HUNTER
The City University of New York

STUDY PROTOCOL

with

STATISTICAL ANALYSIS PLAN

Prevention and Risk: Treatment with a new emphasis on Relationships (Project Partner)

NCT03396367

Sponsor: National Institute of Drug Abuse (NIDA)

Principal Investigator: Tyrel J. Starks, PhD
Professor
Hunter College
City University of New York
New York, NY

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STUDY ABSTRACT

DESIGN:	The study utilizes a randomized control trial design, with two conditions (the experimental PARTNER intervention and an attention-matched Education control) receiving equal allocation.
SAMPLE SIZE:	240 Sexual minority men (SMM) (18-29) who are in a same gender relationship. Or 30-34 if they are in a relationship with a partner who is 18-29
POPULATION:	HIV negative SMM who have used drugs in the past 30 days, and who have engaged in CAS in the past 30 days with a casual partner, a serodiscordant main partner, or a non-monogamous main partner.
STRATIFICATION:	The study will employ a stratified block randomization procedure with will equate study conditions based upon 1) age discrepancy between partners, 2) relationship length, and 3) race and ethnicity using Qualtrics.
DATA COLLECTION:	Participants have the options to first complete a CASI at home before their BL appointment (or during BL if they have not done so beforehand). All other aspects of data collection occur at Hunter College. A second CASI survey will also be administered at the BL appointment. Time line follow back interviews to assess drug use, sexual behavior and PrEP adherence (where applicable) will at all assessments. Drug screening and PrEP adherence will be accomplished by obtaining fingernail samples from participants at all assessments. Blood will be collected for testing PrEP medication adherence. STI testing will be accomplished by collecting urine and rectal samples at BL, 6m, and 12m. HIV testing will be conducted at BL, 6m, and 12m. **Post-COVID:** Participants receive a CASI link via email and an at-home STI and HIV testing kit, a dried blood spot (DBS) collection kit for PrEP adherence, and a fingernail collection kit for drug screening (via regular mail) prior to assessment appointments.

All other aspects of data collection occur remotely via HIPAA-compliant Zoom.

OBJECTIVES:

1) Evaluate the efficacy of PARTNER in regards to three primary outcomes: 1) PrEP uptake and adherence 2) sexual transmission risk behavior and 3) drug use.
2) Identify individual and relationship factors which moderate/mediate intervention efforts.
3) Gather ideographic data to inform a future effectiveness-implementation study.
4) Validate the use of fingernail assays as a biological marker for PrEP adherence.

STUDY DESIGN

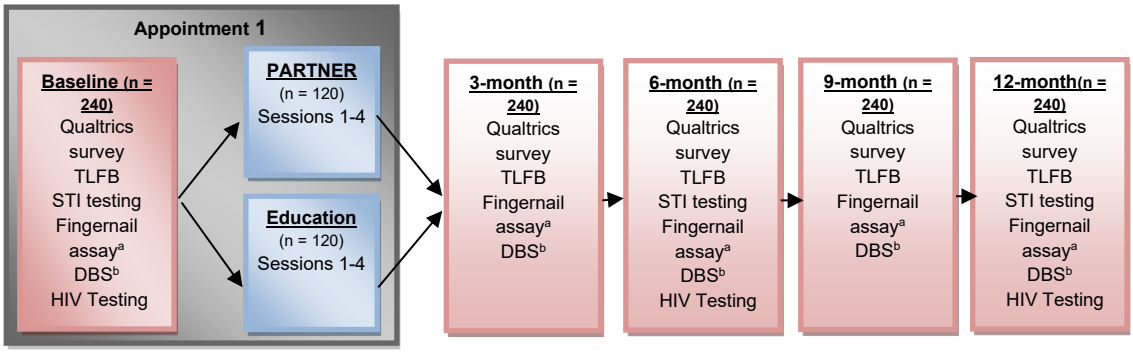
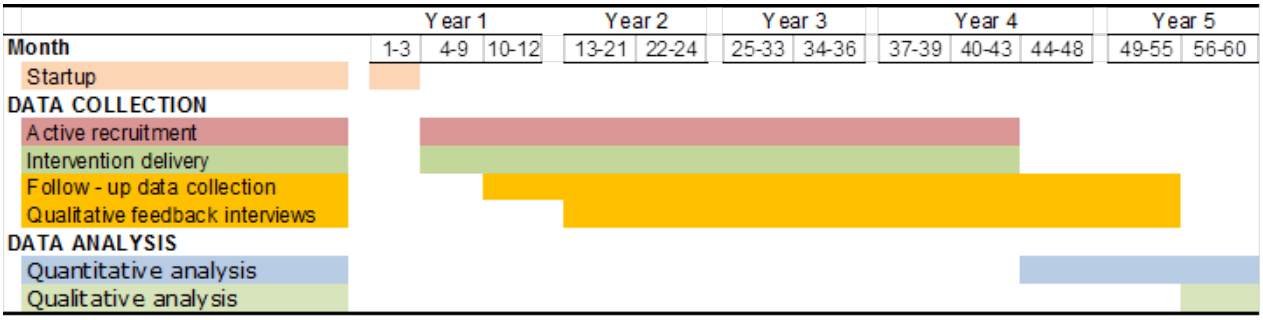


