HUNTER
The City University of New York

Couples Health Project

Development of a couples-based intervention to reduce drug use and enhance sexual health among partnered emerging adults.

NCT# 03386110

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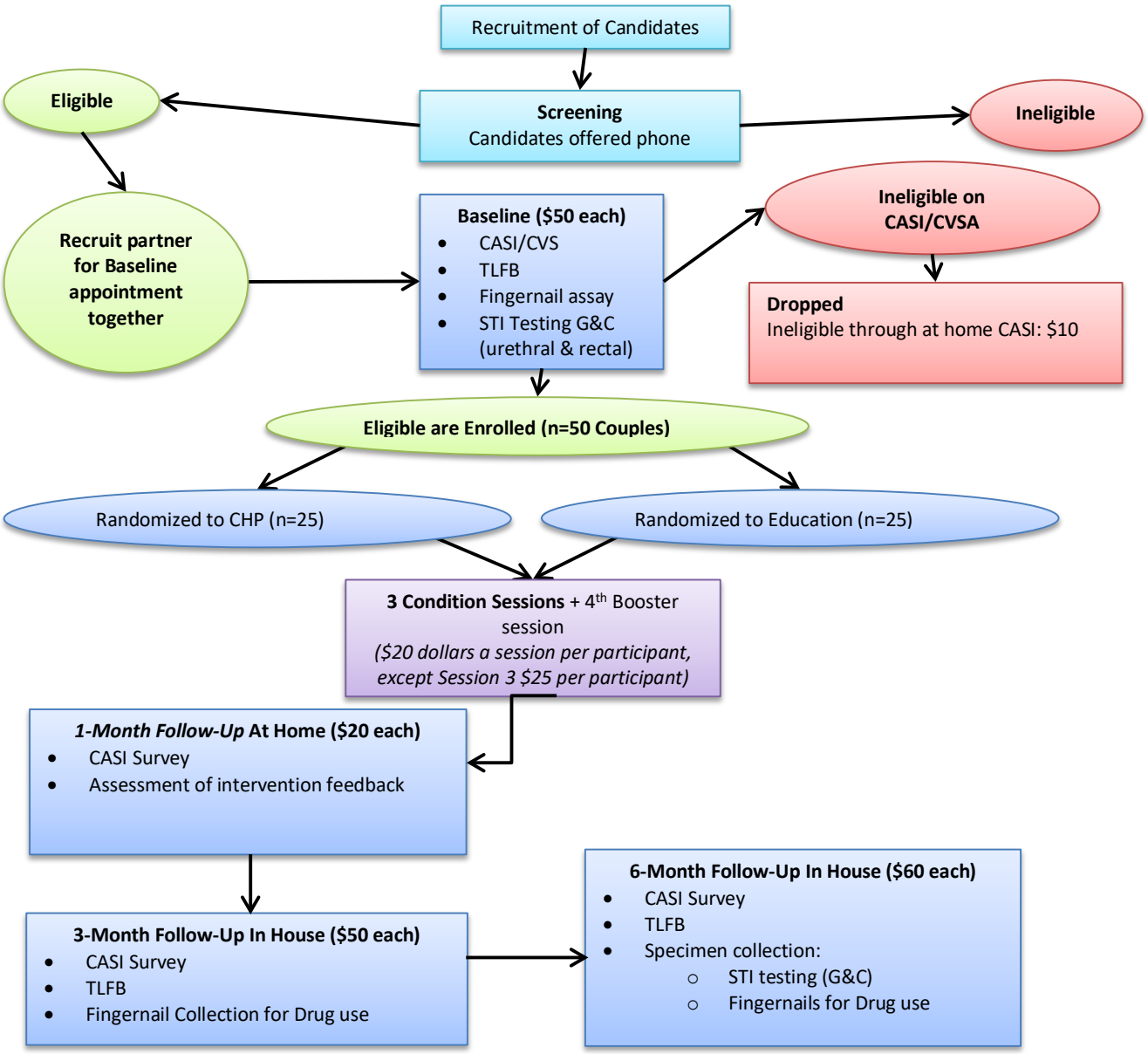
Abbreviations:
TRB – Transmission Risk Behavior
MSM – Men who have Sex with Men
YMSM – Young Men who have Sex with Men
TLFB – Time Line Follow Back
STI – Sexual Transmitted Infection
BL – Baseline appointment
FU – Follow Up appointment

