ATN 139 - Get Connected: Linking YMSM to Adequate Care through a Multi-level Tailored WebApp Intervention

SIGNATURE PAGE

I will conduct the study in accordance with the provisions of this protocol and all applicable protocol-related documents. I agree to conduct this study in compliance with United States (US) Health and Human Service regulations (45 CFR 46); applicable U.S. Food and Drug Administration regulations; standards of the International Conference on Harmonization Guideline for Good Clinical Practice (E6); Institutional Review Board/Ethics Committee determinations; all applicable in-country, state, and local laws and regulations; and other applicable requirements (e.g., US National Institutes of Health, Division of AIDS) and institutional policies.

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LIST OF ABBREVIATIONS AND DEFINITION OF TERMS

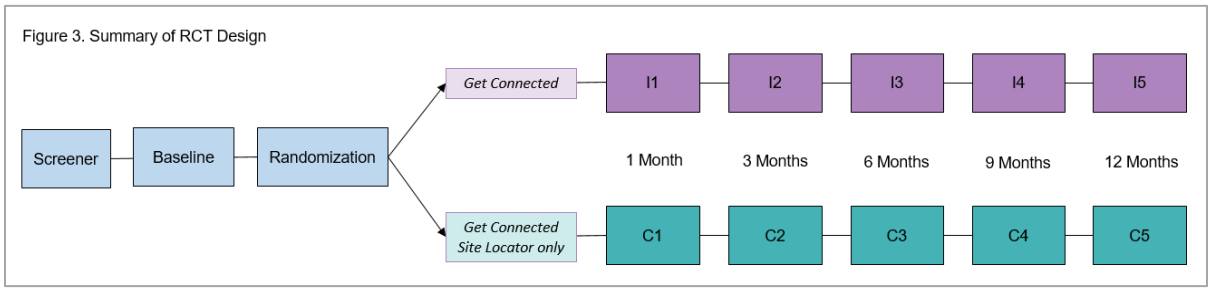
AC	Analytic Core
AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral Therapy
ASO	AIDS Service Organization
ATN	Adolescent Medicine Trials Network for HIV/AIDS Interventions
CASI	Computer Assisted Self Interview
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CRF	Case Report Form
DCF	Data Collection Form
DHHS	U.S. Department of Health and Human Services
EC	Ethics Committee
GC	Get Connected
GCP	Good Clinical Practices
HIPAA	Health Insurance Portability and Accountability Act
HIV	Human Immunodeficiency Virus
ICH	International Conference on Harmonization
IRB	Institutional Review Board
LGBTQ	Lesbian, Gay, Bisexual, Transgender, Queer
MC	Management Core
MTS	Michigan Tailoring System, a platform for eHealth interventions
NICHD	National Institute of Child Health and Development
NIDA	National Institute on Drug Abuse
NIH	National Institutes of Health
NSDUH	National Survey on Drug Use and Health
OHRP	Office for Human Research Protections
PI	Principal Investigator
PrEP	Pre-Exposure Prophylaxis
QNS	Query and Notification System
RDC	Remote Data Capture
SRV	Subject Recruitment Venue
STI	Sexually Transmitted Infection
TC	Technology Core
YMSM	Young Men who have Sex with Men

STUDY ABSTRACT

DESIGN:	*A two-arm prospective randomized controlled trial (RCT) in Philadelphia, Houston, and Atlanta. Participants randomized to the control condition will only see the site locator portion of the Get Connected intervention website. It will include information on HIV prevention services. Participants randomized to the intervention condition will receive tailored online content specific to their demographic characteristics (e.g., age, race/ethnicity, location, and relationship status), HIV/STI risk behaviors (e.g., HIV/STI testing history; substance use; communication with partners regarding status) and sociocultural context (e.g.,homelessness, incarceration). We will also recruit, enroll, and train 10-15 mystery shoppers per city to conduct a mystery shopper assessment. Two mystery shoppers will visit each testing site separately and complete a standardized assessment of their visit. Site directors from 10 randomly selected testing sites in each city will be interviewed to assess sites' satisfaction with the biannual performance assessments and their improvements in service delivery when working with YMSM.*
DURATION:	*Mystery shoppers are enrolled for approximately six months, or the time it takes them to complete approximately ten site visits. YMSM participating in the RCT are enrolled for 12 months.*
SAMPLE SIZE:	*Total study sample size is 480 with the aim of maintaining a randomized sample of approximately 400 online-recruited and retained YMSM for 12 months. After consent, but prior to completion of the baseline survey, YMSM are randomized to either the intervention (n=240) or control (n=240) condition.*
POPULATION:	*Individuals who were assigned male at birth and currently identify as male. 15-24 year-old (inclusive), self-report as HIV-negative or sero-status unaware, speak and read English, live in Philadelphia, Houston, or Atlanta, and meet one or both of the following high risk criteria: have not received HIV testing in past six months and/or report having consensual anal sex with a man in the past six months.*
STRATIFICATION:	*Each site (Houston, Atlanta, and Philadelphia) will enroll 160 YMSM and 10-15 mystery shoppers.*

DATA COLLECTION:	*For study participants, we will use SurveyGizmoto collect YMSM's data. Online surveys allow participants to complete the survey at a convenient location, circumvent barriers (e.g., scheduling, transportation) and decrease social desirability. Participants may complete surveys on a mobile device or desktop or laptop computer on which they feel comfortable, or they may visit the subject recruitment venue (SRV). At baseline, participants will be logged into the SurveyGizmo assessment by site study staff. For follow-up assessments, participants will receive a unique link which will allow them to complete the surveys in multiple sittings or to resume a survey that has timed out or been closed. Mystery shoppers will use Qualtrics to complete an evaluation of each visited site. Interviews with agency directors will be audio-recorded to allow for verbatim transcription of the interview and checked for accuracy and completion.*
OBJECTIVES	*To test the efficacy of an e-Health intervention for increasing HIV-negative or HIV-unknown YMSM's successful uptake of HIV and STI testing willingness (e.g., routine HIV/STI testing) and PrEP awareness and willingness, as compared to the attention-control condition over a 12-month period.* *To examine the quality of HIV test counseling and PrEP-related referrals to YMSM within local HIV/STI testing sites in 3 cities (Houston, Philadelphia, and Atlanta) through the use of mystery shoppers* *Qualitatively assess testing sites' satisfaction with the biannual performance assessments and their improvements in service delivery when working with YMSM across the three regions.*

Study Design or Schema



Per the diagram above, the study is a two-arm randomized controlled trial. Once participants are proven eligible and they have provided informed consent, they will be randomized to one of two arms: intervention (Get Connected) and control (site locator portion of Get Connected). Participants randomized to the control condition will only have access to the site locator portion of Get Connected, with information on HIV prevention services. Participants randomized to the intervention condition will receive tailored online content specific to their demographic characteristics (e.g., age, race/ethnicity, location, and relationship status), HIV/STI risk behaviors (e.g., HIV/STI testing history; substance use; communication with partners regarding status), and sociocultural context (e.g., homelessness, incarceration). Five study assessments (surveys) are conducted at months 1, 3, 6, 9, and 12 for a total of 12 months follow-up for each arm.

1.0 INTRODUCTION

1.1 Background

In 2010, young men who have sex with men (YMSM) (aged 13-24) accounted for 30% of all new HIV infections among men who have sex with men (MSM)[1,2]. The HIV epidemic among YMSM is characterized by strong racial disparities; recent NHBS (National HIV Behavioral Surveillance) analysis showed 26% of African American MSM youth (18-24 years) tested HIV positive, compared to only 3% of White MSM 18-24 year olds[3]. STI infections are also known to increase risk for HIV acquisition. With increasingly promising evidence of the efficacy of biomedical prevention tools, such as PrEP, for reducing risk of HIV infection among MSM[4-9], there is increased attention to the potential for HIV testing to act as a gateway to other HIV prevention tools and care efforts[3,10]. Many of the cognitive and behavioral risk factors that contribute to the high rates of HIV infection among MSM are established during adolescence and the transition into young adulthood. This age group should be considered a priority time for intervening on cognitive and behavioral risks for HIV, while also introducing YMSM to HIV and STI testing as a gateway to other HIV prevention options. However, successful adoption of HIV prevention tools requires that YMSM overcome a series of multi-level barriers at the individual (e.g., risk awareness), systems (e.g., costs, lack of culturally competent care), and structural (e.g., homelessness, stigma) levels. Therefore, developing strategies to promote the use of HIV prevention services among YMSM requires the creation of interventions that are culturally sensitive to their psychosocial needs[11] and facilitate access to comprehensive sexual health services[12].

1.2 Rationale

There is strong evidence of a significant and growing HIV epidemic among YMSM[1]. From 2008–2011, YMSM aged 13–24 years had the greatest percentage increase (26%) in diagnosed HIV infections[2], with approximately 93% of all diagnosed HIV infections from male-to-male sexual contact[2]. The HIV epidemic among YMSM is characterized by strong racial disparities. In an analysis of NHBS data from 2008-2014, Wejnert et al[3] demonstrated that black MSM did not report greater sexual risks than other MSM, but were most likely to be infected with HIV and least likely to know it. Among black MSM aged 18–24 years tested in 2014, 26% were HIV positive, yet among white MSM aged 18–24 years tested in 2014, 3% were HIV positive. The disparity in HIV prevalence between black and white MSM increased from 2008 to 2014, especially among YMSM. YMSM now account for 72% of new infections among people ages 13 to 24, and 30% of all new infections among MSM[20]. HIV prevention tools are needed that can address the unique developmentally specific prevention needs of YMSM, and that are culturally and developmentally adapted for this population in transition[13-16]. Even if they were developmentally adapted, however, most of the existing evidence-based interventions (EBIs) for MSM (e.g., Many Men, Many Voices; MPowerment; d-up!) are delivered in face-to-face group settings. This creates a paradox: for many youth perceived or anticipated stigma, concerns over revelations of sexual or gender identity, and a lack of economic resources create barriers to YMSM attending the very interventions that are intended to reduce these barriers[17]. Hence, *online delivered interventions may have a significant advantage for this population*, particularly

given that YMSM may not be able to access in-person EBIs in their communities, to attend sessions when they are offered, and to engage with the interventions' content when most convenient and appropriate[18,19].

A review of CDC's list of EBIs shows several interventions with efficacy for high-risk youth. Among these, *Assisting in Rehabilitating Kids (ARK), Focus On Youth (FOY), Becoming a Responsible Teen (BART), iCuidate! (Take Care of Yourself) and Be Proud! Be Responsible* are all group delivered interventions, requiring youth to be physical and economically able to attend a group setting, and comfortable with discussing sensitive issues in groups of their peers. The only one-on-one intervention for YMSM classified as an EBI is *Choosing Life: Empowerment, Actions and Results (CLEAR),* but this is specific to improving ART adherence among YMSM living with HIV. Absent from the list of youth-focused EBIs is an online intervention for YMSM that surmounts the barriers associated with attending HIV services, and focuses on creating shifts in cognitive and behavioral HIV-related outcomes for YMSM. If proven efficacious, the proposed intervention – *Get Connected* – can fill this gap by providing an e-delivered, tailored intervention that allows YMSM to learn about local prevention services and build the skills necessary for successful adoption of prevention.