Figure 3. Participation timeline

[a] To detect drug use for all participants and PrEP adherence for those on PrEP.

[b] Gathered only for those on PrEP

STUDY TIMELINE



STUDY POPLUATION

Inclusion and Exclusion Criteria:

Participants who express interest in PARTNER must demonstrate the following inclusion criteria to be enrolled in the study:

- 18 – 29 years old; or 30-34 with a partner who is 18-29 (inclusive)
- Have a main partner who is another male for 1 month or longer
    - Main partner must be 18 years old or older
- Be HIV negative (as confirmed by rapid test)
- Have used drugs in the past 30 days
- Have engaged in TRB in the past 30 days
    - Defined as CAS with a casual partner and/or CAS with a non-monogamous or serodiscordant main partner
- Live in the NYC metropolitan area (Enrollment expanded nationwide in the US in September 2022.)
- Speak English

Participants are excluded from the study if they any indicate the following:

- Any signs of serious mental illness or cognitive deficit
- History of intimate partner violence with their main partner or feel unsafe in their current relationship.

Recruitment and Screening

We utilize a multi-faceted recruitment effort including both active and passive approaches. Our previous research focused on MSM in relationships has indicated that online recruitment is particularly effective at reaching this target population. We anticipate enrolling 6 new participants each month. Contacts obtained through our online screener will be contacted for scheduling. Contacts that come from the online master screener will be sent 2 emails with links to take our study specific screener. Once scheduled, participants are sent their at-home survey link. They do not have to complete this survey beforehand, but we do remind them two times before their baseline appointment to complete it as it cuts down on the time they need to be in the office.

Post COVID: Contacts obtained through our cross project online screener are contacted to schedule a baseline appointment on Zoom. Before the baseline appointment, the study staff contacts the participants via text or phone call to obtain preferred mailing address for testing kit shipments, confirm contact information, and obtain participant PrEP status in order to ship the correct laboratory testing kit. The baseline assessment is scheduled and study staff sends participants their at-home survey link and orders their STI/HIV testing kits. Participants must

complete this survey and have received their testing kits before their remote baseline appointment can occur.

Contact Information

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

STUDY PROCEDURES

Enrollment Procedures

Participants are considered enrolled in the study when they have completed informed consent. Randomization occurs immediately after the baseline appointment.

Informed Consent Process

Details of the study are reviewed with the prospective study participant by a research assistant who is 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 research assistant is available to answer questions about the study including participant responsibilities, benefits, risks, and alternatives. The participant reviews the consent form and it is 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.

Post-COVID: Participants review written consent information prior to their baseline appointment. The baseline survey link directs participants to a landing page containing detailed consent information. At the beginning of the baseline assessment, study staff provides an oral review of consent information and confirms age eligibility via Zoom. After reviewing this information, participants are asked to affirm their consent/assent to participate. A copy of the electronic consent form is emailed to the participant upon request.

Randomization Process/Systems

Participants are randomized at the end of their baseline assessment into one of two intervention conditions: 1) delivery of the 4 session PARTNER intervention or 2)

delivery of 4 education sessions. Each participant's condition is tracked in the access tracking database maintained by the project manager.

The study employs a stratified block randomization procedure with equate study conditions based upon 1) age discrepancy between partners, 2) relationship length, and 3) race and ethnicity using Qualtrics.

Schedule of Assessments

Sessions occurs approximately once per week for three weeks beginning one week after completion of the baseline assessment and session 1. There is a 12 week window for intervention completion, i.e. all four sessions must be completed within 12 weeks of the baseline assessment.

