidentiality. The database will be able to automatically generate the following items at any given time: a list of reminder cards to be sent to participants and a schedule of upcoming appointments. These items will be generated and processed on at minimum a weekly basis throughout the study.

Data on the Locator Form include participant name and study ID; date and location of recruitment; address, phone numbers (home, work, cell) and preference for electronic communication to contact the subject for the next study visit; name, address, and phone number of friends, family members, or other people who are likely to know how to contact them (and who the participant will have given permission for study staff to contact) over the next 4-5 months (their relationship to the participant will be noted), and Facebook account names for the twice monthly messaging (text, e-mail, and voicemail will also be an option).

Contact information may specify whether or not project mail can be sent to this address, and whether or not it is okay to mention the name of the study in a message. Participants will be asked to suggest the best way to contact them (e.g., phone or email; time of day to call and which number to try first). The locator form asks other ways to reach the participant, including café, bar, or club; if it is okay to come by their residence and leave a message; and whether the participant has other ideas about how they could be contacted. This information will be obtained

on a purely voluntary basis (i.e., not a requirement for participation in the study). However, staff will make a judgment call as to whether or not limited contact information is adequate for participation given the individual circumstances and potential for successful staff follow-through with the participant. For example, if a person does not have a phone or email address but they have received services regularly at a known agency for an extended period of time and indicate that study staff may contact them through the agency, then given other circumstances for the individual (e.g., an address, contact information for others close to them) a study staff person may consider this adequate contact information for the individual to participate.

Retention before and during the retreat- Because intervention group participants may be recruited over several weeks, participants will receive a call or note from one of the project staff a few days before the retreat. Participants will be asked at the end of the retreat what would be the best way for us to remind them of the follow-up appointments. Some participants will have a phone and be willing to be called; others may wish to be contacted through e-mail. Those who do not prefer these modes of contact may be contacted through agencies where they receive services (by leaving a note) or through outreach workers going out into the communities where people live. In all cases, the participant will consent to be contacted in the manner used. If a participant consents to have a note left with agency staff, the note will be sealed. We will explain to participants that in all cases, a clear boundary exists between the research project and agency staff that prevents the sharing of information we learn about them during the research study with anyone at the agency.

Participant retention during the intervention will be enhanced in several ways. Participants will receive a token of appreciation for each data collection appointment they attend (described below). Also, at the beginning of the retreat, group leaders will review the schedule for the weekend with participants and encourage full attendance at each session. In addition, if someone misses a session, staff will call or contact the participant to determine why a given session was missed and to try to encourage them to attend the next session. Participants will be asked to call the project if they are going to miss a session.

Retention during the follow-up period- Participant retention after the intervention will be enhanced in several ways. The provision of token of appreciation should enhance participation in the follow-up visit. At the end of each data collection visit, participants will be given tokens of appreciation for their time and effort. Individual tokens of appreciation will be:

- \$25 gift card and a two-way CTA Transit Pass (\$5.00 equivalent) for the baseline appointment,
- \$25 gift card and a two-way CTA Transit Pass for the 3-month follow-up visit,
- \$50 gift card and a two-way CTA Transit Pass for the 6-month follow-up assessment visit, and
- \$50 gift card and a two-way CTA Transit Pass for the exit interview (if selected).

Men who are randomized into CTCA intervention will receive roundtrip CTA Transit Pass (\$5.00 equivalent) for each day of the intervention, but no additional tokens of appreciation.

The amount of tokens of appreciation is based on both prior experience and for appropriate consideration of the potential burden in terms of travel and time commitment men will make to participate in the study. For example, it is not uncommon for research studies such as Brothers y Hermanos or HPTN061 to provide participant remuneration up to \$50. The graduated token of appreciation scale is proposed to provide sufficient but not inappropriate amounts to men in recognition of their completion of study visits to complete baseline, three and six month and exit interviews. If an assessment or CTCA retreat is unable to be completed for any reason and participants have arrived or are en route, they will receive a two-way CTA Transit Pass for their travel and the assessment or intervention will be rescheduled. This procedure will be explained to eligible participants during screening and at the baseline assessment individual session.

