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Development of a Tailored HIV Prevention Intervention for Young Men

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SUMMARY

Surveillance estimates indicate an alarming resurgence of new HIV/AIDS cases among young men who have sex with men (YMSM) between the ages of 18 and 24. Online interventions are a promising modality given their appeal among youth, ability to deliver a customized experience (i.e., tailoring) based on users' behaviors and context, and capability to be diffused across numerous geographic locations^{1,2}. **Single YMSM, in particular, may be at great risk for HIV/STI infections as they are more likely to report multiple partners than YMSM in relationships.** Although MSM couples interventions are underway and may reduce the spread of HIV/STIs in their relationships, these findings may not be translatable to single YMSM who, by definition, are not in a relationship and do not have a "main partner". Single YMSM must learn how to employ different condom negotiation skills and risk reduction strategies with different partners, regardless of whether said partner turns out to be "Mr. Right" or "Mr. Right Now"^{3,4}. We have documented that single YMSM may require skills to discern between partner types, respond to relationships as they evolve (e.g., perceive that a casual partner is interested in a romantic relationship) and select adequate risk reduction strategies for each partner type. While we acknowledge partner-specific variation in YMSM's sexual risk-taking behaviors⁵⁻¹⁰, we have yet to develop an *online* intervention whereby single YMSM may learn how to date and select appropriate HIV/AIDS risk reduction strategies for different sexual partnerships^{11,12}. **Therefore, we will develop and pilot test an online intervention focused on helping single, HIV-negative YMSM who report recent (prior 6 months) unprotected anal intercourse (UAI) to develop skills for same-sex dating and relationship building, while also reducing their HIV risk through the promotion of risk reduction strategies (e.g., consistent condom use, fewer UAI partners, HIV/STI testing).**

Our intervention is informed by a dual processing cognitive-emotional decision-making framework¹³. Given its efficacy in predicting behavior and its prior use to develop HIV interventions¹⁴, we expand the Theory of Planned Behavior (TPB¹⁵) to account for affective motivations. As prior research has noted, individuals who experience tension between their affective and cognitive motivations report less correspondence between their intentions and behavior. Thus, we acknowledge that YMSM's affective motivations may be health promotive (e.g., relationship ideation) or risk enabling (limerence, decisional balance to forego condoms), and may influence risk reduction efforts¹⁶⁻¹⁸. Consequently, in our intervention sessions, we will address how affective motivations may influence YMSM's decision-making regarding consistent condom use, number of UAI partnerships and occasions, and HIV/STI testing behavior. YMSM will have opportunities to then practice affect-regulating skills through interactive role plays that allow them to (1) increase their self-efficacy to engage in risk reduction practices across different settings, (2) reflect on their partner-seeking behaviors and develop sexual-decision making rules to reduce the dissonance between affective and cognitive motivations, and (3) reinforce behavioral skills with different partner types.

We will develop and test a 6-session online intervention for single YMSM who report recent UAI. To maximize appeal and appropriateness, we will convene a youth advisory board (YAB) to provide insight and feedback throughout the three phases of the development process¹⁹. In Phase 1, we will collaborate with our YAB to develop tailored content that promotes YMSM's risk reduction behaviors by helping them address tension that may arise between cognitive and affective motivations. After developing both the tailored intervention (MEET-ME) and the attention-control non-tailored HIV prevention (NTHP) intervention, Phase 2 will then focus on refining the interventions through usability testing with a small group of YMSM (N=16) in preparation for conducting a small pilot randomized controlled trial (RCT). We will conduct a pilot RCT in Phase 3 comparing MEET-ME (N=120) to NTHP (N=60) to collect feasibility, acceptability and preliminary efficacy data at 30, 60, and 90 day follow-ups. **We propose 3 Specific Aims (SA):**

SA 1. To develop a tailored (MEET-ME) and a non-tailored (NTHP) HIV/AIDS prevention intervention focused on addressing the partner-seeking behaviors of single YMSM (ages 18-24).

SA 2. To conduct usability testing of the MEET-ME (N=10) and NTHP (N=6) interventions and collect preliminary data on the feasibility, acceptability, and intervention content in preparation for a small pilot randomized control trial (RCT).

SA 3. To test a small pilot RCT of the refined MEET-ME (N=120) intervention as compared to the NTHP (N=60) intervention, in order to evaluate its feasibility and acceptability and gather preliminary efficacy results

NCT02842060

in promoting HIV risk reduction behaviors (e.g., consistent condom use, decreased UAI partners and occasions, and more HIV/STI testing).

SIGNIFICANCE

Interventions specific to YMSM are needed to curtail the rise of new HIV/AIDS infections. More than 60% of all new HIV infections are transmitted through sexual contact among MSM²⁰. In 2010, YMSM accounted for 72% of new infections among people ages 13 to 24, and 30% of all new infections among MSM²⁰. Consistent with the National HIV/AIDS Strategy for the United States' call to reduce new HIV infections by intensifying prevention efforts in highly-impacted communities²¹, we propose an intervention that promotes HIV prevention behaviors (e.g., condom use, reduction in number of unprotected anal intercourse (UAI), HIV/STI testing) among single YMSM reporting recent UAI in the prior 6 months.

At present, there are few efficacy-tested online HIV prevention interventions for YMSM. 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 format creates difficulties for YMSM when they cannot easily access these EBIs in their communities, are not able to attend the sessions when they are offered, and cannot choose to engage with the interventions' content when most convenient. Increasingly, YMSM report their desire to access comprehensive sexual education through the Internet^{22,23} given their increased use of social media in day-to-day interactions and the ease of accessing needed information at the desired time through tablets, laptops, and smartphones. Collocating online interventions is also important as YMSM often rank the web as their top resource to explore their sexuality, learn about MSM behavior, and refine their interests²⁴⁻²⁶.

Web-delivered HIV prevention interventions present a number of advantages. They can offer tailored content specific to each user's HIV/AIDS risk behaviors and context. Content can be accessed from any location convenient to a participant and can be standardized, ensuring higher intervention fidelity. Furthermore, material can be presented through interactive features, and crucially, web-delivered interventions can be implemented by community-based providers and accessed through smartphones if YMSM are unable to afford internet connectivity at home due to geography and/or socioeconomic barriers. Consequently, web-delivered HIV prevention interventions are ideal to reach and engage YMSM in conversations about their partner-seeking and sexual risk taking behaviors. This intervention will focus on single YMSM reporting UAI in the prior 6 months and help them develop risk reduction skills as part of their partner-seeking behaviors.

YMSM have expressed enthusiasm regarding the inclusion of dating content in HIV prevention programs, as it may provide them with skills to effectively reduce their HIV/STI risk^{11,12}. Most individuals explore and integrate aspects of their sexuality into their personal identity as they transition from adolescence into young adulthood (i.e., ages 18-24 years of age). Serial dating and involvement in different types of relationships has been documented as helping youth to define their sexual identity, to narrow the characteristics sought in long-term relationships, and to practice safer sex negotiation skills³⁰. Compared to heterosexual counterparts, however, YMSM may not readily receive support and advice from family, peer and school systems on how to date and seek out same-sex partners. Furthermore, YMSM do not receive instruction on how to have anal sex as part of their sex education^{11,12,23} nor guidance on how to negotiate condom use with their partners²⁷. This is particularly problematic as YMSM's participation in dating behaviors during this period coincides with their mean age of initiating anal sex^{11,12,27-29}, and may create unique vulnerabilities for UAI as they engage in partner-seeking behaviors. Recognizing the importance of relationship pursuits in this period, we propose to design a preventive intervention that aids single YMSM in developing skills for same-sex dating and relationship building, while also reducing risk for HIV/STIs.

