Young Men's Health Project (YMHP): Examining community-based effectiveness of a substance use and HIV risk reduction intervention for young men of color (YMHP-CBO)

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STUDY PROCEDURE GUIDE VERSION AND AMENDMENT TRACKING

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SCALE IT UP STUDY PROCEDURE GUIDE APPROVAL

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Protocol Lead	Signature	Date

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LIST OF ABBREVIATIONS AND ACRONYMS

AE	Adverse Event
BAC	Bridging Access to Care, Inc.
CAS	Condomless Anal Sex
CASI	Computer-Assisted Self-Interview
CBO	Community Based Organization
CET	Comparative Effectiveness Trial
PRIDE	Center for HIV Educational Studies & Training
CT	Chlamydia trachomatis
C&T	(HIV) Counseling and Testing
DATCAP	Drug Abuse Treatment Cost Analysis Program
DSMB	Data Safety Monitoring Board
DSMP	Data Safety Monitoring Plan
eTAU	Enhanced treatment as usual
GC	Neisseria gonorrhea
GMM	Growth Mixture Modeling
HIPAA	Health Insurance Portability and Accountability Act
IDU	Injection Drug Use
IP	Immediate Post-Test Assessment
ITT	Intent-to-treat
MAR	Missing at Random
MI	Motivational Interviewing
MITI	Motivational Interviewing Treatment Integrity
MSM	Men who have sex with men
MYMSM	Racial and ethnic minority young men who have sex with men
OMS	Online Master Screener
PHI	Protected Health Information
PD	Project Director
PI	Principal Investigator
PrEP	Pre-Exposure Prophylaxis
Rating Form	MI Coach Rating Scale
RPPR	Research Performance Progress Report
SAE	Serious Adverse Events
STI	Sexually Transmitted Infection
YMHP	Young Men's Health Project
YMSM	Young men who have sex with men (ages 15-24 unless otherwise specified)

STUDY ABSTRACT

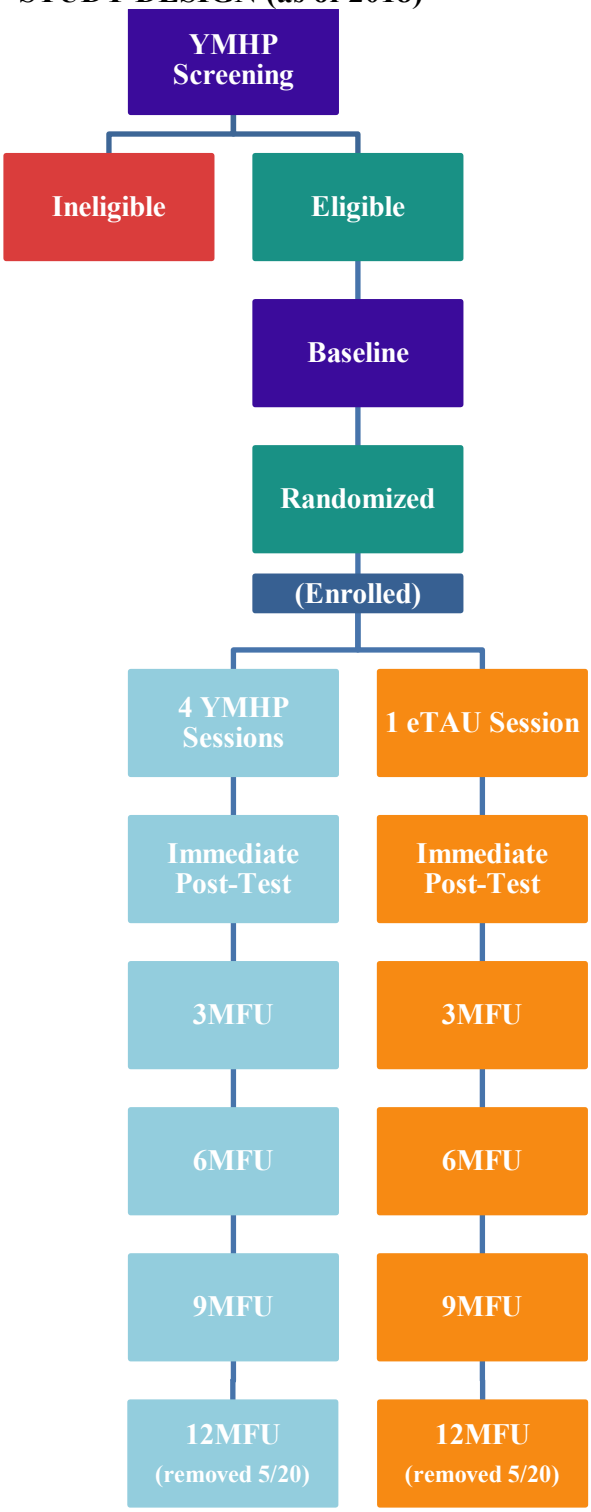
PURPOSE: The purpose of this study is to adapt and test the effectiveness of the Young Men's Health Project (YMHP) motivational interviewing (MI) intervention as delivered in community based organizations (CBOs), in an effort to reduce human immunodeficiency virus (HIV) and sexually transmitted infection (STI) disparities among racial and ethnic minority young men who have sex with men (MYMSM).

DESIGN: This study will use a comparative effectiveness trial (CET) design with two intensities of treatment to be offered following field-based HIV counseling and testing -- the YMHP intervention and an enhanced "treatment as usual" (eTAU) condition involving HIV prevention services provided at two CBOs -- to test their relative effectiveness in reducing substance use and sexual risk behavior among HIV-negative MYMSM. Phase I will include conducting focus groups with CBO staff including HIV counseling and testing (C&T) staff, counselors, and others to obtain implementation feedback about the delivery of the YMHP intervention and intervention components to ensure culturally competent, feasible, and scalable implementation in CBO settings. Phase II will include the recruitment and enrollment of 260 MYMSM aged 15-29 (130 per condition). Intervention sessions will be recorded for Motivational Interviewing Treatment Integrity (MITI) fidelity coding, and Health Educators and supervisors will be given implementation support throughout the full trial. [TBD: Prior to implementation, immediately at the conclusion of the intervention delivery phase, and one year post-intervention, the PRIDE Health Research Consortium (PRIDE) will conduct interviews with counselors, supervisors, and CBO leaders to obtain information about the barriers to and facilitators of implementation and sustainment of YMHP.]

DURATION: The overall study duration is 36 months. There will be approximately 8 months of focus groups, adaptation, and training; 13 months for recruitment and enrollment; and 15 months of follow-up assessments with study participants. Assessment of intervention outcomes will be at immediate post-test (IP), 3-, 6-, 9-, and 12-month time points (12M removed May 2020). An optional qualitative interview will be conducted at any point after the immediate post.

STUDY SITES:	Boom! Health – Bronx, NY Bridging Access to Care – Brooklyn, NY (BAC ended participation May, 2019. BAC participants complete their intervention, follow-up assessments, and STI testing at Hunter College research offices (142 W 36th Street, New York, NY 10018) or Boom!Health)
SAMPLE SIZE:	We will enroll 260 HIV-negative MYMSM (130 per condition)
POPULATION:	We will screen HIV-negative MYMSM aged 15-29 who seek HIV/STI testing at the CBOs or via mobile testing. Enrollment will be limited to HIV-negative YMSM who report recent substance use and condomless anal sex (CAS) or a positive STI test result in the past 90 days.
STRATIFICATION:	Participants will be randomized and scheduled to receive their first YMHP session directly following their baseline assessment. The study will employ a stratified block randomization procedure with strata for substance use and each interventionist using Qualtrics. Randomization is stratified by substance use including (marijuana alone). For the purposes of stratification, any alcohol and/or tobacco use is not considered.
DATA COLLECTION:	Intervention sessions will occur approximately once per week for four weeks, beginning one week after completion of the baseline assessment. There will be a 12-week window for intervention completion, i.e. all 4 sessions must be completed within 12 weeks of the baseline assessment. The IP will occur 3 months after baseline. Subsequent follow ups will be scheduled every 3 months thereafter, ending with the 12-month post-intervention (i.e., 15 months post-baseline) assessment. Baseline, 3-month, and 9-month assessments consist of self-report data collection (CASI) plus HIV and STI testing. The IP, 6-month, and 12-month follow-up assessments require only the CASI and can be completed remotely.
OBJECTIVES	1) To adapt the YMHP intervention for delivery in CBOs by Health Educators 2) To test the effectiveness of the YMHP intervention delivered at two CBOs in high HIV incidence neighborhoods in NYC 3) To assess the cost-effectiveness of YMHP

STUDY DESIGN (as of 2018)



STUDY TIMELINE (as of 2018)

Examining community-based effectiveness of a substance use and HIV risk reduction intervention for young men of color (updated Timeline)																				
TASK	Year 1									Year 2				Year 3				Year 4			
	Aug	Sept	Oct	Nov	Dec	Jan	Feb	March	April	13-15	16-18	19-21	22-24	25-27	28-30	31-33	34-36	37-39	40-42	43-45	46-48
PHASE I																					
Start-up, preliminary meetings	X	X	X																		
Formative Work																					
Formative research with CBO partners: implementation	X	X	X	X																	
Analysis of formative work			X	X																	
Revise intervention manual, prepare eTAU materials,				X	X	O															
IRB approval of updated manual and protocols							O														
Project Development																					
Development of implementation science protocol				X	X	O	O														
Development of Quanitative Measures			X	X																	
Development of Protocols				X	X	O															
Training																					
Staff hiring at both CBO sites					X	O															
Development of a Training Plan					X	O															
Train the Research Coordinators at both sites							O	O													
Train the Staff to do Motivational Interviewing							O	O													
Intervention Mocking and Coaching							O	O													
PHASE II																					
Enrollment (n = 260; 10 MYMSM per site per month for 13 months) - STARTED in March 2018									20	60	60	60	60								
Implement Comparative Effectiveness Trial (CET) and																					
Follow-up assessments																					
Analyze CET results																					
Cost effectiveness analyses																					
Data dissemination																					
Develop protocols for scale-up of the YMHP intervention																					

1.0 BACKGROUND AND SIGNIFICANCE

1.1 MYMSM are disproportionately at risk for HIV and STIs

The annual number and rate of new HIV infection diagnoses in the United States decreased between 2011 and 2016 [1]. However, the number of infections attributed to male-to-male sexual contact did not decrease [1]. In 2016, 70% of new HIV infections were attributed to sexual contact between men [1]. Additionally, the annual number and rate of HIV diagnoses both *increased* among young adults aged 25-29, while decreasing or remaining stable for other age groups [1]. People aged 25–29 had the highest rate of new diagnoses (34.8%) in 2016, followed by those aged 20–24 (30.3%) [1]. Rates of new HIV diagnoses were greatest among blacks/African-Americans (43.6%) and Latinos (17%); the rate amongst whites was the lowest of all racial and ethnic groups (5.2%) [1]. According to the Centers for Disease Control and Prevention (CDC), black YMSM (aged 13 - 24 years) account for more new diagnoses nationwide than any other subgroup by race/ethnicity, age and sex [2]. CDC projects that "if current rates persist" one in two black MSM and one in four Latino MSM are at risk of an HIV diagnosis in their lifetime [2].

