Research Protocol

Linking Young Men who have Sex with Men to Quality Care through a Multilevel Tailored Web App Intervention (Get Connected): Protocol for a Randomized Controlled Trial (ATN 139)

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Abstract
Background: The HIV epidemic among young men who have sex with men (YMSM) is characterized by strong racial disparities and concerns about the availability and access to culturally-appropriate service delivery. Get Connected (GC), an online intervention that employs individual and systems-level tailoring technology to reduce barriers to HIV prevention care (e.g., HIV/sexually transmitted infection [STI] testing, pre-exposure prophylaxis [PrEP]), was developed for young men who have sex with men (YMSM; ages 15 thru 24). This protocol details the design and procedures of a two-phase project that includes mystery shopping and a randomized controlled trial to test the efficacy of Get Connected among YMSM in Philadelphia, Atlanta, and Houston.

Objective: There are two phases of this project: 1) mystery shopping; and 2) a randomized control trial, each for Philadelphia, Atlanta, and Houston. The objective of mystery shopping is to examine the quality of HIV test counseling and PrEP-related referrals for YMSM within local HIV/STI testing sites. The objective of the randomized control trial is to test the efficacy of GC for increasing HIV-negative or HIV-unknown YMSM’s successful uptake of HIV prevention services (e.g., routine HIV/STI testing), PrEP awareness, and likelihood to start PrEP (“PrEP willingness”), as compared to the control condition, over a 12-month period.

Methods: For Phase 1, we will create a master list of HIV/STI testing sites in each city. We will enroll and train 10-15 mystery shoppers per city; each testing site will be visited and assessed separately by two mystery shoppers. After each site visit, mystery shoppers will complete a site evaluation to record their perceptions of various measures including lesbian, gay, bisexual, transgender, and queer visibility and inclusivity, privacy and confidentiality, provider-patient interactions, and the clinic environment. For Phase 2, we will enroll 480 YMSM for 12 months across the three iTech cities into a two-arm prospective randomized controlled trial. Participants randomized to the control condition are directed to the AIDSVu.org testing site locator. Participants randomized to the intervention condition will be granted access to a web application with content tailored to their specific 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). Study assessments will occur at enrollment and one, three, six, nine, and twelve months post-enrollment.

Results: Get Connected research activities began in September 2016 and are ongoing. To date, IRB submission is complete and IRB Authorization Agreements are pending at several other Universities.

Conclusions: The deployment of Get Connected through a mobile-optimized Web app seeks to optimize the intervention’s acceptability, accessibility, availability, and long-term affordability among youth.

Trial Registration: ClinicalTrials.gov (NCT03132415); University of North Carolina at Chapel Hill Institutional Review Board (16-3183)

Keywords: HIV Infections; Adolescent; Internet; Young Adult; Community-Based Participatory Research
Introduction

Young men who have sex with men (YMSM) now account for 72% of new HIV infections among people ages 13-24, and 30% of all new infections among MSM.[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] Among the drivers of the HIV epidemic among YMSM are large numbers of HIV positive youth who are not virally suppressed or are not aware of their serostatus.[3] Increasing HIV testing among YMSM is thus a public health priority.[4] The success of the National HIV/AIDS Strategy’s test and treat approach rests on the ability to increase the number of YMSM that are receiving routine testing.[5] Getting tested is the cornerstone of almost all prevention approaches and the gateway to both biomedical prevention tools (e.g. pre-exposure prophylaxis [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) requires that YMSM overcome a series of multilevel 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, stigma) levels.[6-12] Strategies to promote HIV/sexually transmitted infection (STI) status awareness among YMSM requires the creation of interventions that are culturally sensitive to the psychosocial needs of YMSM [13] and facilitate access to comprehensive sexual health services.[14]

HIV prevention tools that are culturally and developmentally appropriate for YMSM are needed.[1, 7, 15, 16] 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 updated to be contextually responsive over time, particularly as YMSM become sexually active, meet new partners, and/or engage in different risk behaviors. 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.[19]