Participants complete the first follow-up assessment 3 months after the baseline, and subsequent follow ups at 6, and 9 months after baseline with a final appointment scheduled for 12 months following the baseline appointment. Study staff should aim to schedule and complete these follow-ups as close as possible to each target date. To keep track of longitudinal data collection dates, assessment visit windows will be defined as 15 days prior and after the target as "in window." The assessment visit window for the 12 month follow-up ends 30 days after the target date. Site study staff should prioritize the completion of sessions before the first follow-up assessment, and should not schedule this follow-up less than 12 weeks after baseline if a participant is available to complete any additional sessions first.

Post-COVID: The 12-month assessment window ends 60 days after the target date.

Component	*Baseline*	*Session 1*	*Session 2*	*Session 3*	*Session 4*	*3-Month Follow-Up*	*6-Month Follow-Up*	*9-Month Follow-Up*	*12-Month Follow-Up*
Informed Consent	**X**								**X**
Randomization	**X**								
CASI	**X**					**X**	**X**	**X**	**X**
TLFB	**X**					**X**	**X**	**X**	**X**
HIV Testing (Rapid for those not on PrEP –	**X**						**X**		**X**

Architect for those on PrEP)									
STI Testing	**X**						**X**		**X**
Fingernail Assay for Drugs	**X**					**X**	**X**	**X**	**X**
Dried Blood Spot (For those on PrEP)	**X**					**X**	**X**	**X**	**X**
PrEP Video				**X**					
Video Recall Survey for those who seen the Video					**X**	**x**			**x**
Session feedback					**X**				
Qualitative Interview									**x**

Managing and Tracking Study Visits

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

Session Visits: Session visits refer to both the four education and four intervention sessions. Intervention sessions are conducted by trained and cleared MI-trained clinicians. Intervention sessions will be managed by the clinicians with their individual study participants. Clinicians will notify site study staff of whether visits were completed for tracking purposes, provide receipts for session compensation to site study staff, and upload audio files to Project Partners respective folder on the M drive as per study procedures. Education sessions are conducted by trained and cleared health educators. Education sessions will be managed by the educators with their individual study participants. Educators will notify site study staff of whether visits were completed for tracking purposes, provide receipts for session compensation to site study staff, and upload audio files to Project Partners respective folder on the M drive as per study procedures.

Research Visits: Research visits include all assessments including the baseline visit, the post-test assessment, and all other follow-up assessments. All participants, in either condition, are expected to complete five assessment visits as part of full participation in the study.

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 are 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).

Retention and Follow Up

Session visits: For participants who are actively taking part in the PARTNER intervention or the Education control condition, site study staff will not add an additional level of outreach to the procedures.

Specimen Collection Pre-COVID

HIV testing will be performed at the baseline using the HIV 4th Generation assays and those will be administered following the below criteria:

1- Participants on PrEP, upon PrEP self-report confirmation will provide 1 tube of blood to send to the LAB for HIV Confirmatory testing with Architect equipment to avoid any inaccurate test results as a result of PrEP drugs in blood. Results are downloaded from the LAB's web portal.
2- Participants NOT on PrEP, will be administered a rapid HIV Test named "Determine Ab/Ag" which detects HIV antibodies and antigen P24 (the last one is a very sensitive part of this specific test and can detect early acute HIV infections).

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 then to pipette just a portion of that urine sample into a sample tube in order to be sent 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.

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.

A second vial of blood will also be collected at the same time as the HIV test vial with participants reporting being on PrEP, to perform dried blood spot (DBS) cards to test for PrEP adherence, which will be sent to Colorado Antiviral Pharmacology Laboratory.

Post-COVID Specimen Collection

HIV and STI tests are completed using tests shipped and processed by Molecular Testing Labs (MTL). Prior to the RA administered portion of the baseline assessment and 6- and 12-month follow-ups, participants are mailed a package containing an at-home OraQuick testing kit for HIV, self-administered rectal and urethral gonorrhea and chlamydia testing kits, one dried blood spot (DBS) card (if on PrEP), collection

materials (alcohol prep pads, lancets, gauze pad, and adhesive bandages), an instruction card, and a postage-paid shipping envelope. During the RA administered portion of the baseline, 6M, and 12M, the RA will review instructions and demonstrate the collection procedure. The RA will then remain on the Zoom call to provide any additional guidance as needed during the collection procedure. Participants will then place the collected specimens in the addressed envelope for shipping to the lab for processing. Participants will also be mailed a fingernail collection kit to examine drug use rates during all assessments.

