PROTOCOL
Comparative effectiveness trial of a clinic-based delivery of the Young Men's Health Project (YMHP) targeting HIV risk reduction and substance use among young men who have sex with men (YMSM)

ATN *Scale It Up* U19: 145 YMHP

ClinicalTrials.gov NCT03577301

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PROTOCOL TITLE:

Comparative effectiveness trial of clinic-based delivery of an HIV risk reduction intervention (YMHP) for YMSM, Phase 2

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REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
0	10.10.19	Resubmission into new RAMP template, Study Design Changes, names based reporting to DOH,	YES
1.0	4.27.20	Adding that those in Cohort 1 can participate in Qual interview, Long chain referral. We will administer a consent addendum for Cohort 1 participants.	New consent addendum
2.0	9.24.20	Update Study procedures for COVID, Remote study procedures, remote HIV/ STI Testing options, Information sheet for existing appointments with enrolled participants for COVID.	

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1.0 Study Summary

Study Title	Comparative effectiveness trial of clinic-based delivery of an HIV risk reduction intervention (YMHP) for YMSM, Phase 2
Study Design	Comparative Effectiveness Trial (CET), Randomized Control trial (RCT)
Primary Objective	The purpose of this study is to adapt and test the effectiveness of the Young Men's Health Project (YMHP_ at three subject recruitment venues (SRVs) within the Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN), in an effort to reduce HIV and STI disparities among urban young men who have sex with men (YMSM). We will conduct a comparative effectiveness trial to compare the effectiveness of the YMHP intervention delivered via two modalities – clinic-based versus remote delivery – following HIV counseling and testing (HIV C&T).
Secondary Objective(s)	To examine differences in effectiveness and cost by method of delivery, and to use our observations about the implementation of YMHP to improve portability and scalability. The study will also help us better understand HVI-prevention focused self-management behaviors among HIV-negative YMSM.
Research Intervention(s)	We are comparing two modalities for the delivery of the YMHP – clinic-based versus remote. YMHP consists of four sessions during which youth choose which particular behaviors (sexual risk or substance use) to discuss. The community health work (CHW) elicits the client's view of the problem using standard motivational interviewing (MI) techniques, building motivation for change by eliciting and reinforcing change talk and clarifying the youth's own personal priorities (through a structured values card sort activity. The CHW will discuss options for a behavior change plan, and, if the client is willing to proceed, the client sets goals. Starting 10/15/19- comparing YMHP (participants chooses modality for delivery as clinic-based or remote) versus HIV testing and counseling standard of care.
Study Population	Adolescent age (15-24 years) HIV-negative YMSM
Sample Size	Phase 2 N = 180
Study Duration for individual participants	Phase 2: 15 months, Starting 10/15/19- 12 months
Study Specific Abbreviations/ Definitions	Adolescent Medicine Trials Network (ATN) Condomless anal sex (CAS) Comparative Effectiveness Trial (CET) Community health worker (CHW) HIV counseling and testing (HIV C&T) Motivational interviewing (MI)

	Subject recruitment venue (SRV) Sexually transmitted infection (STI) Young Men's Health Project (YMHP) Young men who have sex with men (YMSM)

2.0 Objectives

Aims: In collaboration with three subject recruitment venues (SRVs) in the Adolescent Medicine Trials Network or HIV/AIDS Interventions (ATN), *Scale It Up (SIU),* our goals are to better understand HIV-prevention focused self-management behaviors among HIV-negative YMSM, and to study the implementation of YMHP to improve the portability and scalability. Our CET design gathers information about implementation. In a "Hybrid 2" trial, the dual goals are to determine which treatments work in which settings and to simultaneously answer implementation science questions about the potential barriers/facilitators to a treatment's widespread and sustained implementation. The SRVs will help the study assess and address practical problems at the frontline of service provision to pave the way for a comprehensive program to reduce HIV infection among YMSM that reflects the complexities of real-world adolescent HIV clinics.

Aim 1: Adapt YMHP for clinic and remote delivery (via phone or video chat) by existing HIV clinic staff, CHWs, who work with YMSM aged 15-24. We will consult with staff to obtain input on how best to implement YMHP to maximize feasibility, acceptability, and sustainability. This input will also identify issues with adapting YMHP for delivery for YMSM aged 15-18, and for remote delivery.

Aim 2: Assess the effectiveness of YMHP when delivered in a real world setting compared to a treatment as usual control – individual HIV testing – which represents a common standard of care.

Aim 2a: Assess the cost effectiveness of both delivery formats of YMHP to enhance the likelihood of uptake of this best evidence intervention.

Aim 2b: Assess the five components of the self-management model and how these components vary over time, are directly improved by the interventions, and mediate intervention effects.

Aim 3: Test a sustainable model of YMHP implementation in real world adolescent clinics. We will utilize local supervisors within the clinic setting to sustain the CHWs fidelity to delivering the MI-based YMHP intervention. We will monitor fidelity throughout the trial and conduct assessments and qualitative interviews with key stakeholders to determine the barriers and facilitators of YMHP implementation utilizing the *SIU Exploration, Preparation, Implementation, Sustainment (EPIS)* model (see ATN 153 EPIS Study Procedure Guide).

Secondary Aim: The design will result in a subsample of youth who were randomized to receive YMHP in a clinic-based or remote delivery. It will also yield a subsample who are allowed to self-select delivery method. We will utilize these subsamples to assess youth preferences for

delivery format, evaluate whether delivery format is associated with session retention, and test for any indications that delivery format is associated with response to intervention.

We will achieve our aims over 2 phases of the study.

Phase 1: We conducted focus groups with youth as part of our formative research to obtain implementation feedback about the delivery of the YMHP intervention and intervention components to ensure culturally competent, feasible, and scalable implementation both in the clinic setting and via remote delivery. Feedback from these focus groups at the 3 SRVs has been used to modify the YMHP intervention prior to the launch of Phase 1. Phase 1 focus groups were conducted with youth at each of the 3 SRVs to gather information that would be used to better implement YMHP. Groups were broken down into two age groups, 15-17 and 18-24.
We will train a minimum of 2 CHWs at each SRV to deliver the YMHP sessions, who must demonstrate competence according to the Motivational Interviewing Treatment Integrity (MITI) before providing the intervention in Phase 2.

Phase 2: We will recruit and enroll 270 YMSM, aged 15-24, 90 at each of the 3 SRVs. Enrollment will be limited to HIV-negative YMSM who report recent substance use and either CAS or a positive STI test result. Participants will be randomized to receive a standard of care enhanced HIV testing and counseling versus the YMHP intervention in person or by remote delivery (initial in-person session). The modality of delivery is chosen by the participant and involves completion of the 4 YMHP sessions and the delivery of pre-exposure prophylaxis (PrEP) information and navigation services to interested participants. Fidelity will be monitored throughout the trial. Sessions will be audio-recorded for MITI fidelity coding, and CHWs and supervisors will be given implementation support throughout the study period.

The current application is for Phase 2; Phase 1 has already been complete.

Hypothesis: The primary hypothesis is that receipt of YMHP (regardless of delivery format) will be associated with greater improvements in sexual health management (as measured by decreased STIs, CAS, and increased PrEP uptake/adherence) as well as reductions in substance use, compared with youth who receive the standard of care (individual HIV testing) only.

Secondary Hypothesis: We hypothesize that youth who elect to receive YMHP remotely will report more barriers to accessing health care compared to those who elect to receive the intervention in clinic. In addition, we hypothesize that remote-based YMHP will demonstrate greater improvements in sexual health management (as measured by decreased STIs, CAS, and increased PrEP uptake/adherence) as well as reductions in substance use, compared with clinic-based YMHP, among YMHPS who do report barriers to health care access. In contrast, it is hypothesized that clinic-based YMHP will demonstrate greater improvements in sexual health management and reduced substance use among YMSM who do not report barriers to health care access.