Researchers and practitioners have sought to encourage routine HIV/STI testing by creating online tools that provide the location of testing centers in a given geographic area (i.e., testing 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;[20]) however, there are limited data examining the quality and adequacy of these listed sites for YMSM. This is concerning for several reasons, as it is expected that testing agencies are youth and LGBTQ friendly, but there is little empirical evidence to support this assumption, and in fact evidence to support the contrary.[21-25] Using a mystery shopper methodology to evaluate the LGBTQ cultural competency and quality of services offered in HIV and STI testing sites in Southeast Michigan (n=47 testing sites), we assessed the sites across 13 domains, including the clinic’s structural characteristics, and the test counselors’ compliance with the Centers for Disease Control and Prevention (CDC) HIV testing and counseling protocols.[6] After the mystery shopping assessment, we sent each site a letter describing our process and encouraged them to schedule a meeting with us to discuss the shoppers’ experiences at their agency. Agency staff was eager for the feedback and technical assistance; sixty-six percent of the sites requested to meet. In these meetings, we offered a packet
of personalized results, summarizing how they compared on various quantitative indicators to other sites, and provided feedback from the open-ended portion of the evaluation. Several agencies noted that the report from the site evaluation would help focus their efforts and address identified areas for improvement.

**Theoretical framework for intervention.** Building on the efficacy of the CDC’s Project Connect Health Systems Intervention to link heterosexual adolescents to competent comprehensive sexual health care services,[26] 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 Web app seeks to optimize the online intervention’s acceptability, accessibility, availability, and long-term affordability among youth [4, 7, 17]. Using a consensus approach [27] to conceptualize health behavior change, the model guiding GC synthesizes The Integrated Behavioral Model [28] and Self-Determination Theory [29, 30] as the theoretical underpinnings of our intervention. Consistent with these theories,[31, 32] GC content follows motivational interviewing principles [32-34] by focusing on resolving ambivalence about HIV prevention behaviors, increasing self-efficacy for change, and enhancing motivation moving toward action. GC participants are then recommended high-performing sites based on mystery shopper scores.

Participants in the pilot trial were randomized to receive the full GC intervention or an attention-control condition. Data [35] from this pilot RCT (N=130 YMSM; ages 15-24) indicated high acceptability and feasibility (80% retention) 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
Participants who received the GC intervention reported that the testing site information was more accurate than those in control condition. For all other acceptability items, the GC intervention was equally or slightly better received than the control condition. More than 90% of participants reported that the GC intervention had been useful to identify a HIV/STI clinic that met their needs. We identified one incident HIV-positive case and two STIs (herpes and chlamydia) over the 30-day study period.

As a step towards filling the current gap in efficacious online interventions for HIV prevention and care among YMSM, we propose to implement and test the efficacy of Get Connected 2.0 across three iTech cities heavily impacted by HIV: Philadelphia, Atlanta and Houston. This protocol describes the methods for the testing of the intervention.

Methods

**Trial Registration, Ethics, Consent and Institutional Review Board Approval**

The research and ethics presented in this study has been reviewed and approved by the University of North Carolina at Chapel Hill Institutional Review Board (16-3183). A Certificate of Confidentiality has been obtained from the National Institute of Child Health and Human Development and a waiver of parental consent/assent will be obtained for participants who are 15-17 years old. The study is also registered on ClinicalTrials.gov (NCT03132415).

**Phase 1: Mystery Shopping**

**Design**

We will enroll mystery shopping participants (10-15 mystery shoppers per city) to conduct the mystery shopper assessment in three iTech cities: Philadelphia, Atlanta and Houston. This approach follows best practices suggesting that youth involvement is vital when designing relevant and appropriate HIV interventions for the target population. We will work with iTech
subject recruitment venues (SRV) in each city to recruit and enroll HIV-negative YMSM (ages 18-24) who are interested in serving as mystery shoppers. We will apply a multi-modal recruitment strategy, including ads in online LGBTQ listservs, flyers in HIV/AIDS community-based organizations, local coffee shops and bars, college listservs, and online advertisements on social media sites such as Facebook.

Mystery Shopper Participants

Eligible mystery shoppers are those assigned male sex at birth and currently identify as male; they must be 18-24 years old (inclusive) at time of screening, self-report as HIV-negative, speak and read English, live in Philadelphia, Atlanta, or Houston, able to travel to and from HIV/STI testing sites, report same-sex attraction, and have access to the internet via a computer or smartphone.