STUDY ABSTRACT

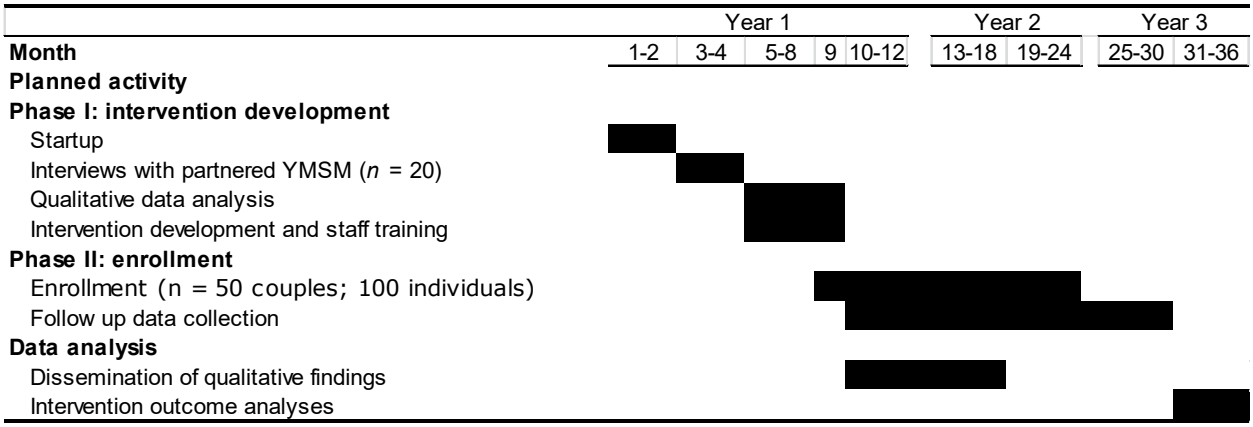
DESIGN:	This study utilizes qualitative methods during a formative phase to inform intervention development. Subsequently a small randomized controlled trial is utilized in Phase 2 to evaluate the feasibility, acceptability, and preliminary efficacy of the new intervention relative to an attention-matched education control condition.
SAMPLE SIZE:	In Phase 2 we will recruit a sample of 50 couples (n = 100 individuals). At least one member of the couple must be a YMSM between the ages of 18 and 29; report recent (past 30 days) drug use; and recent (past 30 day) Transmission Risk Behavior (TRB).
POPULATION:	Partnered MSM aged 18-29 who are in a primary relationship with another man for at least 3 months, who also uses some kind of illicit drug, and also had some TRB in the last 30 days with a casual partner or with a non-monogamous serodiscordant partner. In addition all participants will have to be able to communicate in English.
STRATIFICATION:	Participants will be randomized at baseline to receive their first CHP or Education session directly following their baseline appointment. The study will employ a stratified randomization procedure using Qualtrics.
DATA COLLECTION:	Participants have the options to first complete a brief CASI at home before or during their BL appointment. Regardless, they will then complete another survey at their BL appointment along with a TLFB, STI testing (Gonorrhea & Chlamydia Urethral and Rectal), and Drug testing. During session 3, participants will complete a CHTC session that involves Rapid HIV testing for couples. For 1m FU participants will complete an at home Qualtrics survey. At 3M FU participants will complete a Qualtrics survey, a TLFB and a Fingernail specimen collection for drug use.

	Finally, at 6M FU participants will complete a Qualtrics survey, a TLFB and Specimen collection to test drug use on fingernail sample and Gonorrhea & Chlamydia for STI testing (Urethral and Rectal).
OBJECTIVES	1) Develop content to address PrEP uptake/adherence and integrate biological testing 2) Evaluate the efficacy, feasibility, and acceptability of CHP at 3- and 6-month follow-up.

STUDY DESIGN:



Original Study Timeline:



STUDY POPULATION

3.1 Inclusion and Exclusion Criteria

a. Inclusion

i. One partner must be 18 to 29 years of age
ii. Both partners born male and currently identify as male
iii. One partner must be HIV-negative (one partner can be HIV positive)
iv. In a relationship with another man for at least 3 months
v. Either partner reporting the use of at least one of the following substances in the past 30 days Marijuana, cocaine and crack, amphetamines, ecstasy, GHB, ketamine, nitrates
vi. Either partner reporting CAS with a casual partner and/or CAS with a non-monogamous or serodiscordant main partner in past 30 days.
vii. Must be able to communicate English
viii. Must reside in the NYC metro area

b. Exclusion

i. Either member of the couple reports IPV, which is defined as serious physical or sexual violence that occurs outside the context of consensual bondage or sado-masochistic sexual play, which results in concerns of safety (IPV-GBM scale)
ii. Unstable, serious psychiatric symptoms
iii. Currently suicidal/homicidal
iv. Evidence of gross cognitive impairment

3.2 Recruitment and Screening

This study will utilize an index case approach for the recruitment of couples in which one partner will be screened. Those providing data that indicate they are eligible will then be asked to schedule a baseline appointment during a timeslot on a day that they can attend with their partner. This strategy has proven effective in our previous studies of gay couples, substantially more effective than procedures that require advanced screening of both partners. The study will utilize active and passive approaches to recruit index participants.