3.0 Background

Young (aged 16-24) men who have sex with men (YMSM) are disproportionately at risk for human immunodeficiency virus (HIV) and sexually transmitted infections (STIs). While new HIV infection shave fallen or remained stable among other groups, YMSM have experienced a 132% increase in new infections since 2002. From 2008-2011, YMSM aged 13-24 had the greatest percentage increase (22%) in new HIV infections. YMSM of color are especially at risk: in 2011, among YMSM aged 13-24 with HIV infection, 58% were Black and 20% were Latino.

Young males aged 15-24 are vastly overrepresented in rates of STIs. In 2013, 15-24 year old males accounted for more than half (57%) of all male cases of Chlamydia trachomatis (CT) infection and 46% of Neisseria gonorrhea (GC). Young men aged 20–24 had the highest rate of syphilis from 2008-2012. Further, sexual orientation disparities exist – e.g., men who have sex with men (MSM) accounted for 75% of all syphilis cases in 2013. Ethnic and racial disparities exist in the incidence of other STIs among YMSM. Young Black men aged 15-24 have a rate of CT infection 5.5-9.5 times higher and GC rates 10.4-13.0 times higher than White men. A recent study of HIV-negative MSM diagnosed with rectal CT/GC at STI clinics between 2008-2010 showed that such infections greatly increase HIV incidence. In 2013, MSM accounted for 3 quarters of all primary and secondary syphilis cases diagnosed in the US – an increase of 10% since 2012.

Rates of HIV diagnoses also vary geographically across the US, with urban areas disproportionally affected. Detroit, Philadelphia, and Miami are geographically diverse cities that have high rates of HIV and STIs among MSM and communities of color. The US Preventive Services Task Force and CDC recommend screening sexually active MSM at least annually, and potentially every 3 or 6 months for MSM at higher risk of HIV infection. CDC also recognizes the need for targeted outreach and screening for YMSM of color in non-healthcare settings and accordingly funds CBOs to serve this population through targeted promotion, testing and navigation to continuum of HIV prevention services. This underlines the need to study implementation of the YMHP intervention, for its significant public health potential in tackling HIV/STI disparities among urban YMSM by reducing risk behaviors associated with HIV infection, as part of a continuum of effective prevention services for this population.

Substance Use and HIV Risk among YMSM

MSM use substances at higher rates than the general population, increasing HIV risk. High rates of drug and alcohol use among MSM relative to the general population have been documented, and our research has identified higher rates of drug use among YMSM compared to their heterosexual peers. Higher rates of drug use have also been documented among MSM, including YMSM in tandem with sexual activity. However, drug-use patterns seem to differ among YMSM with increased rates of cocaine use among YMSM, which could have implications for HIV risk given that stimulant use has been linked to condomless anal sex (CAS) and higher risk of HIV infection and other STIs. Nearly half of Black MSM with newly diagnosed HIV infection (48%) reported substance use during their last anal sex encounter. Substance use has been found to increase sexual risk behavior among MSM, placing them at high risk for CAS and HIV seroconversion, exchange sex, and greater number of sexual partners. Our own research using event level data for the previous 30 days has shown that substance use strongly and significantly predicts the odds of whether YMSM will use a condom. A number of other studies have looked

at the impact of substance use on sexual behavior and increased odds of seroconversion. Different substances are associated with sexual risk behavior among specific groups. Among Latino MSM, methamphetamine use and among Black MSM higher rates of marijuana use have been linked to sexual risk. Therefore, there is a critical need for brief, culturally appropriate, effective behavioral interventions that improve self-management to reduce new HIV infections among substance using YMSM.

Effectiveness of Motivational Interviewing

Motivational interviewing (MI) has the potential to improve self-management behaviors in terms of promoting sexual health and reducing substance use among YMSM. There is strong evidence that MI is a culturally appropriate and effective approach for working with racial and ethnic minority populations who are disproportionately affected by HIV. One meta-analysis of MI found greater effect among minorities. MI has been recommended as particularly effective when working with YMSM. MI promotes increased intrinsic motivation to change and, when paired with information regarding health risk behaviors, reinforces the individuals' right and capacity to make well-informed health self-management decisions for themselves. YMHP was the first trial of a structured and manualized MI intervention that also included personalized feedback and problem-solving skills building to reduce CAS and substance use in YMSM. As such, YMHP has the potential to have a significant impact on YMSM seeking sexual health or HIV counseling and testing (HIV C&T) services at clinics.

Remote Delivery

Research on telephone-based MI (TBMI) has consistently found that it produces significant improvements in a wide range of physical health challenges. Furthermore, TBMI reduces mental health and alcohol related problems as well as sexual risk-taking among people living with HIV. Research comparing the effects of TBMI to face-to-face (clinic-delivered) interventions has produced equivocal results. Across studies examining physical activity, mental health, and substance use outcomes, findings suggest no significant differences in delivery method. Carey et al. examined relative efficacy of a telephone versus face-to-face intervention for alcohol use and observed a significant interaction of delivery method with gender. Women on average had better outcome in the face-to-face condition, while men responded equally well to both delivery methods.

Notably, the issue of health care access has not yet been examined as a moderator of relative effectiveness. One advantage of TBMI is that it significantly reduces patient burden. It is therefore plausible that it will show superior effects among YMSM who experience barriers to health care access. However, it is also possible that remote delivery (via phone or video chat using Skype/FaceTime) will decrease engagement and the quality of the relationship between the community health worker (CHW) and the participant. This may result in clinic-based delivery being superior among YMSM who have better access to healthcare. Understanding how health care access intersects with delivery method will substantially inform implementation decisions at clinics and other agencies seeking to utilize YMHP.

We are proposing to give participant the choice of conducting the YMHP Session in person at the clinic or remotely. We find that giving participants the option of delivery modality has the

potential for increasing session retention over randomizing participants to receive either at the clinic or remote delivery. Our new study design will be able to examine those differences.

COVID accommodations- We are also giving the option of completing the YMHP intervention in the clinic, but virtually. This means that the participant would come to the clinic for the appointment, but virtually meet with the CHW in a different room. The procedures would be similar to remote delivery. This reduces the amount of time a participant and a CHW are in the same room together.

CHW Intervention Delivery
Integrating Implementation Science into a comparative effectiveness trial (CET) can minimize the science-practice gap. MI providers need not be clinicians – one study conducted by our team comparing CHWs to clinicians found both were equally effective in providing high quality MI and that clients were more likely to be retained in HIV care when working with CHWs. CHWs are commonly integrated into clinics, and often play a central role in providing HIV prevention services, including HIV C&T. Training CHWs to deliver evidence-based interventions is a critical step towards realistic and cost-effective implementation. The Centers for Disease Control and Prevention (CDC) has called for expanded use of CHWs in the prevention and management of chronic diseases with attention to implementation and training.

Several steps will be taken in this CET to promote adoption and sustainability of the YMHP intervention. First, using staff embedded in the clinic can build capacity for implementation. Second, CHWs have long been the cornerstone of integrating support services into HIV-related prevention efforts. Training CHWs to deliver interventions is a critical step towards realistic and cost-effective implementation. Research has documented the amount of training needed to obtain MI fidelity, concluding that initial training followed by ongoing coaching is required. Such training can be costly when relying on outside trainers. Thus, a “train the trainer” model, where expert trainers provide local supervisors with MI coaching skills, may be more sustainable.

4.0 Study Endpoints
The primary goals of the study are to compare how clinic-based or remote delivery of YMHP help improve sexual health management (as measured by decreased STIs, CAS, and increased PrEP uptake/adherence) as well as reduce substance use among YMSM over a standard of care HIV testing and counseling.

5.0 Study Intervention

Intervention Design and Procedures
YMHP is a CDC Best Evidence Intervention that utilizes motivational interviewing (MI) to reduce CAS and substance use among YMSM. The YMHP intervention will be delivered by MI-trained CHWs employed at clinics, primarily by former HIV C&T counselors, health educators, and trained program peers. Participants will be randomized to receive the intervention either in person or remotely. Both conditions involve completion of the 4 YMHP sessions and the delivery of PrEP information and navigation services to interested participants.

