Young Men and Media Study Protocol

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Detailed Statistical Plan

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1 List of Abbreviations

Abbreviation	Abbreviation definition
ASMM	Adolescent sexual minority males
CAI	Condomless anal intercourse
CBO	Community Based Organization
HIV	Human Immunodeficiency Virus
LGBT	Lesbian, Gay, Bisexual, and Transgender
LGBTQQ	Lesbian, Gay, Bisexual, Transgender, Queer, and Questioning
MSM	Men who have Sex with Men
PI	Principal Investigator
SEOM	Sexually Explicit Online Media
STI	Sexual Transmitted Infection
US	United States
YM&M	Young Men & Media

2 Protocol Summary

Title:	Influences on risk behaviors among young men
Population:	Adolescent sexual minority males (*N* = 150, male sex, male gender identity, 14-17 years old; self-identify as gay/bisexual, report being sexually attracted to males, or report having voluntary sexual contact with a male partner in the past year)
Intervention:	Online sexual health media literacy intervention
Objectives:	The objective of this pilot study is to assess the acceptability, feasibility, and preliminary efficacy of an online sexual health media literacy intervention
Design/Methodology:	A RCT design with two conditions (i.e., online sexual health media literacy vs. control) and three assessments (i.e., baseline, post-intervention, 3 month follow-up). See Appendix 1 for detailed study flow diagram.
Total Study Duration:	24 months
Subject Participation Duration:	3 months

3 Background/Rationale & Purpose

3.1 Background Information

Adolescent sexual minority males (ASMM), ages 14-17, are disproportionately affected by HIV in the United States (US).[1] Racial and ethnic minority ASMM are particularly affected.[2] The disproportionate incidence among ASMM is largely attributed to engagement in sexual risk behaviors, including condomless anal intercourse (CAI).[3,4]

Despite increased risk, few HIV prevention interventions target ASMM < 18 years old.[5,6] For ASMM, adolescence (ages 14-17) is a developmental period when significant biopsychosocial changes are coupled with negotiation of a same-sex attraction.[4,7–11] Further, ASMM are particularly susceptible to perceived peer norms, including media-based perceived norms,[12,13] which predict behavior.[9–11,14] As most sexual risk behavior patterns are established during adolescence among ASMM,[3,4,15,16] it is important for HIV prevention interventions to target ASMM during this vulnerable period. Intervening with ASMM will help them learn and establish healthy sexual behaviors,[4] which will have both immediate and long-term health benefits.[4,15,17,18]

The CDC has highlighted the importance of addressing online media influences on HIV risk among adolescents.[19] One Internet source that contributes to ASMMs' HIV risk is their use of sexually explicit online media (SEOM; i.e., online pornography).[20–26] With limited access to relevant sexual education in school[27–29] or from parents,[24] ASMM use SEOM[20–26,30] and adopt the behaviors they see.[23,26]

The amount of male-male specific SEOM portraying CAI has increased substantially in recent years,[31,32] raising concerns about the encouragement of risky sexual behaviors among consumers.[33,34 105] These concerns are supported by five large-scale studies showing positive associations between exposure to CAI in sexually explicit media and engagement in CAI among adult MSM[35–39] and one among ASMM.[26] Further, ASMM report modeling their sexual experiences after what they view in SEOM, including engaging in CAI.[23,26]

As SEOM triggers and maintains sexual risk-taking among ASMM, [20–26,30] it is critical for HIV prevention interventions to address the influence of this "super peer."[12,13,25] One way to address this influence is by developing a SEOM-targeted sexual health media literacy intervention.[12,25,40] Media literacy interventions have positively impacted many health behaviors,[41] including sexual health behaviors,[42–44] and may be an effective means of addressing the influence of SEOM on the sexual risk of adolescent ASMM. As such, using information from an online survey of ASMM from across the US[24,26,45,45–47] and the guidance of a youth advisory board, we developed an online sexual health media literacy intervention called the Young Men & Media (YM&M) intervention.

The procedures involved in this research (i.e., online assessments, online intervention) are considered low-risk. Thus, participants will incur minimal risks due to their participation in this study. This study will be conducted in compliance with the protocol, applicable regulatory requirements, and BMC/BU Medical Campus Human Research Protection policies and procedures.