Rates of HIV diagnoses also vary geographically across the US. The Northeast has the highest rate of people living with diagnosed HIV (418 per 100,000 people) and the second-highest rate of HIV diagnosis (11.2 per 100,000 people) in the US [3]. New York City remains the epicenter of the domestic HIV epidemic, and reflects even stronger disparities in incidence by sexual orientation, age and race/ethnicity. In 2016, MSM made up at least 71.4% of men newly diagnosed with HIV in New York City, with those aged 20-29 making up the greatest number of new diagnoses (39.8%) [4]. While the number of annual new HIV diagnoses has decreased across all age groups since 2001, the estimated annual percent decrease in new diagnoses for the 20-29 age group (0.87) is a fraction of the decrease for the other age groups (which range from 2.53 amongst New Yorkers over 60 to 22.6 amongst those under 13) [4]. MYMSM in NYC are the most affected; 78.7% of all YMSM diagnosed with HIV between 2012 and 2016 were black and/or Latino [5]. In 2016, MSM aged 20-29 made up 37.6% of all new HIV diagnoses amongst blacks/African-Americans, and 36.1% of all new HIV diagnoses amongst Latinos; together, MYMSM aged 20-29 comprised 20.0% of all new HIV diagnoses in NYC in 2016 [6].

Young males ages 15-24 are vastly overrepresented in rates of STIs, with similar disparities by race/ethnicity and sexual behavior. In 2016, 15-24 year old males accounted for 52% and 38% of all male cases of Chlamydia trachomatis (CT) and of Neisseria gonorrhea (GC) infection, respectively [7, 8]. According to the CDC, in 2016 young black/African American men ages 15-19 and 20-24 had a rate of CT infection 8.8 and 4.9 times higher than whites, respectively. GC rates showed similar racial disparities nationwide: black/African American men aged 20–24 years and 25–29 years had a GC rate 9.1 times and 7.4 times that of white men in the same age group, respectively [9]. 2015 NYC trends in STI incidence by race/ethnicity were similar; black non-Latino young men aged 15-19, 20-24, and 25-29 reported GC at 8.4, 2.8, and 2.9 times the rate (per 100,000 population) as their white counterparts. Nearly half of new GC diagnoses among males in 2015 were among men ages 20-29 [10]. In 2016, MSM accounted for 81% of all

primary and secondary (P&S) syphilis cases diagnosed in the US, with 47.0% of those MSM co-infected with HIV [9]. Considering all race, ethnicity, sex, and age categories, rates of reported P&S syphilis cases were highest among Black men aged 20–24 years and 25–29 years. The rates among black men aged 20–24 and 25-29 years were 6.4 times and 6.2 times those for their white counterparts [9].

The NYC DOHMH found that between 2012 and 2016, male P&S syphilis case rates increased 81%, with the overwhelming majority (88%) of 2016 cases amongst MSM. Even more concerning is the high rate of HIV co-infection among MSM with P&S syphilis: 43.4% in 2016 [11]. Syphilis and HIV co-infection raises the risk of transmission to sexual partners [12]. Similarly, a study of HIV-negative MSM diagnosed with rectal CT/GC at NYC STI clinics from 2008 to 2010 showed that rectal CT/GC infections greatly increase HIV incidence. Among those with CT/GC infections, 1 in 15 was diagnosed with HIV within one year, with HIV incidence highest among YMSM and Black MSM [13].

1.2 Substance Use and HIV Risk among YMSM

MSM, including YMSM, use recreational drugs and alcohol at higher rates than their heterosexual counterparts [14-18]. Substance use increases the likelihood of engaging in sexual risk behavior and HIV seroconversion among MSM [19-21]. Some have even argued that methamphetamine-using MSM are fueling the HIV epidemic [22]. Polydrug use is common among YMSM [14, 23, 24], and "club drugs" like cocaine, ketamine, methamphetamine, ecstasy, and gamma hydroxybutyrate (GHB), are commonly used, often in association with sexual activity [25-27]. Substance use is especially prevalent amongst MSM in urban areas [18]. A recent study of Black MSM in 6 US cities found that 38% reported stimulant use and 57% marijuana use. 48% reported substance use during their last anal sex encounter [28]. Similarly, a study in Boston found that 34% of black MSM reported using stimulants during sex at least monthly in the previous year [29]. Nearly half of Black MSM with newly diagnosed HIV infection (48%) reported substance use during their last anal sex encounter [30].

YMSM who use recreational drugs are particularly susceptible to HIV infection. PRIDE's own research using event-level data for the previous 30 days has found that YMSM's substance use strongly and significantly predicts CAS: CAS was twice as likely on a day that any drug was used [31]. Among Latino YMSM, street drug and methamphetamine use are strongly correlated with sexual risk; among Black MSM higher rates of marijuana use are linked to sexual risk [32].

Given these statistics, 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, and MYMSM in particular.

1.3 The CBO Setting

CDC supports routine HIV testing in clinical settings and targeted HIV testing in nonclinical settings. The nonclinical setting includes community-based organizations, whose location *within* a community makes their services more accessible and comfortable for populations that might have limited or irregular access to medical care. CBOs successfully engage populations that are at high risk for HIV infection and are difficult for traditional clinical settings to reach [33]. HIV testing, counseling and prevention provided by CBOs address many key barriers that these populations face, including lack of health insurance, stigma, medical mistrust, and lack of confidentiality in insurance billing statements. Young people who are covered as dependents on a parent or partner's health insurance plan, for example, may seek testing from a CBO so that the test does not appear on an Explanation of Benefits sent from their insurance company to the policyholder, as it would if they received testing in a clinical setting using their insurance. Unlike the clinical setting, CBOs rely on counselors and lay health workers, with a focus on C&T and social services rather than routine healthcare.

Community-based organizations that offer targeted HIV testing usually conduct same-day rapid HIV tests, active recruitment to reach out to high-risk populations for HIV testing, and offer HIV prevention services, including "structural or behavioral interventions and social services" [33]. Co-locating HIV prevention and substance use treatment at CBO sites is an especially effective strategy for providing accessible HIV prevention services to high-risk populations [34]. CBO partner Boom!Health's harm reduction center is an example of integrated, co-located services: the center includes a syringe exchange program, HIV and HCV testing, care management, common harm reduction support services, primary care, mental health services, suboxone treatment, and pharmacy services [35]. CBO partner Bridging Access to Care (BAC) co-locates HIV primary care services in its behavioral health clinics, including rapid HIV testing onsite for any interested client [36].

Agencies often provide HIV testing and prevention services at multiple venue types in order to better identify high-risk clients, meet the needs of their target populations, and offer a broader range of services. "Offering testing in these venues allows providers to strategically target their services to individuals at highest risk of becoming HIV infected in their community. By providing clients access to prevention, medical, and social services on-site or through external agencies, non-clinical testing programs can expand access to a wide range of medical and social services that can help stem HIV transmission improve health, enhance the quality of life, and prolong life" [37]. BAC, for example, offers C&T at several of their offices, as well as through mobile units and partnerships with churches, schools, and other organizations [38].

BOOM!Health (formerly CitiWide Harm Reduction and Bronx AIDS Services) delivers a range of HIV prevention, behavioral health and wellness services to those at highest risk in the Bronx, a community with some of the highest HIV concentrations in NYC. In January 2015, BOOM!Health opened a 35,000 square-foot Wellness Center with health care services focusing on the unique needs of sexual minorities and youth in the Bronx. BOOM!Health provides HIV testing onsite and via mobile vans, as well as evidence-based HIV prevention interventions and

related services to a large population of MYMSM in the Bronx, making it an ideal collaborating site for testing the effectiveness of YMHP in the field.

Bridging Access to Care, Inc. (formerly Brooklyn AIDS Task Force) (BAC ended participation as a site in May 2019.) is Brooklyn's oldest nonprofit prevention, treatment and health service organization. They provide comprehensive HIV/AIDS, mental health, and substance use services to underserved racial and ethnic minority communities in Brooklyn, as well as HIV testing and prevention outreach across New York City. BAC's Brooklyn Men (K)onnect program specifically serves MYMSM. BAC's offices are located in Flatbush, Crown Heights and Williamsburg, which have the three highest HIV incidence rates in Brooklyn and together comprise 14.7% of all new HIV diagnoses in NYC [6].

Given the success of HIV testing and counseling in the CBO setting, this study places the YMHP intervention in the CBO setting, to directly follow a client's negative HIV test result. YMHP has the potential to be a powerful tool for HIV prevention amongst MYMSM, and the CBO setting is ideal for the intervention to reach this population. The youth population served by BAC and Boom!Health is almost entirely Black and Hispanic, and both CBOs have targeted outreach to YMSM. Boom!Health and BAC are well known and trusted in their communities, which have disproportionately high rates of poverty and HIV incidence. Our study utilizes staff indigenous to the CBO setting to build capacity for implementation of the YMHP intervention. Lay health workers are commonly integrated into CBOs, and often play a central role in providing HIV prevention services, including C&T. We will be studying the effectiveness of YMHP delivery by trained lay Health Educators in these community-based settings, with a focus on intervention sustainment and scalability.

1.4 Motivational Interviewing

Motivational Interviewing (MI) has the potential to improve self-management behaviors in terms of promoting sexual health and reducing substance use among MYMSM. Meta-analyses of MI in medical care settings found that MI had a significant impact on behaviors such as alcohol and substance use, sexual risk behavior, and HIV viral load over and above those who did not receive MI [39-41]. There is strong evidence that MI is a culturally appropriate and effective approach for working with racial and ethnic minority populations [42] who are disproportionately affected by HIV and other STIs. One meta-analysis of MI found greater effect among minorities [43]. MI has been recommended as particularly effective when working with MYMSM [44]. 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 [45]. The autonomy-reinforcing nature of MI may be particularly culturally appropriate for African-American/Black and Latino youth; one study of HIV+ MYMSM found that minority youth who did not feel respected during care encounters were at greater risk of being lost to care [46].