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reduce CAS and substance use among YMSM. The YMHP intervention will be delivered by MI-trained CHWs employed at clinics, primarily by former HIV C&T counselors, health educators, and trained program peers. Participants will be randomized to receive the intervention either in person or remotely. Both conditions involve completion of the 4 YMHP sessions and the delivery of PrEP information and navigation services to interested participants.

Intervention Training and Supervision

YMHP training will occur prior to the initiation of Phase 2, with ongoing coaching and supervision and training of new interventionists, as required. The interventionist training team consists of members of PRIDE Health Research Consortium's clinical team and include at least one member of MINT. The YMHP training procedure includes:

1. Initial three-day training for CHWs and local supervisors;
2. A two to three-month training period of role-play practice, coding and feedback, and supervision modeling, including mock sessions with "standardized clients" role played by Research Assistants;
3. One hour weekly supervision sessions between local supervisors and CHWs;
4. Monthly supervision calls between local supervisors and the investigator team, including a quarterly Skype booster training; and
5. Ongoing quality assurance and feedback using MITI coding.

All materials (e.g., slides, training exercises, supervisory tools) will be packaged for potential dissemination. Prior to dissemination, any copyrighted media will be removed from these materials. The three-day training will be held in Miami and follows a curriculum developed for our previous National Institutes of Health-funded effectiveness trials. CHWs and supervisors participate together in days 1 and 2 of the training. The third day of training will be split so that CHWs can have more practice with the YMHP protocol, and supervisors can focus on coaching MI. REC will provide external MITI coding for the supervisor to use as feedback. Following the 3-day training workshop, all CHWs and supervisors will submit audio recordings of all intervention sessions completed with a mock client. These sessions will be MITI coded and REC trainers will provide coaching and feedback. Once beginner competency is met, the local clinic supervisor will take over weekly individual supervision of the CHWs. If there is staff turnover for any reason (e.g., staff leave the clinic, staff are unable to be cleared to see participants due to quality of delivery), then additional training will be provided to new staff members.

The PRIDE Health Research Consortium Clinical Team will lead quarterly boosters via group Skype for supervisors. Prior to the quarterly boosters, supervisors will submit a recording of a supervision session for review. Boosters will cover successes and challenges, MITI scores, updated MI skill development plans for each CHW, and role-plays of supervision skills. Someone from the Clinical Team will join supervision sessions via Skype if MITI scores fall below competency without remediation. They will also lead annual in-person booster trainings covering MI skills and specific delivery of YMHP for supervisors and CHWs.

Assurance of Intervention Fidelity

All sessions (remote and clinic-based) will be audio-recorded and sent for MITI coding. For the pre-trial phase, both CHWs and supervisors will mock the intervention and submit 4 roleplays of

intervention in-person and 4 roleplays of the intervention remotely delivered. Then supervisors will complete one session of supervision with each CHW and audio recordings will be uploaded onto the site Dropbox Business account.

Mocks will be coded using MITI thresholds for fidelity flagging. Those 5 criteria are: percent reflection, percent complex refection, technical global, relational global and MI non-adherent (MINA) codes. For clearance, trainees should be scoring in the "fair range" on all 5 elements by their final mock. If they are below in one or two areas, they don't have to redo the mock. However, by the mock of Session 4 they should be at least "fair" in all elements to be cleared.

For ongoing monitoring, MITI coding randomizer should flag for additional review any session where the CHW falls below fair on more than 2 of those domains. One recording per CHW will be randomly selected for MITI coding by the study team on a regular basis. All the randomly coded sessions, not just the flagged MITI forms, will be shared with the supervisors for them to trust their barometers for "good enough" MI instead of only having MITI to compare when things were "bad."

For the full-trial, each CHW will complete and submit an electronic Clinical Session Form via Qualtrics upon completion of each YMHP session.

6.0 Procedures Involved

Enrollment and Consent
Utilizing enrollment procedures established within ATN, SRV staff will invite YMSM who are identified through outreach, at their clinic, or through mobile testing efforts to screen for the study. Those interested will complete a brief iPad eligibility screener. HIV testing may be conducted after the screener and before the baseline appointment. If eligible on the screener, SRV study staff will schedule the potential participant for a baseline assessment. Potential participants will complete informed consent following ATN-wide established protocols. This will occur at the beginning of the baseline visit, prior to assessment, but after any HIV testing.

After a potentially eligible participant has given their informed consent to participate in the study, they are then asked to complete the baseline CASI and complete STI testing. Participants are deemed eligible for the study based on screening data and no longer need verification at baseline appointment.

Participants who were enrolled prior to November 1, 2019 will be given a consent/assent addendum at their next follow-up appointment which introduces the long-chain referral and qualitative interview options. Since their initial consent form did not include these items, the addendum will give them the option to receive incentives for providing referrals to the study and to participate in the optional qualitative interview.

Randomization
Participants will be randomized after completing the baseline assessment (i.e., CASI and specimen collection), but prior to their first YMHP session. Participants are randomized into one of two intervention conditions: 1) YMHP (delivery of the YMHP intervention in person or

remotely), or 2) a standard of care HIV Testing and counseling session with referrals to other available services. . If the participant is randomized to YMHP, the first YMHP session will always be conducted in person after the baseline assessment. In the event a participant does not wish to complete the first YMHP session immediately after the baseline assessment, the SRV will postpone the participant's randomization. Randomization will then occur when the participant returns to the SRV for their first YMHP session. If the participant is randomized to HIV Testing, no additional intervention procedures are required, because HIV testing is conducted in conjunction with the Baseline appointment. However, the CHW will meet with the participant to ensure that any individual risk assessment is administered and referrals for PREP and other prevention services are given consistent with clinic standards of care for individual HIV testing.

COVID accommodations- In the event the baseline visit is conducted virtually (see below for details), randomization will still occur after HIV Testing and before the intervention. Since many individuals who are randomized to HIV testing only will have already received that portion of the appointment, randomization may occur before scheduling session 1.

Schedule of Assessments:

Baseline Assessment and First YMHP Session (now called the In-office Face to Face Visit option)

After obtaining informed consent, participants will complete a confidential CASI at the SRV that will ask about their drug use, sexual behavior, and general thoughts and feelings. This will take about 45 minutes to complete. They will participate in STI testing and take a confidential urine drug test. STI testing will consist of a urine sample, an anal self-swab of their rectal mucosa, and a blood draw for syphilis testing. Completion of the CASI and the STI concludes the baseline assessment. At this visit they may also complete the first YMHP session. The entire visit may take 3-4 hours to complete.

Baseline visit (up to $50)

1. Informed consent process
2. Urine drug and STI testing ($25)
3. CASI survey ($25)
4. Transportation ($5 cash or bus ticket)

COVID Accommodations- The baseline assessment and First YMHP Session can also be completed as two other options- (1) In Office Virtual Visit option and (2) Remote Visit option (with Testing at the site or at home). Depending on the site's ability to see participants in the office and the participants' desire to do study visits in office or remotely, the following additional options are available.

(1) In-office Virtual- All study procedures, including collecting samples for HIV and STI testing, are completed similarly to the In-office Face to Face Visit option with the following exceptions. Both HIV pre and post test counseling sessions and the YMHP Sessions are conducted in the office, but virtually. This means that the CHW will meet with participant but located in separate rooms to minimize the amount of contact between individuals. The CHW will meet via HIPAA compliant Zoom while the participant is physically at the clinic.

(2) Remote Visit Option- During the initial phone call after screening, we will confirm the participant's age to offer in-office testing or the ability to offer at-home testing. IF the participant meets the minimum age for at-home testing, we will go through the informed consent with them on the phone since this will need to be done before we can send a testing kit to the participant. It can be conducted virtually by sending the participant a link to the online consent form. The participant is asked a series of questions to gauge comprehension of the consent form. The RA may also schedule a remote visit to conduct the consent process. After obtaining informed consent, participants will complete a confidential CASI at their home that will ask questions about their drug use, sexual behavior, and general thoughts and feelings. This will take about 45 minutes to complete.

Baseline visit (up to $50) When the baseline visit is conducted remotely, the compensation is only given after the participant has completed the baseline components, HIV testing, and YMHP Session 1 if randomized to YMHP. This will ensure participants complete all study components. No transportation will be given for remote baseline visits.