Sample size

We will recruit and enroll 10-15 Mystery Shoppers per city. Each participant can visit up to 10 unique testing sites in their city, with two mystery shoppers visiting each testing site, separately. Testing sites will be identified in collaboration with each city’s health department and by crosschecking sites with AIDSVu.org. We will employ a stratified purposive sampling strategy to ensure age and racial/ethnic diversity across mystery shoppers. Of the 10-15 mystery shoppers per city, 5 to 8 will be aged 18-20 (2-3 Black/African American, 2-3 White, and 1-2 Hispanic/Latino) and 5 to 8 will be 21-24 (2-3 Black/African American, 2-3 White, and 1-2 Hispanic/Latino).

Incentives

Mystery Shoppers will receive a maximum of $600: $100 for attending the one-day training session and $50 for each testing site visit (10 maximum site visits).
**Procedures**

Once mystery shoppers are consented and enrolled, they will attend a one-day training at the iTech SRV where they will learn about the fundamentals of HIV/STI transmission, the guidelines and protocols surrounding HIV/STI testing and PrEP eligibility, and how to use the online site assessment survey to evaluate their site visits. State-specific guidelines and policies will also be discussed in each city. Additionally, they will receive training to strengthen their self-efficacy to feel empowered as a client. Specifically, we will conduct role-plays with 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. 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.

Study staff will create and use a secure database to manage mystery shoppers, site assignments, and testing schedules. Upon completion of the one-day training, study staff will assign mystery shoppers a specific day and time for their initial testing site visit. Mystery shoppers will report to the iTech SRV before each scheduled site visit to check in with a staff member and receive their site assignment. They will be loaned a smartphone equipped with a car share application to use for travel to and from testing sites. All car share trips will be tracked and paid for by the study so no transportation costs will be incurred by mystery shoppers.

Once at the testing site, mystery shoppers will state they have no income or health insurance, nor do they possess any proof of identification. In so doing, we will able to ascertain whether these would be potential barriers to testing at a given location and ascertain the lowest possible fees that would be charged to YMSM. As in the original study [35], we will reimburse
mystery shoppers for any charges linked to their testing experiences. Upon completion of a
testing visit, mystery shoppers will use the smartphone’s car share application to travel back to
the iTech SRV. They will complete the site assessment survey on the smartphone or on a
computer at the iTech SRV. Smartphones will be returned to study staff upon return to the SRV.

The site assessment survey will record shoppers’ perceptions of their testing experience,
specifically: LGBTQ visibility, medical form inclusivity, the clinic environment, privacy and
confidentiality, PrEP information and dialogue, patient-provider relationship context, patient-
provider counseling, safer sex education, perceived provider competency, and participant-
provider interactions (Table 1). Shoppers will also have the opportunity to leave qualitative
feedback in an open text field if they wish to explain any of their responses, or record any other
information pertinent to their experience that the quantitative assessment did not already capture.

Table 1: Clinic and provider interaction visits to be recorded by mystery shoppers
*Figures in parenthesis are Cronbach Alpha scores for validated scales