Incentives and Compensation

Participants will be compensated up to $380 for full participation in the study. They will receive:

$50 for completing a Baseline assessment.
$20 for each completed session (up to $80 total).
$60 for completing a 3-Month Follow-Up Assessment.
$60 for completing a 6-Month Follow-Up Assessment.
$60 for completing a 9-Month Follow-Up Assessment.
$70 for completing a 12-Month Follow-Up Assessment. (**Post-COVID**: $100 for completing a 12-Month Follow-Up Assessment)

INTERVENTION PROCEDURES

The PARTNER intervention comprises 4 sessions of Motivational interviewing (MI) to address 3 target behaviors that correspond to the study's primary outcomes: drug use, PrEP uptake/adherence, and HIV transmission risk. Miller and Rollnick suggested that 4 processes are ongoing during an MI session: engagement (establishment of a therapeutic alliance), focusing (clarification of session goals), evoking (eliciting speech in favor or change while softening arguments for the status quo), and planning (the identification of action steps that can be taken toward the accomplishment of an identified goal). The salience of these various processes is dependent upon the duration of the relationship between the interventionist and the participant as well as the client's stage of change.

The first session emphasizes the engaging process. It begins with an introduction to the participant followed by an exploration of participant's primary relationship, understanding how he and his partner handle sex outside their relationship, and enhancing motivation to reduce both drug use and HIV infection risk. This conversation then focuses on what strategies, if any, the participant and his partner use to manage their HIV risk. The interventionist then seeks to evoke motivation to reduce HIV related risk, potentially through PrEP uptake or adherence. The values card sort activity is utilized midway through the session to integrate a conversation about how the participant's values are expressed in his relationship and the decisions made around HIV prevention. The second session engages the participant in a review of the previous week and then transitions to focus on drug use. The interventionist seeks to evoke motivation to reduce drug use, with particular attention given to how the participant's relationship partner feels about use. The third session integrates a focus on the links between drugs and CAS with main and casual partners, PrEP, and presents video-based modeling to enhance communication skills. This facilitates a longer discussion about planning toward any identified goals. The interventionist gives particular attention to the role of relationship partners during the planning phase. The final session engages the participant in a review of the previous week. The session then proceeds to review the participant's perception of the overall intervention process with emphasis on successes and challenges. The session emphasizes the planning process by inviting the participant to identify long-term goals related to the target behavior and develop plans to accomplish these goals. A discussion of relevant resources and referrals occurs during this time.

PARTNER incorporates a video-based approach to relationship skill building with a structured series of debriefing questions asked by the MI provider after the video is viewed. The video utilized was comprised of 3 scenes, each depicting a different couple. It is integrated into Session 3 of the intervention and serves a dual purpose. First, it provides information specific to PrEP. Each scene depicts either a nonmonogamous or serodiscordant couple discussing PrEP and HIV prevention. In this way, participants viewing the video see men in relationships with men talking about reasons why PrEP might be relevant, while also receiving basic information about PrEP and its efficacy. Second, the videos directly teach communication skills through modeling. Each scene is divided into 2 parts. In the initial portion of the scene, the couple makes a specific communication error. Midway through the scene, a narrator interrupts the couple, explains their error, and suggests an alternative strategy. The scene then continues, and the couple communicates more effectively.

SESSION 1: Focus on CAS with main and casual partners

- Opening statement – provide information as appropriate; set the stage for collaboration; introduce target behaviors
- Values Card Sort – Use Open Questions and Reflections, close with a major Summary
- Use strategies for eliciting change talk & managing discord
- At the end of the session, offer a closing summary highlighting any change talk or steps towards change; evoke commitment to attend future session

SESSION 2: Focus on drug use

- Opening statement – highlight any change talk or plan from previous session; introduce second target behavior and collaborate on setting session agenda with client
- Briefly revisit last session's topic and check for any changes or recent events since you last met
- Ask permission to discuss second target behavior
- Use strategies for eliciting change talk and managing discord
- Offer to help in creating a strategy to change target behavior
- Offer a closing summary at the end of the session, highlighting change talk and any steps taken towards change

SESSION 3: Focus on drugs, CAS with main and casual partners, and PrEP

- Opening statement: Highlight and integrate change talk on both target behaviors and any ideas or goals the client has articulated around these behaviors; work collaboratively to set the agenda for the session
- Ask the client where they would like to go from here; or, ask permission to discuss collaborating on a change plan together
- Evoke client's ideas about change; build on past success; evoke and reinforce self-efficacy for taking steps towards change
- If appropriate, use the Ask-ask-tell-ask-reflect approach for offering information or suggestions; if offering suggestions be sure to reinforce client autonomy and offer a menu of options
- Collaborate with the client to build a change plan that reflects their goals, priorities and readiness to change; elicit the client's ideas about how the plan could be carried out, when the steps will occur – and why these changes are important
- Offer a closing summary highlighting change talk and briefly reiterating the basic plan; reinforce client autonomy; remind the client that the next session will be focused on moving ahead independently.