Additionally, there will be a raffle with three prizes given away to increase study retention (4 sets of raffle prizes will be given away.) When participants complete the intervention, they will receive an electronic message instructing them to reply with their updated contact information to enter in the drawing for one of the raffle prizes. In addition, prior to the raffle, participants in the control group will receive periodic texts requesting their updated contact information. This way, we can ensure that we have the correct contact information to follow-up with all study participants. Anyone who replies to the message would be entered into a drawing to receive the raffle prize even if they do not complete all of the follow-up assessments. The grand prize will be worth up to \$100, second-place prize will be a \$50 gift card, and the third-place prize will be a \$25 gift card.

The rationale for the raffle is that we do not want to conflate the impact of consistent incentives with effect of the intervention, thereby creating an artificial outcome that cannot be replicated in a community setting. By informing men of their entry into the lottery it is a way to keep accurate with their provided contact information. Given that local dynamics and emerging technologies may change we will reserve some flexibility in identifying the exact raffle items to assure they are perceived of value by participants, however we will stay in the cost band.

To enhance retention, letters will be sent out or phone calls will be made up to several weeks or more prior to the follow-up visit dates requesting that the participant contact the main office to confirm or reschedule an appointment, and reminder calls will be made within several days of the appointment. The reminder letter will remind them of the date and time of their follow-up appointment, and note the telephone number that can be called if rescheduling is necessary. The letter will be discrete with regard to the nature and purpose of the study. The letter will state that if they miss this visit, to please call to reschedule.

If a follow-up visit is missed, study staff will attempt to contact participants who do not respond via their preferred contact method. A first attempt will be made to remind them to reschedule their appointment. If there is no response, then a second attempt will be made. Participants who do not respond and cannot be located during one month window period are classified as having missed that visit. The boundaries for the window period will cover a time frame of 2-weeks before and 2-weeks after the anniversary date for the participant. For participants in the comparison arm the anniversary date will be set from the date of randomization. For intervention participants the anniversary date will be set based on the last date of the weekend retreat which the participant attended. Once a participant is voluntarily enrolled in the study, staff will continue with contact attempts until a participant expresses the desire to be dropped

from the study. For example, repeat no-shows will continue to be rescheduled for follow-up until the window closes. If a participant moves away from the original project city during the study, follow-up visits will be conducted over the phone by staff.

Ascertaining reason for losses to follow-up-A list of the study ID's of lost participants will be maintained, with disposition being recorded on the list when it is determined. In some cases, the study staff may learn that the participant has moved away; staff will continue to attempt to reach these participants for follow-up and make every reasonable effort to accommodate the participant in order to complete the follow-up assessment. Relocation information may be provided by the participant, his or her contacts, or by the US Postal Service. Study letters sent to participants will be stamped with "forwarding and address correction requested". This service is provided for 50 cents. Staff may consult local or national death records or indexes to determine whether lost study participants have died. Participants who are in substance abuse treatment or prison will be classified as such. Subjects may also refuse to complete any follow-up visits; these will not be combined with study losses, but classified as refusals. For some lost subjects, reason for loss will not be determined. At the end of the study, follow-up rates will be calculated.

Assessing Non-Response Bias

The use of an eligibility screener will allow comparison of the demographic and eligibility related behavioral data on those who are eligible and ineligible and those who accepted participation and those who did not. Additionally, we will assess differential attrition by comparing the characteristics of participants retained in the study through all follow-up data collection with those who were lost to follow-up. These characteristics will include demographics as well as behavioral risk. Chi-square and t-tests will be used as appropriate to the measure used. We will deal with missing data using multiple imputation. In addition to adjusting for variables for which the treatment and control groups are not balanced and for within participant correlation, we will also adjust for cluster effects by including a given participant's cluster in our models

Accuracy and Reliability of Information Collected

To reduce interviewer bias in the collection of sensitive sexual behavior data [5], we intend to use audio computer-assisted self-interviews (ACASI) for all baseline and follow-up measurements. Previous studies have demonstrated that respondents are more likely to reveal engaging in sensitive behaviors in a computer-assisted self-interview than in a face-to-face format (Ghanem, K.G., et al, 2005; Des Jarlais, D. C., D. Paone, et al., 1999). The assessment includes multiple instruments that have been previously tested with this or similar populations and have acceptable reliability as determined through statistical evaluation. **See Table B4.** below for a summary of the measures used that have been applied with similar populations and the reliability statistics as reported in the literature.