<table>
<thead>
<tr>
<th>Clinic characteristics</th>
<th>Provider exchanges</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Session speed (min)</strong></td>
<td><strong>Relationship context (α = 0.59)</strong></td>
</tr>
<tr>
<td>LGBT visibility (α = 0.84)</td>
<td>The provider asked me about my sexual orientation</td>
</tr>
<tr>
<td>Clinic has symbols aimed at LGBT people (e.g., equal sign, rainbow flag)</td>
<td>The provider asked me about my relationship status</td>
</tr>
<tr>
<td>Clinic has printed materials (e.g., brochures) aimed at LGBT people</td>
<td>Provider asked if I experienced intimate partner violence</td>
</tr>
<tr>
<td>The clinic has LGBT welcoming symbols</td>
<td><strong>Counseling session (α = 0.76)</strong></td>
</tr>
<tr>
<td>Medical Forms (α = 0.59)</td>
<td>The provider explored my motivation for testing</td>
</tr>
<tr>
<td>Clinic uses LGTB-inclusive language on medical forms</td>
<td>The provider offered help to me set goals</td>
</tr>
<tr>
<td>Clinic uses transgender-inclusive language on medical forms</td>
<td>The provider offered to help me set action steps to meet safer sex goals</td>
</tr>
<tr>
<td><strong>Clinic environment (α = 0.76)</strong></td>
<td>The provider offered risk reduction options</td>
</tr>
<tr>
<td>The office staff were generally friendly</td>
<td>The provider’s recommendations were valuable</td>
</tr>
<tr>
<td>The office staff were not LGBTQ sensitive, (reverse-coded)</td>
<td><strong>Safer sex education (α = 0.88)</strong></td>
</tr>
<tr>
<td>I felt uncomfortable in the waiting room, (reverse-coded)</td>
<td>Provider made sure I knew how to use a condom</td>
</tr>
<tr>
<td>Clinic used LGTB-affirming language when speaking to me</td>
<td>Provider helped me identify a condom that works for me</td>
</tr>
<tr>
<td><strong>Privacy and confidentiality</strong></td>
<td>Provider helped me identify a lube that works for me</td>
</tr>
<tr>
<td>The clinic staff kept patient information confidential</td>
<td>Provider discussed PrEP as a prevention strategy with me</td>
</tr>
<tr>
<td>Interactions between clients and staff were kept private</td>
<td><strong>Perceived provider competency (α = 0.63)</strong></td>
</tr>
<tr>
<td>The provider explained confidentiality (either verbally or via a document)</td>
<td>The provider appeared knowledgeable about HIV/STIs</td>
</tr>
<tr>
<td><strong>PrEP-specific indicators</strong></td>
<td><strong>Negative provider interactions (α = 0.89)</strong></td>
</tr>
<tr>
<td>The Clinic had information about PrEP</td>
<td>The provider made me feel comfortable, (reverse-coded)</td>
</tr>
<tr>
<td>The Clinic offers PrEP or PrEP-referrals</td>
<td>I felt pressured by provider to adopt specific risk reduction options</td>
</tr>
</tbody>
</table>

In addition to the site assessment survey, mystery shoppers will complete a secure video
chat session with study staff to discuss their testing experience and have the opportunity to share
any adverse interactions. These video chat sessions will not be recorded; their purpose will be to
ensure mystery shopper safety and prevent subsequent mystery shoppers from being exposed to a site reported to be risky or unsafe (physically or emotionally). Following the video chat session, mystery shoppers will be given their incentive for the visit and will schedule their next visit with study staff before leaving the iTech SRV.

Outcomes

Mystery shoppers’ site assessment scores will be aggregated for use in Phase 2 of the research activities, the RCT to test the efficacy of Get Connected. Specifically, the scores for each site will be averaged and embedded in the intervention condition of the GC Web app: when participants search for testing sites they will only see sites that rank in the top 50% for that city, sorted from highest to lowest ranking.

Phase 2: Randomized Control Trial

Design

The research activities involve a two-arm prospective RCT enrolling 480 HIV negative or status unaware YMSM (aged 15-24 years), with the aim of maintaining a randomized sample of approximately 400 online-recruited YMSM over 12 months. After assent/consent and completion of a baseline survey, YMSM are randomized to either the control or intervention condition (intervention, n=240; control, n=240). Participants randomized to the control condition will be directed to the AIDSVU.org testing site locator. While the provision of a test locator is a low intensity 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 existing testing site locator only, we will still be able to test the effect of GC (i.e., user-tailored content focused on HIV/STI testing and PrEP referral, and the
linkage to high-quality agencies). Online study assessments are conducted every three months across the intervention and control conditions, with a total follow-up period of 12 months. At the end of the RCT, we will make the intervention accessible to YMSM in the control condition.

**Intervention**

The GC intervention was developed by customizing content based on YMSM’s psychosocial and sexual profiles (e.g., sociodemographics, 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 using mystery shopper scores. Participants across both conditions who have been tested will be asked to rate their visit at their quarterly follow-up assessment using the same mystery shopper criteria. Sites then receive biannual summaries, including the aggregated user reviews and brief technical assistance reports, to help sites understand their performance based on quality assurance evaluations from YMSM clients, and optimize service delivery if needed.

For participants in the intervention condition, the tailored Web app has four sections of content: “What,” “Why,” “How,” and “Where.” The “What” section is split into three pages: “Facts,” “STIs,” and “Tests.” On each of those pages, topics are displayed in boxes that are randomly organized and open to display additional information if the user clicks/presses. The Facts page (Figure 1) displays boxes that contain general prevention facts (e.g. “You won’t always know if someone has an STI.”) relevant to this population. On the STI page, if a participant clicks “chlamydia,” for example, additional information about chlamydia appears, 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 Tests page displays boxes with each HIV/STI testing method (e.g. blood test, swab test, urine test), and each contains more specific information (e.g. what STIs it tests for, steps for the test) upon click/press. Figure 1. Facts page.