1.2.1 Repeat HIV/STI testing has the potential to reduce HIV testing by increasing knowledge of sero-status and act as a gateway to other prevention options

In light of the high incidence of HIV among YMSM, creating behavioral shifts towards routine HIV testing must be considered a priority goal. Among the drivers of the HIV epidemic among YMSM are large numbers of HIV positive youth who are not virally suppressed and/or are not aware of their sero-status. Increasing HIV testing among YMSM should thus be considered a public health priority[20]. The success of the National HIV/AIDS Strategy's test and treat approach rests on the ability to increase the number of YMSM who receive routine testing. Getting tested is the cornerstone of almost all prevention approaches and the gateway to both biomedical preventions tools (e.g., PrEP) and to HIV care for those who test positive. Successful engagement in HIV prevention for HIV negative youth (routine HIV testing, consistent condom use, PrEP adoption) and care services for HIV positive youth (e.g., linkage and retention in care; access to ART to promote viral suppression) requires that YMSM overcome a series of multi-level barriers at the individual (e.g., risk awareness, self-efficacy to get tested), systems (e.g., costs, medical mistrust, lack of culturally competent care), and structural (e.g., homelessness, costs, stigma) levels[17,21-26].Therefore, developing strategies to promote HIV/STI status awareness among YMSM requires the creation of interventions that are culturally sensitive to the psychosocial needs of YMSM[11] and facilitate access to comprehensive sexual health services[12]. *In response to these challenges, our intervention recognizes that it is important to activate our target population's awareness of their increased risk and readiness to learn about prevention strategies prior to linking them to services.*

1.2.2 Online delivered HIV prevention interventions are ideal to reach and engage YMSM in conversations about their HIV risks

Given youths' increased use of online media in their day-to-day exchanges, online interventions have numerous advantages over in-person delivered interventions. Online interventions are a promising mode of HIV/STI prevention given their ability to deliver responsive and interactive content specific to each user's characteristics (i.e., tailored content), with extended reach across geographic regions and increased convenience to access content at any time through tablets,

laptops, and smartphones. Furthermore, online content can be refreshed to be contextually-responsive over time, particularly as YMSM become sexually-active, meet new partners and/or engage in different risk behaviors. Delivery of online content may also ensure higher intervention fidelity and may be accessed through smartphones if YMSM are unable to afford internet-based connectivity due to socioeconomic barriers. Data from the 2015 Pew Teens & Technology Surveys[27], noted that 92% of teens go online daily. Internet use[27] among youth in the U.S. was near 97% in 2014, with more than 70% of youth having broadband at home and/or connecting via a mobile device. Although Whites (91%) are more likely than Blacks or Latinos to report owning a desktop or laptop computer (~80% each), Black teens are more likely to own a smartphone (85%) and go online through a mobile device (100%) than Whites (71% ownership, 90% access). Collocating online interventions is also important as YMSM often rank the web as their top resource to access comprehensive sexual education, learn about their sexuality and sexual behavior, and meet partners[18].

1.2.3 Test locators are becoming increasingly popular as a means of linkage to care

Researchers and practitioners have sought to encourage timely and repeated HIV/STI testing by creating online tools that provide the location of testing centers in a given geographic area (i.e., test locators). These testing locator interventions have demonstrated wide reach when evaluated (e.g., AIDS.gov test locator had over 16,000 searches and was adopted by over 100 websites in its first year[28]); however, there are no peer-reviewed published data examining the appeal of these locators within YMSM populations specifically or the quality and adequacy of these listed sites for YMSM. This is concerning for several reasons. First, it is expected that testing agencies are youth and LGBTQ (i.e., lesbian, gay, bisexual, transgender and/or queer) friendly, but there is little empirical evidence to support this assumption, and in fact evidence to support the contrary[21,29-33]. Second, our efforts to encourage and motivate YMSM to engage in repeat HIV/STI testing or to adopt other prevention efforts (e.g. PrEP[4-6]) may be diminished if structural barriers (e.g., medical mistrust, lack of insurance or transportation) and cultural insensitivity to YMSM's needs (e.g., racial/ethnic and sexual orientation stigma) lead to delays or avoidance of HIV/STI services[24,34,35]. *The GC intervention seeks to address these systemic challenges by providing a test locator that accounts for sites' quality of HIV prevention service delivery and their ability to cater to YMSM's needs.*

Building on the efficacy of the CDC's Project Connect Health Systems Intervention to link heterosexual adolescents to competent comprehensive sexual health care services[36], we developed *Get Connected* (GC), an online brief intervention that employs individual and systems-level tailoring technology to reduce barriers to HIV prevention care (e.g., HIV/STI testing, PrEP) for YMSM. The deployment of GC through a mobile-friendly WebApp seeks to optimize online interventions' acceptability, accessibility, availability, and long-term affordability among youth[19,37,38]. GC was developed for YMSM (ages 15-24) through a community-based participatory research approach that included a rapid assessment of existing HIV services through a mystery shopper methodology[21], and the creative input of scientists, service providers, and YMSM. Data[39] from our pilot RCT (N=130 YMSM; ages 15-24) indicated high acceptability and feasibility for GC, and clinically meaningful effect sizes (ES) in self-efficacy to discuss HIV testing with partners (ES=.50-.64), trust in their providers (ES= .33-.35), reductions in number of sexual partners (ES=.21), and HIV/STI testing behavior (ES=.34; 30% of participants tested for HIV/STIs) at the 30-day post-intervention follow-up.

2.0 STUDY OBJECTIVES

As part of the U19 project, we propose to test the efficacy of Get Connected (GC) for increasing HIV-negative or sero-status unaware YMSM's successful uptake of HIV and STI testing willingness (HIV and STI testing). Given the overall low level of PrEP awareness and use among YMSM currently[4-6,40], we also include awareness of and willingness to use PrEP as a primary outcome (PrEP uptake during the trial will be measured as a secondary outcome). At the agency level, HIV/STI testing sites listed in GC will receive biannual performance assessments based on ratings that YMSM provide after visiting their locations. We will examine improvements in the quality of HIV test counseling and PrEP-related referrals to YMSM accessing local HIV/STI testing sites in the 3 cities selected to test GC.

2.1 Primary Objective:

Test the efficacy of GC for increasing HIV-negative or HIV-unknown YMSM's successful uptake of HIV and STI testing (e.g., routine HIV/STI testing) and increase in PrEP awareness and willingness, as compared to the attention-control condition over a 12-month period.

2.2 Secondary Objective:

Examine the quality of HIV test counseling and PrEP-related referrals to YMSM within local HIV/STI testing sites in 3 cities (Houston, Philadelphia, and Atlanta) through the use of mystery shoppers.

2.3 Tertiary Objective:

Qualitatively assess testing sites' satisfaction with the biannual performance assessments and their improvements in service delivery when working with YMSM across the three regions.

2.4 Study Hypotheses/Research Questions

- *Relative to the control condition, YMSM exposed to the GC intervention will report significantly greater increases in routine HIV/STI testing over a 12-month period. HIV testing will be the primary outcome for the trial.*
- *Relative to the control condition, YMSM exposed to the GC intervention will report increases in motivation around HIV testing (conceptualized as HIV/STI testing intentions, self-efficacy to engage in HIV/STI testing, and overcoming testing-related barriers).*
- *Relative to the control condition, YMSM exposed to the GC intervention will report significantly greater PrEP awareness and willingness to use PrEP).*

The primary analyses of the data from the Get Connected 2-parallel group randomized clinical trial will be performed according to the participants' original treatment assignment (i.e., intention-

to-treat analyses) and the inclusion of all data from all participants randomized in the final analysis.

Binary outcomes such as HIV testing:

The percentage of participants who report routine HIV testing over a 12-month period will be compared between the interventions arms (GC and the Control condition). Five assessments will occur at 1 month (visit window ± 1 month), 3 months (± 1 month), 6 months (± 1 month) ,9 months (± 1 month), and 12 months (± 1month). Repeated- measures analyses for HIV testing will be implemented by performing a generalized estimating equations (GEE) analysis via the SAS GENMOD Procedure (version 9.4; SAS Institute, Cary, NC) with an exchangeable correlation structure for the repeated measures within participant (binomial-logit model). The statistical model will include three predictors (intervention arm, time on study and the statistical interaction between intervention arm and time on study). The statistical model will provide estimates of the percentages of participants reporting HIV testing (plus 95% confidence intervals) by intervention arm and time on study. The model-based estimates are unbiased with unbalanced and missing data, so long as the missing data are non-informative (missing completely at random, MCAR). A P value ≤0.05 will be considered statistically significant for the main effects (intervention and time on study) and for the intervention by time on study interaction effect from the repeated measures analysis. **The statistical test for interaction between time on study and intervention arm will be the primary overall hypothesis test to determine whether HIV testing in the intervention groups changed in significantly different ways during follow-up (i.e., different temporal patterns over time).** If HIV testing rates in the two intervention groups are consistently different or similar (i.e., no statistical interaction) then the main effect test for intervention will be used as the primary test of intervention efficacy. If a significant interaction is detected, then Wald chi-square tests will be used to compare the differences between the model-based HIV testing estimates at each time interval and to compare differences over time within each intervention arm. Specific statistical tests will be done within the framework of the generalized linear model. All statistical tests will be 2-sided and unadjusted for multiple comparisons.

The primary assessment for a difference between intervention arms for 'frequent tester' rates will be a two-sided Z-test for independent proportions with pooled variance. Confidence intervals (95%) will also be reported for the observed difference between the GC and control arms in 'frequent tester' rates. The same analysis plan described above will be used for the other primary outcomes that as binary (i.e., STI testing, PrEP awareness).

Continuous outcomes such as Self-efficacy:

Repeated-measures analyses for self-efficacy will be performed with a means model via the SAS MIXED Procedure (version 9.4; SAS Institute, Cary, NC), providing separate estimates of the means by time on study (at 5 scheduled assessments) and intervention group. The model will include three predictors (intervention arm, time on study and the statistical interaction between intervention arm and time on study). A compound-symmetric variance-covariance form in repeated measurements will be assumed for self-efficacy and robust estimates of the standard errors of parameters will be used to perform statistical tests and construct 95% confidence intervals[76]. The model-based means are unbiased with unbalanced and missing

data, so long as the missing data are non-informative (missing at random, MAR). A P value ≤0.05 will be considered statistically significant for the main effects (intervention and time on study) and for the intervention by time on study interaction effect from the repeated measures analysis. **The statistical test for interaction between time on study and intervention will be the primary overall hypothesis test to determine whether self-efficacy in the two intervention groups changed in significantly different ways during follow-up (i.e., different temporal patterns over time)**. If mean self-efficacy in the two intervention groups is consistently different or similar over time (i.e., no statistical interaction) then the main effect test for intervention will be used as the primary test of intervention efficacy. If a significant interaction is detected then t-tests will be used to compare the differences between the model-based intervention means at each time point and to compare differences over time within each intervention arm. Specific statistical tests will be done within the framework of the mixed effects linear model. All statistical tests will be 2-sided and unadjusted for multiple comparisons. The same analysis plan described above will be used for the other outcomes that are continuous (i.e., willingness to use PrEP).

3.0 STUDY DESIGN

3.1 Study Phases

In this four-year study, we will enroll 480 self-reported HIV-negative or sero-status unaware, sexually active YMSM (ages 15-24) across three sites and randomize them into the GC intervention condition or to an attention-control condition. Primary outcomes will include (1) use of HIV prevention services (HIV testing, STI testing) and PrEP awareness and willingness. As secondary outcomes, we will assess PrEP use, sexual risk behaviors, and the linkage and retention in care among newly diagnosed HIV+ cases. We will also examine changes in GC's theorized mechanisms of change, including YMSM's attitudes, norms, self-efficacy, and behavioral intentions to adopt HIV prevention services.

Control condition: Participants randomized to the control condition will have access to the site locator portion of the Get Connected website, which includes information on HIV prevention services. While the provision of a test locator is a form (albeit weak) of an intervention, we felt that withholding referrals to testing and care services would be unethical given YMSM's vulnerability to HIV and STIs. Furthermore, given the availability of search engines to locate HIV/STI testing sites, the test locator condition may be considered usual care. Nevertheless, by providing the testing site locator only, we will be able to test the effect of the GC intervention condition (i.e., user-tailored content focused on HIV/STI testing and PrEP referral and the linkage to high-quality agencies) against the usual care control condition.