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. We found that YMSM randomized to receive the YMHP sessions were 24% less likely to engage in CAS and 18% less likely to use recreational drugs than those who received content-matched educational sessions [47].

1.5 Intervention Delivery by Health Educators

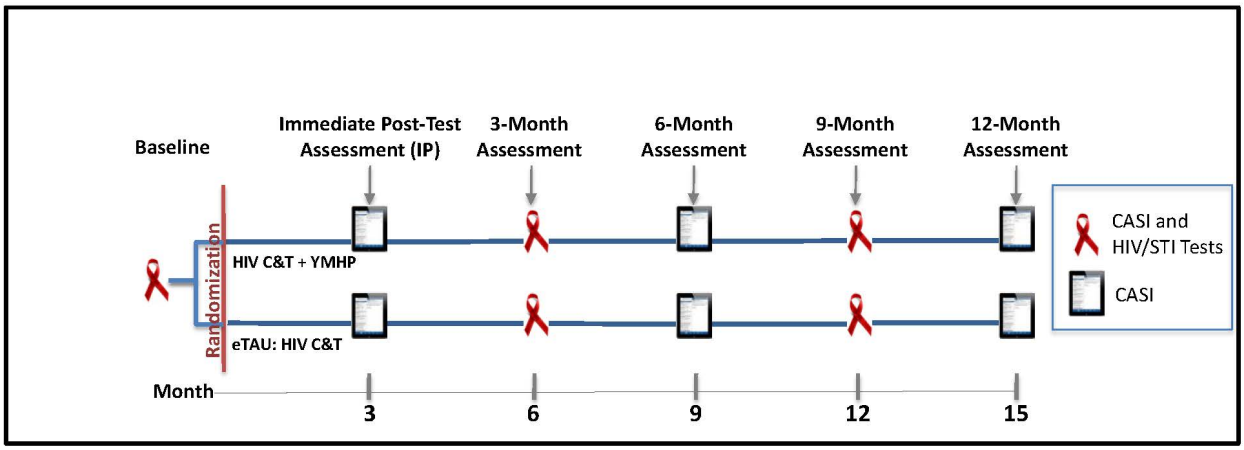
Lay health workers are as effective as clinicians in providing high quality MI, and clients are more likely to be retained in HIV care when working with the lay health workers [48]. Health Educators are commonly integrated into community-based health clinics, and often play a central role in providing HIV prevention services, including HIV C&T. Training lay health workers to deliver evidence-based interventions is a critical step towards realistic and cost-effective implementation[49, 50]. Research has established that in order to obtain MI fidelity, initial training must be reinforced by ongoing coaching [51-54]. 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 [55]. CDC has called for expanded use of lay health workers in services for preventing and managing chronic disease, including leading and supporting self-management programs; CDC suggests comprehensive state policy approaches to supporting lay health workforce, as Massachusetts and Minnesota have done [56].

Lay health workers have long been the cornerstone of integrating support services into HIV-related prevention efforts [57]. The "Hybrid 2" design of this YMHP CET study tests both clinical and implementations interventions/strategies [58]; this allows us to determine which treatment works better as well as answer implementation science questions about the potential barriers and facilitators to a treatment's widespread and continued implementation.

In summary, this study examines the implementation of a brief efficacious intervention that addresses an important problem (high rates of substance use and increasing HIV/STI incidence) among a population experiencing multiple vulnerabilities and health disparities. Given the absence of effective behavioral interventions in reducing both substance use and sexual risk outcomes in HIV-negative MYMSM, this CET is the crucial next step in determining the effectiveness of the YMHP intervention in real-world contexts, i.e. as delivered by frontline staff to their clients.

2.0 STUDY OBJECTIVES

In collaborating with two CBOs (Boom!Health and BAC(BAC ended participation in May 2019)), our goals are to better understand substance use and sexual health-related outcomes among HIV-negative MYMSM who are unlikely to be treatment-seeking and to implement the YMHP intervention in a way that will maximize portability and scalability. Working collaboratively with the CBOs will help to address practical problems at the frontline of service provision to pave the way for a comprehensive program to reduce substance use and HIV infection among MYMSM.



2.1 Specific Aims

Aim 1: Adapt the YMHP intervention for delivery in CBOs by Health Educators. We will conduct focus groups with site staff to obtain further input on the best ways to implement YMHP in CBO settings to maximize feasability, acceptability, and sustainability.

Aim 2: Test the effectiveness of the YMHP intervention delivered in two CBOs situated in high HIV incidence neighborhoods in NYC using a CET. We will test YMHP – an efficacious, MI-based intervention – versus enhanced treatment as usual (eTAU) condition (standard HIV C&T and prevention services with information about PrEP) in reducing substance use and CAS among HIV-negative MYMSM.

Aim 3: Assess the cost-effectiveness of YMHP. In order to enhance the likelihood of uptake if effective, we will conduct analyses to assess the cost-effectiveness of YMHP compared to eTAU.

2.2 Research Overview

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

Phase I: We will conduct focus groups with staff, including HIV C&T counselors, Health Educators, counselors and others. We will train a mininum of 2 Health Educators and 1 supervisor at each CBO. Once Health Educators demonstrate competence according to the MITI, we will move to Phase 2.

Phase II: We will recruit and enroll 260 MYMSM, aged 15-29, 130 per condition. Enrollment will be limited to HIV-negative YMSM who report recent substance use and either CAS or a positive STI result. Participants will be randomized to receive either the 4-session YMHP

intervention, or one session of eTAU. YMHP sessions will be audio-recorded for MITI fidelity coding, and counselors and supervisors will be given implementation support throughout. [TBD: Prior to implementation, immediately at the conclusion of the intervention delivery phase, and one year after, PRIDE will conduct interviews with counselors, supervisors, and CBO leaders to obtain information about the barriers to and facilitators of YMHP implementation and sustainment.]

3.0 STUDY POPULATION

3.1 Inclusion and Exclusion Criteria

Patients who express interest in YMHP must demonstrate the following inclusion criteria to be enrolled in the study:

- HIV-negative test result from the past 90 days
- 15-29 years of age
- Currently identifies as male (regardless of birth sex)
- Sex with men in the past 90 days
- Self-report ≥ 3 days of substance use (including heavy drinking) in the past 90 days
- Self-report ≥ 1 episode of CAS in the past 90 days, *or* a positive STI test result in the past 90 days
- Living in NYC metropolitan area
- Able to communicate in English

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

- ≥5 days of injection drug use (IDU) in the past 90 days
- Currently taking Truvada as pre-exposure prophylaxis (PrEP)
- Mental, physical or emotional capacity that does not permit them to complete the protocol as written.

We expect a study population that is close to 100% black and Hispanic, based on the client population at the partner CBO sites. However, we will not exclude young men of other ethnic or racial backgrounds from the study if they meet inclusion criteria. Given the racial and ethnic breakdown of YMSM clients at BOOM!Health and BAC, we estimate that 44% of our sample will identify as Black/African-American, 48% as Hispanic/Latino, and 8% as "other."

3.2 Recruitment and Screening

Recruitment and screening will be integrated into the HIV testing practices of both collaborating CBOs. BOOM!Health and BAC will continue to conduct HIV testing at their home offices and in the field as usual. YMSM that are tested and receive an HIV-negative result will be offered the opportunity to participate in YMHP. If interested, the HIV tester will ask the potential participant to complete a brief screener via an iPad. If eligible, the potential participant's contact info will be

collected and passed on to the Research Coordinator who will contact them in order to schedule a baseline appointment.

CBO study personnel will also attempt to screen YMSM who have previously received an HIV-negative test result at BOOM!Health or BAC. To do so, CBO study personnel will reach out to YMSM who have received a recent negative HIV test result in the last 90 days. After giving an explanation of the YMHP study, the potential participant will be asked if he would like to answer the screener questions for the study over the phone. If he declines, the study personnel will thank him for his time and end the call. If they agree to answer the questions, the study personnel will deliver the study screener over the phone.

The study will be advertised in the form of flyers, brochures, and cards displayed in public areas of the BOOM!Health and BAC offices frequented by clients, plus their mobile testing units, alongside materials promoting the organizations' other services. These materials will be given to potential participants to encourage HIV testing as well as promote the YMHP study.

PRIDE will assist in identifying potentially eligible participants through its existing ongoing online recruitment efforts. PRIDE utilizes the Hunter College IRB-approved Online Master Screener (OMS) to preliminarily screen individuals who are interested in participating in PRIDE studies. When the OMS determines an individual to be preliminarily eligible for a study, they are asked to provide their contact information to PRIDE for follow-up. For this study, the OMS will be used to recruit, inform, and phone-screen potentially eligible YMSM to YMHP. PRIDE staff will conduct phone screens of potential participant identified by the OMS. If a YMSM screens preliminarily eligible for YMHP, they will be referred via email to BOOM!Health or BAC for free HIV testing to finalize eligibility. This referral email will contain additional information about the study. PRIDE will not provide the contact information collected through the OMS to the CBOs; however, the CBOs will be made aware that a potentially eligible YMSM has been screened for the study and added to the study database for follow up HIV testing.

We anticipate enrollment of 10 participants per site per month**.** We estimate that 80% of enrolled participants will be racial/ethnic minorities.

3.3 Contact Information

Once deemed eligible by the screener, participants will be routed to an online, Qualtrics version of the *Locator Form.* The information provided on the online *Locator Form* will be printed or pulled up by CBO staff for review in-person. The *Locator Form* asks participants to provide a street address, cell phone number, alternative phone number, and valid email address at which they can be reached. Participants will also be asked to provide valid phone numbers for two contacts who can be called in the event the participant cannot be reached by phone or email. Participants will be asked if voicemail messages can be left at the numbers provided. Site study staff will not leave messages unless expressly permitted to do so by the participant, as documented on this form. If permission is given to leave messages, site study staff will assure participants that messages left with a family member or friend will only ask the participant to

contact study staff and will not include any protected health information or information related to study participation. Participants will also be asked for permission to contact them via text message, and given the option to list any additional methods of contact including social media (Facebook, Twitter, Tumblr, Instagram). The *Locator Form* data will be maintained off-line in a password-protected file on a secure server, separate from all study records, with access limited to designated research personnel. A record that will link unique identification codes with names and contact information for participants will be accessible only to study staff and maintained off-line in a password-protected file on a secure server. Participants' names, addresses, email addresses, and social media information will not be collected in the survey, interview, or counseling sessions.