The second section focuses on the “Why,” on two pages: “Values,” and “Pros and Cons.” The basic design and functionality is the same as described above in the “What” section. The Values page (Figure 2) 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 then presented by linking participants’ values from the baseline survey (e.g., being attractive, being religious, being sexy, being loved, being athletic, etc.) to the desired outcomes. For example, a participant who indicated he valued being religious may see a message that says, “Finding strength in your faith. Your religious beliefs are important to you. Getting tested is one way to take care of, and honor, the body that you’ve been given. How might you draw on your faith to find strength to get tested?” The Pros and Cons page presents information on the perceived benefits and barriers of getting tested and of not getting tested. Figure 2. Values page.
The third section is about the “How” of testing and includes pages on potential “Barriers” to getting tested and “Supports” that may help a participant decide to get tested. Barriers (Figure 3) include issues like financial costs, social norms, and prioritization, which may affect participants’ desire to get tested for HIV/STIs. Supports has information on how their strengths and social support systems can help them make a choice about testing. Recognizing that barriers and supports may shift over time, content on these pages is tailored to identify the most recent barriers and supports as indicated by YMSM in their most recent survey.

Figure 3. Barriers page.
The final section is the “Where” of testing and includes a page where a user can “Customize” their search for nearby testing sites (Figure 4) and a “Your Sites” page that displays testing sites based on that customization. Participants can customize their search based on many clinic characteristics, including whether walk-in appointments are available, if they have weekend hours, and if they accept insurance. The “Your Sites” page is a listing of providers
(including contact and location information) based on the participant’s customization selections. Testing sites are initially ranked using an algorithm that accounts for each site’s average mystery shopping scores. These scores are updated as participants get tested and rate sites over the twelve-month study period. Participants can choose sites they may want to visit and then have the site information emailed or texted to them. Along with any site a participant emails or texts to themselves, they will be provided with seven questions they 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.

Figure 4. Customization page.
Participants

Eligible participants will be those assigned male sex at birth who currently identify as male, 15-24 years old (inclusive) at time of screening, have had consensual anal sex with another man in the past 6 months, self-report as HIV negative or unsure of their HIV status, have access to a computer or smartphone, can read and speak English, and live within the city limits of Philadelphia, Atlanta, or Houston.
**Sample Size**

Our target enrollment across both conditions is N=480 (GC, n=240; Control, n=240). This number allows for 20% loss to follow-up and a final analytic sample of 400 MSM across the three cities. Participants may continue the study even if they miss assessments intermittently over the data collection period. We will compare those who completed different follow-up assessments with those who did not on key predictors from the baseline assessment to check for possible bias due to missing data and informative censoring. When appropriate, we will use Expectation-Maximization (EM) algorithm-based imputation methods in our analyses [36, 37].

The primary outcomes for the proposed trial are successful uptake of HIV prevention services (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 control arm. For STI testing, we define it as receiving at least one STI test. 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 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. For mean differences across continuous outcomes (e.g., PrEP willingness), our sample size calculations are based on a two-sample t-test, assuming equal variance using a two-sided significance level of 0.05. We are able to detect a between-arm effect size difference of $d=0.25$ at the final follow-up time point at 80% power. For repeated measures analyses, assuming a within-person correlation of 0.25, we would
be able to detect an effect size of 0.08. A less favorable within-person correlation of 0.75 allows us to detect an effect size of 0.11.

*Incentives*

Participants can earn up to $155 total: Baseline survey = $20, month 1 survey = $20, month 3 survey = $25, month 6 survey = $30, month 9 survey = $30, and month 12 survey = $30.

*Randomization*

After assent/consent and completion of the baseline survey, YMSM are randomized by city 1:1 to either the control or intervention condition (intervention, n=240; control, n=240) [38]. The stratified randomization process occurs upon completion of the baseline survey.

*Outcomes*

*Primary outcomes*

The primary outcomes relate to the successful uptake of HIV prevention services among our sample of self-reported HIV negative or serostatus unaware YMSM. We consider three prevention outcomes: HIV testing, STI testing, and PrEP awareness and willingness.