Intervention condition: Using a consensus approach[41] to conceptualize health behavior change, the model guiding *GC* synthesizes The Integrated Behavioral Model[42] and Self-Determination Theory[43,44] as the theoretical underpinnings of our intervention. These theories emphasize social cognitive factors that impact behavior change and have informed HIV interventions[45-48]. Consistent with these theories[49,50], GC content follows motivational interviewing (MI) principles[46,50,51] by focusing on resolving ambivalence about HIV prevention behaviors, increasing self-efficacy for change, and enhancing motivation moving toward action. The intervention was developed by customizing content based on YMSM's psychosocial and sexual

profile (e.g., socio-demographics, HIV/STI testing history and testing motivations, recent sexual behavior, sources of support, self-reported values), as reported by participants' answers to their baseline assessment. At the individual-level, GC delivers tailored online content specific to each user's demographic characteristics (e.g., age, race/ethnicity, location, relationship status), HIV/STI risk behaviors (e.g., HIV/STI testing history; substance use; communication with partners regarding status) and sociocultural context (e.g., homelessness, incarceration). GC also employs tailoring at the systems-level. Participants across both conditions who report being tested since their last follow-up survey will be asked to complete a site assessment as part of their follow-up survey. Testing sites will receive biannual performance summaries that include aggregated participant scores from the site assessments, qualitative feedback participants provided, and their sites' scores in relation to other testing sites in their city. These summaries are provided in an effort to help sites understand their performance based on quality assurance evaluations from YMSM clients and to optimize service delivery if needed. The study team and Analytic Core will ensure that these summaries will not include any identifying information about participants.

Increasing Awareness:
The first section of the GC tailored website exhibits the "What" of HIV and STI testing. The first subsection, "The Facts," presents a grid of STI facts in a random order. The final box is a list of seven questions participants can ask a provider during a testing visit. These questions were developed by the GC youth and community advisory boards, and were found to be helpful to pilot trial participants when they encountered test counselors who weren't perceived to be effective. The second subsection, "STIs," displays boxes that contain the names of specific STIs. Once clicked, pop-up content presents information specific to that STI including what kind of infection it is, how it can be contracted, possible symptoms, testing options (e.g., oral swab versus blood draw), and treatment options (if applicable). The third subsection "Tests," displays boxes with information on the different types of tests for STIs (e.g., blood test, saliva test, swab test). Once clicked, pop-up content presents information on what STIs each type of test can test for, and the specific steps taken to administer the test and contains general prevention facts (e.g., "You won't always know if someone has an STI.") relevant to this population.

Promoting self-appraisal and increasing motivation for engaging in prevention services: The second section of the GC tailored website, the "Why," encourages participants to assess their motivations, values, and strengths regarding HIV/STI testing. Reasons for getting tested are tailored to participants' testing history (e.g., "Never tested" versus "Tested for HIV, but not STIs") in order to acknowledge their prior behaviors. Building on best practices, persuasive messages regarding the importance of linking to prevention services are presented by linking participants' values to the desired outcomes. GC then reinforces behavioral (e.g., having tested between follow-up assessments) and cognitive aspects of HIV prevention services that participants expressed confidence in doing (e.g., asking a partner to get tested before having sex) based on baseline or follow-up assessments.

Acknowledging and Overcoming Barriers: The third section of the GC tailored website, the "How," explores barriers (e.g., financial costs, social norms, and prioritization) to participants' desire to get tested for HIV/STIs, as well as how their strengths and social support systems can help them make a choice about testing. Recognizing that barriers and supports may shift over

time, the pages' content is tailored based on the most recent responses to questions in the follow-up assessments. This way, GC can address current barriers, provide strategies on how to overcome them, and current supports, with suggestions for how to utilize them.

Linking Users to Culturally-Sensitive Providers:
The final section of the GC tailored website, the "Where," contains a listing of local testing sites and filtering options (e.g., visit can be 30 minutes or less, site is open on weekends, site prescribes PrEP). Testing sites are rank-ordered using an algorithm that accounts for each site's average mystery shopping scores regarding the site's LGBTQ inclusivity and confidentiality during the testing process, providers' LGBTQ friendliness, discussion of sex and relationship goals, ability to discuss motivations for testing, sex positive tone, avoidance of making assumptions about the client, assessment of potential intimate partner violence, and pressure to adopt risk reduction strategies. Participants can choose to send specific site information to themselves via email or text message.

Primary objective:

- **Phase 1a: Populating the Sites**
  We will create a master list of the HIV/STI testing sites and employ our mystery shopper methodology to examine the quality of HIV test counseling and local HIV/STI testing sites in the 3 trial cities (Houston, Philadelphia, and Atlanta). Data will then be entered into our existing GC test locator console. During the first 3 months of the project, we will train research assistants to identify existing HIV/STI locations and PrEP providers across the three cities. Following a sequential method, research assistants will compile an exhaustive list using the local health department HIV testing site directory. They will then triangulate the information obtained through CDC's National Prevention Information Network (NPIN) with HIV/STI testing and PrEP providing locations using Google search. Emory has collected a list of PrEP provider registries already and worked with NASTAD (National Alliance of State and Territorial AIDS Directors), Kaiser Family Foundation and UCSF (University of California, San Francisco) to launch a national provider registry in summer 2016, which is available and updated as necessary for this project. We will then verify the information obtained by calling the clinics and verifying their HIV/STI testing hours, services provided, phone numbers, addresses, language used to describe clients and services, targeted client age, and cost of services. Once this information is reconciled, sites' information will be entered into the open-source GC console. Agency characteristics are used to sort sites based on their geographic area, operating hours, ability to test without an appointment, proximity to public transportation, and insurance or ID requirements.

- **Phase 1b: Recruitment and eligibility for RCT**
  Using 2014 American Community Survey data about the racial/ethnic distribution of children under the age of 18, we propose to sample a racially/ethnically diverse sample of YMSM that parallels the racial/ethnic distribution in each city. We will use geographically targeted ads on sites including Facebook, Tumblr, Instagram, Reddit, and Twitter.

- **Phase 1c: Data Collection and Retention for RCT**
  We will use SurveyGizmo to collect YMSM's data. *At baseline, participants will be logged into the SurveyGizmo assessment by site study staff. For follow-up assessments, participants will receive a unique link which will allow them to complete the surveys in multiple sittings or to resume a survey that has timed out or been closed.* Online surveys allow participants to complete the survey at a convenient location, circumvent barriers (e.g., scheduling, transportation) present in interviewer-administered or phone-based interviews, and decrease social desirability. To maximize completion rates, participants will receive email and/or text reminders that a survey is available. Although we will employ recommended strategies to avoid loss to follow-up, we project a conservative attrition of 20%. In the pilot study, we achieved >80% retention using the approaches proposed here.

Secondary objective:

- **Phase 2a: Enrolling and Training of Mystery Shoppers**
  We will enroll and train 10-15 mystery shoppers per city to conduct the mystery shopper assessments. This approach follows best practices indicating that youth involvement is vital when designing relevant and appropriate HIV interventions for the target population. As study staff, we will work with the ATN site in each city to enroll HIV-negative YMSM (ages 18-24) who are interested in serving as mystery shoppers. We will employ a stratified purposive sampling strategy to ensure age and racial/ethnic diversity across mystery shoppers. Of the 10-15 mystery shoppers in each city, we will attempt to recruit diversity in age and race/ethnicity. Mystery shoppers will be 18 to 24 years old (inclusive).

- **Phase 2b: Site Visits**
  Based on feedback from agency directors in our original study, we will send all agency directors a letter informing them of their site's selection for the study before the mystery shopper visits and contact information to reach the research PIs if they have questions about the procedures. Shoppers will be instructed to report that they do not have income or health insurance and do not possess any proof of identification. In so doing, we will be able to ascertain whether these would be potential barriers to testing at a given location and determine the lowest possible fees that would be charged to a YMSM.

- **Phase 2c: Integration of Scores into GC Console**
  We will enter the 10 domain scores from the mystery shopping evaluations for each site into our GC administrative console, hosted online, and accessible to the study team for maintenance (e.g., if a testing location changes its hours of operation or closes). The rating criteria are not meant to establish an absolute measure of each site, but rather a rating that may then be used relative to an individual's stated needs and desires for his testing experience. An average between the composite site score and the user's stated values will be used to rank a provided list of local HIV/STI testing sites.

Tertiary objective:

- **Phase 3a: Randomly Select 10 Sites from Each City**

We will randomly select 10 sites from Philadelphia, Houston, and Atlanta to carry out semi-structured qualitative in-depth interviews with the agency's director.

Eligibility Criteria for Site Directors:

- Speak and read English
- Site director of an HIV/STI testing site
- The testing site is located in Philadelphia, Atlanta, or Houston

- **Phase 3b: In-Depth Interviews**
  The interviews (60-90 minutes) will focus on 4 domains: (1) existing prevention services used and/or promoted by the agency, (2) agency (internal) resources currently missing, that if identified and addressed, could improve delivery of HIV/STI and PrEP services to YMSM, (3) feedback on the biannual evaluation assessments and their use for service-delivery improvements, and (4) the advantages and disadvantages of GC rollout within ASOs. We will interview providers via teleconference in a private office at the University of Pennsylvania to maximize candidness and privacy while decreasing travel-related costs. We will use BlueJeans, a simple and low cost alternative that requires no server infrastructure to set up or maintain and allows providers to be HIPAA-compliant. University of Pennsylvania holds the BAA for this BlueJeans license. The site directors will not be compensated for their participation in these interviews.

3.2 Study Population

For the primary objective, we plan to recruit a diverse sample of 15-24 year olds. Of the 480 participants, we propose that 98 (20%) will be non-Hispanic white men, 232 (48%) will be non-Hispanic black men, 122 (25%) will be Latino men, 22 (5%) will be non-Hispanic Asian-Pacific Islanders, and 6 (2%) will be other non-Hispanic or multi-racial men. Transgender participants are excluded in this protocol as the intervention has not been adapted to meet the needs of transgender youth.

Eligibility criteria will include the following: Individuals who were assigned male at birth and currently identify as male, 15-24 years old (inclusive), self-report as HIV-negative or sero-status unaware, speak and read English, live in Philadelphia, Houston, or Atlanta, and meet one or both of the following high risk criteria: have not received HIV testing in past six months and/or report having consensual anal sex with a man in the past six months.

For the secondary objective, we plan to recruit a diverse group of 10-15 mystery shoppers per city. Mystery shoppers will be 18 to 24 years old (inclusive).

Eligibility criteria will include the following: Individuals who were assigned male at birth and currently identify as male, 18-24 years old (inclusive) at time of screening, self-report as HIV-negative, speak and read English, live in Philadelphia, Houston, or Atlanta, are able to travel to and from HIV/STI testing sites, report same-sex attraction, and have access to internet via a computer or smartphone.

For the tertiary objective, we will randomly select 10 testing sites per city who participated in the mystery shopper perspective and conduct a semi-structured qualitative in-depth interview with the site's director.

Eligibility criteria will include the following: Individuals who are site directors of an HIV/STI testing site in Philadelphia, Atlanta, or Houston, and who can speak and read English.

3.3 Sample Size

For the primary objective, the research activities involve enrolling a sample of 480 HIV negative or status unaware YMSM (15-24 years), with the aim of maintaining a randomized sample of approximately 400 online-recruited YMSM over 12-months.