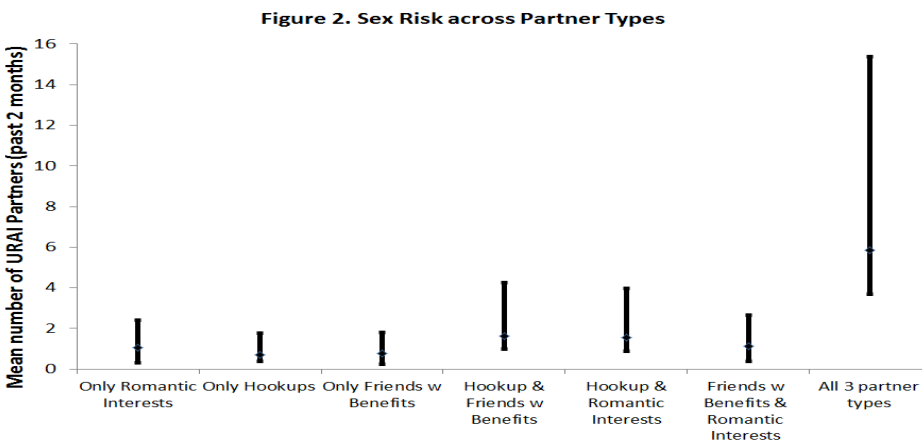
Relationships are a critical component of human development³¹, and may be health promotive for YMSM^{32,33}. In a prospective study of young sexual minority youth (ages 15-19), participation in a same-sex relationship was associated with increases in self-esteem and decreases in internalized homophobia, even after accounting for sexual identity, social support, and outness to family and friends. In studies with single YMSM, we found that participants were less likely to engage in UAI if they could envision having a relationship in the future. Even when single, most young gay and bisexual men indicated their desire to have long-term relationships in the future³⁴⁻³⁶. Consistent with the health promotive effects observed in the future orientation literature, we³⁶ found that YMSM who could envision a committed relationship (relationship ideation) reported fewer UAI partners in the prior two months. A similar association between relationship ideation and UAI has

been documented among older MSM³⁷. These findings are particularly meaningful, as they suggest that providing YMSM with opportunities to develop relationship expectations may serve as a protective factor in HIV prevention. Thus, we will provide HIV-negative YMSM who recently engaged in UAI with interactive activities (e.g., roleplays) that help them think about their relationship expectations and evaluate how HIV risks (e.g., not knowing their partners' HIV status) may create barriers to attaining these future goals.

Relationship explorations may also increase risky decision-making through affective dysregulation.

Beyond the protective association attributable to relationship ideation, researchers have also acknowledged that overzealous ideation (limerence)³⁸, although normative in this developmental stage, may increase sexual risk^{3,39}. In a recent study with single YMSM, we³ found that single YMSM who expressed stronger desires to find a romantic partner were more likely to report a greater number of partners and occasions in which they had UAI in the prior 2 months. Consistent with the larger decision-making literature, we have also noted that YMSM may be more likely to take sexual risks (e.g., decisional balance to forego condoms) with sexual partners if they believe that it will create intimacy and trust^{3,27}. These findings suggest that some youth may be eager to find a relationship, yet increase their HIV/STI risks in the process. Consequently, we will develop tools that help YMSM self-regulate their affective response towards partners, and strengthen their self-efficacy to engage in safer sex practices even when emotionally drawn to a new partner.

HIV prevention interventions for single YMSM must account for different relationship typologies. As part of the dating process, single YMSM are likely to engage in concurrent partnerships. This is particularly problematic when conceptualizing public health strategies, as sexual network research has suggested that compared to serial monogamy, concurrent partnerships (i.e., multiple partners over the same time period) may greatly increase HIV incidence rates among MSM^{40,41}. Although MSM couples-based intervention projects are underway, focusing on encouraging sexual agreements as a prevention strategy within concurrent networks⁴²⁻⁴⁴, these findings may not be translatable to single YMSM who, by definition, are not in a relationship and do not have a “main partner”. Therefore, our intervention will focus on the three most common types of sexual relationships: romantic interests, casual encounters/hook-ups, and friends with benefits.



Using data from a national study of single YMSM (N = 1,638; ages 18-24), we found that 31% of YMSM (N=414; 65% White; 93% gay) reported engaging in unprotected receptive anal intercourse (URAI) in the prior two months. When asked to describe each of these URAI partners as a friend with benefits, hookup, or romantic interest, we found that YMSM's mean number of URAI partners was greater among YMSM who reported UAI with multiple partner types (see Figure 1), as

compared to those who reported only a single type of partner. These findings suggest that single YMSM may have difficulties enacting safer sex strategies if they have different types of sexual relationships over the same period of time. Thus, we propose to develop an intervention that equips YMSM who engage in UAI with opportunities to reinforce safer sex negotiation skills with different sexual partner types.

In a manuscript currently under review in *AIDS & Behavior* (see Appendix A), we also noted that YMSM who reported greater desire for a future relationship (relationship ideation) were less likely to report multiple types of URAI partners and most likely to note that all their partners were romantic interests. Conversely, YMSM who reported higher limerence scores and who believed that foregoing condoms would help create intimacy with a sexual partner were more likely to report having multiple types of partners in the prior two months. These findings underscore the importance of acknowledging the different cognitive and affective processes that may be associated with YMSM's sexual decision-making. Although we have begun to acknowledge the distinction between partner types when discussing sexual risk-taking behaviors⁵⁻¹⁰, we have yet to develop an intervention that helps YMSM distinguish between these partner types and select appropriate partner-specific HIV/AIDS risk reduction strategies. Consequently, our intervention activities will aid YMSM

reflect on their partner-seeking behaviors, develop sexual decision-making rules to reduce their HIV/AIDS risk, and consider various relationship typologies when making sexual health decisions.

INNOVATION

This HIV/AIDS intervention for single YMSM is highly innovative in its ability to customize HIV/STI prevention content to experiences and behaviors with different relationship types (i.e., romantic interests, hookups, friends with benefits). “Tailoring” refers to the use of individual (e.g., user) data to customize intervention content based on their variation in psychological, social, and behavioral factors^{45,46}, and differs from “targeted interventions” which rely on delivering the same message to a previously identified group of individuals^{47,48}. Participants in tailored interventions have reported that the content was more persuasive and relevant than traditional approaches^{49,46,50}. More importantly, tailored interventions have been found to produce higher rates of behavior change and maintenance than non-tailored programs in a variety of health domains including exercise, nutrition, and cancer screening^{51,52}. Compared to these other health domains, the use of tailoring in HIV/AIDS prevention has received limited attention. In a meta-analysis of 12 randomized controlled trials (RCT)⁵³, interventions using tailoring evidenced moderate effect sizes in outcomes such as condom use ($d = .31$ [95% CI: .24-.38]; 10 studies) and number of partners ($d = .42$ [95% CI: .12-73]; 2 studies) across heterosexual populations in the United States. To date, only one RCT study has employed tailoring technology to deliver customized HIV prevention content to MSM and it was done with a non-U.S. sample. Specifically, Davidovich et al.⁵⁴ found that a 1-time tailored intervention was associated with a moderate effect size ($d = .28$) for condom use in a sample of Dutch MSM ($N=1,013$; M age=33 years). Given the promise of tailoring in HIV prevention, we will tailor intervention content based on YMSM’s demographic characteristics, relationship expectations, partner-seeking, and sexual behaviors.