Generalizability

The aim of this study is to establish the preliminary efficacy of the homegrown intervention CTCA and will provide important information about sexual risk behaviors and the context in

which they occur. These data are essential for identifying effective homegrown HIV/AIDS prevention interventions for at-risk African American MSM.

However, true generalizability from a single randomized controlled trial testing an intervention targeted to African American MSM will not be achieved due to the hard-to-reach nature of the population, the strict eligibility criteria, and the geographical limits involving in testing individual-level interventions.

The study site will attempt to recruit a diverse sample of African American MSM. CTCA recruiters/study staff will conduct recruitment activities in a variety of physical (community) and virtual (Internet) venues. During recruitment, sites will perform monthly assessments of these participant characteristics and adjust recruitment strategies as needed.

4. Test of Procedures or Methods to be Undertaken

The measures to be used in the questionnaire were chosen with input from community collaborators and the Community Advisory Boards (CABs). This process helped to insure that the questions are culturally-appropriate and use language that can be easily understood. We presented the final data collection instruments to the CAB, have received feedback, and addressed all concerns. We also piloted the data collection instrument in a previous study and also with staff from the implementing agencies.

In addition, whenever possible, the investigators have selected measures that have been developed for and tested with populations of African American gay and bisexual men. Since there are few measures specifically for African American MSM, we included measures developed for MSM and Black heterosexual populations and adapted the language as needed. In addition, when appropriate measures were not available for adaptation, we developed measures, with input from our Community Advisory Board. Two constructs, childhood abuse and religion/spirituality, are included in the assessment. In recent work conducted by Dr. Wheeler (most notably Brothers y Hermanos & BROTHERS – HIV Prevention Trials Network Study 061) he and colleagues found that upwards of 30% of BMSM in these studies reported childhood sexual abuse (CSA). Research on CSA clearly demonstrates a correlation between adult sexual risk taking and CSA. It is therefore important to assess this in a comprehensive engagement with study participants. The ACE scale provides a simple and highly validated instrument for this purpose. Also, religion and spirituality are frequently identified as important sociocultural variables for African American study participants. The historical role of religion in the lives of African Americans suggests a mixed impact on BMSM with some men experiencing negative and homophobic backlash while others find the religious experiences to be nurturing and supporting. Research has also suggested that there is a difference between religious involvement and spiritual expressions. Given the saliency of both religion and spirituality for and in research focusing on BMSM it is important to assess this domain and to consider its role in protective and/or risk taking among study participants (Bond et al., 2009; Vermund et al., 2010; Wheeler, 2006; Wheeler, Lauby, Liu, Van Sluytman, & Murrill, 2008).

Table B4. Table of Measures

Instrument Name	Population Previously Used With	Publication	OMB Approved?
Demographics	Not Applicable	Self Developed	No
General Health	Not Applicable	Self Developed	No
Sexually Transmitted Diseases	Not Applicable	Self Developed	No
HIV Testing	Not Applicable	Self Developed	No
Sexual Assessment	Not Applicable	Self Developed	No
Sexual Behavior	Not Applicable	Self Developed	No
Knowledge of HIV Treatment	Men who have sex with men	Kalichman, S., Eaton, L., White, D., Cherry, C., Pope, H., Cain, D., and Kalichman, M. (2007). Beliefs about treatment for HIV/AIDS and sexual risk behaviors among men who have sex with men, 1997-2006. <i>Journal of Behavioral Medicine</i> , 30, 497-503.	No
PrEP/PeP	Not Applicable	Self Developed	No
Condom Use Self Efficacy	Young African American Women	Wingood, G., DiClemente, R. (1998). Partner Influences and Gender-Related Factors Associated with Non-condom use Among Young Adult African American Women. <i>American Journal of Community Psychology</i> , 26(1), 29-51.	No
Contemplation Ladder – Condoms During Anal Sex (M/Fversion) Use	Cigarette Smokers	Adapted from - Biener, L. & Abrams, D. B. (1991). The Contemplation Ladder: validation of a measure of readiness to consider smoking cessation. <i>Health Psychology</i> , 10, 360-365.	No