1. Informed consent process
2. Urine drug and STI testing ($25)
3. CASI survey ($25)
4. Transportation ($5 cash or bus ticket)- This is only given if the participants comes the clinic for the STI Testing or for At-home Testing, $5 can be given to the participant as a bonus for returning the STI testing samples.

Intervention
A. (YMHP sessions)
Intervention sessions should occur approximately once per week for 4 weeks with the first session immediately after completion of the baseline assessment. Participants will complete three additional YMHP sessions focused on sexual risk and substance use. The sessions will be completed at the SRV or remotely depending on randomization. All sessions will be audio recorded and should take approximately 40-60 minutes to complete. No video will be recorded. There is a 12 week window for intervention sessions completion, i.e. all four sessions should be completed within 12 weeks of the baseline assessment. Thus, if participants need to miss a week periodically, for any reason, they should have ample time to complete the four sessions during the 12-week window. The participant will make arrangements to have the session be delivered at the clinic or remotely. Each session can be different depending on what works best for the participant.

YMHP sessions:
2nd session: $10
3rd session: $10
4th session: $10
Bonus (if attend all sessions): $20

Audio-recording the intervention sessions is part of the consent/assent process for participation

into YMHP. During the intervention session, the participant can be reminded that the sessions are confidential and recorded only for quality assurance purposes. If the participant declines to be audio recorded, then they cannot participate in the session, but can remain in the study and complete the follow-up assessments.

Due to COVID- All YMHP sessions (including Session 1) can be delivered in person or remotely.

B. (HIV testing condition)
HIV testing is a prevention service already provided by the staff at each SRV as part of their existing outreach and testing services (which are funded and monitored by local health department and CDC contracts). Everyone who is enrolled into the study will have had HIV testing as part of the screening process prior to study enrollment. If a participant is randomized to standard of care HIV testing, they will not attend any further sessions. The study staff will ensure that the participant has received referrals to available services, including PrEP services. They will be scheduled for their immediate post-test assessment 3 months after BL. They will also be given the option to complete the 4 YMHP Sessions after the 9month follow-up (12month follow-up post BL).

Immediate Post-test Assessment (3 months after BL)
After completing YMHP sessions, participants will be scheduled to complete an immediate post-test assessment (IP). This assessment will occur about three months after their baseline assessment (i.e., the first follow-up assessment post-baseline). During this assessment participants will complete a CASI about their drug use, sexual behavior and general thoughts and feelings. In addition to assessing the primary outcomes of the intervention, participants will also respond to process measures. Specifically, participants will be asked to provide an evaluation of their counselor, as well as the health care climate of the YMHP intervention. This CASI can be completed at the SRV or remotely. Participants access the CASI through a survey link sent directly to their email, and takes approximately 45 minutes to complete.

During this visit (or anytime after the Intervention window closes, which is 3 months after Baseline) a participant may be asked to participate in an optional qualitative feedback interview. Participants will be called by a research staff member at PRIDE or at one of the other sites to complete a 30 minute interview over the phone. This interview will be offered in the immediate post test assessment, but can be completed at any time 3 month after the BL.

Immediate post-test assessment
1. CASI ($25)
2. 2. Optional Qualitative Feedback Interview ($25)

Follow-up Assessments
There will be four additional follow up assessments for participants to complete. These follow up assessments will occur in 3-month intervals until 12 months after their IP (i.e., 3 months, 6 months, 9 months after the IP).

The 3-month and 9-month follow-up assessments include completing a CASI and require a

confidential urine drug test, HIV and STI testing. The urine drug test, HIV and STI testing should be performed at the SRV, or by using a self-test kit which will be mailed to the participant if they choose. If participants do not complete the 3 month or 9 month urine drug test, HIV and STI testing they will be asked to complete these tests at their next assessment.

The 6-month assessment does not require urine drug test, HIV and STI testing so therefore these assessments can be completed using an electronic link we send to participants or they can complete the CASI at the ATN site if they choose. This survey will be similar to the baseline survey and it will take about 45 minutes to complete.

3-month follow-up & 9-month follow-up (up to $50)

1. CASI ($25)
2. Urine drug test, HIV and STI testing ($25)
3. Transportation ($5 cash or bus ticket) or $5 bonus of completing testing at home and returns the samples.

6-month assessment

1. CASI ($25)

HIV only Condition

Participants who are randomized to receive HIV testing only will be given the opportunity to complete the YMHP Sessions after the 9month follow-up. They will receive the first session as part of the 9 month follow-up. They are still eligible to receive the bonus if they attend all the sessions.

YMHP sessions:

2nd session: $10
3rd session: $10
4th session: $10
Bonus (if attend all sessions): $20

Subject recruitment venues

The three SRVs participating in YMHP (University of Miami, Children's Hospital of Philadelphia, and Wayne State Prevention in Detroit) are all part of the ATN. All three of these SRVs are currently performing HIV testing as part of the services they offer to the local community. Therefore, each SRV has a protocol in place to deliver HIV-positive results and link patients who test HIV-positive to timely access to health care, including antiretroviral therapy. ATN SRV staff trained in HIV testing and counseling will discuss the meaning of the test results with all youth who test for HIV. As per YMHP inclusion criteria, only those who test negative for HIV will be eligible to participate in YMHP.

Participants who test HIV-positive while enrolled in YMHP will be referred for a confirmatory HIV test when needed. A YMHP research staff member trained in HIV testing and counseling will discuss the meaning of the HIV test results and explain the importance of timely access to health care, including antiretroviral therapy. Participants who have HIV testing performed at an ATN SRV and are HIV-positive at a follow-up assessment will receive positive test results from YMHP clinic research staff trained in HIV testing and counseling.

Participants who relocate or are unable to attend an ATN SRV after baseline will have the option for at-home HIV testing and collecting samples for STI Testing. Such participants who test HIV-positive at a follow-up assessment will receive the result from a member of the PRIDE clinical team who are key personnel on YMHP and trained in HIV testing and counseling. See the attached PRIDE Response Management Plan which includes the protocol for delivering HIV-positive results.

Participants who test positive for an STI at baseline or follow-up assessments will be referred using the ATN clinics' local protocol for positive STI results. Participants who test positive for an STI through at-home or central lab testing such as Quest will follow the attached protocol for delivery of positive STI results. STI results will be sent to the participant via a secured webpage, and participants will receive a unique password to view their results.

If participants choose at home HIV/STI testing, kits may be mailed to a home address if they meet minimum age requirements. This option is not available to those aged 16 and below in Detroit and Philadelphia, 17 and below in Miami (taking into account FDA age approval for OraQuick and state law on age of sexual consent) for at home testing. Research staff will allow kits to be shipped to an alternate location deemed as a safe space, such as a youth center, and will require youth to speak with a trained staff member to ensure these arrangements are both safe and allowable.

Substance use eligibility is determined using self-report. The YMHP urine drug test at baseline and follow-up assessments will only be used to validate self-reported substance use; the result of this test is not part of the inclusion criteria. No counseling or referral swill be made for those with a positive drug screen as this result will only validate confidential self-reported substance use. Participant will be given their drug screen results if requested.

As part of this study, participants may be invited to take part in a one-on-one confidential interview with a member of our research staff to learn about the participant's experience in this research study. The interview will be audio recorded and may take place after the intervention. If participants are invited but are not interested in participating in the one-on-one interview, they may decline and still continue in the study otherwise.

Specimen collection

SRVs will be using standard protocols for specimen collection. Initial HIV testing (for eligibility) will have been performed at the time of screening (or at any time before study enrollment) as part of existing HIV testing services. For follow up assessments, HIV testing will be performed using the rapid test usually used at the SRV clinic.