3.2 Rationale and Purpose

Given ASMMs' increased risk for HIV[1] in combination with their decreased access to relevant sexual health education from traditional sources[24,27–29] and reliance on SEOM for sexual health information,[20–26,30] development of sexual health interventions for ASMM that address male-male sexual practices and SEOM are critical. To our knowledge, YM&M is the first intervention to specifically address SEOM use among ASMM. To ensure that this approach is both feasible and acceptable to ASMM we are proposing to pilot test the intervention.

4 Objectives

4.1 Study Objectives

The goal of this study is to conduct an exploratory clinical trial to pilot test the online media literacy intervention for feasibility, acceptability, and preliminary efficacy.

4.2 Study Outcome Measures

An overview of outcome measure timing is provided in Table 1.

Table 1. Outcome Measures: Purpose and Timing of Administration

Purpose	Construct or Behavior	Baseline	Intervention	Post Intervention	Follow-up
Feasibility	Study recruitment	x			
	Study retention			x	x
	Intervention metrics		x	x	
Acceptability	Webpage ratings		x		
	Satisfaction survey			x	
Preliminary Efficacy	Sexual risk behaviors	x			x
	Antecedents to sexual risk	x		x	x
	Media literacy	x		x	x
	Sexual health knowledge	x		x	x

4.2.1 Primary Outcome Measures

The **primary outcomes** will be feasibility and acceptability of the intervention.

Feasibility measures. To assess study feasibility, banner ad click-through rate, number of individuals recruited per week, and the percentage of individuals who were eligible; assented; dropped out and lost to follow-up will be calculated. To assess the feasibility of the media literacy

intervention we will calculate intervention metrics (i.e., time spent on each piece of intervention content, percentage who complete all intervention content).

Acceptability measures. To assess acceptability, media literacy intervention participants will be asked to complete content ratings on each piece of intervention content using a 5-star rating system. Participants will also be given the option of providing written feedback on each piece of content as well. All participants will also be asked to complete a satisfaction survey at the post-intervention follow-up.[48] Participants will be asked to report on study procedure acceptability (e.g., acceptability of recruitment, consent, assessment procedures). Intervention participants will be asked to report how informative, interesting, and helpful the intervention was; how likely they would be to recommend it to friends; and if they have suggestions for how it could be improved. Participants in the control group will be asked which website they went to, if any, and to report how informative, interesting, and helpful the website was; as well as how likely they would be to recommend it to friends. The satisfaction survey will include a combination of likert scale and open-ended responses.

4.2.2 Secondary Outcome Measures

The **secondary outcomes** will measure preliminary efficacy (i.e., changes in sexual risk behaviors, media literacy skills, and sexual health knowledge).

Sexual risk. Sexual risk behaviors and antecedents to sexual risk behaviors will be assessed. Participants will be asked about the number of sex partners, gender of partners, HIV-status of partners, romantic/primary partner status, sexual activities and condom use, and substance use with sex in the prior 3 months. Participants will be asked to report only on voluntary sexual behavior (i.e., not forced). To optimize the accuracy of these reports, counts of behaviors will be asked in an open response format.[49–52] Antecedents to sexual risk-taking include intentions to have sex and for sexual communication (e.g., communication about HIV/STI status, condom use)[44,53] as well as condom attitudes.[54]

Media literacy skills will be assessed using questions adapted from the two previous sexual health media literacy interventions, including awareness of SEOM myths, awareness of SEOM influence, and SEOM skepticism.[42–44]

Sexual health knowledge will be determined by assessing HIV[55] and STI[56] transmission knowledge; HIV/STI prevention method knowledge;[57] and the levels of HIV/STI transmission risk (low, medium, high) associated with sexual behaviors (e.g., oral sex, anal sex).[53]

5 Study Design

The study design is a pilot randomized controlled trial (RCT) with two conditions (i.e., YM&M intervention vs. control) and three online assessments (i.e., baseline, post-intervention, 3 month follow-up). Prior to randomization all participants (*N* = 150) will complete a baseline assessment. Participants will then be randomly assigned (1:1 randomization) to the intervention or to the control group. The randomization schedule will be generated using a permuted block randomization procedure with small, random-sized blocks. Following receipt of the intervention or control, participants will be asked to complete a post-intervention assessment and a 3-month follow-up. Data will include self-report and usage data. See Appendix 1 for a schematic of the study design and participant flow and Appendix 2 for a schedule of events.