SESSION 4: Focus on drugs, and CAS with main and casual partners

- Opening Statement: Summarize the plan developed previously and collaborate on setting the session agenda; introduce termination / last YMHP session;
- Check in on how the plan has been going since you last met; use strategies for evoking change talk / managing discord as appropriate; affirm client for any steps towards change;
- Evoke client's ideas about how to improve or adapt the plan; evoke and reinforce commitment for maintaining the plan moving forward
- Evoke client's ideas about what to do should problems arise in the future; develop a 'backup plan' as appropriate
- Summarize progress over the 4 sessions and termination

Post-COVID: The PARTNER intervention is administered via Zoom following the procedures outline above. Interventionists share their screen with participants when needed to present video components of the intervention. The values card sort activity is completed using a version of the task programmed into Qualtrics. Interventionists share their screen, and participants direct them how to sort values.

Education Intervention (Control Condition)

The education intervention is administered one-on-one by a health educator. The sessions are guided by a PowerPoint presentation that helps to insure fidelity of delivery while also increasing the participant's engagement through the integration of pictures, animation, and video. The presentation is viewed on a personal computer located in the intervention room. Dual monitors are used to ensure that both the educator and participant can readily view material.

The condition comprises of 4 sessions of health education addressing sexual risk and drug use. The sessions utilize a mixture of modalities including lecture, question and answer, and video. Session 1 focuses on HIV risk and prevention. Lecture content is supplemented by videos focusing on HIV transmission generally and HIV prevention strategies among gay and bisexual men specifically. Session 2 is focused on drug use. Information about the biological effects of drug use is largely provided through videos. Lecture content and discussion questions focus on the impact of drug use within the local gay community. Session 3 examines the intersection of drugs and sex in the local gay community. Education content also focuses on mitigating the risks associated with having sex while intoxicated. Session 4 again focuses on drug use with video and lecture-delivered content describing the signs and warnings of potential substance use disorders.

Post-COVID: The education intervention is administered via Zoom following the procedures outlined above. Health educators share their screen with participants to present PowerPoint slides and review session content.

Intervention Monitoring

All sessions will be audio recorded. MI fidelity in the PARTNER intervention will be evaluated using the Motivational Treatment Integrity coding system[141]. We will randomly select 25% of session to be coded. A team of trained coders is maintained and utilized in all NIH-funded studies involving MI-based interventions. The educators for the control condition will undergo similar fidelity procedures in which 25% of their education sessions will be evaluated for fidelity. These recordings will be reviewed and matched to a fidelity checklist that outlines the content of the Education session. Successful Education sessions will have accurately discussed at least 90% of the content.

DATA MANAGEMENT AND ANALYSIS PLAN

Data Management and Data Quality

Qualtrics, a secure online survey platform which can be accessed from computers on site, is used to administer survey measures during in-person appointments. Qualtrics is sufficiently flexible to permit the use of a wide range of question and response types.

Qualitative interviews will be recorded, transcribed, and de-identified.

MEASURES

CASI Measures

	Construct	Measure
Screening information	Demographics	NHBS demographics inventory[107]
	Sexual HIV transmission risk	Self-Reported Sexual Behavior
	PrEP uptake and related attitudes	PrEP uptake questionnaire[15,68]
	Problematic drug use	Drug Abuse Screening Test – 10[108]
	Alcohol and Drug Use Behavior	NHBS Substance Use History Inventory[107]
	Partner health behavior	Partner health behavior survey
IMB factors	Knowledge: Drug use	Drug use knowledge questionnaire
	Knowledge: HIV infection (including condom and PrEP supplement)	Brief HIV knowledge questionnaire[109]
	Motivation: Drug use	Decisional Balance - Club Drugs[110]
	Motivation: Condom use	Decisional Balance - Unsafe Sex[110]
	Motivation: PrEP	Decisional Balance - PrEP
	Behavioral Skill: Drug use	Drug Taking Confidence Questionnaire[111]
	Behavioral Skill: Condom use	Condom use self-efficacy scale[112]
	Behavioral Skill: PrEP	Adapted Adherence Self-Efficacy Scale[113]
Individual functioning	Condom attitudes/beliefs	Adapted condom attitudes scale[32]
	Anxiety and Depression	Brief Symptom Inventory[114] (subscales)
	Experiences of stigma	Everyday discrimination[115]
	Intimate Partner Violence (IPV)	IPV among gay and bisexual men [116]
	Problematic alcohol use	Alcohol Use Disorders Identification Test (AUDIT)[117]
	Self-reported STI and HIV	