Due to COVID, HIV testing services at sites may look different than originally proposed. Some sites are

Urethral and rectal STIs will be tested as baseline and designated follow up visits by collecting specimens for testing by Quest Diagnostics. Urethral CT and GC will be determined from a first-catch urine sample, and rectal CT and GC will be determined from a sample self-collected using

the APTIMA Unisex Swab Specimen Collection kit. Quest Diagnostics will determine urogenital and rectal CT/GC reactivity using the APTIMA Combo 2 Assay, which utilizes a Nucleic Acid Amplification Test (NAAT) method. SRVs will submit specimens to Quest for testing and they will access test results directly through Quanum, Quest's online portal.
Urine samples for drug use will be tested for metabolites of methamphetamines, cocaine, ecstasy, marijuana, and opiates using the Alere Integrated E-Z Split Key Cup II-5 Panel. Site research staff will record the results in Qualtrics, and any ambiguous results should be verified by the Site PI.

For at home testing, we will send an Oraquick HIV testing kit or Molecular Labs will send an Oraquick HIV and STI testing kit. Urethral CT and GC will be determined from a first-catch urine sample, and rectal CT and GC will be determined from a sample self-collected. Molecular will determine urogenital and rectal CT/GC reactivity using the Roche Cobas with the Cobas CT/NG 4800 Assay. Syphilis antibody testing will be completed by a finger prick to provide a blood sample on Dried Blood Spot, and an additional urine sample will be provided for Drug Testing - 22 Drug Class High Complexity Screen. The participant will put the samples into the return kit to be shipped back to the lab. SRVs will access test results directly through Molecular Labs online portal.

Incentives and compensation
Participants will be compensated for both the assessment visits and intervention sessions as follows: up to $50 for baseline visit, $10 for each of 3 intervention sessions after baseline, $20 for completing all 4 intervention sessions, $25 for the IP, $25 for optional Qualitative interview, up to $50 for the 3-month assessment, $25 for the 6-month assessment, up to $50 for the 9-month assessment, (HIV Testing condition- $10 for each of 3 intervention sessions after 9month follow-up, $20 for completing all 4 intervention sessions.). Participants who complete all sessions and visits will receive a total of $275. Additionally, participants can earn up to $50 by providing referrals to the study ($10 for each referral up to 5). With the referrals, participants who complete all study activities could receive up to $325. All compensation for assessments and sessions is given as gift cards (with the exception of transportation).

COVID-19 modifications
During the COVID-19 pandemic, all remaining intervention sessions and follow-up assessments will be conducted remotely. While recruitment and enrollment have ceased, some participants were previously randomized to YMHP sessions before COVID-19 and were given the choice of in-person or remote delivery. Those remaining sessions were all moved to remote delivery to participants who provided that preference. Before conducting the remote sessions, study staff must assess the participant's desire to participate in the sessions remotely, given the current circumstances, as conducting a session from a participant's home introduces additional confidentiality and other considerations. For follow-up assessments, participants are contacted to determine if they would like to complete their follow-up survey at home. If yes, they are sent a link to complete their CASI and paid $25 via electronic gift card for survey completion. For follow-up assessments that usually require biological testing (3M, 9M), participants will only complete the CASI portion of the assessment. Qualitative Interviews will occur during this time. Participants will be asked if they would like to participate in an optional qualitative interview over Zoom.

7.0 Data and Specimen Banking

Data for Future Use
Participants consent to these procedures as part of the consent/assent process.

The research team, authorized staff, and government agencies that run this type of research may have access to research data and records in order to check on the research. Research records given to approved researchers will be de-identified. If a researcher requests the data, they will be special permission from the Research Compliance Administrator. Data collected during this research study may be used for future research purposes. The data stored will be de-identified.

Data that cannot be linked to participants (i.e., de-identified data) will be kept indefinitely; this data will be saved for future use and may be shared with other researchers.

Biological samples collected for the purposes of this study will not be used to conduct any future research. They will be destroyed after analysis is completed

At the end of the study data collected will be made available, in accordance with the NIH Data Sharing Policy (http://grants.nih.gov/grants/policy/data_sharing). These data will be saved for future use and may be shared with other researchers. By participating in this study, you are agreeing to allow us to save and share your data anonymously.

8.0 Sharing of Results with Subjects

HIV and STI testing results
Rapid HIV tests are performed prior to screening, and ATN SRV staff will share results with the participants per their usual protocols. Rapid HIV tests are also conducted as part of the 3-month and 9-month assessments, and results are shared with participants during the assessment. HIV test results are delivered in-person with referrals for PrEP/PEP and linkage to care (in the event of a positive test result).

STI test results are sent individually to the participant via email. Results are entered into an online Qualtrics portal and sent to participant's email address where they can view and save their results. The participant can confidentially view their STI results through the Qualtrics portal. Positive STI test results will be conveyed to participants using SRV standard protocols, and access to treatment will be provided.

We will be reporting positive STI results to departments of health in Michigan, Pennsylvania, and Florida for surveillance purposes. Reporting of names for this purpose is state law and not exempted by research studies. We will inform the participants in the consent form that this will occur. Name, Date of Birth, and phone number will be reported.

Urine samples for drug use are used to validate participant's self-reported substance use. These results will be shared at participants' request.

All results are not shared with any other individuals.

9.0 Study Timelines

Individual participants are in the study for twelve months (Baseline, Immediate post-test assessment, 3-month follow-up, 6-month follow-up, 9-month follow-up,)

All study subjects will be enrolled over the course of 48 months.

10.0 Subject Population

Inclusion Criteria
Individuals who express interest in YMHP must demonstrate the following criteria to be enrolled in the study:

- HIV-negative test result from the past 90 days
- 15-24 years of age
- Currently identifying as male (regardless of sex assigned at birth)
- Sex with men in the past 90 days
- Self-report ≥ 3 days of substance use* (drugs or heavy drinking) in the past 90 days
- Self-report ≥ 1 episode of condomless anal sex (CAS) in the past 90 days, *or* a positive STI test result in the past 90 days
- Living in the Detroit, Miami, or Philadelphia metropolitan areas
- Able to communicate in English

*substance use includes: heavy drinking (5+ drinks on one occasion), marijuana, crack, cocaine, MDMA, opiates (less than 5 days IDU), ketamine, GHB, meth, prescription drugs for fun, sedatives, amphetamines, and hallucinogens

Exclusion Criteria
Participants will be excluded from the study if they indicate any of the following:

- Mental, physical or emotional capacity that does not permit them to complete the protocol as written
- ≥ 5 days of injection drug use in the past 90 days
- Currently taking Truvada as PrEP
- If the participant is going to test at home, we will exclude those aged 16 and below in Detroit and Philadelphia, 17 and below in Miami (taking into account FDA age approval for Oraquick HIV testing kit and state law on age of sexual consent).

We will include individuals who are not yet adults:
Study procedures involve no more than minimal risk. The nature and scope of the proposed research study and MI-based YMHP intervention sessions do not pose more than "minimal risk" to participants as defined in 45 CFR Part 46.102, "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

We will not include individuals who are adults unable to consent, pregnant women, or prisoners.

11.0 Vulnerable Populations

We will enroll research participants 15-24 years of age. The nature and scope of the proposed research study and YMHP intervention do not pose more than "minimal risk" to participants as defined in 45 CFR Part 46.102, "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." Given that some participants will be under the age of 18, adequate provisions will be made for soliciting informed consent.

We will not require parental consent for study enrollment. Parental consent may decrease participant rates because some youth will fear that they may be "outed" as a result of participant. Disclosure of sexual orientation may place participating youth at risk for parental harassment, abuse, or expulsion from the home.

The intervention and measures utilized in this study are standard in this population, as are waivers of parental permission for survey and interview studies. Additionally, consistent with national policy recommendations from the Society for Adolescent Medicine, requiring parental permission for the proposed study would have a number of possible negative effects, including: (1) reducing the validity of the findings by effectively eliminating potential participants unwilling to share permission forms with their parents/guardians; (2) increasing risk to some youth whose parents have a negative response to the material in the permission forms that would suggest their child has a minority or alternative sexual orientation; and (3) adding little in the way of actual subject protection, given the minimal risk of stud participant. Our procedures for the waiver of parental consent are consistent with the guidelines provided by the Department of Health and Human Services: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartd.