3.3 Contact Information

Once they are screened eligible through our online screener participants contact information will be collected and they will be asked if messages can be left at the numbers provided or if text can be sent. Study staff will not leave messages or send text messages unless expressly permitted to do so by the participant, which also will be documented on the participant Locator Form and Access DB.

4.0 STUDY PROCEDURES

4.1 At-home CASI

Once participants schedule their baseline appointment, they will be sent an appointment reminder email with instructions to find PRIDE's office and the time of the appointment. This email will contain a link to a Qualtrics survey for them to complete prior to the baseline appointment. The index partner (participant 1) will be sent two emails: one will contain their unique Qualtrics survey link and a second email to be forwarded to their partner (participant 2) so they can access their Qualtrics survey link. When participant 2 completes the at-home CASI they will be asked to leave contact information.

In the unlikely event that either participant in the couple answers "yes" to the question about IPV or coercion, both members of the couple will be ineligible for the study. In this scenario, each participant will be compensated $10 for completing the at-home CASI via Amazon gift card.

If participants do not complete this CASI prior to their baseline appointment, they will have to complete it in the office the day of their baseline.

4.2 Enrollment Procedures

Participants are considered enrolled in the study databases when they have completed informed consent in person.

4.2.1 Informed Consent Process

Details of the study will be reviewed with the prospective study participant by a designated site study staff member trained and cleared to conduct assessments and is knowledgeable about the research study. This discussion is a critical component of the consent process and the prospective study participant will be given adequate time for this discussion and to read the written consent form. The Principal Investigator (PI) or his/her designee will be available to answer questions about the study including participant responsibilities, benefits, risks, and alternatives. A shortened version of the consent form will be delivered electronically to the participant prior to beginning participation in the study, and then the full consent form will be reviewed at the

beginning of the in-person baseline appointment. The participant will review the consent form and it will be signed and dated by both the participant and study staff member conducting the assessment. A copy of the signed consent form will be given to the participant and the original will be kept securely by the project coordinator separate from other assessment materials.

4.3 Randomization Process/Systems

Participants will be randomized at the end of their baseline assessment into one of two control conditions: 1) delivery of the 3 session CHP intervention or 2) delivery of a 3 education sessions. Each participant's condition will be tracked in the access tracking database maintained by the Research Coordinator.

The study will employ a stratified randomization procedure for each interventionist using Qualtrics. Randomization will be stratified on:

1. Age discrepancy Question: is the couples age difference (3 years or less/ longer than 3 years)
2. Relationship Length Question: is the couple's relationship length (2 years or less/longer than 2 years)
3. Racial makeup question: is the couples racial makeup (both partners identify as white and non-Hispanic/one or both partners identify as nonwhite or Hispanic)

4.4 Schedule of Assessments

Intervention or education sessions will occur approximately once per week for two weeks beginning one week after completion of the baseline assessment and session 1. There is a 6 week window (45 days) for intervention or education completion, i.e. opportunities to complete all three sessions must be provided before the 1 month online follow up survey is sent out.

Participants will complete the first follow-up assessment online 1 month after baseline (1M FU). For those who have completed all sessions by day 30 post BL, they will be sent their 1 month follow up survey. For those who have yet to complete all 3 sessions they will be given until day 45 post baseline until their session window closes and they must be sent their 1 month follow up survey. The 1 month follow up survey will close 60 days post baseline. Follow up assessment windows for 3 month and 6 month follow ups will be programmed to open on day 90 and day 180 respectively and will remain open for 30 days.

Component	*Screening*	*Baseline*	*Session 1*	*Session 2*	*Session 3*	*Booster*	*1-Month Follow-Up*	*3-Month Follow-Up*	*6-Month Follow-Up*
Informed Consent		**x**							
CASI		**x**					**x**	**x**	**x**
HIV Testing					**x**				
STI Testing (G&C)		**x**							**x**
Fingernail Drug Test		**x**						**x**	**x**
Randomization		**x**							
Randomized Condition Session			**x**	**x**	**x**	**x**			
TLFB		**x**						**x**	**x**
Assessment of Intervention feedback					**x**				
Assessment of Intervention feedback (If not completed or captured in session 3)							**X**		

Refer to "Study Design" for a visual representation of the schedule of assessments.