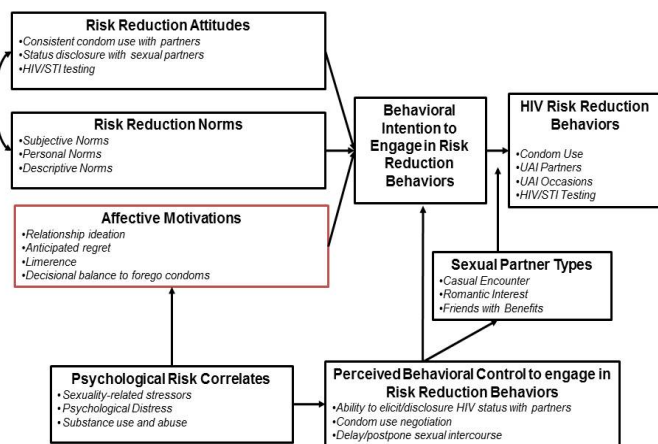
To minimize programming-related costs and increase cross-platform adaptability, we will use the open-source Michigan Tailoring System (MTS). MTS is a standards-based, cross-platform, open source application released to the research community that enables the efficient creation, testing and delivery of richly tailored communications without the need for constant technical support and assistance from a team of computer programmers. These communications include individually tailored text and media (photos, graphics, animations, audio, video) and be delivered via a range of channels, including print, computer, web, email, cell phone, and social media applications. Because of the open-source, common MTS technical platform, it will be easier to update and modify content and images, disseminate, and scale up. Further, technological advances since tailoring’s inception in the mid-1990’s also has reduced the costs previously associated with its use⁵¹.

A strong theoretical framework that acknowledges cognitive and emotional decision-making will inform the intervention’s development. The Theory of Planned Behavior (TPB) is one of the leading behavior change theories in HIV/STI research given its adaptability across populations, its use of mixed-method strategies to identify and measure the theory’s constructs, and its application in health communication research^{14,15,55}. TPB is a value-expectancy theory that proposes that an individual’s **behavioral intention** to engage in a behavior is the best predictor of actual behavior. In order to maximize behavioral intention, however, three psychosocial factors must be ascertained: (a) **attitudes**, (b) **subjective norms**, and (c) **perceived behavioral control** to carry out the behavior in a given context. Regarding the HIV protective behavior of condom use, negative attitudes include discomfort, decreased sensitivity, ineffectiveness in preventing sexually transmitted infections (STIs), interrupting the mood, and assuming sickness or irresponsible/immoral behavior. Positive attitudes include assurance of avoiding STIs, increased control, responsible decision-making, and prolonged and enjoyable sexual encounters. **Subjective norms** refer to the extent to which family members, friends, partners, or respected leaders in society encourage HIV prevention behaviors, as well as the value placed on the opinion of these individuals⁵⁶. Additional normative constructs may independently contribute to TPB’s predictive power⁵⁷⁻⁵⁹. In a study of MSM who met partners through the Internet in the Netherlands, Kok et al.⁵⁷ found TPB constructs accounted for 55% of the variance in intention to use condoms; however, the predicted variance of behavioral intention increased to 70% when both **descriptive norms** (i.e., perceived prevalence of the behavior in YMSM’s social network) and **personal norms** (i.e., feeling of moral obligation for one’s behavior) were included. Inclusion of these norms may elucidate how YMSM’s social networks influence their condom use (e.g., descriptive norm), and acknowledge YMSM’s autonomy to negotiate their safety (e.g., personal norms). We acknowledge that in this developmental period, YMSM’s norms may be highly influential on individual attitudes. Above and beyond attitudes and

norms, **perceived behavioral control** is the strongest predictor in condom use across numerous studies⁶⁰, yet may not be generalizable across all situations⁶¹. As shown in Figure 2, these findings highlight the importance of accounting for **partner type**⁷ (e.g., romantic interest, casual partner, friends with benefits) as a moderator when examining YMSM's ability to enact their risk reduction intentions into behaviors. Although the TPB has invaluable strengths, it has been challenged given the moderate correlation of behavioral intentions and actual behavior in applied settings^{62,63}. Decision-making researchers have noted that affective motivations may be processed more rapidly and may result in decision-making that is affectively motivated rather than analytically motivated⁶⁴. Further, individuals with conflicting affective and cognitive motivations report less correspondence between their intentions and behavior^{16,17,65}. Consequently, in recognition of this limitation to the TPB, our intervention is supplemented by a dual processing cognitive-emotional decision making framework¹³.

As shown in Figure 2, our model acknowledges that YMSM's affective motivations may be health promotive (e.g., relationship ideation) or risk enabling (limerence, decisional balance to forego condoms). While depicted as unidirectional relationships, the proposed conceptual model assumes that the associations between these constructs are non-recursive and reinforce each other over time. Building on our prior work, we hypothesize that YMSM reporting greater **relationship ideation**⁶⁶ will report fewer HIV/AIDS risk behaviors (i.e., health promotive affective motivations). In addition, we include **anticipated regret**^{67,68} (i.e.,

Figure 2. Intervention Conceptual Model



anticipation of an emotional reaction following an unintended behavior) as a health promotive construct, as it has been associated with fewer risk-taking behaviors among MSM⁶⁹. However, we also hypothesize that YMSM who experience greater **limerence**⁷⁰ and who believe that foregoing condoms with their partners will create intimacy, love, and trust (**decisional balance**^{70,71}) may place stronger value on being in a relationship which, in turn, may fuel HIV/AIDS risk behaviors (e.g., more UAI partners and occasions, respectively). Consequently, in our intervention sessions, we will address how affective motivations may influence YMSM's decision-making regarding consistent condom use, number of UAI partnerships and occasions, and HIV/STI testing behavior. YMSM will have opportunities to then practice

affect-regulating skills through interactive role plays that may increase their perceived behavioral control to engage in risk reduction practices across different settings, (2) reflect on their partner-seeking behaviors and develop sexual-decision making rules to reduce their ambivalence and/or dissonance between affective and cognitive motivations, and (3) reinforce behavioral skills (e.g., negotiate condom use) with different partner types.

Finally, the model acknowledges that YMSM's cognitive and affective motivations may be influenced by YMSM's **sexuality-related stressors** (e.g., discrimination, internalized homophobia), **psychological distress** (e.g., depression, anxiety, loneliness, low self-esteem), and **substance use and abuse**. These risk correlates may influence YMSM's ability to regulate their affective motivations (e.g., loneliness) and/or to effectively engage in risk reduction behaviors due to limited behavioral control (e.g., impairment due to being drunk or high). We acknowledge that **demographic factors** (i.e., age, sexual identity, race/ethnicity) may influence the direction and strength of the proposed associations, and may vary across groups⁷²⁻⁷⁴ (e.g., 18-20 year olds vs 21-24 year olds, White vs Black vs Latino, gay vs non-gay identified YMSM). We will tailor intervention content (e.g., images, pictures) based on these characteristics to increase the personal relevance of the intervention to participants. In sum, this cognitive-affective decision-making model is highly innovative and offers a strong theoretically driven foundation to inform our intervention.