4.0 STUDY PROCEDURES

4.1 Enrollment Procedures

Participants are randomized to YMHP or eTAU after completing the baseline session, which includes the YMHP screener, completion of the Locator Form. After randomization, they are counted as officially enrolled in the study. Once enrolled, the participant should complete the session (YMHP #1 or eTAU, as assigned) immediately. The Research Coordinator will be responsible for tracking the visit as completed in REDCap. PRIDE will then verify that the baseline assessment was completed and follow up with the Research Coordinator if there are any data which need clarification.

4.1.1 Informed Consent

Given that some of the participants will be under the age of 18, adequate provisions will be made for soliciting informed consent. At each site, the Research Coordinator will review the consent or assent forms to make a formal assessment of every youth's decision-making capacity to consent prior to signing, using a 2-step process. In the first step, the Research Coordinator will determine whether the person understands the goals by asking "Can you tell me what this study is about?" In the second step, s/he will ask questions designed to assess the potential participant's capacity to understand, appreciate, reason with, and express a choice about participation in our specific protocol. We will use a modified version of the widely used Evaluation to Sign Consent Form. Subjects will be 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.

Participants will be enrolled only once they are able to provide clear and correct answers to each of these items, with assistance and clarification from the research staff member as needed. If the research staff member feels there is a question about the need for more formal assessment of the decisional capacity of a potential participant s/he will contact the Principal Investigator (PI) to make a decision about enrollment.

Consent will be discussed and documentation obtained in person at subjects' baseline visits prior to any data collection or other study procedures. The consent form (**Appendix A**) will be signed and dated by the individual obtaining the informed consent and by the participant at the beginning of the baseline assessment. A copy of the signed consent form will be given to the participant and the original(s) will be kept securely with each participant's research records. Signed consent forms will be filed and stored securely, and securely stored separately from other assessment materials because they contain the full names of participants.

The Research Coordinators will be trained on the protocol and the consent process, as well as receive Collaborative Institutional Training Initiative (CITI) training. CITI certificates will be submitted to the Hunter College IRB. The Research Coordinators will not engage in any research activity until they are registered as YMHP Research Staff with the Hunter College IRB and IRB approval is granted for their role on the research project. It is also possible for other site staff members (e.g., Health Educators) to be trained and cleared to obtain consent.

Sites will use a local authorization to release protected health information (PHI) to PRIDE as per their institutional policy. Participants will also sign a research authorization for use and disclosure of PHI as required by the IRB.

4.1.2 CASI

After obtaining informed consent, participants will complete a confidential computer-based survey (CASI) at the CBO site that will ask about their substance use, sexual behavior, and general thoughts and feelings. CBO study staff will administer the baseline CASI survey on a study-designated iPad or computer and ensure the participant can complete the survey in a quiet place. The participant will be able to reach the assessor if they have any questions or encounter errors completing the survey, but the assessor will not be in the room so that the participant completes the CASI in private. The baseline CASI will take about 45 minutes to complete.

Participants who screen ineligible based upon CASI responses will be dropped from the study and all relevant databases. They will be given a $25 gift card for completing the CASI. This was changed in August, 2019 because too many participants were incorrectly answering study eligibility questions on the BL CASI. After that point, Study eligibility was determined at screening.

4.1.3 STI Testing

If eligible to continue based on the CASI, participants will proceed to STI testing, which will consist of a urine sample, an anal self-swab of rectal mucosa, and a syphilis test (type dependent on participant's history of syphilis). The syphilis tests used in this study do *not* require a phlebotomist. The STI testing process will take about 15 minutes.

All participants will have already taken an HIV test in the last 90 days, with a negative test result. This is the baseline HIV status. The next HIV test will occur as part of the 3 Month Follow Up Visit.

See Section 4.6 for specimen collection and STI test result reporting procedures.

4.1.4 Randomization

Participants will be randomized at the end of their baseline assessment into one of two intervention conditions: 1) delivery of the 4-session YMHP intervention or 2) delivery of a single eTAU session. Each participant's condition will be tracked in the REDcap database maintained by the Research Coordinator.

To assign condition, the study employs a stratified block randomization procedure with strata for interventionist and substance use. Interventionists are crossed by condition rather than nested, allowing for a more statistically powerful design. The assigned interventionist will be used for these particular strata. The substance use strata will randomize based on whether the participant used only marijuana in the past 3 months versus use of another drug in the past 3 months. After a participant completes the CASI, the assessor will open the randomizer in Qualtrics. The assessor will enter the participant's ID, the assigned interventionist, and select either "marijuana-only" or "other substance use" into the randomizer. The block randomization procedure will select the condition.

4.2 Schedule of Assessments

Baseline (first) visit: After providing informed consent, completing the CASI, and collecting specimens for STI testing, participants will complete their first session of YMHP, or their first and only session of eTAU, depending on their randomization. If randomized to receive the YMHP intervention, this first session will take 40-50 minutes to complete, focusing on either sexual risk or substance use, and will be audio recorded. If randomized to receive eTAU, the session will take 30-45 minutes, and will also be audio recorded. After this first visit, there are no additional treatment sessions as part of eTAU.

Additional YMHP sessions: Participants randomized to YMHP will have the first YMHP session immediately after completion of the baseline assessment, and then they will return to the CBO to receive the remaining 3 intervention sessions, focused on sexual risk and substance use. Intervention sessions should occur approximately once per week for a total of four weeks, inclusive of the baseline visit. There is a 12 week window for intervention completion, i.e. all 4 YMHP sessions must 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.

Immediate post-test assessment: After completing all 4 YMHP sessions, or the single eTAU session, participants will be scheduled to complete an immediate post-test assessment. This assessment will occur about 3 months after their baseline visit (i.e. the first follow-up assessment

post-baseline). During this assessment participants will complete a confidential computer-based survey about their substance 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 health educator, as well as the health care climate of the YMHP intervention. This survey can be completed at the clinic or through a survey link, which will be sent to participants electronically, and will take about 45 minutes to complete.

Follow-up assessments: There will be four additional follow-up assessments for participants to complete. These follow-up assessments will occur in three-month intervals until 12 months after their post-intervention assessment (i.e. 3 months, 6 months, 9 months, 12, and 15 months post BL).

The 3 month and 9 month follow-up assessments include completing a confidential computer-based survey (CASI) on an iPad and require confidential HIV and STI testing. The HIV and STI testing should be performed at the CBO clinic but other options are available such as getting tests performed at an outside lab (e.g. Quest Diagnostics) 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 HIV and STI testing they will be asked to complete these tests at their next assessment.

The 6 month and 12 month assessments do not require HIV and STI testing (unless testing is missed at a previous visit) so these assessments can be completed remotely. Participants can use an electronic link provided to them or they can complete the CASI at the CBO site if they choose. The CASI assessment will be similar to the one administered at baseline and will take about 45 minutes for the participant to complete.

The immediate post-test and follow-up assessments will be administered by a Research Coordinator or a trained and cleared Health Educator. No Health Educators may administer an assessment to a participant to whom they administered eTAU or YMHP sessions.

Optional Qualitative Interview: In an effort to understand barriers and facilitators to YMHP program participation, we are adding an optional qualitative interview with study participants post intervention. It can be completed at the immediate post or at any time after the intervention window has closed (3 months post BL). The qualitative interview will be conducted over the phone between a PRIDE Staff member and the participant and should take approximately 30 minutes.

	Screening	*Baseline*	*IP*	*3M FU*	*6M FU*	*9M FU*	*12M FU*
Informed Consent		X				X	
CASI		X	X	X	X	X	X
HIV Testing	X			X		X	
STI Testing		X		X		X	
Randomization		X					

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

4.3 Managing and Tracking Study Visits

All participant tracking and retention activities are managed at the two CBO sites, since participants are mainly recruited at these sites. There are two different types of databases (Contact and Tracking) housed on REDCap, an online application, used to log staff contact with participants and participant progress in the study. This system allows both site Research Coordinators and PRIDE to monitor the completion of study visits and surveys, and generate reports on enrollment and retention as needed. The Research Coordinators are expected to track all completed study components in REDCap immediately after completing an assessment or upon receiving of e-mail notification of session completion no later than the end of the business day.