4.5 Managing and Tracking Study Visits

There are two different types of visits during the study timeline:

Intervention/Education Sessions: All CHP sessions will be managed by trained staff members. Therapists and Educators will notify the project coordinator whether visits were completed for tracking purposes, provide receipt for session compensation and audio files will be uploaded to the designated secure location on PRIDE servers. Session 1 for CHP or Education session will ideally begin directly after the completion of the baseline appointment when feasible. Otherwise it will be scheduled for a later date. Randomization to CHP or education will occur during the baseline appointment.

Research Appointments: Research visits include the baseline visit, 3 sessions, and all other follow-up assessments.

Research visits will be tracked using Access Database, encrypted and secure on a private server at PRIDE offices, as well as Qualtrics which is a secure web application for managing online surveys. This system allows study staff to monitor the completion of study visits and surveys, and generate reports on enrollment and retention as needed. Study staff is expected to track all completed study components in Access immediately after completing an assessment and no later than end of business day.

Study staff will schedule participants during times that they will be available or will contact other staff to ensure coverage for appointments. Study staff will also ensure that there is available space to conduct these assessments.

Future visits should be scheduled during the study visit. Study staff is expected to keep in touch with participants and remind them of the upcoming visit or reschedule if needed. A reminder call should be made the day before a participant is due to come in for their visit (or the Friday before a Monday visit).

4.6 Retention and Follow Up

Intervention visits: For participants who are actively taking part in the CHP intervention or Education condition their assigned clinician or educator will be charged with scheduling sessions and rescheduling missed sessions. Participants will be reminded 1 day prior to their scheduled sessions by a study staff.

Research visits: Study staff will maintain strong and consistent relationships with study participants, and should contact study participants by text, phone, and/or email at minimum once per every follow up assessment to assure follow up scheduling and attendance. During this phone outreach, site study staff can verify existing contact information. Study staff should take note of participants who are less stable in terms of contact information i.e. Phone number/e-mail address, and devote outreach efforts toward these participants strategically.

***NOTE: Due to COVID-19, all follow-up assessments completed after 3/15/2020 were conducted remotely via Zoom and online survey administration via Qualtrics.

4.7 Specimen Collection

At baseline we test for Urethral and Rectal Gonorrhea & Chlamydia presence. The testing method for Urethral G&C will involve the participant urinating in a sterile urine collection cup and then send it for testing to Sunrise medical Laboratory. For Rectal detection we will provide the participant with an anal swab collection kit, and send the specimen for STI detection to Sunrise Medical Laboratory. In addition to the STI detection we will collect participant's fingernails and potentially toenails in case the sample is not enough, to test illicit drug use in the last 6 months, this 5-Panel drug assay will be conducted by USDTL Laboratory. HIV testing is performed at session 3

with both members of the couple present and will be performed utilizing HIV 4th Generation Rapid Test Determine Ab/Ag. Reporting to any required Departments of Health will occur using standard protocols.

4.7.1 Key Biological Testing

- ***5-panel fingernail drug assay.*** Though studies have consistently supported the validity of self-reported drug use data[94-97], when individuals are informed that their self-reported behavior will be validated through biological measurement, they are more likely to report their behaviors accurately[98]. Drug testing will be completed using the Nail Testing Panel from the United States Drug Testing Lab® (USDTL). Participants will clip 100 mg of nail (approximately 10 clippings of 2mm each). Clippings will be weighed on a jeweler's scale to ensure the collection of an adequate sample. Clippings are transferred to a foil packet, stored at room temperature, and shipped to USDTL via secure envelope. Results are available in 4 to 5 business days[52].
- ***Urethral STIs.*** Urethral STIs (chlamydia and gonorrhea) are being tested with laboratory assay from Sunrise Medical Laboratory, which detects both chlamydia and gonorrhea precisely. Participants will collect a urine sample and then place the specimen tube into a clear plastic biohazard bag. Specimens will be sent to Sunrise Medical Laboratory for processing. Sunrise Medical Laboratory will provide us with test results and will report positive results to the NYC DOH complying with New York City Health Department Reporting Requirements 101.
- ***Rectal STIs*.** Participants will also perform testing for rectal chlamydia and gonorrhea using a test kit from Sunrise Medical Laboratory. The swab is approximately the size of a Q-tip and is grasped between the thumb and forefinger about an inch from the base. The swab is inserted until the fingers touch the anus, and then it is rotated as it is removed. Swabs are stored in a specimen tube and a clear plastic biohazard bag. Specimens will be sent to Sunrise Medical Laboratory for processing. Sunrise Medical Laboratory will provide us with test results and will report positive results to the NYC DOH complying with New York City Health Department Reporting Requirements 101.
- ***Disclosure of Urethral and Rectal STI Results:*** Test results will be conveyed to participants through a secure Qualtrics-based interface along with a list of local resources. Per New York City's Health Code Article 11, the lab Sunrise Medical Laboratories will report positive results directly to the DOHMH
- ***HIV testing.*** HIV testing will be conducted in the context of couples' HIV testing conducted in session 3 of both conditions. Testing will be performed using the Alere Determine Ab/Ag Testing Kit®. An RA trained in CHTC will utilize a lancet to gather a sample of blood from the participant's finger. This blood is then collected with a capillary tube and placed on the designated area of the test strip, and then a drop of chase buffer is added to the testing area to culture. Test results are available in 20 minutes and delivered to participants immediately

during the couples HIV testing and counselling session. For additional information on HIV confirmatory testing and reporting see Attachments.