We will obtain assent from participants who are under 18 years of age.

12.0 Local Number of Subjects

Anticipated enrollment: 270 YMSM

13.0 Recruitment Methods

SRV initiated recruitment and outreach
YMHP will utilize three SRVs (University of Miami, Wayne State University, and Children's Hospital of Philadelphia) to complete clinic- and field-based recruitment. All three SRVs have extensive relations with the gay, bisexual, and transgender communities, community service organizations, and local health service organizations, and are providers for MSM. In this aspect, recruitment will occur via routine walk-in visits for HIV testing at their clinics, mobile HIV testing at outreach events, and outreach at events for HIV testing at the clinic. Information about the study will be included in the IRB-approved flyers, brochures and cards, customized for each SRV. Study-related recruitment information will be displayed in waiting rooms and exam rooms at each clinic and will be distributed to potential participants at mobile testing events and local

outreach efforts. The recruitment materials both encourage HIV testing and promote the YMHP study.

Community health workers (CHWs) who conduct standard of care HIV testing services for the YMHP SRVs will be trained to provide information about the YMHP study after HIV-negative results are delivered at the clinic or in the field at mobile testing events. The CHW will be trained in appropriate and ethical methods of recruiting participants in clinical settings and in the field. To minimize the risk for coercion, the staff member and the study information will emphasize the optional nature of participation and that it will not affect, in any way, their access to healthcare services. If the potential participant is interested in finding out if he is eligible for YMHP after learning about the study, the CHW will provide an iPad with a secure online Qualtrics YMHP Study Screener (attached to this IRB application). The confidential YMHP study screener will be completed on the iPad by the potential participant and no one will be able to see the responses; the iPad will only indicate whether the potential participant is eligible. CHWs may also collect contact information to send the study screener to participant via text or email so they can complete the screener at a later time. We have found that potential participants may not want to screen at an outreach event or venue.

YMSM who test HIV-negative at a clinic site or through mobile testing efforts provided by community collaborators in the field will be informed about the opportunity to participate in the YMHP study by study staff members who are certified to conduct HIV testing. Individuals who are determined eligible for the study will be contacted by the YMHP Research Assistant at one of the participating SRVs to schedule an appointment to learn more about the study and review the study consent or assent form. Individuals who test negative and are determined to be eligible for the study on location (i.e. at partnering clinic site) will be able to schedule an appointment after contact information is collected.

Only those who screen eligible for YMHP via the confidential study screener will continue to the next survey link on the iPad. Those eligible will complete an electronic Locator Form (attached to this IRB application). The information provided by the potential participant on the Locator Form will be used by the Research Assistants to contact the potential participant to make an appointment at one of the YMHP SRVs. At the appointment, study staff will review the consent or assent form with the potential participant. If the participant provides consent, a baseline appointment will take place. At the conclusion of the baseline appointment, only those who meet inclusion and do not meet exclusion criteria will be considered eligible for randomization in YMHP.

YMSM who screen ineligible for the study do not need to provide contact information and may screen again after 30 or more days, provided they tested HIV-negative at the clinic site in the past 90 days or they again test HIV-negative at the clinic site. Participants are also able to re-screen should they test HIV-negative at the clinic site or through mobile testing efforts associated with the clinic site.

Participant Referrals for Recruitment

Sites will also be asking enrolled participants to refer their friends to screen for YMHP. Participants who complete the baseline appointment will be provided up YMHP study cards with

a unique ID on them. Or they will be given an electronic link to the study screener with a unique ID embedded into the URL, which will track study screeners completed and connected to that participant. They can give these cards or send the link to friends who may be interested in screening and participating into the study. For each friend (up to 5) who takes the study screener, is eligible, and shows for a baseline appointment, the participant who referred them will receive $10 gift card (up to $50).

PRIDE-initiated Online Recruitment

The PRIDE Health Research Consortium (formerly the Center for HIV Educational Studies & Training (CHEST)) at Hunter College will use a variety of recruitment strategies to also recruit participants for this study.

PRIDE will assist in referring potentially eligible participants to the YMHP study through existing online recruitment efforts. PRIDE utilizes the Hunter College IRB-approved Online Master Screener (OMS) to preliminarily screen individuals who are interested in participating in studies being conducted through PRIDE. The OMS, in this instance, will primarily be used as a referral mechanism for the study, directing participants to which study they may be eligible for, including YMHP. If an individual is preliminarily eligible for a study, the individual is asked to provide contact information to PRIDE for follow up. For the purposes of this study, the OMS will only be used to refer potentially eligible YMSM to HIV testing sites by sending them an email referral informing them about the YMHP study. YMSM who complete the OMS and screen preliminarily eligible, will be called for phone screening to determine study eligibility. If they are eligible, they will be referred to the ATN clinic for the Baseline appointment. The contact information collected through the OMS will not be provided to the HIV testing clinic sites. However, YMHP clinic sites will be made aware that a potentially eligible YMSM has been referred to their testing services for the study.

Potential Participants may be identified through online social media and dating apps (e.g., Facebook, Instagram, Reddit, Tumbler, Grindr, Scruff,Adam4Adam). While advertising will be distributed through SIU's REC, they will be targeted to the geographic areas surrounding the ATN sites for this project and will contain information about participation at the ATN clinic.

Contact information

Once deemed eligible by the study screener, the individual will be automatically rerouted to a separate Qualtrics locator form to provide his contact information. Participants will be asked to provide a home address and zip code, working phone number, valid email address, and/or handles or URLs to be contacted via social media (e.g., Facebook, Instagram, and Snapchat). The locator form asks participants if messages can be left at the numbers provided. Research staff will not leave messages unless expressly permitted to do so by the participant, as documented on this locator form. If permission is given to leave messages, the research staff will assure participants that messages left with a family member or friend will only ask the participant to contact study staff as indicated on the locator form and will not include any protected health information (PHI) or information related to study participation. The research staff will identify the study as-requested by the participant on the locator form (e.g. "Hunter College"). At the

baseline appointment, after fully consenting to participation in the study, each participant will be asked to provide valid contact information for a family member and/or friend who can be called in the event that the participant cannot be reached by phone, email or other contact information provided. Scheduling and reminders about study activities will take place via email, text message, and/or phone.

Information gathered from the electronic locator form will be password protected on the PRIDE Health Research Consortium server. The information will be password protected in a REDCap contact database that will be accessible by REC and authorized SRV study staff. Contact information will be kept separate from all other study records, with access limited to designated research personnel. The contact information should be updated every time there is contact with the participant.

14.0 Withdrawal of Subjects

Criteria for Premature Discontinuation
Below, there are categories of "dropping" participants along with their definitions. These categories should be accurately used in the site's tracking materials if one of the conditions below occurs.

Category: Definition	Procedure	Notes
Refused BL (Prior to Consent): Screened eligible, but never shows up for appointment and/or no longer wishes to be contacted.	Remove from rescheduling call lists and mark as "Do Not Contact" in REDCap.	Counted towards screened number only.
Withdrew during BL (After Consent): Provided consent but refused to finish BL appointment.	Mark as "Baseline concluded" but not "Baseline completed"	Counted towards screened number only; these participants get marked as "Withdrew from Study" for sIRB purposes.
Withdrew after BL (After Consent): Participant completed the BL but asked to be removed from the study thereafter.	Remove from Follow Up Call Lists; should be Tracked as enrolled. If the withdrawal occurs after randomization, they should remain in the randomizer and count towards randomized totals. If the withdrawal occurs after baseline completion but before randomization, do not randomize.	Counted towards enrolled total. If randomized, the participant also counts towards randomized total and stays in all denominators for Follow Up retention; these participants get marked as "Withdrew from Study" for sIRB purposes.
Ineligible during BL (After Consent): Provided consent but was found to be Ineligible during the BL appointment.	Mark as "Baseline concluded" but not "Baseline completed" They should not be randomized	Counted up to and including in the enrolled number; these participants get marked as "Withdrew from Study" for sIRB purposes.