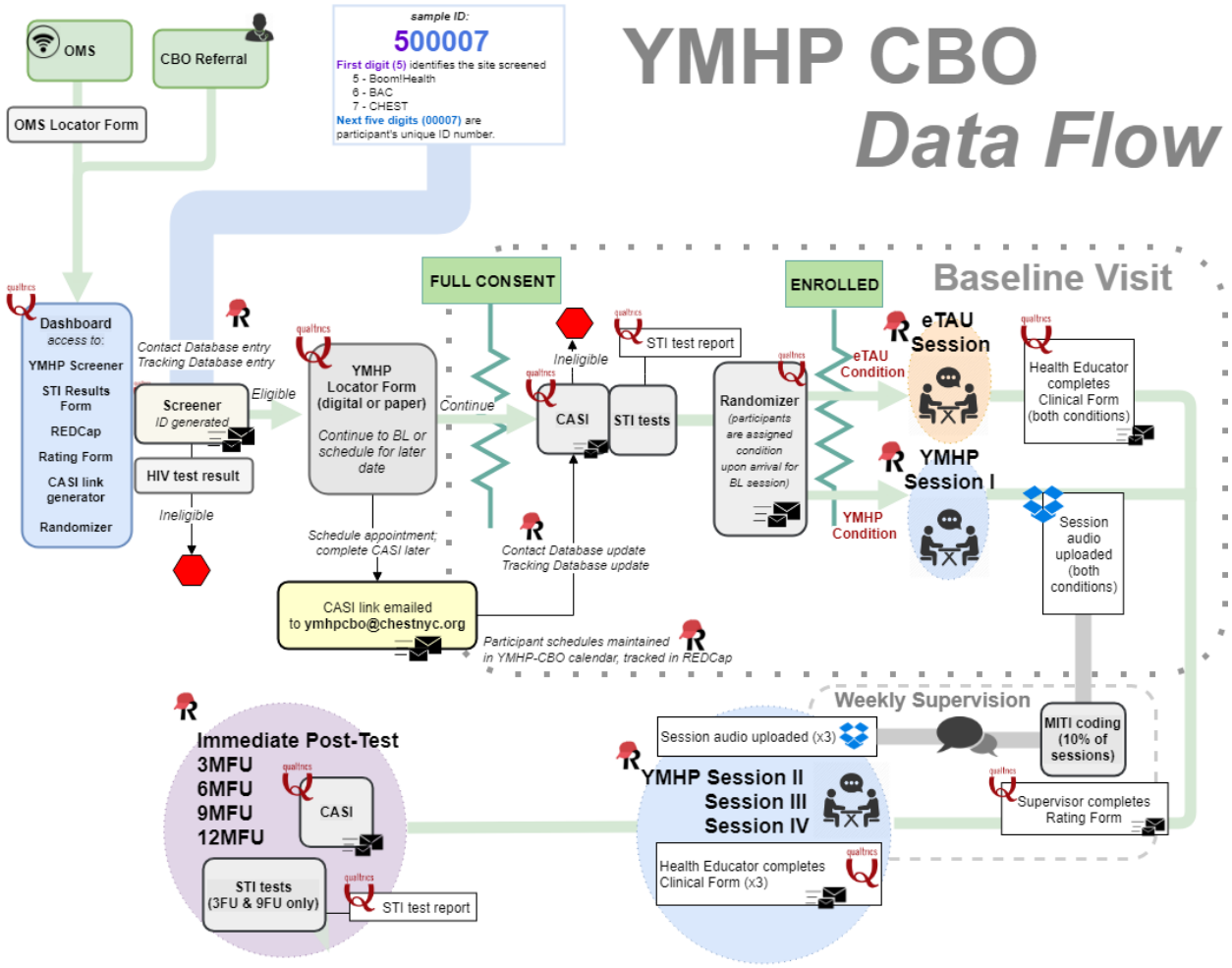
Intervention Visits: Intervention tracking includes database entries of all YMHP sessions completed by the participants. Intervention sessions will be largely managed by the Health Educators with their individual study participants. The tracking mainly involves four components – delivery of the YMHP session, completion of the *Clinical Session Note Form*, uploading audio files, and sending an e-mail notification to the study team. Using the central study e-mail account, Health Educators will notify their CBO's Research Coordinator and PRIDE of whether sessions were completed for tracking purposes, submit electronic *Clinical Session Form*, and upload audio files to the study Dropbox folder as per study procedures. PRIDE will notify the Health Educators to acknowledge receipt of the *Clinical Session Form* or to remind them to complete the form. The Health Educators will be responsible for scheduling the YMHP sessions 2-4 for participants randomized into YMHP.

Intervention visits include all YMHP sessions between enrolled study participants and MI-trained Health Educators. Intervention visits will be largely managed by the Health Educators with their individual study participants. Health 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 Dropbox as per study procedures. The 1st YMHP appointment or one-time eTAU occurs directly after the baseline appointment.

Assessment Tracking: Assessment tracking includes entries of the baseline visit, the immediate post-test assessment, and all four follow-up assessments in REDCap. All participants, regardless of randomized condition, are expected to complete the six assessments as part of full participation in the study.

For each assessment, the participant will complete the CASI using an iPad (if completed in person at the clinic) or using a phone, tablet, or other computer device (for assessments that can be completed at home). Research Coordinators will schedule participants for in-person assessments during times that they will be available. Research Coordinators will also ensure that there is available space at clinic sites to conduct these assessments. Research Coordinators are expected to keep in touch with participants and remind them of the upcoming visit and reschedule if/when needed. A reminder call should be made one business day before a participant is due to come in for a study visit (i.e. the Friday before a Monday visit). Participants who wish to forego an in-person visit to the clinic site have the option of completing follow-up assessments online (i.e. without coming to the clinic) for visits which do not require HIV and STI testing (6-Month Follow-Up and 12-Month Follow-Up). These assessments consist only of an online CASI. Participants may contact Research Coordinators by phone or email about any questions or concerns that arise while completing these surveys. The *Study Data Flow* is presented below.



4.4 Retention and Follow Up

We estimate that retention for the IP and the 3, 6, 9, and 12-month Follow Up assessments will be about 97%, 94%, 91%, 88%, and 85%, respectively, based on our prior work on YMHP. Through the REDCap Tracking Database, PRIDE YMHP staff will generate weekly reports listing all participants who are due for follow-up assessments. PRIDE will provide extensive training to the CBO Research Coordinators on retention efforts.

Session Retention: For patients who are actively taking part in the YMHP intervention and working with Health Educators, site study staff will not add an additional level of outreach to the procedures. Health Educators will be instructed to adhere to the already-present procedures of the CBO for contacting and re-scheduling patients. Research Coordinators should prioritize the completion of intervention 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.

Assessment Retention: A target date for completing each follow-up will be established at every 12-week point from the baseline. Research Coordinators should aim to schedule and complete these follow-ups as close as possible to each target date. Given that this is an effectiveness trial in a real-world setting, assessment windows are liberal. To keep track of longitudinal data collection dates, assessment windows will be programmed to 30 days prior and after the target as "in window." If Research Coordinators attempt to assess a participant 60 or more days before or after the established target date, then they should contact PRIDE to authorize the assessment prior to compensating the participant.

Research Coordinators are to maintain strong and consistent relationships with study participants, and should contact study participants by phone at least once per month. During this phone outreach, Research Coordinators can verify existing contact information and inquire as to whether the participant foresees any potential changes in the near future. Research Coordinators should take note of participants who are less stable in terms of housing/phone numbers, and devote outreach efforts toward these participants strategically. Retention success/challenges will be based on outreach and assessment reporting from Research Coordinators at each site to PRIDE via Qualtrics. PRIDE will generate weekly reports using REDCap and distribute them to staff at each site. PRIDE and the Research Coordinators will meet regularly to discuss recruitment and retention efforts, based on these reports and any other relevant feedback.

4.5 Specimen Collection and HIV/STI Test Reporting

4.5.1 CBO specimen collection

Sites will use standard protocols for specimen collection for this study, as outlined in the Standard Operating Procedure guide for STI Specimen Collection and summarized below.

HIV testing (performed at follow-up appointments only) will be performed using the OraQuick rapid test. The test result should be recorded in the participant's health record

[For BAC only] For syphilis serologic testing, the Research Coordinator will use the Syphilis Health Check™ Antibody Rapid Immunochromatographic Test from Diagnostics Direct. This test involves a finger prick blood draw, and the test takes 10 minutes to incubate before results are ready to be read. During this time, the Research Coordinator should have the participant collect his urine and rectal swab specimens. BAC visits with a phlebotomist will do syphilis testing via venipuncture as part of a full panel. In all cases, the participant's syphilis test result will be recorded in their health record. Note: Participants who indicate a past syphilis infection will *not* be tested for syphilis at baseline or follow-up visits, except if doing a full panel at BAC with the phlebotomist.

STI testing supplies for Boom!Health will be ordered by PRIDE staff through Quest Diagnostics. BAC will order its own STI testing supplies through LabCorp.

CBO study staff will escort the participant to the participant restroom with the printed instructions on specimen collection and all labeled specimen collection devices and containers. They will instruct the participant where to place specimens when collection is completed, as well as where they can be found after completion of the specimen collection process, and will leave the participant to carry out the procedure in private. Once specimens are obtained, the study staff will ensure that urine and rectal swab samples are labeled correctly and will place them in the appropriate area in the laboratory designated for specimen pick-up.

BAC samples will be picked up and processed by LabCorp. Boom!Health samples will be picked up and processed by Quest Diagnostics. The Research Coordinators will track participants' STI results on RedCap and complete the Test Results Form on Qualtrics.

All positive HIV and STI test results will be conveyed to participants by CBO site staff using their standard protocols, and participants will be provided with access to treatment.

PRIDE will provide STI testing supplies to Boom!Health. CBO study staff may pick up the supplies from the PRIDE office, or PRIDE will deliver as-needed. STI test kit supplies include:

- Anal swabs
- Pee cups
- Beakers
- Test tubes (for urine and rectal swab samples)
- Syphilis Health Check™ kits (each with 20 test devices, 20 pipettes, and 5 ml diluent in a dropper bottle)
- OraQuick rapid tests

4.5.2 Alternative means of specimen collection

When participants move away or are otherwise unable to complete specimen collection at the clinic site, specimens may be collected via at-home testing or testing at central lab facilities (e.g. Quest Diagnostics). At-home testing kits may be mailed to a home address with instructions for use. YMHP research staff at PRIDE may be asked to ship kits to an alternate location deemed as a safe space, such as a youth center, and will require youth to speak with a trained PRIDE staff member to ensure these arrangements are both safe and allowable.

4.5.3 HIV/STI Test Result Delivery

All HIV and STI test results will be delivered following the CBOs' existing protocols for delivery of HIV/STI test results. Test results for participants who utilized at-home testing kits will by delivered following the corresponding PRIDE protocol for delivery of HIV or STI test results. Participants utilizing at-home testing kits determined to be HIV-positive at a follow up YMHP assessment will receive the results from a member of the PRIDE clinical team who is trained in HIV C&T, following the PRIDE protocol for delivering HIV positive test results. If a HIV/ STI test results in a positive test result, then a participant's results will be reported to State Health Departments in New York for surveillance purposes. Participants will be informed that their results will be shared with health departments in the site-specific consent form.

All participants who test positive for HIV will be referred for services, including referral for a confirmatory HIV test if needed. Similarly, all participants testing positive for an STI will be offered a referral for STI treatment.

4.5.4 HIV/STI Test Reporting

Upon receiving the test results from Quest/LabCorp, generally within 3 days, the CBO Research Coordinators will complete the Qualtrics STI Test Results reporting form for these and the rapid test results already recorded for that visit in the participant's CBO health record (HIV and syphilis).

Reporting to the NYCDOHMH will occur using existing standard protocols at each CBO, or by existing standardized protocols at PRIDE or the participant's testing provider for specimen collection done outside of the clinic setting.