APPROACH

Overview and Design. This study uses a mixed-methods design to develop and test a novel, theoretically driven HIV prevention web-based intervention for single YMSM (ages 18-24). The intervention, MEET-ME, is an interactive, tailored website that is also compatible with a smartphone interface. We divide the intervention

NCT02842060

development activities into three phases (see Figure 2). The Youth Advisory Board will help us develop and evaluate intervention content in the first two phases of the study; in Phase 3, we will test a 90-day prospective randomized control trial (RCT) with 4 observation points (baseline, and 30-day, 60-day, and 90-day follow-ups; FU). We will build and pilot test MEET-ME using a racial/ethnically diverse sample of single YMSM living throughout the United States (N=120), using an attention-control comparison condition (N=60) to test our intervention's feasibility, acceptability and preliminary efficacy. Primary outcomes of interest include increased consistent condom use across partner types and HIV/STI testing, and decreased UAI occasions and partners.

In Phase 1, we will build modular content using our prior work with single YMSM in the United States, and findings from other colleagues working with YMSM populations²⁹. We will convene a youth advisory board (YAB) to provide insight and feedback during the intervention development process. This approach follows best practices indicating that youth involvement is vital when designing a relevant and appropriate HIV/AIDS intervention for our target population^{19,75}. We will invite 8 YMSM (ages 18-24) from the Detroit Metro Area to participate and be compensated as YAB members over the three years of the study. The Youth Advisory Board will reflect the population of YMSM living in the Detroit Metro Area in terms of age, race/ethnicity, and sexual orientation identity. YAB members will meet with the research team biweekly to have a space to provide continuous feedback on intervention and study materials (e.g., recruitment ads) as they are developed. We will collaborate with the University of Michigan's Center for Health Communication Research ([CHCR](#)) and YAB to develop content. Thus, as recommended by Kreuter et al.⁴⁶, we will be able to develop/refine theoretically-driven content that fits the unique needs of the target population.

In Phase 2, we will then evaluate the usability and acceptability of the MEET-ME tailored online prevention intervention, as well as an attention-control *non-tailored* HIV/AIDS prevention (NTHP) comparison intervention. We will recruit 16 single YMSM in the Detroit Metro Area and assign them to the MEET-ME (n=10) or NTHP (n=6) condition. They will be then asked to interact with the site and report their satisfaction with the site's layout, language, and content-heaviness (see *Acceptability Assessments* below). We will also ask participants to reflect on whether the site met or exceeded the participant's expectations for design and ease of use. We will use these data to revise site content, layout, and usability in preparation for our pilot RCT.

In Phase 3, we will conduct a 2:1 pilot randomized controlled trial (RCT) of MEET-ME (N=120) compared to NTHP (N=60), in order to assess the acceptability and feasibility of the intervention, and to gather preliminary data that will be needed for a larger-scale efficacy trial in a subsequent application. Assessments will be collected at 30-, 60-, and 90-day FUs. Following implementation of the intervention, we will analyze the data from this trial and make any necessary modifications to the intervention prior to a large scale trial.

Our research team. We are well-suited to conduct the proposed intervention given our expertise in HIV prevention and intervention development among YMSM. **Dr. Bauermeister** completed Career Development award (K01MH087242) focused on innovative, online HIV prevention approaches for YMSM. Dr. Bauermeister has worked with the Center for Health Communication Research (CHCR) previously, including a CDC-sponsored online testing intervention for YMSM in Southeast Michigan (PI: Bauermeister, Co-I: Harper; U38 HM000449). **Dr. Harper** is a clinical child psychologist and member of the Adolescent Trials Network's Behavioral Leadership Group, where he contributes to several on-going ATN protocols with youth focused on developing innovative HIV prevention interventions. He has developed multiple evidence-based primary and secondary HIV prevention interventions for youth, and is currently PI of an R34 focused on developing a HIV prevention intervention for Black YMSM in Chicago (R34MH095571-03). Our **CHCR collaborators** have decades of experience developing web-based interventions and will provide expertise in the development of tailored content, graphic design, and multiplatform programming.

Phase 1: Developing the intervention's content. We will employ modern Agile software development principles and iterative, incremental development as we design the intervention. Cyclical developmental processes are key to encourage frequent interactions between our research team, the CHCR programmers, and YAB during prototype development iterations. It also provides opportunities to develop components that are innovative and are not lagging behind the technology (e.g., developing a prototype in Year 1 that would not be implementable if a new operating system emerged by Year 3). Consistent with our prior collaborations, Dr. Bauermeister's team will have weekly meetings with CHCR to discuss progress and solve arising challenges.

YAB Formation. To maximize intervention appeal and appropriateness to our target population, we will convene a YAB (to provide insight and feedback throughout the intervention development process. This approach follows best practices indicating that youth involvement is vital to design a developmentally and

NCT02842060

culturally appropriate HIV/AIDS intervention^{19,75}. We will initiate the YAB through the recruitment of YMSM (ages 18-24) from the Detroit Metro Area via advertisements on Facebook, local LGBT listservs and contacts at community-based organizations. As we select participants, we will ensure diversity across age (e.g., 18-20, 21-24), race/ethnicity, and sexual orientation identity (e.g., gay, same-gender loving, queer, bisexual). We have had success recruiting a socioeconomically and racially diverse sample of YAB in prior intervention development projects. The success of our past YAB was contingent upon several key ingredients including hiring/paying YAB as interns, rotating the location of the meeting to equitably distribute travel time, providing transportation through carpooling, making quick turn-around decisions via Skype, and reimbursing travel.

YAB Procedures. The YAB will enhance the translation of the theoretically informed data into intervention content⁷⁶. In order to maximize our interactions and conversations with our YAB, we will create summaries of content into relevant domains (e.g., partner-seeking behaviors, negotiating condoms, deciding to engage in anal sex, benefits and barriers of condom use), which we will then present to the youth for feedback. Harper et al.⁷⁷ documented how this approach was a feasible and effective strategy to empower YMSM to participate actively in the translation of research findings and intervention development process. In our biweekly meetings, we will ask YAB members to react to the developed content using both written (e.g., whiteboard, easels) and verbal (e.g., group discussion) feedback. Our feedback sessions will resemble cognitive interviewing sessions⁷⁸. We will jointly critique the content's readability and comprehension, and identify instances where we should divide the content so as to minimize cognitive burnout and retain respondents' attention. The Project Director and research assistants will note YAB members' reaction to the content, including questions that emerge as participants think about the tailored content. They will evaluate YAB reactions based on frequency, type (e.g., comprehension of a sentence, reading level, vocabulary used), and severity. Throughout Year 1, we will follow the same approach to note YAB's views on the following areas of intervention design: (a) intervention structure and format [e.g., organization of the intervention, appropriateness and appeal of language/images, ease of navigating the web-based content]; (b) intervention content [e.g., relevance/applicability of intervention content to the population, comprehension of content, interest in the content]; (c) intervention activities [e.g., comprehension of activity instructions, acceptability/relevance of activities, desire to engage in activities]; and (d) overall impressions of the intervention [e.g., overall utility, overall interest, overall enjoyment]. In addition, we anticipate that YAB members will suggest strategies to market the intervention to other young men, with a focus on challenges to consider during recruitment. Research assistants will take detailed notes of each meeting's proceedings. We will iteratively incorporate YAB feedback into drafts of the intervention content. The YAB will also be involved in critiquing and providing feedback on the design, navigation, and interactive features of the intervention. As we design the site layout and interface, YAB will collaborate with us to select imagery reflecting the key constructs, the content that should be subjected to tailoring, and the graphic design layouts and site navigation features. These activities are vital to ensure that the developed site is perceived as relevant, persuasive, and interesting to our population. We have employed this approach in a prior online HIV/STI testing intervention for YMSM with great success (see Appendix B). Once a mock site is assembled, we begin programming the intervention.