***NOTE: Due to COVID-19, collection of biological specimen data was suspended on 3/15/2020. All follow-up assessments completed after that date were conducted remotely via Zoom and online survey administration via Qualtrics.

4.8 Incentives and Compensation

Participants can be compensated individually up to $245 for participation in the study.

$50 for completing a Baseline assessment
$20 for session 1
$20 for session 2
$25 for session 3
$20 for completing a 1-Month Follow-Up Assessment
$50 for completing a 3-Month Follow-Up Assessment
$60 for completing a 6-Month Follow-Up Assessment

4.9 Measures

-Table 1-	Construct	Measure
Screening information	Demographics	NHBS demographics inventory[73]
	Sexual HIV transmission risk	Self-Reported Sexual Behavior
	Problematic drug use	Drug Abuse Screening Test – 10[74]
	Alcohol and Drug Use Behavior	NHBS Substance Use History Inventory[73]
	Intimate Partner Violence (IPV)	IPV among gay and bisexual men [75]
	Verification of couple status	Couples Verification Screener[63]
Individual functioning	Interpersonal Communication Skills	Interpersonal Communication Competence Scale[76]
	HIV knowledge	Brief HIV knowledge questionnaire[77] *
	Pros and Cons of substance use	Decisional Balance - Club Drugs[78]
	Pros and Cons of Condomless sex	Decisional Balance - Unsafe Sex[78]
	Condom use skills/efficacy	Condom use self-efficacy scale[79]
	Condom attitudes/beliefs	Adapted condom attitudes scale[30] *
	Anxiety and Depression	Brief Symptom Inventory[80] (subscales)
	Experiences of stigma	Everyday discrimination[81]
	Problematic alcohol use	Alcohol Use Disorders Identification Test (AUDIT)[82]
	Self-reported STI and HIV testing history; PrEP; and ART	
Dyadic functioning	Relationship satisfaction, cohesion, consensus & affectional expression	Dyadic adjustment scale[83]
	Partner communication strategies	Communication patterns questionnaire[84]
	Couples HIV Coping	Perceived severity of HIV infection[85]
		Preferences for sexual health outcomes[85]
		Couple efficacy to reduce HIV threat[85]
	Stigma directed at the relationship	Relationship marginalization[86]
	Relationship Control & Dominance	Sexual Relationship Power Scale (SRPS)[87]
	Attitudes about Sexual Agreements	Sexual Agreement Investment Scale (SAIS)[88]

5.0 CHP INTERVENTION/EDUCATION PROCEDURES

5.1 Intervention Design and Procedures

CHP is an intervention that utilizes motivational interviewing (MI) and personalized feedback to reduce CAS and substance use among partnered emerging adults. The CHP intervention will be delivered by MI-trained Clinical staff members. Participants will be randomized to receive the intervention during baseline appointment. The CHP intervention is comprised of 3 sessions. The intervention focuses on enhancing communication skills, and addressing drug use, risky sexual practices, couples HIV testing and counseling, PrEP and PEP, as well as navigation services to for PrEP for interested participants.

5.1.1 Three Sessions of CHP (Intervention)

Session Objectives	Purpose	Method
Session 1		
1. Establish rapport	Facilitate intervention delivery	**MI**
2. Assess communication and problem solving skills	Determine the extent of skills training necessary	**MI** focused on: Communication challenges with others and then within the couple
3. Develop communication skills	Improve partner's ability to express and understand one another's attitudes, opinions and emotions	**CBST**
4. Develop explicit problem solving strategy	Improve partner's ability to effectively identify problems, generate and select solutions	**CBST**
5. Plan a date	Practice communication skills and increase positive dyadic interaction	**Positive event scheduling**
HOMEWORK	Practice communication and problem solving skills. Go on a date.	
Session 2		
1. Assess use of skills and date completion	Assess successes and barriers to skill generalization	**MI**
2. Discuss mutual and individual goals	Assess the degree of dyadic dependence and broader goals and values	**MI**: Value's card sort completed jointly
3. Discuss the impact of substance use on goals	Identify potential areas in which substance use may interfere with broader individual and couple-level goals and values	**MI**
4. Establish substance use goals	Assess each partner's perception of ideal use for themselves and each other. In addition, identify ways in which partners can support goal achievement.	**Mutual reinforcement training**