*HIV testing*

The baseline survey will include questions on lifetime HIV testing history. Follow-up surveys will repeat the questions from the baseline, and will also include questions on HIV testing in the prior 3-month period, including test results. The HIV testing outcome will be: the proportion of MSM tested for HIV two or more times at least three 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.
**STI testing**

The baseline survey will include questions on lifetime testing history of gonorrhea, chlamydia, and syphilis, as well as questions about ever having an anal pap smear or vaccinations for Hepatitis A, and B, human papilloma virus, and meningitis. Follow-up surveys will repeat the questions from the baseline, but will ask about STI testing behavior in the prior 3-month period, including test results if a participant indicates they received a test. The STI testing outcome will be: the proportion of MSM tested for any STI two or more times at least three 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 STI test.

**PrEP awareness and willingness**

The survey will contain a brief description of PrEP to orient the participant. Most questions were adapted from recent studies of PrEP attitudes with YMSM [39-42]. PrEP awareness will be a single item measure of whether the participant has heard of PrEP [40]. For participants who do not report current PrEP use, PrEP willingness will be assessed by asking how likely the participant would be to start PrEP in the next three months and the reason(s) why the participant is not currently taking PrEP (e.g., never heard of PrEP; worried about side effects; lack of support from friends or family).

**Secondary outcomes**

As secondary outcomes, we will examine uptake of PrEP, changes in sexual risk behavior, and the linkage and retention in care among newly diagnosed HIV+ cases. While we expect a small number of newly diagnosed HIV infections, we will measure initiation of antiretroviral therapy (ART) and self-reported adherence as a secondary outcome. We are not
powered to measure differences in engagement in HIV care across trial arms, so we include this as an exploratory analysis.

**Mechanisms of change**

Consistent with our theoretical framework, we will assess YMSM’s psychosocial correlates predicting adoption of HIV services (i.e., attitudes, norms, self-efficacy and behavioral intentions to get HIV tested). Integrated Behavioral Model constructs will be assessed with subscales assessing YMSM’s attitudes, social norms, and behavioral intentions [43] that we have used in the past with this population [44]. Social norms assess the extent to which participants feel that friends and family believed the participants should test for HIV. Behavioral intentions items assess participants’ intention to adopt HIV testing. Self-efficacy to access HIV/STI services and to discuss sexuality-related issues with partners and provider will be ascertained.

**Uptake of PrEP**

At each follow-up assessment, PrEP-eligible (per CDC guidelines), HIV-negative YMSM will be asked whether they have begun using PrEP [40]. YMSM who report using PrEP will be asked to report their adherence to PrEP.

**Sexual risk behavior**

Sexual risk behavior will be assessed using the Sexual Practices Assessment Schedule used in previous online studies with YMSM.[45, 46] This assessment will 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 three months, and knowledge about partners’ HIV status and PrEP use. Assessments ascertain sexual behaviors with male partners, and will be conducted at baseline and each follow-up. At-risk sex will be defined as any anal intercourse without condoms or PrEP.
with a person of known positive and detectable viral load, or a person of unknown serostatus during the follow-up period. We will assess the number of partners with whom participants had “at-risk sex,” as well as estimate the incidence of at-risk sex acts (i.e., incidence density: the numerator being number of at-risk sex acts and the denominator being person-years of follow time).

**Linkage and retention in care among newly diagnosed HIV+ cases**

Among newly diagnosed HIV+ cases, we will measure participants’ linkage and engagement with appropriate medical care after initial diagnosis, using criteria employed in prior ATN protocols with youth.[47-50] 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.[49] Onset of ART initiation, self-reported adherence to ART, and viral suppression are exploratory indicators,[48] as we recognize that our follow-up period may not be a sufficient amount of time to see these changes.

**Covariates**

We will also measure the following constructs as potential predictors and/or moderators in our analyses.

**Socio-demographic information**

We will include questions on participants’ race/ethnicity, educational attainment, employment status, place of birth, housing status, and history of incarceration, sexual identity, and “outness” to their social network.

**Site evaluations**

Across both trial arms, YMSM who report testing in the prior three months will complete site assessments of their testing experiences to measure comfort, quality, and concerns after
visiting a site for HIV/STI testing. The site assessment form is the same form used by the mystery shoppers. We will use these assessments to send aggregate data of YMSM’s satisfaction with services to agencies biannually.