Intervention Description. The proposed intervention will consist of a 6-session web-based program (henceforth referred to a MEET-ME). Cognizant of challenges maintaining users' attention in a web application and to facilitate delivery through a smartphone, we will design each session to be no more than 20 minutes in length. In the course of these 6 sessions, YMSM will have a total of 120 minutes of intervention exposure. Across sessions, we will emphasize the importance of sexual decision-making across different partner types, help YMSM consider what type of relationship(s) they want, and align these relationship desires with safer sex practices. At the end of each session, participants in both intervention conditions will answer a brief acceptability assessment. Participants will have to wait 24 hours to unlock the next session in order to ensure that they avoid cognitive burnout and have time to think through the content offered in each session.

Once participants have completed the baseline assessment (see Measures below), YMSM randomized to the MEET-ME intervention will receive their personalized tailored content based on their demographic information (e.g., race/ethnicity, age), partner-seeking behaviors and relationship desires, and prior sexual attitudes and behaviors (e.g., decisional balance, UAI). In line with Hawkin's framework⁷⁰, tailored content will match HIV/AIDS prevention messages and safer sex skills with YMSM's outcome expectancies when meeting new partners and thereby help them consider how to integrate safer sex practices into different partner types. This approach aims to maximize content persuasiveness and relevance and facilitate behavior change by

NCT02842060

enhancing message processing and message impact through personalization, content matching, and feedback. Personalization increases a user's attention to the message by raising awareness to customization of content (e.g., "Based on your answers...") and making it more meaningful (e.g., refer to the participants' behaviors; match photographs to age group, and race/ethnicity). Content-matching is a way to target factors known to influence behavior change. Participants receive information that is relevant to them and designed to support positive behaviors. For example, participants who score high on condom self-efficacy might receive a simple positive reinforcement message, whereas those low would receive a prompt to complete an interactive activity where they may test possible strategies to improve their efficacy across different scenarios. Feedback about participants' answers increases attention and impact through self-referential thinking, comparative feedback ("Compared to others...") to validate positive beliefs and adjust errors in normative beliefs, and evaluative opportunities linked to individuals' underlying values and motivations.

Although the final total number of sessions, content and order may change based on feedback garnered in Phases 1 and 2, we foresee the development of 6 core sessions, each having tailored content and informed by our conceptual model (Figure 2). Each session's modular content will be delivered through interactive tailored story-telling, case scenarios, motivational interviewing strategies, and graphics and videos (e.g., condom demonstration). **Session 1** will serve as an introduction and focus on the importance of feeling comfortable talking about sexuality and relationship desires in order to be healthy and achieve one's hopes, aspirations, and dreams. This session will focus on acknowledging and normalizing YMSM's affective motivations. **Session 2** will transition into a discussion regarding different relationship types (e.g., romantic relationships, friends with benefits, hookups) and sexual decision-making; it will highlight the importance of knowing what kind of relationship one desires, both in the short-term and long-term, and the role of sex in exploring these relationships with different types of partners (e.g., friends with benefits, hookups, or romantic interests). In this session, we will use these discussions as an entry-point to address YMSM's attitudes and norms regarding risk reduction strategies. **Session 3** will provide an opportunity for YMSM to think through the HIV/AIDS risks associated with various partner-seeking behaviors. Through scenarios, we will ask YMSM to reflect about their perceived behavioral control to reduce their risk. In **Session 4**, we will reinforce how condom use promotes having fun safely while getting to know a new partner, building a strong connection with a partner, and expressing care and respect for partners. This component will help YMSM strengthen their behavioral intention. In **Session 5**, YMSM will consider how the benefits and barriers to condom use and HIV status disclosure may vary across different relationship scenarios, and will learn strategies to improve their condom communication and self-efficacy across different relationships. This module will focus on the role that perceived partner type may have in moderating the enactment of intentions to behavior. The final module (**Session 6**) will summarize key messages from prior modules, provide YMSM with sexual health advice, and offer HIV/STI testing resources (e.g., test locator).

After completing each session, participants will be directed to a brief "MEET-ME" activity. These activities will be developed and designed to build their HIV risk reduction skills, promote self-reflection about YMSM's sexual health, and consider how their partner-seeking behaviors and sexual decision-making may promote or hinder the achievement of these relationships. We will develop finalized activities alongside the YAB members; however, we foresee interactive activities that help YMSM role play scenarios and negotiate condom use with hookups, friends with benefits, and romantic interest; describe their ideal relationships, including short-term and long-term relationships; develop their own list of sex and relationship rules and strategies to stick to them, respectively; and contrast how these expectations and rules align with their prior partner-seeking and sexual behaviors. We will program the online modules and activities so that YMSM may compare whether their answers are consistent with the tailored suggestions, and revisit content and/or revise their answers to reinforce the material. Participants will be able to print and/or email these activities as a reference.

Attention-Control Condition Description. We will create a 6-session web-based attention-control comparison to match MEET-ME in time and attention yet have *non-tailored* and non-interactive content (NTHP). Similar to the design used in KEEP IT Up!⁷⁹, NTHP will include HIV/STI information currently available on sex education websites. CHCR will also be responsible for the design and development of the NTHP so as to avoid confounding due to aesthetics and site features. Our attention-control condition allows us to avoid confounding due to content (i.e., comparing MEET-ME to a non-HIV "health promotion" intervention) and ensures that all YMSM receive *some* HIV prevention content given their high vulnerability to HIV. Further, this

comparison will help us critically examine the extent to which tailoring increases YMSM's acceptability to the program, above and beyond having a non-tailored, non-interactive intervention. We acknowledge that the comparison condition will make it harder to detect an intervention effect in our outcome assessments; however, consistent with the R34 guidelines, we are seeking to test the intervention's feasibility and acceptability and to estimate critical parameters required for adequate power estimation in a subsequent large scale RCT trial, even if we are unable to detect small differences between conditions (see "Power Analysis" below).

Phase 2: Testing the Design and Interface through Usability Evaluation. Pilot testing for acceptability and feasibility will occur for both the MEET-ME and NTHP interventions. To develop, refine, and standardize the interventions, we will use best practices in usability testing⁸⁰ to examine the developed interventions.

Recruitment. We will recruit 16 YMSM to participate in our usability evaluation. Candidates must (1) be male at birth and identify as male, (2) ages 18 to 24 (inclusive), (3) self-report as single, (4) self-report as HIV-negative, (5) have had UAI with a male partner in the past 6 months, and (6) live in Southeast Michigan.