	testing history; PrEP; and ART	
Relationship functioning	Relationship satisfaction, cohesion, consensus & affectional expression	Dyadic adjustment scale[118]
	Interpersonal Communication Skills	Interpersonal Communication Competence Scale[119]
	Partner communication strategies	Communication patterns questionnaire[120]
		Sexual communication[121]
	Couples HIV Coping	Perceived severity of HIV infection[122]
		Preferences for sexual health outcomes[122]
		Couple efficacy to reduce HIV threat[122]
	Stigma directed at the relationship	Relationship marginalization[123]
	Relationship Control & Dominance	Sexual Relationship Power Scale (SRPS)[124]
	Attitudes about Sexual Agreements	Sexual Agreement Investment Scale (SAIS)[100]

Primary outcomes

Drug use. During TLFB interviews, participants indicated whether they used any of 10 different drug types. Responses produced two count variables indicating the number of days participants used cannabis and the number of days they reported the use of any illicit drugs, including: cocaine, crack, methamphetamine, ecstasy, ketamine, GHB, and psychedelics. Self-reported drug use was corroborated by fingernail assay. See supplemental material for details.

Current PrEP uptake was assessed using a single survey item, “Have you ever been prescribed PrEP (HIV pre-exposure prophylaxis)?” Participants taking PrEP reported days they missed their PrEP on the TLFB interview. Responses were used to create a dichotomous variable indicating whether or not participants took PrEP on at least 57% of days (corresponding to at least 4 days out of 7 on average). Self-reported PrEP adherence was corroborated with DBS results. See supplemental material for details.

Sexual HIV TRB. During TLFB interviews, participants indicated days they had (insertive or receptive) anal sex with any casual partners and whether a condom was used. Responses were aggregated to create a variable indicating the number of times the participant had CAS with a casual partner. If participants were prescribed PrEP and reported missing 13 doses or fewer, they were assigned a value of 0, reflecting that the use of PrEP on at least 4 of 7 days is sufficient to achieve reductions in HIV TRB (28). Self-reported CAS with casual partners was corroborated by bacterial STI diagnosis. See supplemental material for details.

Putative moderators

Relationship satisfaction was assessed using the approximation to ideal subscale of Kurdek's (29, 30) Multiple Determinants of Relationship Commitment Inventory (MDRCI). The subscale consists of 4 items (e.g., "My current relationship comes close to matching what I would consider to be my ideal relationship"). Response options ranged from 1 (strongly disagree) to 5 (strongly agree). Total score reliability was good (Cronbach's $\alpha = .848$).

Communication skills. Self-disclosure, social anxiety, assertiveness, and empathy subscales of the Interpersonal Communication Competence Scale (31) assessed aspects of communication skills. Each subscale was assessed by 3 statements (e.g., "I can put myself in others' shoes" and "It's difficult to find the right words to express myself"). Participants evaluated each statement using a 5-point scale Likert-type scale ranging from 0 ("Almost never") to 4 ("Almost always"). Total score reliability was good (Cronbach's $\alpha = .787$).

Quantitative Analysis Plan

The primary hypotheses are that SMM receiving the PARTNER intervention will be more likely to initiate and/or be adherent to PrEP throughout the follow up period. As a result, it is hypothesized they will have a lower probability of TRB. In addition, it is hypothesized that the PARTNER intervention will be associated with lower levels of drug use (number of use instances) compared to the education condition.

Corroboration of self-reported behavior with biomarkers

Self-reported drug use was corroborated by fingernail assays. At baseline and all follow-ups, at least 80% of participants who tested positive for cannabis indicated at least one instance of cannabis use. In addition, at least 60% of those who did not test positive for cannabis on fingernail assays indicated they used cannabis at least once. At baseline, and all follow-ups, at least 55% of those who tested nail positive for cocaine, crack, or amphetamine use reported at least one instance of illicit drug use. In addition, 12% of those who did not test positive for illicit drug use on nail samples self-reported the use of at least one drug.

Self-reported PrEP adherence was corroborated with DBS results. At baseline and all follow-up time points, no fewer than 69% of participants who reported taking their PrEP on 57% of days or more had a DBS test result of 700 units of TFV-DP per DBS punch or greater at all follow-up time points. One participant at baseline and another at the 3month follow-up reported missing more than 57% of their PrEP but produced a DBS result of 700 units of TFV-DP per DBS punch or more.