**Substance use and psychological distress**

Previous studies have demonstrated higher vulnerability to HIV risk behaviors and engagement in prevention and care among YMSM who report ATOD (alcohol, tobacco and other drug use) and psychological distress; therefore, we will measure both ATOD and psychological distress as potential effect moderators.

We will assess frequency of ATOD use (as measured in the National Survey on Drug Use and Health) over the past three months in the baseline survey and follow-up surveys for alcohol, tobacco products, marijuana, non-prescription drugs, cocaine, amphetamines, inhalants, opioids (including heroin), hallucinogens, and depressants [51]. If respondents indicate any ATOD use within the past three months, we will ask for each substance how often the substance was used and if it was used immediately before or during sex.

We will measure psychological distress using existing, well-validated scales: the Patient Health Questionnaire-8 (PHQ-8) [52] and the 7-item Generalized Anxiety Disorder (GAD-7) [53] scale. We will use the first two items from each scale to screen participants for symptoms of depression and anxiety (PHQ-2 [54] and GAD-2 [55]). Participants who report depressive symptoms (score of three or more on PHQ-2) will be asked the last six items from the PHQ-8. Participants who report symptoms of anxiety (score of three or more on GAD-2) will be asked the last five items from the GAD-7.

**Intervention acceptability**

At each follow-up, participants will report on the acceptability of their assigned study arm. We will use the Systems Usability Scale [56] 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 from the intervention, including counts of user sessions, length of sessions, 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.[57]

**Technology & social media**

We will include Pew Internet Survey questions [18] regarding use of different devices, the number of hours spent online through each device, reasons for social media use, sites commonly frequented, and extent to which the Internet supplements face-to-face interactions. We will also measure participants’ frequency of social media use to look for HIV or sexual health-related information,[44, 58] and their online partner-seeking behaviors.[59, 60] We will ask these questions at each follow-up except the 1-month follow-up. We will also use the eHealth Literacy Scale (eHEALS) [61] to assess participants’ perceived ability to use the internet to find health resources.

**Statistical Analysis**

Descriptive statistics of the psychosocial and demographic characteristics of the participants will be used 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 (HIV testing, STI testing, and PrEP awareness and willingness) 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). 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, sexual risk behaviors, sexual risk behaviors, PrEP uptake).

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 are count, and some continuous traits and thus need to be treated differently. The general form of the GLMM will be $g(\mu_{ij}) = \beta_0 + \beta_{\text{cov}} \cdot \text{cov} + \beta_{\text{Time}} \cdot \text{Time} + \beta_{\text{Arm}} \cdot \text{Arm} + \beta_{\text{Arm x Time}}$, where $\mu_{ij}$ 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); $Tr_{ti} = 1$ if the i-th subject is in the intervention group and 0 if the i-th subject is in the control group. The interaction coefficients $\beta_{Tr X Time}$ 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 $\beta_{0i}$ 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 criteria such as Akaike Information Criterion (AIC), Bayesian Information Criterion (BIC). For some binary outcomes, such as 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 follow-up 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 conduct exploratory regression analyses to examine regional differences. These regressions will be run with group assignment and region in the model, controlling for socio-demographic characteristics. Interactions between group assignment and region will be tested to explore potential site-specific moderators of treatment effect.

As a secondary analysis, we will build on our GLMM framework to examine whether the intervention effects in the theoretical mediators (e.g., attitudes, norms, and self-efficacy) 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.

Cost analysis

In order to inform the eventual scale-up of GC, we will also conduct a cost analysis of GC as compared to the control condition to inform discussions of sustainability and roll out of the GC intervention. We will collect information on costs associated with the delivery of the intervention. No costs associated with research data collection will be included. These components of cost will be summed over the 12-month study period for each participant to generate an estimated per person cost. Effectiveness will be measured by examining HIV-related outcomes reported by YMSM over the 12-month period. Incremental cost effectiveness ratio (ICER) across treatment arms will be defined as $\Delta C/\Delta E$, where $\Delta C$ denotes the estimated
difference in mean cost of the intervention and $\Delta E$ reflects the estimated difference in mean effectiveness between the intervention and control group. Non-parametric bootstrap resampling will be used to estimate the 95% confidence interval of ICER.[62] Analysis will be performed on participants with complete data. Sensitivity analysis will be conducted by including all participants with multiple imputations for those with missing data.