4.6 Incentives and Compensation

For taking part in this study, participants will be paid for both the treatment sessions and assessments as follows, up to $245 in gift cards if the participant completes the whole study:

Visit	Compensation amountok
Baseline survey, STI and HIV testing, and YMHP Session 1 or eTAU session	$50 in gift cards ($25 gift card for completing the computer based survey and $25 gift card for completing first YMHP or Treatment as Usual session, HIV and STI tests).
Program Sessions 2-4 (ONLY if randomized into YMHP)	MetroCard ($5.50 value) and food voucher ($7 value) for each of the three additional YMHP sessions. If the baseline and three additional YMHP sessions are complete participant will receive an additional $20 gift card.
Post-test assessment (IP)	$25 gift card (CASI-only assessment)
3-month assessment	$50 in gift cards ($25 gift card for completing the CASI plus $25 gift card for completing HIV and STI testing).
6-month assessment	$25 gift card (CASI-only assessment)
9-month assessment	$50 in gift cards ($25 gift card for completing the CASI plus $25 gift card for completing HIV and STI testing).
12-month assessment	$25 gift card (CASI-only assessment)
Optional Qualitative Interview	$25 gift card (phone interview-only assessment)

4.7 Criteria for Premature Discontinuation

Dropping participants simply means we have stopped following them but they remain enrolled. This is for two reasons: (1) Participants should not be dropped after randomization in any trial, in order to remain consistent with the guidelines for intention-to-treat (ITT) analyses; and (2) These situations reflect the reality of implementing an intervention in a real world setting and make meaningful data points in an effectiveness trial. The only legitimate reason to drop an individual from the total number of enrolled participants is if someone is found to be ineligible at the time of randomization. Anyone marked as "Withdrew from Study" for IRB purposes should be included in the IRB continuation, Data Safety Monitoring report, and the Research Performance Progress Report (RPPR).

Below are the 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.

4.8 Measures

All measures except HIV and STI Testing are administered at study assessments using a web-based CASI survey on an iPad at each site. See below for the CASI measures and schedule of measures by visit.

Primary Outcomes

- Substance Use/Abuse
    - ASSIST
    - PRIDE Grid
    - Cannabis Use – Perceptions of Criminality
- Sexual Risk Behavior
    - Main and Casual Partners
    - Harmonized Sexual Risk Behavior
- Pre-Exposure Prophylaxis (PrEP) Uptake
    - Motivational PrEP Cascade
    - General PrEP Experiences and Acceptability
    - Decisional Balance for PrEP Use
    - PrEP Treatment Adherence
    - Perceived Risk of HIV scale (only 2 questions)
    - The Contemplation Ladder: PrEP Use

Other Self-Reported Measures

- Demographics/Socioeconomic Characteristics
- Subjective Social Status
- Condoms during Anal Sex Contemplation Ladder
- Drug Use Contemplation Ladder
- STI Testing

- HIV Testing
- Patient Health Questionnaire for Anxiety and Depression (PHQ-8, GAD-7)
- Visual Analog Scale for Self-Efficacy of Five Outcome Behaviors
- Unmet Physical or Behavioral Health Care Needs
- ATN Social Support Measure
- Poor Family Management
- Parenting Style Questionnaire
- Comfort in Sexual Communication with Parents
- The Parent-Teen Sexual Risk Communication Scale
- Brief Perceived Ethnic Discrimination Questionnaire Community Version
- Group Membership Questionnaire
- Everyday Discrimination- Race and Ethnicity
- Everyday Discrimination- Sexual Orientation

Client Evaluation of Intervention

- Health-Care Climate Questionnaire
- Client Evaluation of Counseling
- Client Satisfaction Questionnaire

Self-Management Measures

- Behavior Rating Inventory of Executive Functions (BRIEF-A)
- Patient Activation Measure (PAM)

See schedule of measures by visit on next page.

	Brief CASI on iPad	**Baseline**	**Immediate Post-Test**	**Follow-Up**
Primary Outcomes	Substance Use/Abuse			
	ASSIST + PRIDE Grid	✓	✓	✓
	Cannabis Use Perceptions of Criminality	✓		
	Sexual Risk Behavior			
	Sexual Risk Behavior Main Partner	✓	✓	✓
	Sexual Risk Behavior Casual Partner	✓	✓	✓
	Harmonized Sexual Risk Behavior	✓	✓	✓
	Pre-exposure Prophylaxis (PrEP) uptake			
	Motivational PrEP Cascade	✓	✓	✓
	General PrEP Experiences & Acceptability	✓		✓
	Decisional Balance for PrEP Use	✓		✓
	PrEP Treatment Adherence		✓	✓
	Perceived Risk of HIV scale	✓	✓	✓
	The Contemplation Ladder: PrEP Use	✓	✓	✓
Other Self-Reported Measures	Demographics/Socioeconomic Characteristics	✓		
	Subjective Social Status Scale	✓		
	Condoms during Anal Sex Contemplation Ladder	✓	✓	✓
	Drug Use Contemplation Ladder	✓	✓	✓
	STI Testing (in past 3 months)	✓	✓	✓

	HIV Testing		✓	✓
	Patient Health Questionnaire Anxiety and Depression (PHQ-8,GAD-7)	✓	✓	✓
	Visual Analog Scale for Self-Efficacy of Five Outcome Behaviors	✓	✓	✓
	Unmet Physical or Behavioral Health Care Needs	✓	✓	✓
	ATN Social Support Measure	✓		✓
	Poor Family Management	✓		
	Parenting Style Questionnaire	✓		
	Comfort in Sexual Communication with Parents	✓		
	The Parent-Teen Sexual Risk Communication Scale	✓		
	Brief Perceived Ethnic Discrimination Questionnaire Community Version	✓		
	Group Membership Questionnaire	✓		
	Everyday Discrimination- Race and Ethnicity	✓		
	Everyday Discrimination- Sexual Orientation	✓		
Client Evaluation	Client Evaluation of Counseling		✓	
	Client Satisfaction Questionnaire			✓
	Healthcare Climate Questionnaire		✓	
SMM	PAM	✓	✓	✓
	BRIEF-A	✓		

4.8.1 Self-Management Model Measures

The AC will develop and apply analytic approaches to assess the Five Components of Self-Management Model[1-2] as a synergistic model within and across the *Scale It Up* projects, and how these components vary over time, are directly improved by interventions, and mediate intervention effects. Four components are considered predictive variables, and the AC will choose measures in collaboration with project leads and PRIDE PI. Sample measures, which were all used in the PIs' previous trials, include the Behavior Inventory of Executive Function for Problem Solving and Decision Making, Services and Support measure for Resource Utilization, and the Measures of Processes of Care for Provider Relationship. We hypothesize that these will predict the fifth component, patient self-management action.

5.0 INTERVENTION PROCEDURES

5.1 Intervention Design and Procedures

YMHP is a CDC Best Evidence Intervention [59] that utilizes MI and personalized feedback to reduce CAS and substance use among YMSM. The YMHP intervention will be delivered by MI-trained Health Educators employed at each of the two CBOs. Participants will be randomized to receive either the intervention or an eTAU session with the Health Educator. The intervention condition involves completion of 4 YMHP sessions and the delivery of PrEP information and navigation services to interested participants. The control condition involves the completion of a single session eTAU that reviews the array of services offered by the CBO and also provides an overview of PrEP and PrEP-related services.

5.1.1 Four Sessions of YMHP

Session One: Engagement; Focusing & Evoking on the First Target Behavior
In Session 1, participants will choose which behavior to discuss first (sexual risk or substance use), and the Health Educator will elicit the client's view of the problem using standard 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). Basic information on PrEP efficacy will be provided using the ask-ask-tell-ask-reflect approach. The Health Educator will discuss options for a behavior change plan, and, if the client is willing to proceed, the client will set goals. The session ends with MI strategies to evoke the client's ideas about how to take steps towards change, consolidate their commitment to the plan, and problem-solving.

- Opening statement – Provide information as appropriate; set the stage for collaboration; introduce target behaviors
- Background and Priority Card Sort Activity – Use Open Questions and Reflections to understand what is truly important for each participant

- Ask permission to discuss the first target behavior; ask the client which one they would like to begin with and summarize participant's concerns
- 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 sessions

Session Two: Second Target Behavior; Continue Focusing & Evoking

Session 2 follows the same format as Session 1, but revolves around the second target behavior.

- 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 a closing summary at the end of the session, highlighting change talk and any steps taken towards change

Session Three: Consolidating Change Plan/Considering PrEP

In Session 3, the Health Educator will review the change plan, continue to elicit and reinforce change talk, problem-solve barriers, consolidate commitment, and address maintenance of behavior change.

- 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 [60] for offering information or suggestions about PrEP education and work together on a navigation plan if appropriate; 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; and how PrEP may or may not fit into change plans the participant has already made for their substance use and sexual health
- 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 (as it is the final YMHP session)

Session Four: Consolidating Commitment; Relapse Prevention/Termination

- 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 address termination

5.2 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 trainers from PRIDE's clinical team. The training procedure includes:

1. Initial 3-day training for Health Educators and their supervisors;
2. A 2-3 month training period of role-play practice, coding and feedback, and supervision modeling, including mock sessions with "standardized clients" role-played by PRIDE Research Assistants;
3. 1 hour weekly supervision sessions between the Health Educators and their supervisors;
4. Monthly supervision calls between supervisors and trainers from the PRIDE clinical team, including a quarterly Skype booster training (see *Booster Trainings* below); 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. Any copyrighted media will be removed from these materials prior to dissemination.

5.2.1 Initial and Pre-Trial Training

The 3-day training will be held at PRIDE and follows a curriculum developed for our previous NIH-funded effectiveness trials. Health Educators and supervisors participate together. Days 1 and 2 include introductions to YMHP and MI, followed by an overview of how to deliver each of the 4 YMHP sessions. The full third day is dedicated to mocks, supervision, and introduction to the MITI. PRIDE will provide external MITI coding for the supervisor to use as feedback.

Following the in-person 3-day training workshop, all Health Educators and supervisors will each mock the intervention with a "standardized client" (played by a trained PRIDE RA) and submit the 4 roleplayed sessions to PRIDE. Then, supervisors will complete one supervision session with each Health Educator, with audio recordings uploaded into the study Dropbox. After each audio recording is uploaded to Dropbox, the Health Educator and supervisor will notify PRIDE

via the study email account. All mock sessions should be saved in the Dropbox sub-folder named "Pre-Trial." All audio recordings uploaded to Dropbox will be downloaded to the PRIDE multimedia (M:) drive. They will be tracked in an Excel spreadsheet for MITI coding assignment. PRIDE will delete audio files from Dropbox monthly, and notify sites in advance via email each time.

The mock sessions will be MITI coded and PRIDE trainers will provide coaching and feedback. PRIDE trainers will use MITI thresholds for fidelity flagging. Those criteria include percent reflection, percent complex reflection, technical global, relational global, and MI non-adherent codes. For clearance, trainees should score in the "fair" range on all 5 elements by their final mock. If they are below in 1 or 2 domains, they will not have to redo the mock. However, by the 4th mock they should score at least "fair" to be cleared.