Self-reported CAS with casual partners was corroborated by bacterial STI diagnosis. Participants were indicated as having a bacterial STI if they received a positive result for rectal or urethral gonorrhea or chlamydia at baseline, 6, or 12-month follow-up or if they self-reported receiving a diagnosis in the past 3 months at any assessment point. At baseline, 30.5% of those who

reported CAS with a casual partner had a bacterial STI compared to 7.7% of those who did not. Similarly, 44.2% of participants who reported having CAS with a casual partner at either the 3 or 6-month follow-up had a bacterial STI, compared to 23.9% of those who did not. Finally, 39% of those who reported having CAS with a casual partner at the 9 or 12-month follow-up had a bacterial STI compared to 9.5% of those who did not.

Detailed analytic plan

A series of bivariate analyses ($\chi 2$ tests of independence and independent samples t-tests) conducted in SPSS (version 29) evaluated the success of randomization and the presence of differential attrition. The generalized linear model function in SPSS was used to evaluate between-condition differences in baseline frequency of primary outcomes with count distributions (cannabis use days, other illicit drug use days, sexual HIV TRB) and baseline odds of PrEP uptake (a dichotomous variable).

Outcome analyses were conducted using piece-wise latent growth curve (LGC) models following procedures outlined by Chou et al. Growth trajectories over time following the delivery of an intervention may be characterized by a large initial response followed by a more sustained trajectory with a less dramatic slope. Piece-wise LGC models quantify this kind of trajectory using two slopes. Slope 1 quantifies the change from baseline to the immediate post-test (3-month follow-up). Meanwhile, Slope 2 quantifies the trajectory over the post-intervention follow-up period.

Two models were calculated for each outcome. Model 1 included the main effect of treatment on growth factors. Model 2 added the main effects of moderators (communication skills and relationship quality) as well as the interaction terms between these moderators and the main effect of treatment.

Several considerations led to the inclusion of model covariates. Consistent with guidance for the analysis of data from randomized controlled trials that utilize stratified randomization (16), stratification variables were included as covariates in regressions predicting latent growth factors. The COVID-19 pandemic and recovery corresponded with changes in substance use and sexual behavior among SMM. To account for this, models incorporated a dichotomous, time-varying predictor indicating whether an assessment occurred before or after March 2020.

All models were calculated using full-information maximum likelihood estimation in Mplus Version 8.0. This permitted the retention of all randomized cases consistent with the intent-to-treat paradigm. Model significance was evaluated using a robust log-likelihood $\chi 2$ test comparing the log-likelihood of the specified model to a null-model – in which all structural coefficients associated with the regression of latent growth factors on condition and site were constrained to be zero. Where model results were significant, the effect of the PARTNER intervention was evaluated by examination of regression parameters for Slopes 1 and 2. Given the directional nature of hypotheses, single-sided p-values were used to determine the

significance of the intervention effect. When evaluating the significance of putative moderators and associated interaction terms, two-sided p-values were used.

Power analyses

We utilized the *Test for the Ratio of Two Negative Binomial Rates* module in PASS 19 to evaluate power to detect between-condition differences in drug use frequency at any one follow-up time point. Power (1-beta) was set to .80 and the probability of type II error (alpha) was set to .05. The number of exposures was set to 30 (the number of days of use assessed in the TLFB). The rate of use in the education condition was set to 3, 6, and 9. Meanwhile dispersion values of 1, 2, and 4 were tested. Power was highest at low levels of dispersion and high based rates of use in the education condition. Under these circumstances, the study has power=.80 to detect a rate ratio of 0.70 or a 30% reduction in drug use instances. At high levels of dispersion and low base rates, the study would be expected to detect a rate ratio of 0.48.

Power to detect differences in HIV transmission risk behavior was calculated in 2 ways. First, using procedures similar to those described for drug use, the study has power to detect a rate ratio between 0.48 and 0.69 in the number of CAS events in the absence of PrEP. This calculation tested average rates of CAS in the absence of PrEP in the education condition of 1, 3, and 5 instances and dispersion was tested at values of 1, 2, and 4. Power to detect significant differences in the odds of a positive STI test was calculated using the *inequality tests for 2 proportions in a repeated measures design* module [60]. Analyses specified 4 waves of data, power (1-beta) was set to .80, and the probability of type II error (alpha) was set to .05. Autocorrelation (rho) was permitted to vary between .25 and .75. The proportion of positive STI diagnosis in the education condition was tested at values of .13, .10, and .07. Power declined as rho increased. Power increased with the proportion of positive diagnoses in the education condition. Analyses suggested that the study is adequately powered to detect large effects, associated with an odds ratio between 0.20 (under the least favorable conditions) and 0.32 (under the most favorable).