5. Ongoing skill practice	Strengthen the use of effective communication and problem solving skills as applied in session.	**MI** and **CBST**
HOMEWORK	Practice communication and problem solving skills. Go on a date. Implement plan to achieve substance use goals.	
Session 3		
1. Assess use of skills and substance use goals	Assess successes and barriers to skill generalization	**MI**
2. Complete individual or couples HIV testing†	Establish sero-status and discuss joining sexual goals and risk reduction	**CVCT** or individual HIV testing and counseling
3. HIV medication adherence counseling††	Increase partner support for health-related behavior, particularly medication adherence	Life Steps
4. Establish a sexual agreement ††	Establish joint sexual goals and risk reduction	**MI**
5. Discuss links between substance use and sexual risk goals	Increase awareness of substance use and sex links	**MI**
5. Ongoing skill practice		**MI** and **CBST**
† Completed by HIV negative participants. Note: men in HIV negative seroconcordant couples will complete sexual agreement negotiation as part of CVCT.		
†† Completed by HIV positive participants and HIV negative participants in serodiscordant relationships.		
6. Relapse Prevention/Planning	Develop long-term goals for substance use, sexual behavior, and HIV risk reduction	MI Change planning
7. Termination	Summarize intervention work and conclude the intervention	

5.2 Three Sessions of Education

Session	Objectives	Purpose	Method
Session 1			**Lecture + Question & Answers**
Introductions		What do we "want" in a partner?	
		What do we "need" in order to get close?	
		What do couples "do" in relationships generally?	

	Strategies to reduce HIV risk	
Session 2		**Lecture + Question & Answers**
Drug Use Education	Review the effects of several drugs on the brain and body	
	Short term effects of drug use	
	Long term effects of drug use	
	Review the literature on drug use and sex	
	Discuss drug and alcohol use in the gay community	
	Review the effects of several drugs on the brain and body	
Session 3		**Lecture + Question & Answers + CHTC**
Communication	Do's and Don'ts of Couples Communication	
Couples HIV Testing and Counseling (CHTC)	Introduces testing	
	Finger stick	
	Sexual agreement	
	Deliver test results	
	Debrief	

5.3 Sessions Training and Supervision

CHP Sessions training will occur prior to the initiation of Phase 2, with ongoing coaching, supervision and training of new therapists as well as educators, as required. The training manuals are located on appendix B for Intervention & CHTC and Appendix C for Educators.

Training for CHTC entails going through a series of trainings as well as mock sessions in order to get "Cleared" by clinical staff to conduct CHTC with participants.
The same procedure will be followed for Educators, but they will be evaluated in their ability to present the education information and how to engage with the participant while avoiding the use of MI techniques.

5.4 Intervention Fidelity and Process Measures

We will assess the fidelity of CHP in two ways. First, CHP is an MI-based intervention. We will utilize the Motivational Treatment Integrity coding system, with additional codes relevant to MI with couples developed in our formative work, to evaluate fidelity to MI during the intervention. Dr. Starks is a member of the Motivational Interviewing Network of Trainers, and PRIDE maintains a staff of coders trained to use the system. We will MITI code 25% of CHP sessions. In addition, Dr. Starks will develop

a checklist based on the existing protocol which will be used to ensure that essential skills training components are completed.

5.5 Intervention & Education Monitoring and Supervision

All sessions (in-person based) will be audio-recorded, and one recording per facilitator will be randomly selected for MITI coding by the research team on a regular basis. Supervisors will complete fidelity checklists for the supervision session so the team can monitor implementation.

Education providers were trained by the project director or a trained clinical staff member. This involved a two-day workshop and subsequent mock deliveries of the education sessions. Educators were required to achieve fidelity to the protocol before delivering the condition to participants. The project director developed a session check-list that was approved by Dr. Tyrel Starks, which was used to determine fidelity. A trained clinical staff member reviewed each mock session and provided feedback. After being cleared to deliver the education condition to participants, a trained clinical staff member reviewed a minimum of 30% of completed sessions and provided feedback to education providers to ensure fidelity overtime.

CHP CHTC Supervisors: Tyrel Starks.