6 Potential Risks and Benefits

6.1 Risks

The procedures involved in this research (i.e., online assessments, online intervention) are considered low-risk. Thus, participants will incur minimal risks due to their participation in this study. Potential untoward events that may occur include:

- Emotional discomfort.
- Breach of confidentiality.

The level of risk for each of these events is minimal.

Emotional discomfort. Some of the topics that are asked about or discussed (e.g., SEOM use, sexual behaviors) may cause discomfort or anxiety. There is also the potential for anxiety related to acknowledging behavior with potential legal implications (alcohol/drug use, condomless sex which placed someone at risk of contracting an infectious disease).

These risks are recognized. Nonetheless, recent research assessing the psychological impact of similar questions among LGBT adolescents found that 90% of the participants reported feeling "very comfortable" or "comfortable" with the questions they were asked and only 3% reported feeling "very uncomfortable," which is similar to what has been found in other research assessing reactions to questions about sexuality and substance use.[58,59]

To minimize the potential for participant psychological distress or discomfort during the online assessments and intervention participants will be notified that they can skip any questions or intervention content that they are uncomfortable with and stop the assessment or intervention at any time. Participants will also be invited to contact the PI should any discomfort arise.

Breach of confidentiality. The study will take every precaution to ensure that the privacy of study participants is protected. To guard confidentiality, each participant will receive a unique ID number. All computer records will be protected by standard measures that limit data access to authorized personnel. Online data will be collected and managed using the REDCap[60] electronic data capture tools managed by Boston University Medical Campus IT. REDCap is a secure, web-based application designed by network engineering and approved by IT Security. REDCap servers are backed up daily and monitored for hardware failures. Self-report and usage data will be collected from respondents, and likewise retrieved by the PI, over an SSL encrypted connection.

The intervention website is designed and implemented by LongTek, Inc., a technology provider with extensive experience creating secure, encrypted websites for research projects. All data (e.g., email addresses, content ratings, time spent on intervention content, number of log-ins) will be housed, monitored, and downloaded by the PI from the PI portal within the intervention website. The intervention website data is protected with SSL in transit via TLS 1.2 using 256 bit RSA encryption. Certain fields within the intervention database (including participant and administration user's emails and passwords) are encrypted at rest using hashed and salted SHA256 bit encryption. Participant data can only be accessed by the specific participant by entering a username and password via the participant login page. The PI login portal has a logically separated data table and dedicated login page that allows PI users access to a real-time view of aggregate data regarding time spent on intervention pages and number of log-ins. The log-in page will not indicate the content, purpose, or target population. Website servers are housed in a highly secure environment, backed up daily (nightly backup of database and file system retained for at least 7 days), and monitored for hardware failures (99.9% uptime).

Participants will be encouraged to go to a private location at the beginning of the survey, assessments, and when they log into the intervention. To mitigate the chance of another person seeing that the participant is in this study, a time limit will be set on the intervention such that if no movements have occurred on the participant's screen within 20 minutes the screen will be redirected to the log-in page. Lastly, all correspondence with participants will be devoid of any indication of the content, purpose, or target population of the study and participants will be encouraged to delete correspondence (e.g., emails) as soon as the participant decides they no longer need the contained information.

In addition, because of the potentially sensitive nature of the data that are being collected, we have received a Certificate of Confidentiality to ensure that participants' data cannot be subpoenaed with a court order. No individual identities will be used in any reports or publications.