Power to detect differences in PrEP uptake was similarly calculated using the *inequality tests for 2 proportions in a repeated measures design* module [60]. Analyses specified 4 waves of data, power (1-beta) was set to .80, and the probability of type II error (alpha) was set to .05. Autocorrelation (rho) was permitted to vary between .25 and .75. We estimated that on average 35% of the education condition would be on PrEP during the follow-up period. The proposed sample is sufficient to detect an odds ratio

of 1.90 even at the highest values of rho, which corresponds to approximately 51% of the PARTNER condition initiating PrEP. With regard to adherence, assuming approximately 100 participants (45% of the sample assuming 80% retention) are on PrEP at any follow-up point and 75% of the control condition is adherent to their PrEP medication (Cronbach alpha=.05; and ρ=.25 to .50), results suggested that the study has power=.80 to detect an odds ratio of approximately 3.0.

Equivalency Checks

We will strive to ensure that randomization will not produce any significant differences in participant characteristics that require control in subsequent longitudinal analyses. Baseline cross-site variance in participant characteristics will be assessed using standard tests of mean differences for both biological markers and self-reported measures of substance use, TRB, and PrEP uptake/adherence. Assignment differences in baseline demographics will be assessed using standard non-parametric measures of association. Any observed differences will be controlled for in subsequent models.

IMPLICATIONS AND LIMITATIONS

Policy/Methodological Implications

This application has focused implications for the biomedical prevention of HIV in a highly vulnerable population as well as broad methodological implications for PrEP research. The proposed project tests an intervention which addresses PrEP uptake in a high-priority population for whom no existing interventions are tailored (partnered SMM meeting CDC criteria for PrEP candidacy). It therefore addresses PrEP uptake and adherence (critical steps in the cascade) for an under-served and highly vulnerable population. Furthermore, the secondary aims of this proposal include the validation of fingernail assays to assess PrEP adherence. This innovation has broad implications for the study of PrEP.

Primary limitations

1) The absence of data from relationship partners. The use of individual (rather than dyadic) intervention is intended to enhance scalability. Participants will report relationship functioning as well as their perception of their partners' drug use, sexual behavior, PrEP uptake (see APPENDIX B; Partner health behavior survey). This will provide proxy data which can inform future studies. 2) Limited data on the efficacy of the PARTNER intervention. We have completed all aspects of intervention development and established the acceptability/feasibility of PARTNER. The need for pilot efficacy data is reduced by the fact that PARTNER incorporates all aspects of YMHP, which has demonstrated efficacy[16], and the use of a control condition which has been employed in previous NIH funded trials[16]. 3) Recruiting partnered SMM. A strong infrastructure exists to support recruitment efforts. We have developed recruitment

protocols and tracking systems that have facilitated a detailed examination of the efficiency of recruitment efforts[18,105,106,146]. We have also specifically examined issues related to dyadic vs. individual participation in research on partnered MSM[18].

SAFETY MONITORING PLAN

Adverse Events Reporting

The Site PI is responsible for the detection and documentation of events meeting the criteria and definition of an AE or SAE. Study staff may ask PI questions concerning adverse events, but must formally report them via email. Information on unexpected events including serious adverse effects (SAEs) will be reported as per the policy of the IRB.

Information to be collected includes the nature, date of onset, stop date, intensity, duration, treatment, causality, and outcome of the event. PIs should follow usual clinical practices for reporting serious, unexpected events related to standard of care. SAEs that occur after 30 days after completion of the study will be collected only if they are considered by the PI to be related to study participation. In addition, any AE resulting in potential participant withdrawal must been reported to the PI prior to participant withdrawal when possible.

PIs must report any Adverse Event to the IRB within five business days of learning of it.

ETHICAL CONSIDERATIONS

Informed Consent Process

Site PIs must ensure that participants are fully informed about the purpose, responsibilities of participating and potential risks or other critical issues related to participation in the study. Written informed consent is obtained from every participant or, in those situations where consent cannot be given by participants, their legally acceptable representative, prior to clinical study participation.

The rights, safety, and well-being of study participants are the most important considerations and should prevail over interests of science and society. If there is any question that the prospective participant will not reliably comply with study procedures and/or follow-up, they should not be enrolled in the study.

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