For the secondary objective, the research activities involve enrolling a sample of 30-45 HIV negative YMSM (18-24 years), with the aim of visiting each city's public testing sites twice - two mystery shoppers will visit each testing site (i.e., the same shopper will not go to the same testing site twice).

For the tertiary objective, the research activities involve enrolling a sample of 10 HIV testing site directors per city, with the aim of conducting a semi-structured qualitative in-depth interview.

3.4 Study Randomization, Stratification, or Description of Non-Random Assignment Procedures

For the primary objective, participants will be randomly assigned to one of two groups, stratified by city/SRV site: intervention and control. After consent, YMSM are randomized to either the control or intervention condition (Intervention, n=240; Control, n=240). **We intend to blind participants to the intervention arm assignment in order to improve the internal validity of the study, the rigor of the assessment of outcomes, and to minimize bias due to awareness of treatment assignment.**

For the secondary objective, mystery shoppers will visit testing sites that have been randomized such that each site has an equal likelihood of being shopped on any given day at any given time (during normal operating hours).

For the tertiary objective, participants will be randomly selected from participating HIV testing sites in each of the three cities. Only sites that have been visited and assessed by study participants will be included in each city's sample for randomization.

4.0 ELIGIBILITY AND SCREENING

4.1 Primary Objective (RCT): Inclusion Criteria

- *Assigned male sex at birth and currently identifies as male*

- *Aged 15 to 24 years (inclusive) at time of screening*
- *Self-report as HIV-negative or sero-status unaware*
- *Speak and read English*
- *Not be on PrEP at time of enrollment*
- *Report having consensual anal sex with a male partner in the prior 6 months and/or report having not received HIV testing in prior 6 months*
- *Reside in Philadelphia, Houston, or Atlanta*
- *Access to internet*

4.2 Primary Objective (RCT): Exclusion Criteria

- *Assigned female sex at birth*
- *Assigned male sex at birth but does not currently identify as male*
- *Aged 14 years or younger or 25 years or older at time of screening*
- *HIV-positive*
- *Does not speak or read English*
- *Currently taking PrEP*
- *Does not reside in Philadelphia, Houston, or Atlanta*
- *Currently incarcerated*
- *Planning to move out of the region in next 12 months*

4.3 Secondary Objective (Mystery Shoppers): Inclusion Criteria

- *Assigned male sex at birth and currently identifies as male*
- *Aged 18 to 24 years (inclusive) at time of screening*
- *Self-report as HIV-negative*
- *Speak and read English*
- *Report same sex attraction*
- *Reside in Philadelphia, Houston, or Atlanta*
- *Able to travel to and from HIV/STI testing sites*
- *Access to internet via a computer or smartphone*

4.4 Secondary Objective (Mystery Shoppers): Exclusion Criteria

- *Assigned female sex at birth*
- *Assigned male sex at birth but identifies as transgender or gender non-conforming*
- *Aged 17 years or younger or 25 years or older at time of screening*
- *HIV-positive*
- *Does not speak or read English*
- *Does not report same sex attraction*
- *Does not reside in Philadelphia, Houston, or Atlanta*
- *Currently incarcerated*
- *Planning to move out of the region in next 12 months*
- *Unable to travel to and from HIV/STI testing sites*
- *Does not have access to internet via a computer or smartphone*

4.5 Tertiary Objective (Site Directors): Inclusion Criteria

- *Speak and read English*
- *Site director of an HIV/STI testing site in Philadelphia, Atlanta, or Houston*

4.6 Tertiary Objective (Site Directors): Exclusion Criteria

- *Does not speak and read English*
- *Is not a site director of an HIV/STI testing site in Philadelphia, Atlanta, or Houston*

4.7 Recruitment

For the primary objective, we will use geographically targeted ads on a range of social media outlets. We will work closely with the U19 Management and Technology Cores for guidance on recruitment, including use of the Technology Core's bank of recruitment images. We will also recruit from socio-sexual networking sites (e.g., Grindr, BBRT) for YMSM who are 18 years or older. Promotional materials will describe the study and provide a link to the SurveyGizmo Participant Eligibility Screener (see Section 4.0 for eligibility criteria). Once determined eligible, YMSM will be contacted to schedule their baseline visit at the SRV. We will also follow respondent-driven sampling (RDS) methods and use a long-chain referral method to supplement recruitment, especially with the adolescents (15-17) who may be harder to reach than young adults (18-24).

For the secondary objective, we will use geographically targeted ads on a range of social media outlets. We will also work closely with the ATN site in each city to recruit in community spaces. If an individual is interested in being a mystery shopper, they will complete a Qualtrics screening survey to determine their eligibility. If they are eligible, the study team will contact them for an interview.

For the tertiary objective, we will randomly select 10 directors of HIV testing clinics in each city. To be included in the sample for randomization, the site must have been visited and assessed by participants in the GC study. If a site is selected, the study team will contact the site or the site director (if contact information is available) to schedule an interview.

4.8 Informed Consent

For the primary and secondary objectives, the informed consent process will occur on the day the enrollment visit is held. Interested persons will arrive to the SRV location, where they will be guided through the informed consent process by study staff, who will explain all study procedures and answer questions concerning the study and consent process. The research staff member will give the participant as much time as needed and will address any questions or concerns they may have. The research staff member will ask the participant questions to gauge comprehension. The consent/assent form describes all study procedures, including confidentiality and privacy, information about potential risks, discomforts, benefits of participation, and information regarding

who they can contact with further questions. It also states that participation is voluntary, that participants may decide not to take part or to withdraw from the study at any time without penalty or loss of any benefit to which they might otherwise be entitled. Participants can refuse to answer any question, and can withdraw from the study at any time. The PIs, Co-PIs, or designee at each site will review all informed consents and assents.

Assessing for decisional capacity. For all participants, the study staff reviews the informed consent/assent to make an assessment of the youth's decisional capacity and ability to provide consent/assent prior to signing, using a 2-step process. First, the study staff determines if the person understands the study goals by asking "Can you tell me what this study is about?" In step 2, potential participants will be asked questions designed to assess their capacity to understand, appreciate, reason with, and express a choice about participation in our specific protocol. Participants will be asked to: name things they will be expected to do during the study; explain what they would do if they no longer wished to participate in the study**;** explain what they would do if they experienced distress during the study; and identify potential risks for participating in the study. For youth who cannot answer these questions, the study staff will go back and review the relevant elements of consent with the participant again and repeat the process. Youth who appear not to understand after repeated review will not be enrolled in the study.

Waiver of parental consent. We will request that the UNC-CH IRB as the central/single IRB (IRB of Record) grant a waiver of parental consent to participate in this research study for youth participants who are 15 to 17 years of age. The research team has been granted waivers of parental permission for prior studies with sexual minority youth. Under 45 CFR 46.408 (c), an IRB has the authority to waive parental permission if it determines that "a research protocol is designed for conditions or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects" and "an appropriate mechanism for protecting the children who will participate as research subjects is substituted" and "that the waiver is not inconsistent with Federal, State, or local law." A waiver of parental/legal guardian permission will be sought given that minor individuals can often seek sexually transmitted infection (STI) and HIV testing without parental/legal guardian permission, depending on each site's state laws. Requiring parental permission may place participants at risk for outing themselves as part of the LGBT community or being at risk for HIV infection. A waiver of parental permission for studies with LGBT youth that do not involve greater than minimal risk is a common practice among researchers working in the area of gay and lesbian health/mental health. This is done to avoid the selection biases operating in only recruiting youth whose parents are both aware of and comfortable with their sexual orientation. Commonly, these youth have explored their sexual orientation without their parents' knowledge as the youth struggle with issues of disclosure and its consequences within the social, religious, and economic context of their families. A requirement for parental permission in this type of study could not only affect a person's willingness to participate, but could also potentially impact the ability of researchers to engage in this type of research with sexual minority youth.

If the purpose of requiring parental permission as stated in CFR is to protect the minor subject, then requiring parental permission for youth in these circumstances is not a reasonable requirement. Additional privacy protections are provided in that all assessments, notes, reports, and other records will be identified by only a coded number to maintain participant confidentiality. These records and any forms that do contain identifying information (e.g., consent/assent forms, contact information) will be kept in a locked, limited access area (such as a locked file cabinet) at the participating site.

For the tertiary objective, any randomly selected site director who is eligible, willing, and capable of being interviewed will be consented over BlueJeans and will be offered a copy of the consent form.

4.9 Screening

Primary objective: Web-based recruitment screener:

Participants who click on the banner advertisements will be taken to an online screening survey, hosted on SurveyGizmo.com, which will include the eligibility script and questions from the RCT Participant Eligibility Screener. For those who meet eligibility criteria, we will ask for a first name, email address, and phone number. For those who do not meet eligibility criteria, there will be an option to provide a first name and email address if they want to be contacted about future studies. Those individuals who initially screened ineligible because they did not report having anal sex with a man in the past 6 months will be re-contacted to take the online screener again. Web-based screening instruments allow for real-time data collection across multiple outreach modes (e.g., banner ads, flyers, in-person outreach) pooled into a single stream. We will use Secure Socket Layer (SSL) encryption for transfers of information online and data will be stored in the secure, HIPAA-compliant servers of SurveyGizmo. The Emory AC team maintains a business partner HIPAA agreement with SurveyGizmo.

Secondary objective: web-based recruitment screener:

Participants who have clicked on an online ad or saw an ad in person for the study will be directed to an online screening survey hosted by Qualtrics. The survey will include the eligibility script and questions found in the Mystery Shopper Participant Eligibility Screener. Analogous to SurveyGizmo, Qualtrics abides by HIPAA rules to ensure that data are properly protected and best security practices followed. Qualtrics safeguards all customer data, and uses secure data centers to ensure the highest protection as per the Health Information Technology for Economic and Clinical Health Act requirements.[54]

5.0 STUDY PROCEDURES

5.1 Enrollment Procedures

For the primary objective, eligible participants (as identified by screener) will be contacted by email and/or phone, and invited to the SRV in their city. Once at the SRV, study staff will consent the participants, randomize the participants, and then provide a computer for the participants to complete the baseline survey. Once they have consented, participants will be considered formally enrolled in the study. After completion of the baseline survey, study staff will assist participants with accessing the WebApp, creating a strong but memorable password, and bookmarking the WebApp (if participants choose to). If more than 30 days occurs between screening and the baseline visit, eligibility will be re-determined at the baseline visit.

For the secondary objective, eligible participants (as identified by screener) will be contacted by the study team to schedule an interview. If the individual is deemed capable and willing, they will be consented by a member of the study team.

For the tertiary objective, eligible participants will be contacted by calling the site or the site director directly (if contact information is available) to schedule an interview.

5.2 Locator/Contact Information

For the primary objective, at the participant's baseline study visit, study staff will collect participants' contact information for follow-up assessments: this information will be entered into SMART (Study Management and Retention Tool). We will collect each participant's cell phone number, email address, as well as encourage them to share their Facebook, WhatsApp, and/or Skype usernames, and/or contact information for 2 peers who could help us contact them in the event the participant cannot be reached. Participants will be asked if messages can be left at the peers' numbers they provided. Study staff will not leave messages unless expressly permitted to do so by the participant. If permission is given to leave messages, site staff will assure participants that messages left with peers will only ask for the participant to contact study staff and will not include any protected health information or information related to study participation. Peer contact information will be maintained using the same confidential data management practices used for all study data.

For the secondary objective, participants will be asked if they would like to be contacted by email, phone, or text message for site visit reminders and other study communication. If participant selects the phone option, the study team will ask for explicit permission to leave voice messages that will not include any protected health information or information related to study participation. Participant contact information will be maintained using the same confidential data management practices used for all study data.

