**R34 DA036419:** ***Addressing Substance Use through CVCT***
**PI Tyrel J. Starks**
NCT03125915

*** *Please see the following for more details and primary outcome results:*

Starks, T.J., Dellucci, T.V., Gupta, S., Robles, G., Stephenson, R., Sullivan, P., & Parsons, J.T. (2019, March). A pilot randomized trial of intervention components addressing drug use in Couples HIV Testing and Counseling (CHTC) with male couples. *AIDS and Behavior.* DOI: 10.1007/s10461-019-02455-2

Correspondence concerning this protocol should be addressed to Tyrel J. Starks, Department of Psychology, Hunter College of the City University of New York, 695 Park Ave., New York, NY 10065. Fax: 212-206-7994. Email: tstarks@hunter.cuny.edu

Document Approved: 6/15/2017

**Project Summary**

Two factors suggest the need for HIV prevention efforts focused on partnered young men who have sex with men (YMSM). First, HIV rates are rising in this population, which already bears a disproportionate burden of HIV infection. Second, main partnerships – rather than casual partners – account for a majority of new infections, and younger age has been associated with an increased risk of main partner transmission. Substance use remains a critical factor associated with HIV sexual transmission risk behavior. Couples based approaches to HIV testing have been developed for gay men; however, existing protocols do not include a focus on substance use. In addition, existing protocols are predicated on the assumption that members of the couple possess adequate assertive communication skills to discuss relationship agreements, which may be underutilized by YMSM.

The proposed project will develop a novel intervention to reduce substance use and sexual risk behavior among partnered YMSM through the modification of an existing Couples Voluntary HIV Testing and Counseling (CVCT) protocol originally created by Drs. Sullivan and Stephenson (co-investigators). The new intervention protocol combining Couples HIV Testing and Counseling (CHTC) with a substance use module (SUM) will be informed by qualitative data gathered from 20 HIV testing providers and existing qualitative data from 21 gay couples. In addition to the development of the novel CHTC +SUM protocol, the project will develop two brief assertive communication training (CT) videos specifically for use with partnered YMSM.

The final two years of the project are devoted to a randomized controlled trial (RCT) comparing the new CHTC+SUM to the standard CHTC protocol and testing the added efficacy of the CT component. A total of 70 couples were randomized to one of four conditions (standard

CHTC, CHTC +SUM, CHTC +CT, or CHTC +SUM and CT) in a factorial design. Follow-ups were completed online at 1-, 3-, and 6-months post-intervention.

**Objectives**

The purpose of the current pilot study was to test the feasibility, acceptability, and preliminary efficacy of two adjunct Couples HIV Testing and Counseling (CHTC) components: assertive communication training (CT) videos and a substance use module (SUM) module intended to facilitate a discussion around drug use and the formation of joint substance use goals. It was hypothesized that these two experimental components would significantly decrease the occurrence and severity of drug use. It was further hypothesized that these components would significantly reduce the occurrence of CAS with casual partners, a behavior which might increase HIV infection risk for the couple. Two variables relevant to intervention safety were also examined: the emergence of Intimate Partner Violence (IPV) and relationship dissolution post-intervention.

**Trial Design**

This study utilizes a factorial (2 X 2) randomized controlled trial (RCT) design to evaluate the efficacy of the We Test intervention components. Baseline assessment is conducted prior to randomization and the receipt of intervention (CHTC as usual, CHTC + SUM, CHTC + CT or CHTC+SUM+CT). Follow-up assessments are conducted at 1-, 3-, and 6-months post-baseline.

**METHODS: Participants, Interventions and outcomes**

**Study setting**

All study assessments and intervention sessions are conducted at the PRIDE Health Research Consortium affiliated with Hunter College of the City University of New York. PRIDE

is located centrally in Manhattan with easy access to a mass public transportation hub, linking it to the larger metropolitan area. Assessment and intervention sessions are conducted in private rooms.

**Eligibility Criteria**

An index approach to screening was used. One member of the couple (the index partner) completed a telephone screener, which gathered demographic and behavioral information about them and their partner. To be eligible, index participants must have reported being sexually active (engaging in oral or anal sex) with their partner in the past 90 days and also identify as being in a relationship for at least 90 days. Both partners in each couple were at least 18 years of age, cis-gender male, lived in the New York City metropolitan area, and able to communicate in English. In addition, at least one member of the couple had to be 18-29; have a negative or unknown HIV status; and use drugs in the past 30 days. Finally, couples were excluded at screening if the index partner indicated that they had "physically abused their partner" or "been physically abused by their partner." Those men who screened eligible were asked to schedule a baseline appointment at a time they could attend with their partner.