Table 1. Sampling Plan	Age	
	18-20	21-24
Race/Ethnicity		
White/Caucasian	3	3
Black/African American	3	3
Asian American/Pacific Islander	1	1
Hispanic/Latino	1	1

We will employ a stratified purposive sampling strategy to ensure racial/ethnic diversity across participants based on their race/ethnicity and age group (see Table 1). This racial/ethnic distribution is commensurate to diversity in the area. We will apply several recruitment strategies, including study promotion through online LGBT listservs, flyers in HIV/AIDS community-based organizations,

bars, and advertisements on Facebook. All promotional materials will briefly describe the study, provide a number to call in order to determine study eligibility and schedule a potential interview, and mention the \$20 participation incentive. A member of the study team will conduct a 5-minute screening telephone interview with study candidates. While we considered creating a small website to track a candidate's eligibility, we decided against it given that a phone call may be more personable and may facilitate answering study candidates' questions. Qualifying individuals will be invited to participate in an in-person interview at one of the University's interview centers in Ann Arbor, Dearborn, Flint or Detroit. We have used this recruitment approach in prior studies to ensure the participation of a racially/ethnically and socioeconomically diverse set of YMSM living throughout Detroit Metro⁸¹. Recruitment will continue until sampling target is achieved. YMSM will be reimbursed for travel.

Procedures. We will conduct 16 individual usability interviews (10 MEET-ME; 6 NTHP; 2 hours) in a private interview room. We will assign participants to the MEET-ME or NTHP condition and allow them to interact with the preliminary layout and design of the interventions. Participants in the MEET-ME intervention will receive tailored content as part of the usability testing phase. Similar to the cognitive interviews carried out with YAB members, participants will be asked to think aloud as they navigate through either intervention. The moderator will note participant's behavior and any questions that YMSM have regarding the site. As YMSM go through the interventions, we will record any nonverbal behavior that might be important to take into consideration (e.g., frowns, sighs, or fidgeting in the chair). Furthermore, we will record valuable data related to how respondents navigate the site (i.e., Do YMSM go back to read a prior page? How long does it take participants to go through the different modules?). We will use these data as exploratory indicators of item difficulty, attentiveness, and task difficulty. After participants have completed the assessment, we will collect self-reported metrics such as participant satisfaction with the site's layout, language, and content-heaviness (see *Acceptability Assessments* below). We will also ask participants to reflect on whether the site met or exceeded the participant's expectations for design and ease of use. We will use these data to revise site content, layout, and usability in preparation for pilot testing. We will incorporate these changes and continue to pilot test the MEET-ME and NTHP interventions internally (i.e., Does content come together correctly based on individuals' characteristics? do emails, text messages, and sessions happen at the right time?, does the database save the answers we type in?, do the buttons, links, and pages do what we expect), how does the system react if we do unexpected things?, and does the process work from start to finish?. We will also pilot the online survey assessments to ensure that the survey layout works with different platforms (e.g., Safari, Mozilla, Chrome), that skip patterns are correct, and that the server is saving the data appropriately. We place less emphasis on pilot testing our measures since we have used them in prior studies with YMSM^{70,82-85}.

Phase 3: Pilot Testing the Intervention through a small RCT. The purpose of Phase 3 is to evaluate the MEET-ME intervention as a pilot study using a prospective randomized control trial design⁸⁶. This design (see Table 2) benefits our study in three ways: (1) the longitudinal structure provides a method for analyzing change

NCT02842060

in outcome objectives over time, (2) it also allows for analysis of individual differences in response to treatment, and (3) randomization maximizes the internal validity of the study by creating equivalent groups at pretest⁸⁶. Our primary outcomes will be YMSM's consistent condom use, number of UAI partners and occasions, and HIV/STI testing behaviors. To avoid overwhelming participants with assessments and/or confounding results with practice effects, we will only collect outcome data via online surveys at 30, 60, and 90 day FUs. FUs are important as YMSM may require time to contemplate and apply the intervention's content into their partner-seeking and sexual behaviors. As a pilot, we recognize that we may not have sufficient power to detect small effect sizes; however, this design will inform our subsequent large-scale RCT, allowing us to identify and address implementation and retention challenges that could arise in the larger trial. Specifically, the primary purposes of this pilot trial are: 1) to demonstrate the feasibility of the methods proposed for a subsequent trial; 2) to stabilize procedures that are replicable; and 3) to determine important parameters with sufficient accuracy to reliably estimate sample size and power for a future RCT.

Table 2. RCT Design

Baseline	Randomization	Condition	FU 1 (30 d)	FU 2 (60 d)	FU 3 (90 d)
○	R	MEET-ME (N = 120)	○	○	○
○		NHTP (N= 60)	○	○	○

Recruitment. Our intended sample size across both conditions is N=180 (MEET-ME, n=120; NHTP, n=60). We include a 2:1 ratio so we may increase our ability to examine the MEET-ME condition in greater detail. Candidates must (1) be male at birth and identify as male, (2) be between the ages of 18 and 24 (inclusive), (3) self-report as single, (4) self-report as HIV-negative, (5) speak and read English, and (6) report UAI with a male partner in prior 6 months. Consistent with the Internet's potential reach, we will allow YMSM from around the country to participate in the intervention. We will reach the population using social media ads on Facebook and Twitter. Promotional materials will describe the study and provide a 1-800 number to call to verify eligibility. Once determined eligible, YMSM will receive a code to access the site.

Once YMSM enter our website, we will verify that participants live in the US using the American Registry for Internet Numbers (ARIN) regional IP codes and zip codes. Participants will complete a 30 minute baseline questionnaire and be randomized in a 2:1 ratio into the MEET-ME or NHTP site. As part of the baseline questionnaire, we will ask participants to provide information that may help us contact them for FU assessments and verify that they are not fraudulent or duplicate entries^{87,88}. We will use best practices^{89,90} to retain participants (e.g., comprehensive locator information that includes participants' cell phone number, e-mail, Facebook and/or Skype username, and contact information for 2 peers who could help us contact them).

Although we will employ recommended strategies to avoid loss to FU⁹¹, we project a conservative attrition rate of 20% by the 90-day FU; however, we will use this R34 as an opportunity to estimate an attrition rate specific to MEET-ME. These data will help identify who may be more vulnerable to loss to FU, and how to develop retention strategies for the subsequent trial. We will compare those who completed each FU interview with those who did not on key predictors to characterize the profile of non-responders. Missing data generated from recording errors will be minimized due to the computer-based entry for all measures. The generalized linear mixed model analysis that we will conduct for the longitudinal outcome data is valid under missing at random mechanism. The use of Intent to Treat (ITT) principle for the longitudinal analyses will also aid to overcome missing data concerns when appropriate⁹².

Data Collection. We will use MTS' web survey feature to collect YMSM's data. Web surveys allow participants to complete the survey at a convenient location (e.g., home, friend's house), circumvent barriers (e.g., scheduling, transportation) present in interviewer-administered or phone-based interviews, and decrease social desirability. Participants will be able to earn up to \$70 total (VISA e-cards; Baseline= \$30, FU1 = \$15, FU2 = \$20, and FU3 = \$25). We backloaded the FU incentives to encourage completion of all three data collection time points and reduce participant attrition over time. Participants will create a username and password, allowing them to log into the different sessions and complete the surveys (or return to them later if they are interrupted). To maximize completion, participants will receive e-mail and/or text reminders. See Human Subjects section for a comprehensive description of the protections and safety procedures embedded into our web-survey data collection.