Other considerations: Mental health and substance use. As mental health and substance use issues are prevalent among ASMM, we will provide all participants with links and phone numbers for LGBT-specific services (e.g., the National Alliance on Mental Health LGBTQ website, PRIDE Institute Substance Use Treatment website, GLBT National Youth Talkline phone number, Trevor Helpline Crisis Intervention for LGBTQ Youth phone number). Although none of the proposed measures specifically ask about reportable issues, the satisfaction survey for the intervention will include open-ended responses. The PI will check these open-ended responses daily in the unlikely event that a participant reports any indication of current, ongoing abuse or neglect of children or elders and/or of imminent danger to self or a specified individual as these indications will have to be considered for clinical intervention and mandated reporting to the appropriate authorities. Daily checks will be documented via PI initials on a study calendar.

Other considerations: Website developer training. To ensure the website developer is informed of research ethics and participant confidentiality they have completed on-line CITI Human Subjects Protection training and signed an

agreement to keep all participant information confidential. The developer has a background in designing/programming websites for research purposes, thus have completed these trainings and signed research confidentiality agreements before.

6.2 Potential Benefits

The largest anticipated benefit is from participating in the YM&M intervention. We expect that individuals who complete the YM&M intervention will gain insight into their sexual health and SEOM consumption that could lead to sustained sexual behavior and attitude change.

By participating in the research, participants will also benefit from knowing they may ultimately be helping others to reduce their risk behaviors. Possible risks are likely to be outweighed by the new knowledge gained regarding the potential of this approach to reduce HIV risk and increase the sexual well-being of ASMM. The risks of participating in the research will be minimized through our extensive efforts to maintain confidentiality and to reduce discomfort or distress.

6.3 Analysis of Risks in Relation to Benefits

We expect the benefits will outweigh the risks of participating in this research. In previous research conducted by the PI many participants have reported that they enjoyed participating. In addition, some participants noted that completing self-report assessments, which ask them to reflect on their health behaviors, was a helpful experience; based on previous research, it is likely that the act of filling out detailed health behavior assessments can result in positive health behavior changes.

7 Study Subject Selection

A convenience sample of ASMM (*N* = 150) from across the US will be recruited online through social media.

7.1 Subject Inclusion Criteria

In order to be eligible to participate in this study, an individual must meet all of the following criteria:

- Be age 14 to 17.
- Report having been assigned male sex at birth and self-identify as male (i.e., be cisgender male).
- Self-identify as gay/bisexual, report being sexually attracted to males, or report having voluntary sexual contact with a male partner in the past year.
- Have intentionally accessed SEOM in their lifetime.
- Have a valid personal email address.
- Be a US resident.
- Be new to the study.

All inclusion criteria will be determined via self-report except for having a valid email address. Having a valid email address will be determined by requiring participants to use a unique link sent to their personal email address to access the assessments.

7.2 Subject Exclusion Criteria

An individual who meets any of the following criteria will be excluded from participation in this study:

- Are unwilling or unable to provide informed assent, which would preclude meaningful participation in the research.
- Are unable to understand and read English. Participants who are unable to understand and read English will not be included because they would not be able to complete the assessments nor would they benefit from the intervention.
- Do not have the appropriate device and necessary software to allow them to experience all the intervention content. Because (a) 94% of sexual minority adolescents reporting at least daily Internet use[61] and (b) participants will be recruited from websites that are likely to have similar device and software requirements, this

criterion should not limit our sample. A recent online sexual health education pilot intervention targeting LGBT adolescents (ages 16-20) had a similar requirement and found that only 4% of the 1,734 potential participants who completed their eligibility screener were ineligible due to the technology requirements.[53]

8 Study Intervention

Four main topics areas were identified by youth in our previous survey[24,26,45,45–47] and the youth advisory board as important foci for the intervention: (1) male anatomy, including information about how anal sex can be pleasurable and about anal health; (2) HIV/STI prevention information (e.g., transmission risks, accessing testing, condom use); (3) general sexual health information (e.g., types of male-male sex, consent, dating safety, partner communication); and (4) SEOM literacy (e.g., differences between porn and reality, what's behind the scenes on a pornography set, normalization of porn use among male youth). Youth felt that intervention content should be interactive (e.g., games, videos, animations) and the website should have an interface that would be familiar to ASMM (e.g., similar to Netflix). Youth preferred a website with a responsive design (i.e., will work on a mobile device, tablet, or computer) as opposed to a downloadable phone application. Please see Appendix 3 for screen shots from the intervention website and a more detailed description of the content.