**Interventions**

*Couples HIV Testing and Counseling (CHTC).* All participants, regardless of condition, completed a CHTC session. Completion of CHTC takes approximately 30-40 minutes and involves 8-steps: (1) Introduce CHTC and Obtain Concurrence: an introduction to CHTC process and receiving the couple's consent; (2) Prepare for and Conduct HIV Test: explanation of the HIV test and possible results couples could receive, followed by a rapid HIV test; (3) Explore Couple's Relationship: an exploration of the couple's relationship to build rapport; (4) Discuss HIV Risk Concerns and Reasons for Seeking CHTC: discussion of current risks, reasons for

testing and HIV prevention strategies (i.e. condom use, PrEP use, etc.); (5) Discuss Couple's Agreement: exploration of the couple's sexual agreement and rules in regards to outside sexual partners; (6) Provide Results: results are given to the partners together as a couple and can be the same (concordant negative or positive) or different (discordant); (7) Develop Care, Treatment, and Prevention Plan Based on Result: discussion of future steps regarding HIV transmission risk prevention strategies (i.e. discussion of introducing condoms or PrEP use); and (8) Link with Follow-up Services: referrals given in light of current HIV test results (i.e. for confirmatory testing and other health services).

As part of CHTC, a rapid HIV test was administered. HIV testing was conducted using the OraQuick Advanced Rapid HIV-1/2 Antibody Test. This test uses a single drop of blood and takes 20 minutes to complete. Samples were collected in a phlebotomy room and the result was read by the research assistant conducting the assessment and provided to the CHTC tester.

*Assertive Communication Training (CT) Videos.* The CT video component was self-delivered. Partners viewed the videos together on an audio-equipped computer in an assessment room. The video duration was approximately 20 minutes. After viewing, the partners collaboratively completed a video recognition survey as a check of intervention receipt. In the CT videos, four male couples are depicted in separate scenes discussing HIV testing, drug use, sexual agreements, and drug use during sex. Each scene is viewed twice. Initially, the couple makes one or more communication errors. In the second viewing, the couple utilizes more effective communication skills, resulting in a more adaptive resolution. Each scene is introduced by a narrator who orients viewers to the communication errors and skills in each scene.

*Substance Use Module (SUM)*. The SUM was administered after step 5 of CHTC and prior to the delivery of HIV-test results. The SUM was designed to be completed in 5 to 10

minutes. First, the HIV-tester asked the couple to fill in a paper calendar of the past 30 days, indicating days on which either member used drugs or alcohol. The HIV-tester then asked a series of debriefing questions designed to elicit the couples' perspective on their use, establish goals and limits for drug use, and make plans to achieve these goals.

**Training of Interventionists**

CHTC providers were trained by Drs. Tyrel Starks and Rob Stephenson following the CDC's standard training protocol. This involved a two-day didactic workshop and subsequent mock delivery of the intervention. Providers required between 4 and 8 mock sessions to achieve fidelity to the protocol. The first author reviewed each mock session and provided feedback. The first author personally reviewed all mock-training session recordings. A session check-list was developed for this study based upon the CDC's checklist for the delivery of CHTC. Providers were trained to deliver the intervention covering the content on the checklist.

**Fidelity Monitoring and Supervision**

Supervision of all CHTC sessions was conducted by Dr. Tyrel Starks. Providers met weekly with Dr. Starks for CHTC supervision, and also had one-hour of weekly group supervision in which cases were reviewed and discussed.

**Outcomes**

<u>Primary outcomes</u>

1) *Drug Use Instances.* Participants reported their use of a range of illicit drugs in the 30 days prior to assessment. Drugs included: cannabis, prescription drugs, opioids, cocaine/crack, stimulants, psychedelics, and club drugs (ecstasy, ketamine, and gamma aminobutyric acid). Responses were aggregated to create a dichotomous variable indicating the use (or non-use) of any of the drugs assessed.

2) *Problematic Drug Use.* Assessed using the 10-item Drug Abuse Screening Test (DAST-10). Participants who indicated the use of any of the substances listed above were subsequently asked to indicate the presence or absence of 9 symptoms associated with drug use. Responses were summed to produce a count of problems. Those participants who did not indicate the use of any substances assessed were assigned a value of zero.
3) *Condomless Anal Sex (CAS) with Casual Partners*. Assessed using a series of survey items. Participants indicated the number of times they had sex with casual partners alone and in the presence of their main partner. Those who indicated that sex with casual partners had occurred were then asked to indicate the number of times they had insertive and receptive anal sex with a casual partner. Responses were aggregated into a single variable indicating the occurrence of any CAS with a casual partner.