Acceptability Assessments. Acceptability data will be collected right after completing each intervention session. We will use two different assessments: (1) Intervention Evaluation Forms (SEF)⁹³ and (2) Client Satisfaction Questionnaires (CSQ-8)⁹⁴. The SEF is a brief 13-item questionnaire that elicits information about the participant's experience with the intervention (i.e., was the intervention interesting, was it relevant to their life, did they learn from the intervention). The CSQ-8 will be used at the completion of the intervention and at

the 90-day FU to assess YMSM's satisfaction with the intervention, including the content, site layout and design, and general satisfaction. These domains are assessed on a 4-point response scale with individually specified anchors. The CSQ-8 has demonstrated high internal consistency across a large number of studies⁹⁵. The SEF and CSQ will take approximately 10 minutes to complete. We will also track users' actions in the intervention as process evaluation data. These data will include the number of times that they visited the site, their geographic location and the website from which they linked to our site, time spent in each session, number of times a user returns to a session, and which interactive features were "clicked on" during sessions.

Behavioral Assessments. The web surveys will be programmed to minimize out-of-range or inconsistent responses. Data exports will be automated into SPSS. The survey will be designed using best practices to encourage completion⁹⁶. Planned domains are listed below and may be refined based on the intervention content developed and YAB feedback. Based on our prior success in recruiting YMSM to complete online surveys, we will use best practices (e.g., surveys are dynamic and take less than 30 minutes to complete) to reduce participant burden. We have used all measures previously; scales have strong psychometric properties (i.e., adequate factor structure and $\alpha > .65$). Table 3 documents when domains will be assessed.

Table 3. Assessment Summary Table	BL	FU1	FU2	FU3
Sociodemographic Information				
Demographic data (e.g., race, sexuality)	X			
Social media use	X			
Changes in relationship, housing, work	X	X	X	X
Outcome indicators				
Sexual behavior	X	X	X	X
Recent HIV/STI test	X	X	X	X
Substance use	X	X	X	X
Predictors of Behavior Change				
TPB Constructs	X	X	X	X
Affective Motivations	X	X	X	X
Partner-seeking behaviors	X	X	X	X
Psychological Risk Correlates	X	X	X	X

information.

Outcome indicators: Consistent with our model, we have 3 primary risk reduction outcomes: increased consistent condom use across partner types (continuous), reduced number of UAI partners and occasions (continuous), and increased HIV/STI testing rates (dichotomous). We detail their assessment below:

Sexual behaviors will be assessed using the Sexual Practices Assessment Schedule⁹⁷ used in previous online studies with YMSM to explore the number of occasions of different sexual acts (oral, anal; receptive, insertive) with different partner types. SPAS allows us to estimate the number of UAI partners and occasions across partner types, as well as the proportion of instances when condoms were not used^{70,98,99}. SPAS also ascertains YMSM's use of condoms during the past 30 days (1=Never/5=Always) and their HIV status disclosure practices with each partner. SPAS measures behaviors with male and female partners, respectively.

HIV/STI Testing Behaviors. We will ask YMSM to indicate the date of their more recent HIV and STI tests. Subsequently, we will ask participants to note if they have ever been medically diagnosed as having one or more STIs, the date of their most recent STI test if available, and whether a medical provider had previously diagnosed them with a STI. At each FU, we will ask participants whether they have gone to get tested for HIV and/or STIs, respectively. If tested, participants were asked to indicate what tests they received and whether they had been medically diagnosed as having HIV or STI. At FU, we will ask YMSM whether they have had any changes in their HIV status. Newly diagnosed cases will be asked if they were linked to care.

Psychosocial indicators of behavior change. To measure *TPB constructs*, we will measure YMSM's attitudes, subjective norms, self-efficacy using previously tested scales with MSM^{7,100,101}. We will use existing items measuring condom use intentions with different partner types, and self-efficacy to negotiate condoms with different partner types¹⁰². Descriptive and personal norms will be measured separately for different partner types (1=Strongly Disagree/Strongly Agree)¹⁰⁰. We will measure these constructs at baseline and FUs.

Substance use. We will assess alcohol, tobacco, and other drugs (ATOD) use over the past 30 days. If respondents indicate alcohol use, we ask if the respondent has had five or more drinks in a row during the last two weeks (binge drinking), and how often the respondent drinks to get drunk. For cigarette and marijuana, we will how many cigarettes they smoke daily and past year attempts to quit smoking. We will also assess alcohol and/or illicit drug use during UAI on a 5 point scale (1=never,5=always). We will also assess non-prescription drugs, cocaine, amphetamines, depressants, and heroin use.

Affective Motivations. We will YMSM's relationship ideation¹⁰³ using a 7-point scale (1=Not at all important; 7=Extremely important). Anticipate regret^{68,100} will be measured by asking YMSM how worried or

Sociodemographic information. We will ascertain age, race/ethnicity, educational attainment, place of birth, year of immigration, and sexual orientation identity data only at baseline. Other information to be collected at each assessment will include relationship status, employment status, and changes in residential status. We will also include questions regarding use of different devices, the number of hours spent online through each device, the reasons for social media use, sites frequented, and social media use to find sexual health

regretful they would be in various situations (e.g., after having UAI with [partner type]; after having UAI with a new partner) and will be measured on a 5-point scale (1=Strongly Disagree/Strongly Agree). We will also measure limerence using an 8-item scale⁷⁰ (e.g., “My desire to find a boyfriend has interfered with my ability to get into a meaningful relationship”). We will measure decisional balance to forego condoms¹⁰⁴ for Pleasure and Emotional Connection (e.g., “Sex [with/without] condoms makes feel close to my partner”) using a 5-point scale (1=Strongly Disagree/4=Strongly Agree; $\alpha = .82$).

Partner-seeking behaviors. We will ask participants to indicate how much time they spent seeking potential partners of each type⁴ (e.g., romantic, casual, friend with benefit), where they sought out these partners (online and/or offline), and how comfortable they felt interacting with these prospective partners.

Psychological risk correlates. We will measure *depression*, *anxiety*, and *loneliness* symptoms as markers of psychological distress. Depression and anxiety symptoms in the past week will be measured using the Brief Symptom Inventory¹⁰⁵. Both scales include 6 items rated on a 5-point scale (1=never, 5 = very often), respectively. We will use the UCLA Loneliness scale¹⁰⁶ to measure feelings of loneliness (1=Never;4=Often). We will also measure *self-esteem* using Rosenberg’s scale¹⁰⁷, a 10-item measure using a 5-point scale. We will measure *internalized homophobia*¹⁰⁸ with 12 items measured on a 4-point scale (0=Strongly disagree; 3=Strongly agree). Finally, we will measure *sexuality-related stressors* using a 9-item scale (0=never/4=3+ times) with strong reliability¹⁰⁹ assessing the frequency of discriminatory events (e.g., verbal insults) due to someone knowing/assuming YMSM were gay/bisexual.

Data Analyses. Prior to conducting our multivariate analyses, we will examine study variables using descriptive statistics and test for differences across demographic characteristics (e.g., race/ethnicity, age, education) using t-tests, ANOVAs, and Chi-squares, as appropriate. As participants will be randomized to the two treatment groups, systematic baseline differences are not expected; however, in the event that some parameters differ across conditions at baseline, they will be included as covariates in subsequent multivariate models. We will calculate descriptive summary statistics corresponding to the study variables at each visit to understand any temporal patterns, as well as compare the two treatment groups in terms of average change from baseline after intervention (averaged across all three FU times).