9 Study Procedures

Overview

- ***Recruitment, screening, and assent (described in more detail below):*** Participants will be recruited via online advertisements. Once they click on an advertisement they will be presented with information about the study and a brief online screener to establish eligibility. If they are eligible they will be presented with assent materials and complete capacity to assent questions. If they agree to participate they will then be emailed a unique link to the baseline assessment.
- ***Baseline assessment:*** Participants will be sent an email with a link to a self-report online survey (*N* = 150; Approx. 25-35 minutes); compensation for time ($15 electronic gift card via email). If participants do not complete the baseline assessment within three days of assenting, we will send them up to 3 reminder emails in a 10-day period.
- ***Randomization:*** immediately following the final question in the baseline assessment, REDCap[60] will be programmed to randomly assign participants (1:1 randomization) to the YM&M intervention or to a control group. The randomization schedule will be generated using a permuted block randomization procedure with small, random-sized blocks.
    - Participants randomized to the YM&M (*n* = 75) intervention will be sent an email with username (their email) and a temporary password and asked to complete all of the website content within three weeks of receiving the email. Participants will be asked at first log-in to set up their own password. If a participant has not logged into the website within one week of receiving the original email, they will be sent up to 3 reminder emails in a 10-day period.
    - Participants in the control condition (*n* = 75) will be sent an email with links to various HIV prevention websites (e.g., the CDC HIV Prevention site, the National HIV and STD Testing Resource site) and encouraged to visit at least one site in the next three weeks.
- ***YM&M intervention exposure:*** Intervention content, language, and length was informed by a youth advisory board and a previously completed online survey.[24,26,45,45–47] Although the intervention is designed to be completed in one sitting (i.e., < 90 minutes in length), participants will be given the option of logging out and logging in again to continue where they left off, should they need to. Intervention content is described in more detail above and in Appendix 3.
- ***Post-intervention assessment:*** Three weeks after the baseline survey participants will be sent an email to complete a second online survey (*N* = 150; Approx. 15-25 minutes); compensation for time ($25 electronic gift card via email). If participants do not complete the post-intervention assessment within three days of receiving the email, we will send them up to 3 reminder emails in a 10-day period.
- ***Follow-up assessment:*** Fifteen weeks after the baseline survey participants will be sent an email to complete a final online survey (*N* = 150; Approx. 20-30 minutes); compensation for time ($35 electronic gift card via email). If

participants do not complete the follow-up assessment within three days of receiving the email, we will send them up to 3 reminder emails in a 10-day period.

- ***All participants:*** Participants will be offered a bonus if they complete all assessments ($20 electronic gift card via email). All participants will receive a list of youth-oriented resources at the end of the survey or if they are inelegible (Appendix 4).

Detailed description of recruitment, screening, assent, and retention procedures.

Recruitment Processes. Participants will be recruited using advertisements and posts on social networking websites (e.g., Facebook, Instagram, Snapchat). Potential participants recruited via advertisements will be directed to the screening website which will assent them for screening and then ask potential participants to continue on for eligibility questions.

Screening Procedures. Study eligibility will be determined via inclusion criteria questions (nested among foil questions so that these criteria are not obvious) and cross verified using additional questions throughout the survey. Eligibility screening will occur on the screening website, which will be hosted and created using REDCap,[60] a highly secure online survey program. To protect against the possibility of multiple enrollment of the same participant, eligibility screening information will be cross-referenced against: date of birth, age, race/ethnicity, and geographic location.[62,63] Online advertisements and the eligibility screener will not indicate the necessary requirements for eligibility in order to minimize the potential for faking eligibility.[64] To ensure ethnic and racial diversity, eligibility criteria and advertisements will be adjusted to oversample racial/ethnic minority participants, as needed.[65] Screening data will be retained for eligible and ineligible individuals as described in the assent for screening.