*Secondary Outcomes*

1) *Depression*. Assessed using the 20-item Center for Epidemiological Studies in Depression Scale Revised (CESD-R), a revised version of the CESD scale that was used to assess depressive symptoms. The items cover all the criteria for depression indicated in the Diagnostic and Statistical Manual of Mental Disorders (DSM). Total scores were calculated as a sum of responses for all 20 questions.
2) *Communication Patterns*. Assessed using the 11-item Communication Patterns Questionnaire (CPQ). Participants were asked to identify their typical communication patterns during moments of relational conflict at two different time points: when an issue or problem arises and during discussion of the issue or problem. Scores for each item range from 1(*very unlikely*) to 9 (*very likely*).

**Participant Timeline**

Figure 1: SPIRIT Flow of participants through randomized controlled trial.

| | **STUDY PERIOD** | | | | |
|---|---|---|---|---|---|
| | **Enrolment** | **Allocation** | **Post-allocation** | | **Close-out** |
| **TIMEPOINT** | ***-$t_1$*** | **0** | ***1*** | ***3*** | ***6*** |
| **ENROLMENT:** | | | | | |
| **Eligibility screen** | X | | | | |
| **Informed consent** | X | | | | |
| ***Baseline*** | X | | | | |
| **Allocation** | | X | | | |
| **INTERVENTIONS:** | | | | | |
| ***CHTC*** | | | ← | — | → |
| ***CHTC + SUM*** | | | ← | — | → |
| ***CHTC + CT*** | | | ← | — | → |
| ***CHTC + SUM + CT*** | | | ← | — | → |
| **ASSESSMENTS:** | | | | | |
| *Demographic; HIV status; PrEP Uptake; Relationship length;* | X | X | X | X | X |
| *Drug Use Events; Problematic Drug Use; Condomless Anal Sex with casual partner; Relationship Functioning* | X | X | X | X | X |

**Sample Size**

Results were generated by Monte Carlo simulation using Mplus. All estimates were based upon 10,000 sample replications and power was defined as the percentage of randomly generated samples in which the specified parameter was statistically significant. All models specified that individuals were nested within couples. Models focused on detecting between-condition differences at any one follow-up time-point. The main effects of the two interventions

were modeled at level 2. Given the pilot nature of this RCT, no a priori hypothesis was made about the size of the interaction effect anticipated. Therefore, all analyses were conducted under the conservative assumption that the interaction effect is of equivalent size and opposite direction. In this case, there is a significant effect of one treatment only at one level of the other.

Assuming 80% of the sample endorsed drug use at baseline, a sample of 70 couples has power approximately = .60 to detect a treatment effect associated with a 10% decrease in the odds of drug use at any follow-up time point. Similarly – assuming an average DAST-10 score of 2.0 at baseline – the study had power ≥ .60 to detect a 0.5 SD difference in DAST-10 scores at any follow-up time point. CAS with casual partners and concurrent CAS with casual and main partners were both reported by approximately 26% of the sample at baseline. Under the most conservative default assumptions about the size and direction of the interaction term, this study has power approximately = 0.40 to detect a main effect associated with a 15% decrease in the odds of these variables. Under somewhat less conservative assumptions, assuming a null interaction effect, power to detect a treatment effect of this size was largely unchanged.

**Recruitment**

Eligible participants were recruited through a variety of online and outreach-based methods in the New York City area between January 2016 and August 2017, follow-up assessments continued through February 2018. Online recruitment efforts included the distribution of study information via listservs as well as websites and smartphone applications targeting YMSM. Outreach strategies included study staff attendance at community and social events frequented by YMSM in the New York City area.

An index approach to screening was used. One member of the couple (the index partner) completed a telephone screener, which gathered demographic and behavioral information about

them and their partner. To be eligible, index participants must have reported being sexually active (engaging in oral or anal sex) with their partner in the past 90 days and also identify as being in a relationship for at least 90 days. Both partners in each couple were at least 18 years of age, indicated a male sex and gender identity, lived in the New York City metropolitan area, and were able to communicate in English. In addition, at least one member of the couple had to be 18-29; have a negative or unknown HIV status; and use drugs in the past 30 days. Finally, couples were excluded at screening if the index partner indicated that they had "physically abused their partner" or "been physically abused by their partner." Those men who screened eligible were asked to schedule a baseline appointment at a time they could attend with their partner.