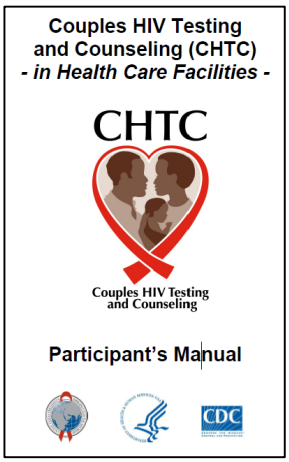
CHP Education Supervisors: Gabriel Alberto

6.0 SAFETY MONITORING PLAN

7.1 Data and Safety Monitoring Board

The study will be conducted under the supervision of an independent DSMB compried of Drs. Karen Ingersoll (chair); David Huebner and Eli Rosenberg. All DSMB members have extensive experience in either clinical trials and/or management of HIV or HIV prevention experience. The DSMB is responsible for the ongoing review of CHP research and for making recommendations concerning the continuation, modification, and termination of the study.

Appendix A (CHTC Training Manual and Protocol)



- For Full Manual (142 pages) for CHTC please follow the Link:

https://www.cdc.gov/globalaids/resources/prevention/docs/2014docs/chtc-participant-manual.pdf

Step 1	
Introduce yourself	Hello, my name is ____, and I will be your HIV testing counselor for your session today.
Explain CHTC	Today, you'll be completing an HIV test together, you will receive your results together, which means you'll hear each others' test results. And you will have the opportunity to discuss how you guys handle HIV risk in your relationship together. (OPTIONAL) We think of CHTC as being "forward looking." In other words, I'm not going to ask you to discuss your sexual history, instead we'll focus on how you guys want to handle HIV risk going forward.
Benefits of CHTC	The benefit of completing CHTC is that you'll both know each other's status and can make plans to keep each other healthy.
Conditions of CHTC	1. Agree to discuss any concerns you have about HIV and the ways you'll handle HIV risk going forward. 2. Agree to receive your results together as a couple. 3. Agree to handle disclosure decisions together.
Roles/Responsibilities	Because CHTC is a bit different from individual testing, I would like to take just a minute to talk about what is expected of you as individuls and as a couple during the session. The couples who get the best out of this experience are the ones who agree to... Some couples think of these as ground rules. 1. Participate equally 2. Listen and respond to one another 3. be respectful, open and honest 4. be understanding and supportive
Overview of procedures	I'd like to tell you about how the session typically proceeds 1. We'll complete the HIV test itself 2. While the test developes, we'll talk about your relationship and what brought you in for testing together. 3. We'll discuss HIV risk concerns and any agreements you have about sex. 4. We'll review your HIV test results. 5. I'll provide any information you'd like about results and risk management and we'll discuss your agreement in light of your results today. Any questions?
Obtain concurrence	How does that sound? Are you both comfortable continuing with the session?

Step 2	
Explain the test	We use a finger prick test here. I'll prick your finger with a small needle and draw a small amount of blood. We'll then wait 20 minutes for the test to develop.
Explain individual results	The test looks for HIV antigens and antibodies to the HIV virus A positive test result means antibodies or antigens were detected in your blood. Antigens stimulates the immune system to produce antibodies, so this test is better at picking up recent infections. 1. The test we use is highly accurate, which means it is highly likely that you have HIV if the test comes back positive. 2. When a positive test result occurs, a confirmatory test is done. We do not offer confirmatory testing services however, we have agreements with community partners who provide confirmatory testing and linkage to care for anyone who receives a preliminary positive HIV test result here at PRIDE. **An HIV-negative test result means that the test did not detect HIV antibodies or antigen.** 1. While our tests are very accurate for detecting antibodies, there is a "window period." It takes a while for your body to produce antibodies to HIV, so we cannot reliably detect an infection that occurred in the past 3 months, but if your test comes back antigen positive you might have been infected recently but the virus is not settled yet in your system, that's why we offer a confirmatory test option for that type of results and the turnover it's 24 hours approx and requires 1 blood vial to send the laboratory. 2. We recommend to all couples that you be retested in 3 months. 3. For couples who are considering stopping condom use, we generally recommend they continue using condoms until they are retested.
.	
Explain couple results	So there are three possible results that you could have as a couple. 1. You could both be HIV negative 2. You could both be HIV positive 3. Or your results could be different. One of you could be HIV negative and the other HIV positive.
Obtain consent to test Collect specimen	

Step 3	
Explore couple's relationship	While the test develops, we have some time to talk about the two of you. 1. Tell me a bit about your relationship. (OPTIONAL) When and how did you meet? (OPTIONAL) Do you live together now? 2. What is most important to you about this relationship? 3. When you look ahead in this relationship, what do you envision?
Summarize and reflect strengths	