5.3 Randomization Procedures

For the primary objective, after consent, YMSM are randomized to either the control or intervention condition, stratified by city/SRV site (Intervention, n=240; Control, n=240). Participants will be randomized on a 1:1 basis to either the control or intervention arm.

For the secondary objective, testing sites are randomized by day of the week and time of day. After consent and training, participants will work with study staff to find day and time slots for their site visits.

For the tertiary objective, 10 eligible testing sites in each city will be randomly selected. The site director for those sites will be contacted for an interview.

5.4 Intervention/Investigation Procedures

5.4.1 Get Connected Intervention

Participants will complete a 30- to 45-minute baseline survey that includes questions on lifetime HIV testing history, lifetime STI testing history and knowledge about STIs, date of their most recent STI test (if known), and whether they were ever diagnosed with an STI. GC will use baseline survey data to select and deliver personalized, tailored content to YMSM assigned to the intervention. Furthermore, as part of the participant's baseline visit, study staff will collect contact information where participants may be reached for follow-up assessments. We will use best practices to retain participants (e.g., collecting participant's cell phone number, email address, Facebook, WhatsApp, and/or Skype username, and contact information for 2 peers who could help us contact them). Additional surveys will occur at 1, 3, 6, 9, and 12 months after intervention initiation, and can be completed online. These follow-up surveys will repeat many of the questions from the baseline survey and will also include additional questions on HIV and STI testing in each 3-month period, including test results. These surveys will be the same for participants in the control and intervention arms. For participants in the intervention arm, the GC WebApp will be retailored after each follow-up survey, based on any different information provided on key questions.

5.4.2 Mystery Shoppers

Two mystery shoppers will visit each location separately. Each HIV/STI/PrEP clinic will require two round-trip visits during the mystery shopper phase. There are up to 60 registered HIV testing sites offering free HIV tests for men within each city's 25-mile radius: Atlanta (up to 20 sites), Houston (up to 26 sites), and Philadelphia (up to 55 sites). We will use time space sampling to ensure that varying days (weekdays versus weekends when applicable) and times (e.g., morning versus afternoon or evening) are selected for visits, thereby maximizing the chance of getting different counselors at each agency. The project manager will create a calendar for mystery shoppers to know when and where they will be getting tested. We will reimburse the mystery shoppers for all charges linked to their testing experiences. Mystery shoppers will be instructed to be honest about their sexual behaviors during their visits. By avoiding creating 'personas' or 'scripts,' shoppers will increase the social validity of the assessment and avoid arousing suspicion due to exaggerated or unrealistic scenarios. Upon completion of a testing visit, the mystery shoppers will complete the Qualtrics site follow-up survey immediately. Mystery shoppers will also be asked to summarize their qualitative impressions using an open text field.

5.4.3 Assessment of sites' satisfaction with biannual performance reports

Directors of ten randomly-selected agencies in each city will participate in a one-time 60-90 minute semi-structured interview that will focus on 4 domains: (1) existing prevention services used and/or promoted by the agency, (2) agency (internal) resources currently missing, that if identified and addressed, could improve delivery of HIV/STI and PrEP services to YMSM, (3) feedback on the biannual evaluation assessments and their use for service-delivery improvements, and (4) the advantages and disadvantages of GC rollout within ASOs. We will interview providers via video conference in a private office at the University of Pennsylvania to maximize candidness and privacy while decreasing travel-related costs. We will use BlueJeans, a simple and low cost alternative that requires no server infrastructure to set up or maintain and

allows providers to be HIPAA-compliant. The iTech Technology Core will facilitate access to and provide any technical support needed.

5.4.4 Mystery Shopper Training:
We will work with the ATN site in each city to recruit and enroll HIV-negative YMSM (ages 18-24) who are interested in serving as mystery shoppers. We plan to recruit and enroll a diverse group of 10-15 mystery shoppers per city.

Shoppers will be trained to work with our site assessment tool to optimize standardized data collection across sites. A key aspect of the training will be role-playing through mock clinical scenarios. They will also receive training to strengthen their self-efficacy to feel empowered as a client. Specifically, we will conduct role-plays with different scenarios and interactions that might occur during a visit. We will underscore the importance of being well versed in their rights and procedures, and provide skills on how to respond to worst-case scenarios (e.g., how to turn down any unwanted procedures) were they ever to occur.

5.4.5 Intervention Monitoring/Quality Control
The RCT will be managed through weekly site meetings, monthly meetings with iTech Core Leaders, and annual meetings. Research staff will meet regularly to ensure standardization of procedures, and share details on recruitment strategies. Standardization of RCT activities will be ensured by providing consistent training to all study staff and by using a central research protocol that will be developed for the project to ensure guidelines are followed.

6.0 EVALUATIONS AND MEASURES

6.1 Behavioral Evaluations

6.1.1 Pre-intervention (Baseline) Evaluations/Measures

- *Socio-demographic information*: We will include questions on race/ethnicity, educational attainment, employment status, housing status, and history of incarceration, sexual identity, and “outness” to their social network.

- *HIV Testing:* The baseline survey will include questions on HIV testing history.

- *STI Testing:* At baseline, we will assess STI testing history and knowledge about STIs. We will ask participants what STIs they have been tested for, the date of their most recent STI test (if known), and whether a medical provider has ever diagnosed them with an STI.

- *Mechanisms of Change*: We will assess YMSM’s psychosocial correlates predicted to adopt HIV services (i.e., Attitudes, Norms, Self-Efficacy, and Behavioral Intentions to get HIV tested). Integrated Behavioral Model constructs will be assessed with 3 subscales assessing YMSM’s attitudes, social norms, and behavioral intentions[59] that we have used in the past with this population[60]. Each attitude item is measured with three five-

point semantic differential scales (good-bad; worthless-valuable; pleasant-unpleasant). Social norms assess the extent to which participants felt that friends and family believed he should test for HIV on a 1 to 5 scale. Behavioral intentions items assess participants' intention to adopt HIV testing, on a 1 (very unlikely) to 5 (very likely) scale. Self-efficacy to access HIV/STI services and to discuss sexuality-related issues with provider will be ascertained, as well as YMSM's perceived confidence of visiting a testing site or requesting a home kit.

- *Sexual Risk Behavior*: Sexual risk behavior will be assessed using the Sexual Practices Assessment Schedule used in previous online studies with YMSM[61,62] to explore the number of occasions of different sexual acts (oral, anal; receptive, insertive) with three different types of partners (romantic interest, casual partner "hookup," or friend with benefits), use of condoms during the past 3 months, and knowledge about partners' HIV status and PrEP use. Assessments ascertain sexual behaviors with male and female partners, and will be asked at each follow-up. At-risk sex will be defined as any anal intercourse without condoms and/or PrEP that occurs with a person of known positive or unknown sero-status. We will assess the number of partners with whom participants had "at-risk sex."

- *PrEP Awareness and Willingness:* The survey will contain a brief description of PrEP to orient the participant. Questions are adapted from recent studies of PrEP attitudes with YMSM[5,6,40]. PrEP awareness will be a single item measure of whether the participant has heard of PrEP[57] (yes/no/I don't know). PrEP willingness will be measured with an existing 8-item scale developed for YMSM[58] to gauge likelihood of PrEP use across different conditions (e.g., partner types; experiencing potential side effects).

- *Technology and Social Media Use:* Given the online interface of the intervention, we will include Pew Internet Survey questions[27] regarding use of different devices, the number of hours spent online through each device, the reasons for social media use, sites commonly frequented, and extent to which the Internet supplements face-to-face interactions. We will also measure AMSM's frequency of use of social media to look for HIV or sexual health-related information[60,71], and their online partner-seeking behaviors[72,73]

- *ATOD (alcohol, tobacco, and other drug) use:* We will assess frequency of ATOD use (as measured in NSDUH) over the past 30 days (3 months in 3-, 6-, 9-, and 12-month follow-up surveys) for alcohol, tobacco products, cannabis, cocaine, amphetamine type stimulants, inhalants, sedatives or sleeping pills, hallucinogens, and opioids[63]. We will also ask age of onset. If respondents indicate alcohol use, we will ask the Alcohol Use Disorders Identification Test (AUDIT) developed by the WHO (World Health Organization). AUDIT[64] is a 10-item screening questionnaire with 3 questions on the amount and frequency of drinking, 3 questions on alcohol dependence, and 4 on problems caused by alcohol.

- *Psychological Distress:* We will measure this using existing, well-validated scales. We will use subscales from the Brief Symptom Inventory[65] to measure depressive symptoms and anxiety symptoms. Depressive symptoms include 6 items rated on a 5-point scale (1=never, 5=very often). Items include feelings of loneliness, blue or sad, and having

thoughts of ending one's life. Anxiety also includes 6 items measured on the same 5-point scale and includes reporting nervousness or shakiness, feeling fearful, or suddenly scared for no reason. We will use the 10-item Rosenberg Self-Esteem[66], measured on 4-points (0=Strongly disagree-3=Strongly agree).

6.1.2 On-study Evaluations/Measures

- *HIV Testing:* Follow-up surveys will repeat the HIV testing questions in each follow-up survey. The HIV testing outcome will be: the proportion of MSM tested for HIV two or more times at least 3 months apart in the 12-month follow-up period ("frequent tester"). As an additional analysis, we will also examine the proportions of participants who receive one HIV test.

    - Among self-reported newly diagnosed HIV+ cases, we will measure their linkage and engagement with appropriate medical care after initial diagnosis using criteria employed in prior ATN protocols with youth[24,67-69]. We will define linkage as an HIV-related medical visit within 45 days of referral, and engagement as a second HIV-related medical visit within 16 weeks of initial visit[68]. Onset of ART initiation, self-reported adherence to ART, and viral suppression are exploratory indicators[67], as we recognize that our follow-up period may not be a sufficient amount of time to see these changes.

- *STI Testing:* The STI testing outcome is defined as the proportion of YMSM tested for STIs at least once in the 12-month follow-up period. We will ask participants what STIs they have been tested for, the anatomic sites where they were tested, the date of their most recent STI test (if known), and whether a medical provider had diagnosed them with an STI. In the follow-up surveys, we will ask participants whether they had been tested for STIs in the past 3 months (for the 1-month follow-up survey, we ask about the past 30 days). If STI testing is reported, we will ask participants to indicate what tests they received, and whether they were diagnosed with an STI by a medical provider.

- *PrEP Use:* At each follow-up assessment, PrEP-eligible HIV-negative YMSM (per CDC guidelines) will be asked whether they have begun using PrEP[6]. We will also ascertain if a provider recommended PrEP and/or were offered a prescription for PrEP.

  Site Evaluations: Across both trial arms, YMSM who report testing in the prior 3 months will complete self-evaluation forms of their testing experiences to assess comfort, quality, and concerns after visiting a site for HIV/STI testing and PrEP prevention services. The assessment form is the same form used by the mystery shoppers. We will use these data to update the WebApp and to send aggregate data of YMSM's satisfaction with services to agencies biannually.

- *Intervention Acceptability:* At each follow-up, YMSM will report data on the acceptability of their assigned arm. We will also use the Systems Usability Scale[70] to ascertain participants' overall satisfaction with the intervention, perception of the information quality, and perceived usefulness of their intervention to improve their health.

- *Use of Intervention over time:* We will measure intervention exposure using paradata

(e.g., process data emerging from use of the WebApp) from backend database of the intervention website, including counts of user sessions, session lengths, pages visited, and functions utilized. This information will assist in examining whether intervention dosage influences the overall efficacy of the intervention, and inform the cost analysis and wider implementation and scalability.

6.1.3 Premature Discontinuation/Off-Study Evaluations/Measures

RCT participants who request voluntary withdrawal and discontinue study participation after the Baseline survey but prior to the completion of the final survey at 12 months will be contacted by SRV staff in an attempt to understand the reason(s) for the participant's withdrawal and to potentially improve the service experience of the study and refine procedures.