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.

5.2.2 Booster Trainings

The PRIDE Clinical Team will lead quarterly boosters via group Skype for supervisors. Prior to each quarterly booster, 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 Health Educator, and role-plays of supervision skills. Someone from the PRIDE Clinical Team will join supervision sessions via Skype if MITI scores fall below competency without remediation. PRIDE will also lead annual in-person booster trainings covering MI skills and specific delivery of YMHP for supervisors and Health Educators.

5.2.3 Ongoing Monitoring and Supervision

Once beginner competency is met, the supervisors will take over weekly individual supervision of the Health Educators. To prepare for these weekly meetings, supervisors are expected to listen to at least one session recording per week and review MITI coding when available. In cases of flagged sessions, supervisors are expected to review the MITI scores with the Health Educator and discuss ways to address fidelity concerns. If multiple sessions take place in the week of the meeting, the supervisors should work with the Health Educator to identify which session they would like to go over in the supervision meeting. If no sessions take place in the week of the meeting, the supervisor should use the meeting time to review and practice MI skills with the Health Educator, and/or review past sessions that were not discussed.

The MITI coding randomizer should flag for additional review any session where the Health Educator falls below "fair" on more than 2 domains. 10% of each Health Educator's recordings will be randomly selected for MITI coding. These randomly coded sessions will be shared with the supervisors as a way to reinforce their internal barometers for "good enough" MI, rather than MITI only being used for comparing unsatisfactory delivery of MI. Ongoing fidelity issues may result in a Health Educator being required to attend additional training and/or removed from active session delivery until fidelity is achieved.

After reviewing a supervisee's session and before supervision, supervisors will complete the MI Coach Rating Scale ("Rating Form") via Qualtrics.

Each Health Educator will submit an electronic *Clinical Session Form* via Qualtrics upon completion of each non-mock YMHP session. PRIDE will notify the sites acknowledging the receipt of the *Clinical Session Form* or send a reminder to complete the form.

Supervisors will have monthly 30-minute supervision calls with trainers from the PRIDE Clinical Team to discuss ongoing implementation issues at their sites. Each monthly call will be audio recorded. If circumstances prevent a supervisor from attending a call, they are expected to review the recording. PRIDE staff will be available to answer questions as needed

6.0 DATA MANAGEMENT AND ANALYSIS PLAN

6.1 Data Management and Data Quality

PRIDE will be handling data management. Data will be entered directly by participants through Qualtrics. Data dictated by participants who request assistance completing surveys may also be entered by the Research Coordinators. The database, data structure, and data quality will be routinely reviewed by PRIDE. Where indicated, we will use full-information maximum likelihood estimation to account for missing data under Missing at Random (MAR) assumptions.

6.2 Quantitative Analysis Plan

Primary Outcome Measures:

- Days of Illicit Drug Use (past 30 days)
- Days of Marijuana Use (past 30 days)
- Condomless Anal Sex Acts (past 30 days)

Secondary Outcome Measure:

- Days of Alcohol Use (past 30 days)

Phase 1

The primary purpose of data analysis in Phase 1 is to inform the adaptation of the YMHP intervention for delivery by Health Educators in CBO settings, and the development of CET implementation protocols. Focus group dialogue will be transcribed by a team of 10-15 undergraduate and graduate student interns at PRIDE, thematically coded by the Research Scientist and Principal Investigator using NVivo, and analyzed following procedures outlined by Miles and Huberman and Patton for thematic analysis. Our focus will be on factors that can enhance intervention acceptability and sustainability, both from the perspective of the peer counselors and participants.

Phase 2

Qualitative analysis: Interviews will be transcribed prior to data analysis. The team will use NVivo to conduct thematic content analyses to identify implementation barriers and facilitators. Using constant comparison analytic methods, a preliminary codebook will be developed both deductively and inductively. Research Scientist and another member of the team will code each interview. Divergent coding will be discussed, decision trails will be created at key decision-making junctures, and consensus-building strategies will resolve discrepancies. Findings will be used to inform revisions of the YMHP implementation package.

Statistical analysis: The primary hypothesis is that participants randomized to receive YMHP will demonstrate significant reductions in sexual risk behavior and associated health outcomes as well as substance use frequency and severity when compared to those who randomized to eTAU. We will utilize stratified block randomization with substance use and interventionist as the strata in order to assign all participants to a condition.

A series of bivariate analyses within SPSS (version 27) evaluated the success of randomization and the presence of differential attrition. With respect to randomization, $\chi 2$ tests of independence evaluated between-condition differences across demographic characteristics (race and ethnicity, sexual identity, relationship status, education, income, and age). Where cell sizes for categorical variables were too small ($n < 5$) to permit chi-square tests, we utilized a Fisher's exact test. The generalized linear model function in SPSS – which permits the specification of Poisson and negative binomial outcome variable distributions – was used to evaluate between group differences in baseline frequency of primary (marijuana use days, other illicit drug use instances, and CAS with male partners) and secondary (alcohol use days) outcomes. Likewise, $\chi 2$ analyses were used to evaluate whether the probability of retention at each follow-up was associated with site, condition or categorical demographic factors; meanwhile, the generalized linear model component of SPSS was used to test whether retention at follow-up was associated with baseline primary or secondary outcome frequency.

Outcome analyses were conducted using piece-wise latent growth curve (LGC) models following procedures outlined by Chou et al., (Chou et al., 2010) and used previously in similar studies (Flora, 2008; Kohli et al., 2013; Li et al., 2001; Naar-King et al., 2009; Naar et al., 2020). 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 through the use of 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.

All primary (marijuana use, other illicit drug use, and CAS with male partners) and secondary (alcohol use) outcomes were modeled as negative binomial distributions. All models were estimated using full-information maximum likelihood estimation in MPlus Version 8.0. This permitted the retention of all randomized cases consistent with a true intent to treat paradigm. Many commonly used indices of model fit are not available for growth models with count-distributed outcomes (i.e., root-mean square error of approximation (RMSEA) ≤ 0.05, Tucker-Lewis fit index (TLI) > 0.95, and comparative fit index (CFI) > 0.95). Model fit was therefore

evaluated using a robust log-likelihood $\chi 2$ test (Satorra & Bentler, 2001) 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.

6.2.2 Equivalency Checks

PRIDE will ensure that randomization is stratified by substance use (including marijuana). Further, we will monitor randomization to ensure that condition is not associated with characteristics that would require adjustment in proposed analyses.

6.2.3 Equivalency Tests

A series of bivariate analyses will be conducted to examine between condition differences at baseline and evaluate the success of randomization procedures. We will utilize chi square tests of independence, t-tests, ANOVA and Spearman's rho correlations as appropriate to examine whether intervention conditions differed significantly with respect to key demographic variables and outcome variables at baseline. In the event that significant baseline differences are observed, these demographic factors will be incorporated into subsequent outcome analyses.

6.2.4 Power Analysis

We will enroll a total of 260 substance-using MYMSM (130 per condition) engaged in HIV risk behavior; this will be 1.8 times more participants than in the original efficacy trial, providing adequate power to detect differences in this real-world setting. We conducted a series of simulations using SAS 9.2 PROC GLIMMIX to examine power to detect intervention effects on primary outcomes. In each simulation, 500 draws were requested and effects averaged across samples assuming 260 enrolled participants with retention of 85% at 12-month follow-up (n = 221). All models included a random effect for counselor assuming approximately 12 peer counselors across sites by the end of the study. Consistent with existing CDC and NYCDOH data on 12month STI incidence among MYMSM,141 we allowed the proportion of positive diagnoses in the eTAU/YMHP groups to vary between 0.15/0.04 and 0.20/0.07, respectively, and found 81.0% average power (i.e., $1 - \beta$) to detect statistically significant differences at $\alpha = 0.05$ (i.e., 95% confidence). Utilizing the effect sizes found within the original YMHP efficacy trial (that utilized an intensive attention-control group), we set the proportion of individuals in the eTAU group who engaged in CAS at follow-up to 0.50 and to 0.30 in the YMHP group and found 85.4% power to detect significant differences at $\alpha = 0.05$, suggesting effects of this magnitude or larger will be sufficiently powered. Finally, examining substance use, assuming that the proportion of individuals in the eTAU group who persist in substance use over time is .80, we will have power to detect proportions of .62 or smaller in the YMHP group as statistically significant with power of 83.0% or greater at $\alpha = 0.05$.

6.3 Cost-Effectiveness Analysis Plan

In order to enhance the likelihood of uptake if effective, the AC will conduct analyses to assess the cost-effectiveness of two delivery models of YMHP in reducing sexual risk and substance use utilizing CDC's guidelines for cost effectiveness analysis on HIV infections averted.

Interventions such as YMHP are intended to prevent infection in HIV-negative YMSM. Therefore, YMHP can be evaluated to determine the number of infections prevented that would have otherwise occurred had it not been provided at our sites. We will model our analyses based on the framework for a cost-utility analysis of addiction treatment, with emphasis on the Holtgrave and Kelly model [61-65] because they also examined a behavioral health intervention to prevent HIV infection [66].

Our economic analysis will have two components: 1) a cost analysis of the YMHP intervention; and 2) an incremental cost effectiveness analysis that compares the value of clinic-delivery of YMHP over remote delivery.

6.3.1 YMHP Program Cost Analysis

In order to enhance the likelihood of uptake if effective, we will conduct analyses to assess the cost-effectiveness of YMHP in reducing substance use and sexual risk behaviors compared to eTAU utilizing CDC's guidelines for cost effectiveness analysis on HIV infections averted [67]. Our economic analysis will have two components: 1) a cost analysis of the YMHP intervention; and 2) an incremental cost effectiveness analysis that compares the value of YMHP to eTAU.

We will use a modification of The Drug Abuse Treatment Cost Analysis Program (DATCAP) [63, 68] plus study contact and expenditure records, to estimate the cost of the YMHP and eTAU conditions. Using both conditions will increase the stability of the measurements. The DATCAP is a standardized data collection instrument that estimates the economic cost of addiction treatment programs. Administration of the DATCAP is generally a collaborative effort involving an economist (Dr. Simpson) and various members of the intervention staff (Health Educators, administrators, accounting/finance personnel, etc.). The DATCAP organizes program resources into personnel, buildings and facilities, supplies and materials, and miscellaneous resources. Client case flow data are incorporated to determine the average annual cost per client for each service type. Other useful computations include weekly cost per client, average cost per intervention episode (based on length of stay in the program), and marginal cost per contact [69-71][76-78][71-73][71-73][71-73][70-72][69-71].