**METHODS: Assignment of interventions**

**Randomization**

Participants will be randomly assigned to one of for study conditions using data provided by the index partner at screening. A stratified random assignment procedure will be implemented using Qualtrics. Stratification insures that conditions are balanced on: (1) age discrepancy: participant age difference with his partner (three years or less/ longer than two years); (2) relationship length with his main partner (two years or less/longer than two years); (3) race/ethnicity makeup of the participant and his partner e.g., both partners identify as White and non-Hispanic/one or both partners identify as non-White or Hispanic. Within each strata, assignment to condition is random.

**Blinding**

Participants were informed at the time of consent that they would complete CHTC regardless of condition assignment and that they may view CT videos and/or discuss drug use depending upon condition assigned. By virtue of this consent process and the nature of the

intervention themselves, participants therefore could not be blinded to whether or not a particular intervention component was completed. CHTC providers were blinded to whether or not participants view the CT video prior to the completion of CHTC. CHTC providers were instructed whether or not to administer the SUM as part of CHTC based upon condition and so inherently could not be blinded with respect to that intervention component. Assessment staff was blinded to condition at baseline because participants were not randomized until after the baseline assessment was completed.

**METHODS: Data collection, management, and analyses**

**Data Management**

Data will be collected on-site at baseline and at 1-, 3-, 6-months post-intervention to participants independently of their relationship partners at baseline. For each survey, participants received an email reminding them of consent information and containing the survey link. Participants were compensated $30 for completion of each follow-up assessment. Compensation varied by participant presence: it was either delivered online via Amazon.com gift-card or in-person as cash. All survey instruments are administered using a Qualtrics-based CASI interface. To reduce the time required to attend the in-office baseline appointment, participants have the option of completing a portion of the baseline survey at-home online prior to the appointment through a Qualtrics link. Participants were be contacted to inform them their 1-, 3-, or 6-month follow assessment was available online and was provided a Qualtrics link to the survey. All procedures were approved by the Institutional Review Board of Hunter College of the City University of New York and study visits took place at a research center in New York City. In addition, we have set up a Data Safety Monitoring Board consisting of leading experts in YMSM

with particular specific expertise in randomized controlled trials, epidemiology statistical analysis, and clinical research broadly.

**Data Analysis Plan**

The success of randomization, the presence of differential attrition, and between-group differences on safety indicators (relationship dissolution and IPV) were assessed using repeated-measures Analysis of Variance (ANOVA) for continuous variables. To account for the nesting of people-within-couples, between-condition differences in categorical variables were assessed by testing differences among Estimated Marginal Means in Generalized Estimating Equation (GEE) models. Where indicated, pairwise comparisons were conducted using a Least Significance Difference (LSD) post-hoc test.

Between-condition differences in primary outcomes were tested within a Latent Growth Curve (LGC) framework in Mplus (version 8.0). For each outcome, a latent intercept and linear slope were specified with the first post-intervention follow-up as the initial time-point. Binomial distributions were specified for Drug Use; CAS with casual partners; and concurrent CAS. DAST-10 scores were modeled using a Poisson distribution. Growth factors were specified at both the individual level (to allow for variability between partners within couple) and the couple level (reflecting dyadic assignment to condition). For each outcome, the direct effect of the CT video and SUM were included along with a CT-by-SUM interaction effect. In this procedure, a significant effect of treatment on the latent intercept factor indicates the presence of a group difference at that time point. Meanwhile, a significant effect on the latent linear slope factor indicates that the trajectory over time differs between groups. Missing data were handled within the context of full-information maximum likelihood estimation.

**Data Monitoring**

The study protocols are approved by the research ethics board of the principal investigator's academic institution and are registered with clinicaltrials.gov (NCT03125915).

**Abbreviations**

| | |
|---|---|
| CAS | Condomless Anal Sex |
| CHTC | Couples HIV Testing and Counseling |
| CT | Assertive Communication Training |
| PRIDE | PRIDE Health Research Consortium |
| PrEP | Pre-Exposure Prophylaxis |
| SUM | Substance Use Module |
| YMSM | Young men who have sex with men (ages 18-29, unless otherwise specified) |

**DECLARATIONS**

**Availability of data and material:** Not applicable as this manuscript contains no data.

**Competing interests:** The authors declare that they have no competing interests.

**Acknowledgements:** The authors acknowledge the contributions of the *We Test* Project Team, particularly Mark Pawson, Andrew Cortopassi, Nahuel Smith Bacerra, Ruben Jimenez, Chris Hietikko, and Scott Jones. We also thank Rich Jenkins for his support of the project as well as CHEST staff, recruiters, interns and our participants who volunteered their time.

**Funding:** This study is supported by a grant from the U.S. National Institute of Drug Abuse (R34 DA036419; PI Starks).