Ineligible after BL (After Consent): Participant either completed the BL, both BL and sessions, OR all BL, sessions and follow-ups but was found ineligible for enrollment at a later date (e.g., found to have psychiatric conditions while collecting BL data◊)	Remove from Follow Up Call Lists; should be Tracked as enrolled and have a condition assigned	Counted up to and including randomized/enrolled and stays in all denominators for Follow Up retention; these participants get marked as "Withdrew from Study" for sIRB purposes.
Refused intervention (if applicable), Still Enrolled: Participants who are no longer interested in the intervention sessions, but have indicated a willingness to continue to be followed for Follow Up Visits	Remain in Database to be called for Follow Up visits	Treated as other enrolled participants except they wouldn't show up on session-specific call lists.
Passed away: Participant was enrolled but later passed away	Notify REC immediately with details regarding the situation (i.e. Date of Death, Date Notified, Cause of Death, Participant Age and Sex); Remove from Follow Up Call Lists	Counted up to and including randomized/enrolled and stays in all denominators for Follow Up retention; these participants get marked as "Withdrew from Study" for sIRB purposes.
Withdrawn from the study by the Research Team: Participant was enrolled but later dismissed from the study by the Protocol Lead	If a participant is administratively dismissed from the study by the Protocol Lead for being verbally abusive to staff and we do not plan on re-engaging them.	Treated as other enrolled participants except they wouldn't show up on follow-up call lists and should be marked as Do Not Contact (DNC) in the database; these participants get marked as "Withdrew from Study" for sIRB purposes.
Other	If a participant withdraws for any other reason not listed here, please contact the REC immediately to discuss how to proceed.	

15.0 Risks to Subjects

The risks and discomforts associated with participation in this study re no greater than those ordinarily encountered in daily life, standard medical care, or physical/psychological tests. However, there is some risk of emotional discomfort or distress due to the personal nature of the topics in the surveys and discussed during the intervention sessions. There is also a risk that

parents, family members, or others will learn about the participant's sexual orientation or sexual activity based on participation in this research study. Those who choose at-home HIV/STI testing may be mailed kits to a home address or another address specified by participant.

Other risks: There is a risk of pain at the site of the finger prick for the HIV test and syphilis testing.

16.0 Potential Benefits to Subjects

The benefits of study participation include the potential for the participant to learn more about themselves, their sexual behavior, their drug and alcohol use, and other thoughts, feelings, and behaviors. The benefits also include helping to develop a program to reduce the risk of exposure to HIV among YMSM, which will likely benefit other members of the community.

17.0 Data Management and Confidentiality

We have strict guidelines to protect privacy of participants during recruitment, consent process, and research procedures.

For recruitment, the HIV tester or phone screener discusses the study with the participant in a private setting. The screening survey is done through an online survey to make the screening process private. If the participant is eligible, contact information is collected electronically and not with paper and pencil. That contact information is password protected and kept separate from the screening questions.

For the Consent process, being consented into the study will take place in a private setting. The signed consent will be kept separate from all other participant information, survey data, and other materials in a locked cabinet.

For the research process, authorized research staff who are trained on the ethical conduct of research will contact participants by telephone, email, or mail, depending on the participants' preferred method of contact, to schedule appointments for study visits. Staff are trained to be discrete when contacting participants. Furthermore, to offset the risk of violation of data confidentiality, strict confidentiality will be maintained; records that have personal identifiers (i.e., contact information) will be stored in files that have password protection and are kept separate from research records. All research forms are stripped of personal identifiers, with the participant number being used to identify specific research forms. No presentation or publication of the study results will refer to participants individually. Manuscripts published regarding this work will be based on the accumulated database. A federal Certificate of Confidentiality, which protects subjects' records against subpoena, will be obtained prior to study start. Exceptions to confidentiality for participants are those required by law (information that would lead to suspicion of child abuse, elder abuse, or threat of imminent action on suicidal or homicidal ideation, or STI/HIV surveillance). Participants will be informed of these exceptions in the informed consent process.

No identifying information about participants will be recorded on audio files. Participants will be instructed not to identify themselves or third parties during their study visit. Audio record of the interviews conducted will be stored electronically; to which only research staff and those authorized will have access to transcribe the material. Audio recordings will only be identified with alphanumeric IDs. No identifying information about participants will be recorded in the Internet based survey. The structured questionnaires will be computerized and self-administered. We are using a software program called Qualtrics to program the online survey for this study. Developed by a social psychologist, the Qualtrics software program is a sophisticated electronic survey creation and management tool. It is recognized as a valuable assessment program and is currently used in a vast array of research and academic settings across the US. The survey will be SSL encrypted and accessible using an HTTPS URL. Data are encrypted, downloaded, and stored on a secure server, which is password protected and routinely backed up. Participants will be identified in the questionnaire only by an assigned numeric study ID. No identifiers (e.g., name, address, date of birth, social security number) will be collected using the questionnaire itself. The programmed questionnaire and any data resulting from it will reside on a server that is protected by an internal firewall.

The information obtained during this research will be kept confidential to the extent permitted by law and will be stored at our research offices for 3 years after the study is completed. Data that cannot be matched to you may be saved for future use and may be shared with other researchers. As part of the consent process, participants will be agreeing to allow us to save and share their data anonymously.

Storing Participant Data
Participants are assigned a unique ID number that is 5 or 6 digits. Links to codes are stored in our Access databases in our password-protected computers.

PRIDE staff and other site staff will have access to links, including the Protocol Leads, research assistants and project coordinators, will have access to the links to be able to contact participants for follow-up assessments during the period of time prior to anonymizing the data. Links will not be released to external researchers.

Identifiers that will be stored
For interviews with SRV staff members only, audio files are stored on our secured server and may contain names of ATN SRV staff members implementing the projects. After three years, we delete all audio files for this study, including any link between information on a SRV staff person and the information in the qualitative interview. YMHP intervention sessions and the ETAU session with the study participant will also be audio recorded, these audio files are stored on our secured server will not contain names and only be labeled with the participant ID number.

Code Deletion
Codes will be deleted, and data anonymized, at a later date. NIH, our funding agency, mandates that we keep records for a period of at least 3 years for auditing purposes and therefore, data will be retained for a minimum of 3 years after study completion. At the end of this time, all identified information (e.g., contact information) will be deleted, effectively destroying the link between the data, unique codes, and participants' identities and de-identifying/anonymizing the

data. The codes themselves will be retained indefinitely to allow for identifying each participant across datasets, but the codes will no longer be linked to any identified information and thus the data will be anonymous.

Data Bank

Once the research has been completed, we will save the data for future use/create a data bank. The purpose of the data bank is to allow external researchers to access the data bank for future analyses and meet requirements for submitting data to repositories as required for publication in some journals. This data is also collected as part of a larger NIH priority to study the epidemiology of HIV; thus, researchers will likely conduct future analyses with pooled data across studies. All de-identified data (i.e., survey data and test results, but not the specimens themselves) will be included in the data bank.

18.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

This research involves no more than Minimal Risk to subjects.

The protocol has a Data Safety Monitoring Plan and is reviewed semiannually by a Study Monitoring Committee.

The Scale-It-Up (SIU) U19 Data Safety and Monitoring Plan will utilize a single monitoring system for all SIU protocols (including YMHP) in order to harmonize review standards across protocols. The review process of the most vulnerable protocol will be applied to all SIU protocols thereby ensuring adequate oversight. We propose utilizing an independent study monitoring committee (SMC). A SMC was selected as the Clinical Research Management (CRM) as it is the highest-level CRM needed for the most vulnerable SIU protocol. The proposed SMC will be composed of three independent experts who possess the relevant expertise (e.g., HIV-related research and prevention, adolescent medicine, and sexual health) to evaluate each SIU protocol and whom do not have a conflict of interest. Mary Velasquez, Jim (Xinguang) Chen, and Dushyantha Jayaweera have formally agreed to serve on the SIU SMC. Together, they represent an academically diverse and highly experienced team capable of providing the necessary foresight and oversight to ensure data safety monitoring plans are diligently designed and implemented. SIU has the appropriate funding available to financially support the activities of the SMC. The SMC will review each research protocol and plan for data and safety monitoring every 6 months, with additional ad-hoc reviews as necessary. All SMC meetings and reviews will be held via telephone conference.