We will first estimate the marginal costs of delivering YMHP as compared to eTAU. Using data from the modified DATCAP and study contact and expenditure records, key statistics from the cost evaluation will include total annual economic cost for the program, weekly economic cost per client, and total economic cost per intervention [episode/session]. To highlight the relative contribution of the various cost components and necessary future budgeting, we will also perform a descriptive analysis of the cost accounted for by resource category.

The mean aggregate cost of the interventions will be used as inputs in the cost effectiveness model. The number of HIV infections averted due to the YMHP intervention will be estimated

using the results from the clinical trial combined with published HIV infection risk rates for the specific risk behaviors. These data will be combined in a mathematical model structured as a decision tree with a long-term follow-up component using a Markov model structure. This combined structure will best capture the complexity of the clinical trial data and well as the uncertainty embedded in the HIV risk prediction equations, and minimize the number of assumptions required for the cost effectiveness estimate.

Cost-effectiveness will be modeled for YMHP as compared to eTAU and for the differences in CAS and predicted through Markov modeling for 5 and 10 years and over a lifetime using varying assumptions about decay of the effect of the intervention over time. Modeling will be performed from the perspectives of 1) a third party payer, 2) the medical care system, and 3) society.

Model Structure. We will use an HIV mathematical model with clinical findings from the study, YMHP cost data, clinical and epidemiological data from published studies, and cost data from archival databases. The model uses a combined decision tree and Markov approach to estimate treatment effects of CAS on HIV infection rates. Crystal Ball Monte Carlo estimation software will be used to simulate outcomes for a patient cohort under varying assumptions about the distribution of the data for the model parameters.

Model Parameters: Critical data in the model will come from the clinical parameters (substance use and CAS) and the study intervention cost data. Incidence of HIV infection projections after the end of the study will be based on analysis of epidemiologic data from large patient cohorts or on reported values in the literature. Quality of life weights are based on literature reports and archival data. Direct intervention costs for YMHP and eTAU will be estimated as described above. Cost of medical care will be based on Medicaid data; other costs will be based on the literature or archival data. The effects of different costing perspectives will be assessed. Both cost and years of life will be discounted by 3% when cost effectiveness is examined.

Model Outputs: The model will estimate 5-year and 10-year flow of fund differences to example individuals, Medicaid, private insurers, and other payers under specific assumptions, as well as overall cost effectiveness and cost utility estimates. Differences in expected population survival, quality of life, and costs attributable to YMHP will also be reported. We will perform sensitivity analysis using a Monte Carlo simulation.

Limitations: We will minimize the effects of data variation by using several data sources, boot-strapping, and sensitivity analysis with a Monte Carlo approach to examine the effect of variations in parameters and differences in distributional assumptions in our model.

6.3.2 Data Collection for YMHP Cost Analysis

Data will be collected for two distinct purposes:

1. To collect treatment site cost data for a cost analysis to capture the cost of the intervention used in the study.

2. To collect subject resource use data to be used to estimate the cost differences of events between treatment groups.

In addition, records will be made to obtain cost data for the following:

A. Cost of Adaptation of YMHP for clinic delivery months 1 to 3
   1. Cost to conduct focus groups with staff
      a. Number of attendees
      b. Time
      c. Venue
      d. other
   2. Adapting YMHP for clinic delivery

B. Cost of training a minimum of 2 Health Educators at each clinic at time of training
   1. Development of training materials
   2. Training time
   3. Numbers trained
      a. Initial 3-day training for Health Educators and local supervisors;
      b. A 2-3 month training period of role-play practice, coding and feedback, and supervision modeling, including mock sessions with "standardized clients" role played by PRIDE Research Assistants;
      c. 1 hour weekly supervision sessions between local supervisors and Health Educators;
      d. Monthly supervision calls between local supervisors and the investigator team, including a yearly Skype booster training; and
      e. Ongoing quality assurance and feedback using MITI coding.

Treatment site cost data collection: Cost of delivery at 6 months after initiation of YMHP
Treatment site cost data collection will be based on the approach described by Kim et al. (2015) for the economic evaluation of the Positive Charge multisite program aimed at linking HIV-infected youth to care [72]. Data collection will be completed for this component by having each CBO site's financial management contact fill out a standard Excel spreadsheet, which contains resource use categories relevant to calculation the cost of the intervention. Not all categories will be relevant to each site or to each intervention. To minimize the burden of data collection on the sites, we will contact a designated site Financial Management Contact (FMC). The FMC and Dr. Simpson will discuss the content of the spreadsheet and agree which data elements in the spreadsheet are relevant to the site. .

However, these will be tailored to each site's financial information system and collected using an Excel standardized spread sheet: All information provided in the spreadsheet will be treated as confidential, with any site-identifying information removed and replaced with a site code as soon as the spreadsheet is returned to Dr. Simpson. Examples of data elements that might be collected from a site are provided below.

Clinic Cost Structure	**Year of Report:**

Staff/Personnel	*Hourly Wage*	*Fringe Rate*
Case managers		
Counselors		
Nurses		
Peer-opinion leaders working as staff		
Outreach workers		
Providers who conduct training		
Staff support/clerical		
Other project supervision		
Other staff		
Materials and Other Consumables	*Unit*	*Cost per Unit*
Staff/personnel (not client) travel costs		
Travel tokens (not already entered above)		
Equipment devoted intervention services		
Other equipment		
Brochures/handouts/other printed materials		
Incentives		
Risk reduction supplies		
Printing		
Computer supplies		
Office supplies		
General supplies		
Postage and handling		
Rent		
Phone		
Other materials and consumables		
	Rate	
Standard overhead rate not included in above services		
Site charge code list with 2017 charges by CPT or billing codes		

Study Subject Resource Use Data: Healthcare resources used by study subjects will be tracked via REDcap. The data collection units will be the number and types of contacts used for the interventions such as in-person sessions, telephone contacts or text messages sent. *Costs or payments to participants should not be collected***.** The resources will be recorded and aggregated at the level of the individual subject. These resource counts will be converted to cost by using a set of standard cost weights developed from pooled data from both study sites and/or mean payment data estimated from archival data sets containing Medicaid payment for similar services. The following resource use data will be collected for each subject:

A. Visits (YMHP or eTAU) with CPT code (or visit clinic charge code if CPT codes are not available).
B. Telephone contacts
C. Actively produced text messages (not automatic messages)

D. Other type(s) of resources that are either very frequent or rare but very time consuming that are specific to each intervention may also be recorded. Any such resources will be specified by the PI.
E. Transportation demands: To assess how financial barriers related to transportation may differ by site, we will compare the public transportation cost to the Uber cost by site. We will capture the costs by identifying the distance between the participant's home address (or school address depending) and the clinic site and then applying an Uber rate to estimate the costs of getting to and from the clinic. The cost-effectiveness analysis of the YMHP program would utilize the Uber values for the sites with poor public transportation and the public transport cost for the site that use this approach.

7.0 SAFETY MONITORING PLAN

7.1 Data and Safety Monitoring Board

The study will be conducted under the supervision of an independent DSMB. All DSMB members have extensive experience in either clinical trials and/or management of HIV or HIV prevention experience. The study team will draft a Data Safety Monitoring Plan (DSMP) and update it as-needed. The DSMB will be responsible for ongoing review of the research study and for making recommendations concerning the continuation, modification, and termination of the study.

7.2 Adverse Events Reporting

Adverse events in this study are not anticipated as this is a comparative effectiveness trial. The Site PI is responsible for the detection and documentation of events meeting the criteria and definition of an AE or 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 email, but must formally report them via REDCap. 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. Site PIs 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 PI to be related to study participation. In addition, any AE resulting in potential participant withdrawal must been reported to PRIDE prior to participant withdrawal when possible.

Site PIs must report any Adverse Event within one business day of learning of it. PRIDE 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.

7.3 NIH Reporting

The PRIDE team will complete the annual Research Performance Progress Report (RPPR). The PI will submit it electronically to the NIH according to NIH policies and procedures.

8.0 ETHICAL CONSIDERATIONS

8.1 Regulatory and Ethical Compliance

Study Procedure Guidelines are designed and shall be implemented in accordance with the HHS 45 CFR Part 46.

8.2 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 YMPH. 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.

A waiver of parental permission has been obtained for minors choosing to participate with parental permission.

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 YMHP.

8.3 Responsibilities of the Site PI

Study materials will be reviewed and approved by a single Institutional Research Board (sIRB), as needed. A signed and dated statement that these materials were approved by the sIRB will be sent to each participating CBO site before site initiation occurs. Prior to study start, a Reliance Agreement was received from each site confirming their agreement to conduct the study in accordance with the sIRB approval. Site PIs are to give access to all relevant data and records to monitors, auditors, quality assurance representatives, sIRB and regulatory authorities as required. Site PIs also agree to apply due diligence to avoid protocol deviations.

8.4 Early Termination of the Study

The Principal Investigator retain the right to terminate the study, a study site or a Site PI at any time. The PI will monitor the progress of the study. If warranted, the study may be suspended or discontinued early if there is an observation of safety concerns posing an unreasonable risk to the study population. If the study is terminated early, the PI will provide a written statement to the IRB and the Site PI to enable notification to study participants. The PI may terminate enrollment activity at a site, or participation in the study by the Site PI and/or site if there is evidence of a Site PI's failure to maintain adequate standards or failure to comply with the protocol. Notification of enrollment suspension or termination of the study or study site/Site PI will be sent to the Site PI and the IRB.

9.0 STUDY ORGANIZATION

YMHP is sponsored by the NIH. The PI maintains responsibility for the overall conduct of the study. Each CBO site will be responsible for site management, site monitoring, and recruitment, enrollment, and retention. The data team at PRIDE will be responsible for Data Management and data analysis, while the PD and PI will be responsible for reporting and research dissemination.

10.0 DATA ACCESS AND SHARING

The Leadership Team will authorize access to study data. Site PIs and members of auxiliary committees must submit a proposal requesting approval to access study data.

11.0 PUBLICATIONS POLICY: OVERVIEW

Primary and secondary reports of study findings will be published in peer-reviewed journals. Proposals for presentations and publications incorporating data obtained from participants involved in YMHP must be submitted for review by the PI. The primary publication will be authored by the trial's writing committee. No site is permitted to present or publish data obtained during the conduct of this trial without prior approval from the PI.

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