Participants who are prematurely discontinued by a study PI or SRV staff will not be allowed to re-enroll into the study. Reason(s) for study discontinuation will be recorded through a CRF.

7.0 DATA COLLECTION AND SITE MONITORING

7.1 Development of Protocol and Case Report Forms

The Protocol Team in collaboration with the Management Core and Analytic Core, is responsible for the development of this protocol as well as the Case Report Forms (CRFs) needed to collect the information required to implement this protocol.

7.2 Data Records

Participant-related study information will be identified through a study ID number (SID) on all participant CRFs, audio files, transcripts, and Computer Assisted Self Interviewing (CASI) files. Participant names or other personally-identifying information will not be used on any study documents and will be redacted from interview transcripts. Participant names and their SID will be stored separately from other study information in SMART, accessible only to designated study staff, iTech site monitors, and representatives from the NICHD. SIDs will not be entered into the WebApp; instead, a unique WebApp ID will be assigned to each participant when they create an account for the WebApp. These unique WebApp IDs will be provided by the developer. Original source documents for individual participants will be maintained at the respective SRV and will be accessible only to the study staff. Data from original source documents will be transcribed on CRFs as applicable.

7.3 Data Collection

7.3.1 CRFs

Study monitoring data, including untoward effects will be collected on CRFs. All CRFs for this study will be completed through iDataFax, an electronic CRF system.

7.3.2. Mystery Shopper Data

For the second objective, mystery shopper participants will video chat, audio chat, or chat in-person with a study team member about every site visit, following the visit(s). If a video chat occurs, the BlueJeans platform will be used. These conversations are designed to give mystery shoppers an opportunity to discuss and process their visit and any notable incidents at a point when the visit is very recent and easily memorable. If any troublesome or adverse events are reported to the study team member, the study team member can provide the participant with support and external services, in addition to documenting the incident.

After each visit, Mystery Shoppers will complete a brief evaluation of the site using a web-based CASI at the SRV. All survey data will be collected using Qualtrics. Data will remain confidential; no personal identifying information will be collected during the computer session. The participant's unique SID# will be used in order to link the interview responses to the participant's CRF data. We will download the data directly from the administrative web application interface and manage it using Microsoft Excel. The data collected will be stored in a database held within a University of Pennsylvania secure server.

7.3.3 CASI Data

Data collected using a web-based CASI method will be on a portable computer, tablet, or mobile phone via an internet-based application. All survey data will be collected using SurveyGizmo. Data will remain confidential; no personal identifying information will be collected during the computer session. The participant's unique SID# will be used in order to link the interview responses to the participant's CRF data.

Self-administered surveys will be done at baseline and months 1, 3, 6, 9, and 12. They will be completed by participants on personal devices or laptop or desktop computers via surveys hosted on SurveyGizmo.com. We use SSL encryption for transfers of information online and data will be stored in the secure, HIPAA-compliant servers of SurveyGizmo. The Emory AC team maintains a business partner HIPAA agreement with SurveyGizmo.

7.3.4 CASI Data Security

To ensure data privacy, as soon as data is entered (in real-time), it will be encrypted during transmission to the AC using Secure Socket Layer (SSL) technology. The data will then be immediately stored in a secure database on an AC server within the AC data center.

The survey data collected through SurveyGizmo utilizes Amazon Web Services servers for hosting, located in controlled data center facilities in Boulder, Colorado. We clean, manage, and download the survey data directly from the SurveyGizmo application interface. The survey data collected through SurveyGizmo is encrypted while in transfer using SSL certificates, encrypted at the disk level in the Amazon Web Services database servers, and encrypted at the row level. Access to the SurveyGizmo account where the data can be downloaded is password-protected with a sufficiently complex password. The data collected through our web application is encrypted while in transfer using SSL certificates and access to the administrative web application where the data can be downloaded is password-protected using sufficiently complex passwords for each approved user.

7.3.5 BlueJeans Platform Description

For the mystery shopper debriefing sessions that occur over video chat, the BlueJeans platform will be used. BlueJeans is compatible with PCs, Macs, and any device with a web browser, including tablets and smartphones. Unlike other video-chat platforms (e.g. Skype), BlueJeans is HIPAA-compliant. BlueJeans includes the following functions to protect users:

Media handling and encryption. In WebEx, Vidyo, Tandberg, and Polycom architectures, media is sent to a server (also called a video relay or MCU). Although encryption is applied from the user's computer to these servers, the servers still have full access to the user's media. In contrast, Blue Jeans does not record or store your information; they simply encrypt and transmit it. Blue Jeans Network does not store any video conference content, in any format. This security infrastructure means Blue Jeans has no control over the content shared via video conference. BlueJeans supports standards-based encryption (AES-128) for video conferencing. .

Infrastructure and network security. BlueJeans employs a wide range of security management. This includes network firewalls throughout the infrastructure to create security zones for different applications and services. BlueJeans also deploys proxy servers that terminate all third party/customer traffic at a proxy layer. All web traffic passes through industry-leading load balancers to protect against a suite of application attack vectors. Beyond the firewall, proxy servers, and load balancers, BlueJeans also periodically scans for network, port, and application-level vulnerabilities. Vulnerability scans are conducted by a leading third party SaaS provider, in addition to some special-purpose, in-house scanning tools. Furthermore, all of the third party applications and operating system software is checked for security advisories and is patched periodically. Routers, firewalls, load balancers, and proxy application servers are all configured to mitigate numerous types of DOS attacks. BlueJeans also engages with third party consultants to perform penetration testing of the service.

No-install client. Video conferencing software clients tend to be large and to leave a big footprint on the user's system. Almost all of them require administrator permissions to install.
Once the client software gains administrator permissions, they can severely compromise computer security. BlueJeans offers browser-based conferencing system that does not require administrator permissions or installation.

BlueJeans offers the HIPAA-required Business Associate Agreement (BAA) where BlueJeans agrees to be responsible for keeping all patient information secure and to immediately report any breach of personal health information. In this study, University of Pennsylvania will maintain a BAA with BlueJeans, and this will be extended to cover the proposed activities. The BlueJeans sessions will include identifying information (e.g., images of the participant, voice recordings). All identifying information will be stripped from the recorded BlueJeans sessions before they are sent to the analysis team for content analysis.

7.4 Data Submission

7.4.1 CRFs

Although the iTech projects will involve substantial online follow-up, we will use CRFs to collect data on study milestones such as completion or discontinuation, protocol deviations, any social impact reported by participants, and adverse events (AEs).During study conduct, the SRVs will complete electronic CRFs, transmit to the AC using iDataFax, a leading multi-site database environment for HIV RCT. DataFax can receive and transcribe CRF data via fax and scan, or allow for direct data entry. It provides for monitoring form completion and data-quality, and a system for data querying and resolution with SRVs, while maintaining an audit trail. The AC uses DataFax for MSM studies and RCTs and maintains a secure DataFax Linux server at Emory.

7.4.2 Audiotape Data

Interviews with agency directors will be audio-recorded to allow for verbatim transcription of the interview, and checked for accuracy and completion. We will format all transcripts and import them into qualitative data analysis software. Data analysis will be primarily conducted by Drs. Stephenson and Bauermeister, and will also involve ATN members from the Analytic Core and Get Connect study team members when appropriate. After one year when the study is over, audio recordings will be destroyed.

7.4.3 CASI Data Transmission

Only authorized users will be able to access and open the survey through SurveyGizmo. To ensure data privacy, as soon as data is entered (in real-time), it will be encrypted during transmission to the AC using Secure Socket Layer (SSL) technology. The data will routinely be downloaded and stored in a secure database on an AC server within the AC data center.

7.4.4 Retention data

The study will use a HIPAA-compliant web-based platform entitled Study Management and Retention Toolkit (SMART), which is a SaaS (Software as a Service) based mobile application aiding studies with various aspects of participant recruitment, study implementation, and retention. The application has the ability to securely manage participant information across multiple studies and customers simultaneously, stratifying participant information by study and site. SMART includes an admin web portal and a participant facing mobile app (optional), which allows for secure messaging, study calendar management, self-scheduling by participants, secure photo uploads, and longitudinal tracking of participants from screening to study completion. The ability to designate specific roles to all SMART users allows for greater control around permissions and accessibility to participant information. Users can even be limited to a reporting only role, which allows for study oversight through real time aggregate reporting, but no access to PHI. SMART is a licensed service of the Center for AIDS Research (CFAR) at Emory University, Prevention Science Core. Utilization of the mobile app is optional and the admin web portal will fully function without it.

As a backup in the event that the web portal is down or SRVs cannot access it, the study will use a non-web-based version of SMART, which maintains all contacts and scheduling records into a dynamic database that can be queried, in order to facilitate participant retention and communication. SMART was developed by the Emory Tech Core team in a Microsoft Access and SQL (Structured Query Language) Server environment. All data will be stored on an SQL server in the "trusted zone" (HIPAA compliant) area of the Emory Rollins School of Public Health computing service. Access to this database requires user permissions, connection to the Emory network via a VPN, and two-factor authentication using Duo. Daily backups of the entire database are performed. In the event that there are technical difficulties with site access to the Emory SQL Server environment, the SMART back-end database file will be stored in a user-restricted folder on the Emory network (the “T: drive research share”, which requires secure Emory VPN access and two-factor authentication. If there are difficulties with the VPN connection to the Emory network, then a password-protected Microsoft Excel version of SMART will be made available to SRV users in their site-specific (and user-restricted) Box folder. These back-up systems provide a comparable level of data security and will be limited to the same number of users as the primary management system. These back-up systems are necessary for ensuring secure maintenance of study data, and secure, uninterrupted access to study data.

7.5 Data Quality Assurance

Investigators receiving federal funding must adhere to the Code of Federal Regulations (CFR) to protect research participants and produce reliable study information. The iTech AC will monitor data entry and will have an internal quality assurance plan that will identify problems and correct errors in research study records.

7.6 Role of Data Management

The AC will provide instructions concerning the recording of study data on the CRFs, and entry of the data into the AC data management systems.

7.7 Study Site Monitoring and Record Availability

Site monitors from the MC and AC will visit participating study sites to review a selected portion of the individual participant records, including assent/consent forms, CRFs, and supporting source documentation to ensure the protection of study participants, compliance with the protocol, and accuracy and completeness of records. Regulatory files, as required, will also be inspected to ensure that regulatory requirements are being followed.

The site investigator will make study documents (e.g., assent/consent forms, case report forms) and pertinent hospital or clinic records readily available for inspection by the local IRB, the central IRB, the site monitors, the NICHD, the Office for Human Research Protections (OHRP), or the sponsor’s designee for confirmation of the study data.

8.0 PARTICIPANT MANAGEMENT

8.1 Tracking RCT Participants for Follow-up

For the primary objective, participants will be emailed once the appropriate time period has elapsed (30 days after baseline, 2 months after the 1-month survey, and 3 months after that for all other follow-up surveys), to notify them that a new follow-up survey is available. Multiple contact methods will be used for participants who do not complete their follow-up surveys after being emailed (e.g., phone calls, alternative email addresses, text messages, Facebook/other social media accounts). Participants will be asked whether or not messages can be left for any phone numbers they provide. They will be informed that messages will not contain any information regarding the nature of the project.

8.2 Compensation

For the primary objective, participants will be able to earn up to $155 total: Baseline survey = $20, FU1 (Month 1) = $20, FU2 (Month 3) = $25, FU3 (Month 6) = $30, FU4 (Month 9) =$30, FU5 (Month 12) = $30. This is the standard compensation used by both Drs. Bauermeister and Stephenson in their ongoing YMSM studies, each of which has maintained >90% retention. We back-loaded the FU incentives to encourage completion of all data collection time points and reduce participant attrition over time. To receive the month one survey incentive, participants must complete the survey within 30 days of receiving the email with their unique survey link. To receive their month three, six, nine, and twelve survey incentives, participants must complete the surveys within 45 days of receiving each email with their unique survey link.