Step 4	
Why CHTC?	What brought you in to receive HIV testing as a couple?
Feelings on CHTC?	How do you both feel about getting tested (and receiving your results) together?
Current risk management	Assess current risk management practices in the couple 2. How do you guys handle or manage HIV risk?
HIV risk concerns	Again, my goal here is not to "look back" or review sexual history, but I am curious, right now, as of today: 1. What effect has HIV risk or thinking about HIV had on you guys as a couple? 2. What concerns do you have about HIV and the risk for HIV in your relationship. 3. How concerned are you both about the results you might receive today?
Summarize	

Step 5	
Explain agreements	Many couples have agreements or understandings about how they have sex together and with partners outisde their relationships. Some couples may be monogamous or exclusive. Some couples may be open, which means one or both partners may have sex with other people. Other couples go for something in the middle.
Explore agreement	What agreements or understandings do the two of you have around sex? If yes, explore the agreement 1. What does it look like? 2. Where do condoms fit in? If no, normalize and clarify

	It's ok to not have an agreement. Many couples don't. Most couples find it useful to develop an agreement. It can help guys get on the same page, build trust, and reduce risk. 1. What kind of an agreement do you think would work for you guys? 2. What kinds of "rules" or "terms" would you like to establish if you were to put an agreement in place? 3. Where would condoms fit into this agreement?
Summarize agreement Obtain concurrence	
Agreement and risk	Whatever agreement you guys choose is ultimately up to you. With any couple, I ask them to think about a couple of things related to HIV risk. 1. In what ways does this agreement reduce your risk for HIV? 2. Where might HIV risk occur in this agreement? 3. If someone were to step outside of the agreement (and even in the best relationships, that's not impossible), what would you want to know and how would you want to be told?
	Step 6
Confirm ready Provide results	I have your test results. Are you ready to receive them together? Say one of the following: 1. Your results are the same, you are both HIV negative 2. Your results are the same, you are both HIV positive. 3. Your results are different, (look at positive partner) and your result is HIV positive.
	Step 7
Explore reaction to result	What thoughts, if any, do you have about these results?
[FOR CONCORDANT NEGATIVE COUPLES]	
Risk Prevention Planning	Revisit (Summarize) Sexual agreement and existing HIV risk reduction strategies Given your result today, what if anything do you guys plan to do to manage HIV risk going forward? 1. Revisit condom use if relevant and not addressed previously 2. Revisit PrEP if relevant and not addressed previously a. What have you heard about PrEP? b. Provide information as needed, confirm that couples know where they could access PrEP if they wanted to c. How useful do you guys think PrEP would be for you personally?

What have you heard about U=U?

Retesting

[IF NO EXPOSURE CONCERNS WERE DISCLOSED] "We recommend that all couples get retested in 6 months, just as part of routine sexual-health care."

[IF SPECIFIC EXPOSURE CONCERNS WERE DISCUSSED] "For any couple, we recommend they get retested routinely every 6 months, just as a part of routine sexual-health care. For you guys, we recommend that you get retested in 3 months, just as a routine follow up given the exposure you discussed earlier."

[FOR COUPLES WHERE ONE OR BOTH PARTNERS ARE HIV POSITIVE]

Connection to care [for positive member(s)]

1. Allow the participant to express his feelings about this result.
2. Remind the participant of confirmatory testing options and ask, "What would you like to do from here?"
3. Plan for connection to care:
If the participant does not wish to be taken for confirmatory testing: Discuss a plan for confirmatory testing access.

If the participant wishes to be taken for confirmatory testing: Complete step 8 and proceed with post-test protocol

4. Discuss self-care, including sexual risk reduction and emotional/physical health care referrals

Risk Prevention Planning

Revisit (Summarize) Sexual agreement and existing HIV risk reduction strategies

Given your result today, what if anything do you guys plan to do to manage HIV risk going forward?

[For discordant couples]

1. Revisit condom use if relevant and not addressed previously
2. Revisit PrEP if relevant and not addressed previously
   a. What have you heard about PrEP?
   b. Provide information as needed, confirm that couples know where they could access PrEP if they wanted to
   c. How useful do you guys think PrEP would be for you personally?

Retesting [for negatives]

If you have not already, make sure to check in with the **negative partner** in a discordant relationship.

1. How are you feeling?
2. What do you need right now?
3. What are your thoughts, hopes, or concerns about PARTNER NAME's next steps.

Discuss the need for retesting

"For any couple, we recommend they get retested routinely every 6 months, just as a part of routine sexual-health care. For you guys, we recommend that you get retested in 3 months, just as a routine follow up given the exposure you discussed earlier."

Step 8	
Provide referrals	All couples should get the We Test referral sheet Specifically point out: 1. Locations for HIV testing (though it likely will not be CHTC) 2. PrEP providers (for any couple with at least one negative result) 3. The presence of general health, mental health, as well as sexual health providers on the list