Decisional Balance for Condom Use	Women at risk for HIV Infection	Adapted from Semaan, S., Lauby, J., O'Connell, A. A., & Cohen, A. (March 01, 2003). Factors Associated with Perceptions of and Decisional Balance for, Condom Use with Main Partner Among Women at Risk for HIV Infection. <i>Women & Health, 37, 3.</i>)	No
Self-Efficacy Condom Use	Late Adolescent College Students	Adapted from Parsons, J. T., Halkitis, P. N., Borkowski, T., & Bimbi, D. (2000). Perceptions of the benefits and costs associated with condom use and unprotected sex among late adolescent college students. <i>Journal of Adolescence, 23, 377-391.</i>	No
HIV Stigma for Positive Men – Negative Self Esteem Subscale	Young men who have sex with men	Dowshen, N., Binns, H. J., & Garofalo, R. (January 01, 2009). Experiences of HIV-Related Stigma Among Young Men Who Have Sex with Men. <i>Aids Patient Care and Stds, 23, 5, 371-376.</i>	No
HIV Stigma for Negative Men – Disclosure Concerns Subscale	Young men who have sex with men	Dowshen, N., Binns, H. J., & Garofalo, R. (January 01, 2009). Experiences of HIV-Related Stigma Among Young Men Who Have Sex with Men. <i>Aids Patient Care and Stds, 23, 5, 371-376.</i>	No
Sexual Communication	Young Adult African American Women	Adapted from Wingood, G., DiClemente, R. (1998). Partner Influences and Gender-Related Factors Associated with Non-condom use Among Young Adult African American Women. <i>American Journal of Community Psychology, 26(1), 29-51.</i>	No
Collective Self Esteem	General Public	Luhtanen, R. & Crocker, J. {1992}. A collective self-esteem scale: self-evaluation of one's social identity. <i>Personality and Social Psychology Bulletin, 18{3}, 302-318.</i>	No
Negative Experiences	Not Applicable	Self Developed	No
Adverse Childhood	Over 17,000	Felitti VJ, Anda RF, Nordenberg D,	No

Events	adult, middle class Americans.	Williamson DF, Spitz AM, Edwards V, Koss MP, et al. The relationship of adult health status to childhood abuse and household dysfunction. <i>American Journal of Preventive Medicine</i> . 1998; 14:245-258.	
Partner Violence Questionnaire	Substance Abusers	Adapted from Walker, D. D., Neighbors, C., Mbilinyi, L. F., O'Rourke, A., Zegree, J., Roffman, R. A., & Edleson, J. L. (September 01, 2010). Evaluating the Impact of Intimate Partner Violence on the Perpetrator: The Perceived Consequences of Domestic Violence Questionnaire. <i>Journal of Interpersonal Violence</i> , 25, 9.)	No
Every Discrimination – Sexual Orientation	Black Women	Adapted from Essed, Philomena. 1991. <i>Understanding Everyday Racism</i> . Newbury Park, California: Sage.	No
Everyday Discrimination - Race	Black Women	Adapted from Essed, Philomena. 1991. <i>Understanding Everyday Racism</i> . Newbury Park, California: Sage.	No
Black Identity (Items from the Multidimensional Inventory of Black Identity/MIBI)	African Americans college students and adults	MIBI; Sellers, Rowley, Chavous, Shelton, & Smith, 1997	No
Identification and Involvement with the Gay Community Scale	Gay Men	Vanable PS, McKiman DJ, Stokes JP. <i>Handbook of sexuality – related measures</i> . Thousand Oaks, California: Sage Publications; 1992. Identification and involvement with the gay community scale [IGCS] pp. 407–409.	No
Internalized Homophobia Scale	Gay Men	Ross, M. W. and Rosser, B. R. S. (1996), Measurement and correlates of internalized homophobia: A factor analytic study. <i>J. Clin. Psychol.</i> , 52: 15–21. doi: 10.1002/(SICI)1097-4679(199601)52:1<15::AID-JCLP2>3.0.CO;2-V	No
Religion and Spirituality	Not Applicable	Self developed	No
Cross-site	Not Applicable	Self Developed	No

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The primary person involved with statistical aspects of this project and data analysis for this study is Michael Lewis of the Hunter College School of Social Work. The study design and development of data collection instruments were a collaborative effort between CDC, Loyola University Chicago, Hunter College, and Black Men's Xchange. The site will be collecting the data for this study and analyzing data generated by the study. The federal staff members who are involved with the various aspects of designing and implementing the study are listed below.

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