For the secondary objective, participants will earn $100 for the training session and $50 per site visit. The site visit includes an appointment at the designated site, completion of the post-visit survey, and a debriefing session with a member of the study team.

For the tertiary objective, site directors will not be compensated for the qualitative interview.

8.3 Intervening on “Social Harms"

All sites have specific policies governing the treatment of human participants. These policies specify that medical and psychological assistance will be available in the immediate environment in the event a participant should experience any adverse reactions resulting from study procedures.

While participants will be informed that they may refuse to answer any question at any time, responses or reactions to certain questions may indicate distress on the part of the participants. If at any time during the study, a participant divulges that he is at risk for harm, including but not limited to being abused or experiencing violence, if harm is suspected or likely, or if the participant states he is suicidal/homicidal, measures will be taken to ensure his or her safety. Reporting will be done as appropriate to the situation and the legal statutes, including reporting

to child protection agencies or other appropriate agencies and referrals will be provided to appropriate support, counseling, or treatment resources.

8.4 Criteria for Premature Study Discontinuation

The principal investigator has the authority to withdraw any participant at any time if it their opinion it would be in the best interest of the participant. The participant will be informed of this withdrawal and explained the rationale. Withdrawal will be documented in the study tracking system.

For the primary objective, participants will be prematurely discontinued from the study if any of the following occurs:
8.4.1 The participant withdraws consent/assent (see below);
8.4.2 The study is cancelled by the NIH (or iTech, or other administrative entity);
8.4.3 The study is cancelled for other administrative reasons;
8.4.4 The participant becomes incarcerated or placed in detention during the study
8.4.5 The participant reports an HIV positive diagnosis; or
8.4.6 Death of the participant.

For the secondary objective, participants will be prematurely discontinued from the study if any of the following occurs:
8.4.7 The participant withdraws consent (see below);
8.4.8 The participant is found to be dishonest about their site visits;
8.4.9 The study is cancelled by the NIH (or iTech, or other administrative entity);
8.4.10 The study is cancelled for other administrative reasons;
8.4.11 The participant becomes incarcerated or placed in detention during the study; or
8.4.12 Death of the participant.

For the tertiary objective, participants will be prematurely discontinued from the study if any of the following occurs:

8.4.13 The participant withdraws consent/assent (see below);
8.4.14 The study is cancelled by the NIH (or iTech, or other administrative entity);
8.4.15 The study is cancelled for other administrative reasons;
8.4.16 The participant becomes incarcerated or placed in detention during the study; or
8.4.17 Death of the participant.

Participants may end their participation in the study at any time. No further data collection will occur from the date the decision is made to permanently discontinue the subject from the study. Participants who experience distress during the survey can access our list of community referrals, which can be viewed on our study's website, or contact the research staff using the information provided to the participant within the consent/assent process. Any unexpected adverse events that meet the New Safety Information reporting criteria will be immediately reported to the UNC-CH IRB and the respective sites' IRBs if applicable. All study activities will halt pending UNC-CH IRB review and recommendations if necessary. If a participant withdraws from the research, all data collected in the interview will be immediately destroyed and will not be used in subsequent analysis.

For all objectives, if a participant withdraws or is removed from the study, the Get Connected Off Study Form will be completed.

9.0 MONITORING UNTOWARD EFFECTS ASSOCIATED WITH OR RESULTING FROM STUDY

Site staff must first follow their own IRB's procedure for reporting and managing untoward effects.

There are three types of untoward effects to be identified: (1) those related to the participant, (2) those related to the site visits by mystery shoppers, and (3) those related to the neighborhood/community *(if applicable).*

First, the study will catalogue any untoward effect related to the participant. Reporting is required for occurrences including social harms, psychological distress, and serious life threatening events such as suicide attempts. These may be immediately apparent to the study staff, such as the participant's emotional upset state requiring referral for counseling; or they may be delayed and reported later to study staff, such as physical harm to an individual for having participated in the study. Study staff will notify the team of these untoward effects using the iTech QNS accessible through the iTech website (https://itechnetwork.org). Study staff will be briefed during the training on the scope of possible untoward effects and instructed to report events.

Second, mystery shoppers may encounter untoward events during sessions that personally affect them. Training and guidance will seek to minimize this risk. Nonetheless, an assessment of the cost of conducting this study must include cataloguing these events as well. The protocol chairs should be notified of these events so that they may be immediately addressed, evaluated, and guidance modified or expanded to minimize similar risk to other study staff.

Third, this community-based study intends to evaluate its impact in site-level service delivery, including unexpected effects of the project on the community. This will be done both formally (through in-depth interviews) and informally through community dialogues with ATN sites, with untoward events being reported to the protocol team.

10.0 STATISTICAL/ANALYTIC CONSIDERATIONS

10.1 Introduction

10.1.1 We will test the efficacy of GC in increasing HIV-negative or HIV-unknown YMSM's successful uptake of HIV and STI testing (e.g., routine HIV/STI testing) and increase in PrEP awareness and willingness, as compared to the attention-control condition over a 12-month period. Descriptive statistics of the psychosocial and demographic characteristics of the participants will be described for all and by intervention group. These will be compared between treatment groups using t-tests or Wilcoxon rank sum tests for continuous variables and chi-square tests for categorical variables. To test for intervention efficacy, we will conduct primary

analyses of our primary outcomes using regression analyses to compare our treatment group to the control using the appropriate link function (identity for continuous outcome, logit for binary outcome, and natural log for count outcomes). The regression will be run with group assignment only in the model, as well as, controlling for participants' socio-demographic characteristics, ATOD and psychological distress, and intervention-related process data (e.g., frequency of use, acceptability). Interactions between group assignment and these characteristics will be tested to explore potential moderators of treatment effect. We will repeat these analyses for the secondary outcomes (e.g., theoretical mediators)).

10.2 Power Estimates

10.2.1 The primary outcomes for the proposed trial are HIV-negative and HIV-unknown YMSM's successful uptake of HIV and STI testing willingness (e.g., HIV/STI testing), and PrEP awareness and willingness. For HIV testing, we define power as correctly identifying the difference in the proportion of YMSM who engage in HIV testing 2 or more times at least 3 months apart in the 12-month follow-up period ("frequent tester") in our treatment arm (GC) vs. our attention-control arm. For STI testing, we define it as receiving at least one STI test during the 12-month follow-up period. For proportions (e.g., HIV testing; PrEP awareness), our sample size calculations are based on a two-sample test of proportions using a two-sided significance level of 0.05. In order to have 80% power to compare GC to the attention-control group, we require at least 400 participants to find an absolute difference of 13% in cross-sectional analyses. Assuming within-person correlation of 0.25, we can detect an 8.8% difference. A less favorable within-person correlation of 0.75 allows us to detect an 11.3% difference.

10.3 Statistical Analysis Plan

10.3.1 We will use the general framework of generalized linear mixed models (GLMM) to test for intervention effects over time. Note that some of our outcomes are binary, some count and some continuous traits, and thus need to be treated differently. The general form of the GLMM will be g(μij)=$\beta 0i$+βcov $Covariatesij$+ βTime$j$+ βTrtArm$i$+ βArm x Time, where β is the mean response corresponding to subject i at Time j (baseline and 4 follow-ups), with its appropriate link function (identity for continuous outcome, logit for binary outcome and natural log for count outcomes); Trt =1 if the i-th subject is in the intervention group and 0 if the i-th subject is in the attention-control group. The interaction coefficients are of interest here, measuring the difference in the rate of change in outcome across the two treatment groups over time. The subject-specific random intercepts are assumed to be normally distributed with a common variance and they account for within-person correlation. We will also explore if we need a subject-specific random-slope corresponding to visit in the above model. Maximum likelihood estimation will be used for fixed effect parameters. Models will be compared according to information criterion like AIC, BIC. For some binary outcomes like HIV testing, we will perform an aggregate analysis after collapsing across the repeated measures using simple logistic regression comparing whether the probability of having tested at least once over the entire FU period is different across treatment groups, after adjusting for baseline values. To ensure robustness, we will also apply an exchangeable working correlation structure to its corresponding generalized estimating equation (GEE) model. We will also conduct exploratory regression analyses to examine city differences in the outcomes. These regressions will be run with group assignment and city in the model, controlling for socio-demographic characteristics.

Interactions between group assignment and city will be tested to explore potential site-specific moderators of treatment effect.

10.3.2 As a secondary analysis, we will build on our GLMM framework to examine whether the intervention effects in the theoretical mediators (e.g., intentions, self-efficacy, perceived barriers) are associated with our outcomes. We will also test whether these relationships vary as a function of YMSM's varying engagement with the intervention (intervention acceptability; use of intervention over time). Interactions between group assignment and these characteristics will test for potential moderators of treatment effect.

10.3.3 For the qualitative interviews of agency directors, initial reading and coding of the transcripts will be reviewed, compared, and refined in team meetings. This systematic process will lead to the creation of a coding structure that includes a hierarchical set of constructs seen in the data. We will analyze several transcripts jointly to establish inter-coder reliability. The team will then code all transcripts using our coding structure and add inductive codes throughout the iterative analysis process. Throughout, we will discuss emerging themes, resolve difficulties or concerns that may arise while coding, and adapt the codebook as necessary. Since we were seeking to gain a multi-level understanding of the structural, organizational, and interpersonal barriers and facilitators of implementing GC, our analysis will utilize a phenomenological framework[74]. Although our analysis will rely primarily on a phenomenological inductive approach, we will also employ aspects of deductive analysis that take into account our guiding conceptual framework. This combination of analytic strategies will allow us to conduct a phenomenological analysis (inductive) that was initially informed by existing research and theory via the conceptual framework (deductive). We will analyze the qualitative data using thematic analysis until we have reached saturation[55,56,75].

10.4 Missing Data

Several procedures will be used to conduct data analysis when data for either outcomes or covariates are missing. The first step will be to assess the extent and pattern of missing data. If data are missing for only a few cases, then data analysis will be conducted only on study participants with complete data. However, when such a strategy would result in loss of data from a substantial proportion of participants, or if this approach would lead to biased or inaccurate results, then some form of imputation will be performed. The form of imputation used will depend on the nature of the data that are missing. For example, data that are collected repeatedly might be imputed using the "last value carried forward" method; and in some instances, interpolation between neighboring points might also be used.

When the primary endpoint is missing, one data analysis will be conducted using only cases with the endpoint. Subsequent analysis will be done where missing endpoints are imputed. Hot-deck imputation or regression imputation may also be used in this context.

11.0 HUMAN SUBJECTS

This study will be conducted in compliance with the protocol, ICH Good Clinical Practice guidelines, and 45 CFR Part 46.

11.1 Participants' Confidentiality

All questionnaires, evaluation forms, reports, transcripts, and other records will be identified by a coded number only, to maintain participant confidentiality. All records with personally-identifying information will be kept in a locked file cabinet in a limited secure access area at each SRV site. All computer entry and networking programs will be done with coded numbers only. Clinical information will not be released without written permission of the participant, except as necessary for monitoring by the MC or NICHD.

Every effort will be made to ensure that study participants are protected from risks. The main risk specific to the role of the Analytic Core is breach of confidentiality.

Breach of Confidentiality: A potential risk to participants is violation of confidentiality. We will take the utmost caution to protect the confidentiality of all responses. We will minimize this risk by maintaining confidentiality and discretion throughout all iTech research procedures and data management and analysis.