**Qualitative assessment of testing sites’ satisfaction**

We will qualitatively assess testing sites’ satisfaction with the biannual performance assessments and their improvements in service delivery when working with YMSM across the three regions. Ten site directors will be randomly selected from testing sites in each city. Eligible participants will be able to read and speak English and serve as the site director of an HIV/STI testing site in Philadelphia, Atlanta, or Houston. We will conduct semi-structured qualitative in-depth interviews (60-90 minutes) that focus on four 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 performance assessments and their use for service-delivery improvements, and (4) the advantages and disadvantages of GC rollout within AIDS Service Organizations.

Interviews will occur via teleconference to maximize candidness and privacy while decreasing travel-related costs. We will use VSee, a simple and low-cost video-chat platform that requires no server infrastructure to set up or maintain and allows providers to be HIPAA-compliant. Interviews will be audio-recorded to allow for verbatim transcription, then checked for accuracy and completion. 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 during the iterative analysis process. Throughout, we will discuss emerging themes, resolve difficulties or concerns that may arise, and adapt the codebook as necessary.

Since we seek 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.[63] Although our analysis will rely primarily on a phenomenological inductive approach, we will also employ aspects of deductive analysis that consider our guiding conceptual framework. This combination of analytic strategies will enable 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.[64-66]

**Results**

Get Connected research activities began in September 2016 and are ongoing. IRB submission is complete, with IRB Authorization Agreements being finalized across the participating universities and SRVs.

**Foreseeable challenges**

There are several potential challenges to the success of the proposed activities. First, we did not include biological measures (e.g., presence of HIV/STI), as we would have to dramatically increase our sample size to detect significant effects in biomarkers among newly diagnosed HIV/STI cases. Second, we propose to recruit a diverse (in terms of race/ethnicity and age) sample of 15-24 years-old. It is possible that we may experience more success in recruiting YMSM at the older ages of this range (i.e. >18 years old). To counteract this, we will include a broad range of social media outlets in our recruitment, allowing us the potential to recruit our full
age range. Collectively, the team has vast experience of recruiting youth into HIV research efforts and substantial experience in recruiting online samples of urban race/ethnic minority YMSM. Third, we are unable to untangle race from Latino ethnicity, as it would require a much larger sample size to examine race by ethnicity subgroup differences. Because we propose to quota sample across race/ethnicity in each of the regions, the breakdown of Latino race would create some small sample sizes. Finally, we recognize that socioeconomically disadvantaged participants may require access to a computer or secure Wi-Fi connection to participate fully in the study. YMSM who are interested in participating but require access, or who prefer to complete assessments at a study location, will be able to complete intervention activities at their local iTech SRV.

Discussion

With increasingly promising evidence of the efficacy of biomedical prevention tools, such as PrEP, for reducing risk of HIV infection among MSM [39, 40, 67-70], there is increased attention to the potential for HIV testing to act as a gateway to other HIV prevention tools and care efforts.[71, 72] 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 should be considered a priority time for intervening on cognitive and behavioral risks for HIV, while also introducing YMSM to HIV testing as a gateway to other HIV prevention options.

Efforts to encourage and motivate YMSM to engage in repeat HIV/STI testing or to adopt other prevention efforts (e.g. PrEP [39, 40, 67]) 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.[10, 73, 74] HIV prevention tools must be designed to help YMSM overcome a series of multilevel barriers at the individual (e.g., risk awareness), systems (e.g., costs, lack of culturally competent care), and structural (e.g., homelessness, stigma) levels. Developing strategies to promote the use of HIV prevention services among YMSM requires the creation of interventions like GC that are culturally sensitive to their psychosocial needs,[13] and facilitate access to comprehensive sexual health services.[14] If proven efficacious, GC has the potential to fill a gap in HIV prevention 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.

Acknowledgements

This work was supported by the NIH Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN 139; MPI: Bauermeister & Stephenson) as part of and the UNC/Emory Center for Innovative Technology (iTech; PIs: Drs. Hightow-Weidman/Sullivan, 1U19HD089881). The content is solely the responsibility of the authors and does not represent the official views of the funding agencies.

The authors would like to thank Adi Ferrara, MS, ELS, for help in the preparation of this manuscript.

Conflicts of Interest

None declared.
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