Estimation of parameters for a subsequent R01. Consistent with the R34 mechanism, the primary role of this pilot RCT is to ensure that the critical parameters required to plan a large trial are estimated as informatively as possible. Certain principles then follow: (1) If alterations are necessary to address measurement or performance problems, these will be permitted in an effort to establish optimal procedures and design parameters before a future trial, precisely so that no changes in protocol will be required during a future trial; and, (2) Estimation of critical design parameters with point and confidence interval estimates will be considered highly important, as large sample sizes are not required to locate these parameters adequately when planning for a subsequent trial. As a result, we are not powered to estimate small effect sizes or carry out sophisticated statistical analyses; rather, we seek to estimate key study parameters with sample means and proportions together with two-sided 95% confidence intervals, and test the primary null hypotheses at the

traditional two-sided level $\alpha=.05$.

To test for intervention effects over time with pilot RCT data, we will use the general framework of generalized

linear mixed models (GLMM) to model the longitudinal outcome trajectories¹¹⁰⁻¹¹². 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 $(\mu_{ij}) = \beta_{0i} + \beta_{cov} Covariates_{ij} + \beta_{visit} Visit_j +$

Table 4. Detectable Effect (.80 power, alpha=.05)	N = 140	N = 160	N = 180
<i>Continuous Outcomes</i>			
Within-subject correlation (rho=.4)	.39	.35	.33
Within-subject correlation (rho=.5)	.41	.38	.35
Within-subject correlation (rho=.6)	.44	.40	.37
<i>Binary Outcomes (p(NTHP)=.40)</i>			
Within-subject correlation (rho=.4)	2.19	2.04	1.93
Within-subject correlation (rho=.5)	2.31	2.14	2.02
Within-subject correlation (rho=.6)	2.43	2.24	2.11

$\beta_{Trt} Trt_i + \beta_{Trt \times visit} rt_i \times Visit_j$, where μ_{ij} is the mean response corresponding to subject *i* on visit *j* (*baseline and three follow-ups*), *g* denotes the link function (identity for continuous outcome, logit for binary outcome and natural log for count outcomes); $Trt_i = 1$ if the *i*-th subject is in the MEET-ME group and 0 if the *i*-th subject is in the NTHP group. The variable Visit can be coded in different ways depending upon how one wants to model the effect of time on the mean response. For example, for characterizing only pre vs. post effect Visit can be coded as a binary indicator with 0 representing baseline and 1 representing post-randomization; Assuming a linear time trend, Visit can be coded as 0, 1, 2, 3, or it can be simply coded as a categorical variable representing the distinct effect of each visit compared to the baseline. The interaction coefficients $\beta_{Trt \times Visit}$ are of interest here, measuring the difference in the rate of change in outcome across the two treatment groups at each visit. If the baseline outcome measure is included as a part of the covariates on the right hand side of the

NCT02842060

above equation, then we only have three repeated measures on the left hand side of the model ($j=1,2,3$) and we can look at average treatment effect across visits without including the $Trt \times Visit$ interaction term. In this particular case, the GLMM analysis with continuous outcome will be equivalent to a repeated measures analysis of covariance after adjusting for baseline values. The subject-specific random intercepts β_{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 criterion like AIC, BIC. For some binary outcomes like STI/HTV 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.

Power for primary analysis: As shown in Table 4, we will have 80% power to detect a medium intervention effect (Cohen's $d > .35$) at $\alpha=.05$ in a continuous measure using a repeated measures group design (N=180) with 4 observations (baseline + 3 FUs) when the standard deviation is 1 and the correlation between observations on the same subject (ρ) is 0.6. For dichotomous outcomes, we estimate 80% power at $\alpha=.05$ to detect an odds ratio of 2.11 or greater assuming that the proportion for the intervention condition is .58 and the attention-control condition is .40, with ρ also being .60. We note that there is some controversy regarding the use of "pilot data" to estimate the actual effect size, as specified by Kraemer et al.¹¹³. We agree with their view that clinically meaningful effect sizes should be decided based on extrinsic, clinical judgment grounds, and not based on the pilot data which are too few, typically, to obtain reliable conclusions. However, we can use these data to rule out unusually large or small effects through standard 95% confidence interval procedures. Thus, we will confirm that extrinsic effect sizes are contained within our confidence intervals¹¹³ and use these Even with 20% attrition, we will have preliminary effects with adequate error margins to inform the subsequent trial.

In exploratory analyses, we will use structural equation modeling (SEM¹¹⁴) to examine our model's adequacy to predict behavior change. Using our theoretically informed model (see Figure 2) as a blueprint¹¹⁵, these SEM analyses will help us begin to unpack what theoretical constructs and pathways were influential in YMSM's behavior change, and aid us to refine our conceptual model for the larger RCT. For example, we will test the hypothesis that cognitive (e.g., attitudes, norms, behavioral control) and affective factors (e.g., anticipated regret, decisional balance) independently contribute to the behavioral outcomes through behavioral intention. We will examine the Lagrange Multiplier and Wald Tests to consider the deletion or inclusion of paths¹¹⁶; ultimately, however, the deletion or inclusion of paths will be informed by theoretical underpinnings. Once the model is identified, we will test for group differences (i.e., MEET-ME vs NTHP) in latent constructs and in the paths between these constructs (e.g., intention to use condoms, consistent condom use). This method will allow us to estimate the intervention effects on the constructs directly as well as their relationships to one another¹¹⁷. We will follow guidelines for adequate reporting of SEM using three goodness-of-fit indices: Bentler-Bonnet's Normed Fit Index (NFI), Bentler-Bonnet's Non-Normed Fit Index (NNFI), and the Comparative Fit Index (CFI). We will also verify the root mean-square error of approximation (RMSEA) as an index of misfit. Well-fitting models will have fit indices of .90 or higher and $<.06$ for RMSEA. **Power for secondary analysis:** SEM power calculations are computed by estimating the best fit for a full latent model. Based on calculations provided by MacCallum, we have ample statistical power given the repeated measures design¹¹⁸ (e.g., 80% power is achievable with $\alpha=.05$ & 95 df with a N=180 for close model fit, where null RMSEA value is .05 and the alternate value is .08).

Intervention Modifications. Based on the data obtained throughout the study, we will work with the YAB and CHCR to make appropriate modifications to the intervention over the last three months of the project. As newer technologies evolve, we may also need to adapt our intervention to newer platforms, whether they be tablet or smartphone based. Assuming intervention findings indicate a reduction in HIV risk behaviors among single YMSM, we will seek funding to test the efficacy of our intervention in a large scale RCT.

Foreseeable challenges. We did not include biological measures (e.g., presence of STI/HIV), as we would have to dramatically increase our sample size to detect significant effects in biomarkers. At this early stage of intervention development and testing, the added cost of biological testing is not warranted; such testing would be included in larger, full-scale efficacy trial. In addition, we recently finished collecting data on PrEP acceptability among single YMSM¹¹⁹. As we continue to analyze these data in the context of YMSM's relationship expectations and partner-seeking behaviors, we will decide with our YAB whether to introduce a

NCT02842060

module on PrEP as part of the intervention. Finally, we will develop the intervention web-interface to be easily readable in a smartphone browser. Based on how many YMSM access the intervention through a smartphone, we may decide to develop the intervention into an “app” in the subsequent large scale efficacy trial.

Timeline. The proposed research will take 3 years to complete. Phase 1 will take 12 months to complete, which includes the development of the intervention content. Phase 2 is estimated to take 9 months to complete, including the refinement of the intervention and the usability testing. The last 3 months of Year 2 will be used to begin recruiting YMSM for the pilot RCT. The remaining 12 months will be used to pilot and test the intervention, examine the intervention’s feasibility and acceptability, and assess changes in our outcomes (i.e., consistent condom use, reduced UAI, and HIV testing).

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