Participants may be concerned about the security of their data, particularly since it is collected and stored electronically. The Analytic Core has significant experience developing security protocols for Internet-based studies, and we will take a variety of steps to ensure participant security, including using a dedicated server behind a firewall, encryption of data, separation of identifiers from responses, and password-protected access to data. Therefore, we believe that this risk will be minimal. All of the apps and websites included in the iTech have features to ensure app security and privacy.

11.2 Certificate of Confidentiality

This research specifically targets a vulnerable population, children - YMSM ages 15-17. We will take every available step to minimize the risk of identifying/linking data being subpoenaed, stolen, or inadvertently released. First, per Section 2012 of the 21st Century Cures Act as implemented in the 2017 NIH Certificates of Confidentiality Policy, all ongoing or new research funded by NIH as of December 13, 2016 that is collecting or using identifiable, sensitive information is automatically issued a CoC. As noted on the NIH website (http://grants.nih.gov/grants/policy/COC/faqs.htm#187), a Certificate of Confidentiality will help the research team "...avoid compelled 'involuntary disclosure' (e.g., subpoenas) of names and other identifying information about any individual who participates as a research participant (i.e., about whom the investigator maintains identifying information) during any time the Certificate is in effect." We have applied for and received Certificates of Confidentiality for other NIH-funded research projects, and given the sensitive nature of the data collected for this project, do not foresee difficulty securing one for this study. Second, all research staff members are required to complete ethical clearance certification regarding protection of human's subjects through their relevant IRBs. Third, all studies will have documented procedures to safeguard against the risk of the linking information being stolen by keeping such information in locked spaces to which only essential study personnel who have completed CITI certification for human subjects research ethics training (http://citiprogram.org) will have access.

11.3 Risks and Benefits

11.3.1 Risks

Some participants may be uncomfortable answering questions about their past sexual behavior and HIV-related behaviors. All information used in enrollment and recruitment describing the research activities will include a detailed description of the content and expected participation of the respondent, such that the respondent is aware of the nature of the questions and topics to be discussed. Respondents will complete their surveys online to maximize convenience and privacy. Informed consent documents will inform research participants of their rights as participants. During the consent process, participants will be reminded that they are free to refuse to participate in any study activities or choose to terminate their participation at any time. Our consent forms will also include information on limits of confidentiality (e.g., suicidal intent, homicidal intent, child abuse, etc.) and mandatory reporting requirements, which will be reviewed by all participants. While our surveys do not directly ask participants about child abuse or harm to others, it is possible that participants may volunteer this information. In such occurrences, we will follow established protocols used in our prior studies to assess risk level and follow-up appropriately.

Participants will provide their names and addresses or other personally identifying information as part of the study. There is a risk that these data could be unintentionally disclosed to someone not authorized to access the data, compromising the privacy of the participant. To reduce this risk, all contact information for the study participants will be kept in a password-protected location, with access restricted to the Study Coordinators and PIs.

Although we are not directly providing HIV testing, we are providing information on where participants can test for HIV in their locale. Participants who learn that they are HIV-positive or STI sero-positive may be distressed to learn of their health condition. This poses the greatest emotional and physical risk to participants in the research study. Given that our intervention seeks to link YMSM to HIV/STI testing locations, risks of distress are minimized by encouraging YMSM to receive their results at an agency that may offer counseling and referrals.

To minimize the risk of participants feeling uncomfortable about answering personal questions, we will use Computer Assisted Self Interview (CASI) methods for the study's surveys. In a CASI, participants read survey questions on a computer or mobile phone and use a combination of mouse click and keyboard/touchscreen entry to input the answers themselves. Participants will also be able to refuse to answer most questions that make them uncomfortable.

For mystery shoppers who evaluate testing sites, the potential risk will be minimal. There is a risk of untoward events occurring during sessions that may personally affect them. Training and guidance will seek to minimize this risk. Additionally, a post-visit debriefing session with a member of the study team will help ensure any untoward events are discussed and resources are offered that may assist the mystery shopper.

For agency directors who participate in qualitative interviews, the potential risk will be minimal. There is a risk of violation of confidentiality and potential distress when discussing HIV/STI-related issues, but agency directors will be informed of the confidential nature of the research. These interviews will occur via a secure, encrypted teleconference interface (BlueJeans) to maximize security and privacy. We will remove all identifying information from quotes (agency names, etc.) and if quotes clearly identify an agency, they will not be included in the

presentations of results.

To minimize risks to confidentiality, we will secure study data with all appropriate physical, electronic, and operational protections. Data will be stored in a physically secure environment. All data files will have encryption and strong password protection. Any identifiable data will either be stored on Emory University's secure servers or will be on fully encrypted laptops. CASI surveys and online eligibility screening will take place on an encrypted commercial survey website, SurveyGizmo (http://www.surveygizmo.com/survey-software-features/secure-link/). This site has been used by the investigators for thousands of online surveys with MSM with no data security breaches. Access to data will be on a role-based standard; only those study staff who require access to each type of data to complete their study-related roles will be allowed access. All study staff will be trained in security and confidentiality procedures, and will sign a confidentiality agreement before receiving access to any participant data.

We will also develop procedures to minimize indirect disclosure that a participant is participating in an HIV- related research study, or a study that enrolls MSM. For each mode of contact information, we will ask specifically whether anyone else potentially has access to that mode of communication, and if it is acceptable to leave a non-specific message about participation in a health study. No study-related messages will ever mention HIV prevention or the nature of the research study. Additionally, all scripts for email, text message, and telephone contact with participants will be reviewed and approved by the UNC IRB before being used for contact with participants.

We use SSL encryption for transfers of information online, and SurveyGizmo has a business partner HIPAA agreement with Emory. SurveyGizmo’s servers are HIPAA compliant.

The Analytic Core will use Dedoose software to perform all qualitative analyses. Dedoose is a web-based application for organizing and analyzing textual, audio, and video data (qualitative) along with outstanding functionality for their integration with survey, test score, ratings, and demographic data (quantitative). Dedoose employs the highest levels of data encryption available for a web application in all data storage, back up, and transmission. Dedoose allows for project specific encryption feature. When using this feature, only Dr. Kate Muessig or her designee will hold the additional encryption key needed to be entered in order to view the project. This gives Dr. Muessig exclusive control over who can view the project under any circumstances.

In addition to a Certificate of Confidentiality, we will protect participants in the following ways (which correspond to the potential risks described earlier):

1. Breach of confidentiality. We will take every precaution to minimize risks to study participants. All AC research staff members are required to complete ethical clearance certification regarding protection of human subjects through UNC-CH or Emory University. We also have an iTech U19 Data and Safety Monitoring Plan in place to protect participants. Adverse events will be reported to the UNC-CH IRB, individual research PI institutional IRBs and SRV site-specific IRBs per each institution’s IRB reporting requirements using Adverse Event Reporting Forms created by the Analytic Core (AC). When possible, reports will be sent within 24 hours of notification by the PIs. Annual updates on enrollment and retention will also be sent to the IRBs.

All data collection will take place in secure and supervised clinical settings. All study personnel

have completed training and received certification in Human Subjects Research Protection (CITI Program) and HIPAA regulations. They will continue to renew this training in compliance with institutional policies.

11.3.2 Benefits

Participants will be asked about sensitive information, and adequate protections for internet data collection are in place for this study. Participants may benefit from becoming cognizant of their risk behaviors as they discuss HIV/AIDS and STI topics, including circumstances and motivations behind their HIV/AIDS and STI risk behaviors and the potential to reflect on changing behaviors or taking steps to reduce risk. YMSM will have the opportunity to learn their own HIV status and STI results, and to receive information and counseling about how to reduce their future risk of HIV infection. All participants will receive a resource guide listing local HIV/STI/PrEP services, and will have the ability to be linked to care and treatment (for HIV/STI and PrEP services). Furthermore, participation in the proposed study could potentially benefit participants in a few important ways. First, it is possible that the screening, baseline, and follow-up assessments may be beneficial to all participants by asking them to review their risk behaviors. Therefore, these assessments may actually serve as a very minimal intervention (as could any study-assessing risky behaviors). Indeed, YMSM in our prior investigations have commented that they have found the questions to be helpful. Second, all participants in both conditions will receive standard of care and have an opportunity to explore their risk behaviors. Participants will have access to the test locator if they desire to contact community organizations providing HIV/STI/PrEP education, prevention, and care services in their area. In sum, potential benefits for the research far outweigh the risks for the participants.

Others will benefit because the study will result in increased knowledge about prevention interventions to serve those at highest risk for HIV infection, and benefit from a more culturally aware and competent service environment.

Mystery shoppers participating in the training session and site visits may benefit from increased knowledge of HIV, STIs, and testing services. Additionally, they may become more savvy consumers of health care and gain skills around communicating with medical professionals and knowing how to refuse services.

Agency directors participating in qualitative interviews will not benefit personally from participation in the in-depth interviews. However, they may gain some satisfaction in knowing they are contributing to an important HIV prevention research effort and receiving feedback on their agency's performance.

11.4 Institutional Review Board (IRB) Review and Informed Consent

This protocol, the informed assent/consent documents, and any subsequent modifications will be reviewed and approved by the UNC IRB who is responsible for the oversight of the study. The informed assent/consent will describe the purpose of the study, the procedures to be followed, and the risks and benefits of participation.

11.5 Waiver of the Requirement for Signed Consent Form

11.5.1 For Study Participation

For the RCT phase of the study, once a participant is deemed eligible by completing the eligibility screener, he will be presented with the electronic assent/consent form. The assent/consent form will outline the voluntary nature of the study, YMSM's freedom to discontinue the study at any time, approval to retain email addresses for future study opportunities, and the procedures to guarantee their confidentiality. The assent/consent form includes a yes/no checkbox option instead of signature lines. For the Mystery Shopper phase, once a participant is deemed eligible by completing the eligibility screener, he will be presented with a hard copy of the consent form to sign. The assent/consent form will outline the voluntary nature of the study, YMSM's freedom to discontinue the study at any time, approval to retain email addresses for future study opportunities, and the procedures to guarantee their confidentiality. Email addresses of the participants who agree to the content of the assent/consent will be stored in a password-protected file housed within a secure, encrypted sever at the University of Pennsylvania School of Nursing and only available to designated study staff.

11.5.2 For Eligibility Screening

The screening presents minimal risk to participants and involves no procedures that would require written consent outside of a research context. Under these conditions the IRB is authorized to modify the requirements to obtain a signed consent form for some or all participants (45 CFR 46.117 [c]).

Potential participants will enter a link to a website that is listed on recruitment materials and begin by completing a short eligibility screener. If found eligible, participants will then be directed to a page to provide their contact information. For those who do not meet eligibility criteria, there will be an option to provide a first name and email address if they want to be contacted about future studies.

11.6 Prisoner Participation

NICHD has concluded that this protocol does NOT meet Federal requirements governing prisoner participation in human subject research and should NOT be considered by local IRBs for the recruitment of prisoners. Participants enrolled who subsequently become incarcerated or are placed in detention may not continue study participation. Study visits cannot be conducted during the period of incarceration or detention.

11.7 45 CFR Parts 160 and 164 Standards for Privacy of Individually Identifiable Health Information ("Privacy Rule" Pursuant to the Health Insurance Portability and Accountability Act - HIPAA)

Each site is responsible for adherence to their individual institution's HIPAA policies and procedures.

11.8 Study Discontinuation

This study may be discontinued at any time by the UNC IRB, NICHD, or other government agencies as part of their duties to ensure that research participants are protected.

12.0 PUBLICATION OF RESEARCH FINDINGS

Any presentation, abstract, or manuscript will be made available for review by the study sponsor(s) prior to submission.

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