Adverse Events Reporting

The Site Protocol Lead (PL) is responsible for the detection and documentation of events meeting the criteria and definition of an adverse event (AE) or serious adverse event (SAE). Data for monitoring participants' safety will be captured within the REDCap database as part of the required study data. Site study staff may ask questions concerning adverse events via the SIU query system but must formally report them via email and REDCap. Information on unexpected events including SAE will be reported as per the policy of SIU's single IRB (sIRB).

Information to be collected includes the nature, date of onset, stop date, intensity, duration, treatment, causality, and outcome of the event. Site PLs should follow usual clinical practices at

their institutions 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 PL to be related to study participation. In addition, any AE resulting in potential participant withdrawal must been reported to the SIU REC prior to participant withdrawal when possible.

Site PL s must report any AE to the REC within one business day of learning of it. The REC will then report all SAEs to the IRB within 3 business days and all AEs within 5 business days, upon learning of them from site study staff.

Anticipated Events Reporting
Since this study involves working with high risk HIV negative participants, it is possible that a participant will test HIV positive during the course of the study. This is deemed an anticipated event and will only be reported at time of annual review.

19.0 Compensation for Research-Related Injury

N/A – The research does not involve more than minimal risk to subjects.

20.0 Economic Burden to Subjects

Research subjects are responsible for their transportation to and from the research facility/office for their YMHP sessions – they are provided transportation vouchers for their assessments.

21.0 Consent Process

Site PLs must ensure that participants are fully informed about the purpose, responsibilities of participating and potential risks or other critical issues related to participation in SIU studies. Written informed consent or assent must be 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 SIU 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 a SIU study.

Consent will be discussed and documentation obtained in person at subjects' baseline visits prior to any data collection or other study procedures. Informed consent procedures will be conducted privately with each participant in order to minimize the potential that youth feel pressured by a partner to participate in the study.

The Research Assistants (RAs) at the participating SRVs will be the individuals who will obtain consent from participants. The RAs will be trained on the protocol and the consent process, RAs will obtain CITI training which will be submitted to the IRB. The RAs will not engage in any research activity until they are registered as Research Staff with the FSU IRB and IRB approval is granted for their role on the research project.

Subjects are asked to: (1) name things they will be expected to do during the study, (2) explain what they would do if they no longer wished to participate in the study, (3) explain what they would do if they experienced distress during the study and (4) identify potential risks for participating in the study.

Non-English-Speaking Subjects
Eligibility includes criteria that participants must speak English. No separate plan for obtaining consent is needed for non-English speakers.

Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception).

We are obtaining a waiver of parental consent. Our research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects.

Parental or guardian permission is not a reasonable requirement for our research with the 15-17-year-old participants. Youth will be completing surveys and discussing sensitive topics such as their sexual behavior and substance use. Parental permission would put those youth whose parents do not already know about their sexual orientation at risk of their parents learning about this by the nature of requesting their permission to participate in a study of this kind. This may then place these youth at risk for parental harassment, abuse or expulsion from the parental home. Parental permission could not only place these youth at increased risk, but it would also substantially limit the generalizability of our research.

Our justification for this waiver is informed by prior research with the target population, which has demonstrated risks of parental victimization during coming out or discussions of sexual orientation. Most YMSM are unwilling to ask their parents' permission to be in an HIV-focused study and those who are willing are significantly different on key variables. In addition, research suggests that young YMSM have the capacity to make an informed decision regarding participation (e.g., appreciation of risks/benefits to themselves, understanding research components such as randomization) despite this not meeting the legal definition of consent. As shown in prior research—including that of our consultant, Dr. Brian Mustanski, parents with LGBT-identified children appreciate the rationale for waivers of their permission when the study and its purpose are explained. This evidence supports the fact that YMSM are a population for whom parental or guardian permission is not a reasonable requirement to protect the participants and a waiver of parental permission is appropriate under 45 CFR 46.408(c). This determination was further supported by the fact that this study poses minimal risk (i.e., does not expose participants to greater risk than encountered in everyday life) and therefore the waiver could also be approved under 45 CFR 46.116(d) based on the evidence described above that the research is not possible if parental permission is required. Additionally, consistent with national policy recommendations from the Society for Adolescent Medicine, requiring parental permission for the proposed study would have a number of possible negative effects, including: (1) reducing the validity of the findings by effectively eliminating potential participants unwilling to share permission forms with their parents/guardians; (2) increasing risk to some youth whose parents

have a negative response to the material in the permission forms that would suggest their child has a minority or alternative sexual orientation; and (3) adding little in the way of actual subject protection, given the minimal risk of study participation.

Cognitively Impaired Adults
N/A

Adults Unable to Consent
N/A

22.0 Process to Document Consent in Writing

Consent will be obtained in writing using a consent or assent form which details all study procedures and expectations for participation. The RAs and the participant will both sign two copies of the consent/assent forms. The RA will retain one for filing and the participant will be able to take a copy with them. The consent and assent forms were written using the Template consent document (HRP-502).

23.0 Setting

This research is being conducted at Wayne State University Prevention (W'SUP) at Wayne State University in Detroit, MI, the University of Miami Division of Adolescent Medicine in Miami, FL, and the Children's Hospital of Philadelphia (CHOP) Division of Adolescent Medicine in Philadelphia, PA.

Please see submitted local context forms for additional information about each site.

Potential participants are identified at these local sites through testing services, outreach activities, and online social media and dating apps. Please see recruitment sections for more information.

At all three locations, the research will be conducted in private assessment rooms equipped with either a computer or iPad for the participant to complete the online CASI. All research procedures will be performed in the offices of the research facility. Rapid HIV tests will be performed in the facilities' phlebotomy room and STI sample collection will take place in a private restroom.

The Community Advisory Board for this protocol is a part of the national Youth Community Advisory Board for the Scale It Up program of research. They meet on a quarterly basis via skype to discuss study progress, recruitment strategies, and recommendations for youth engagement.

24.0 Resources Available

The resources available to conduct this research include the ability of sites to conduct HIV testing and counseling both at their site and in the community. The sites have the experience and expertise to do outreach in their respective cities to connect high risk HIV negative youth who

may be eligible for the study. Although they are located within academic/ medical centers, they often partner with other community based organizations to reach the target population.

Additionally, PRIDE Health Research Consortium at Hunter College has extensive experience administering this research, having previously implemented the efficacy trial of YMHP in New York City. They also provide extensive support for recruitment efforts to the individual sites, including doing national social media ads to get potential participants that may be eligible for YMHP in Detroit, Miami, and Philadelphia.

25.0 Multi-Site Research

This research is being conducted at Wayne State University Prevention (W'SUP) at Wayne State University in Detroit, MI, the University of Miami Division of Adolescent Medicine in Miami, FL, and the Children's Hospital of Philadelphia (CHOP) Division of Adolescent Medicine in Philadelphia, PA.

Each site will enroll 60 individuals.

Recruitment

All three sites will recruit individually for participants as outlined in the recruitment section above. Each site will have site-specific recruitment materials for potential participants. See attached materials.

Enrollment

All sites have site-specific consent and assent forms for participants to sign. All data is collected with Qualtrics, which means that the sites will not have local copies of the data at their offices. All data will be stored on the cloud through program servers.

Site Oversight

The Scale It Up Management Core have daily contact with the sites regarding participant procedures. The Protocol Leads meet monthly with the site PIs. The Site PI for the PRIDE site is also the Protocol Lead for this protocol. So there is constant communication between sites. In addition, there is an online support request form through the Scale It Up Site Communication System for sites to submit queries and questions regarding this protocol. Additionally, the Management Core sends quarterly reports to each site outlining whether the site meets the established expectations for site enrollment and progress.

Reporting of Serious Adverse Events and Unintended Events

All sites have procedures set in place to report any unintended events to the Scale It Up Management Core. The sites can submit an online support request of any events through the Scale It Up Site Communication System.