Assent Procedures. In line with ethical recommendations[66–70] and standard practice[5,6,15,24,26,45,53,59,71–75] for sexual health research with LGBT adolescents, a waiver of parental consent is being requested to decrease risk to participants and ensure validity of the results. Parental consent would decrease participation rates because some youth will fear that they may be "outed" (i.e., involuntary disclosure of their sexual minority status) as a result of participation. Specifically, disclosure of sexual preferences may place some participating youth at risk for parental disapproval leading, in some instances, to harassment, abuse, or even expulsion from the home.[45,58,76–79] Recent research by the CDC reports that ASMM commonly experience homonegativity which leads to internalized homonegativity, HIV stigma, silence about homosexuality, and forced housing displacement due to their sexual orientation, which, in turn, leads to increased risk for HIV seroconversion. This is especially true for racial/ethnic minority ASMM.[80] It is crucial that the proposed research reach these high-risk ASMM.

The nature and scope of the proposed research does not pose more than "minimal risk" to participants (45 CFR Part 46.102) (i.e., "that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests"). Study measures and exposure to sexual health topics are standard in this population, as are waivers of parental permission.[5,6,15,24,26,45,53,59,71–75] The majority of adolescents will have received some form of formal sexual education by the time they are 14 years old.[81] Thus, the proposed intervention will most likely not be a participant's first exposure to formal sexual health education and instead will be an ASMM-specific supplement to the sexual health education they have already received. Additionally, only participants who self-report have voluntarily been exposed to SEOM will be included. Participants will <u>not</u> be exposed to SEOM as a part of this study. Further, all 50 states plus the District of Columbia allow most minors 14 years old or older to consent to STI services without parental permission.[82] Similarly, youths of any age can buy condoms without parental consent.

To compensate for waiver of parental consent**,** participants will receive a formal assessment of capacity to assent (described below) to ensure their understanding of study goals, procedures, and risks from disclosure of sensitive information. Further assent material will include a table clearly outlining the pros and cons of participation. Consistent with national policy recommendations from the Society for Adolescent Medicine and the American Psychological Association,[83,84] requiring parental permission for the proposed study would have a number of possible negative effects, including: (1) reducing the validity of the findings by effectively eliminating potential participants unwilling to share permission forms with their parents/guardians; (2) increasing risk to youth whose parents would have a negative

response to the material in the permission forms that would correctly suggest their child has a minority sexual preference; and (3) adding little in the way of actual subject protection, given the minimal risk of study participation.[45,58,76–79] The procedures for the waiver of parental consent are consistent with the guidelines provided by the Department of Health and Human Services (45 CFR Part 46, Subpart D).

There will be two assent procedures as a part of the study: (1) assent for screening and (2) assent for the full study. Both of those assent procedures will occur online and affirmation of desire to take part in either the screening or full study will be shown by potential participants clicking acknowledgment that they would like to proceed.

When a potential participant clicks on a study advertisement they will be portalled to the assent for screening materials. Those materials will describe screening procedures, confidentiality, and subject rights. At the end, potential participants will be asked to indicate whether they would like to move on to eligibility questions or not, which is the documentation of their decision to proceed with the screening.

Assent procedures for the full study will describe the study, its risk and benefits, confidentiality, no deception, and how to contact the investigators. The assent process will highlight that potential participants have the option of refusing to participate in the study, withdrawing their participation at any time, and/or refusing to answer any questions that they feel uncomfortable responding to. Further, potential participants will be informed that their decision to participate or not participate in the study will not affect their relationship with any websites, LGBT youth-oriented CBOs, clinics, or Boston University. Capacity to assent will be further confirmed by administering multiple choice questions that will evaluate participants' ability to: (1) name things they will be expected to do during the study, (2) explain how they will be assigned to their group, (3) explain what they would do if they experienced distress during the study, and (4) identify potential risks for participating in the study.[85,86] Participants who are unable to accurately answer the multiple choice questions will be redirected to the relevant portions of the assent materials and asked the questions again. Capacity to assent questions and answers will be automatically re-ordered each time they are presented to reduce the chance of participants blindly choosing answers until they get the right ones. Participants will be given three chances to correctly answer capacity to assent materials. If after three chances they continue to answer questions incorrectly they will be considered ineligible. Potential participants will be given the option of contacting study staff (via e-mail, telephone number, and mailing address) to ask questions before enrolling. After potential participants have been determine to have capacity to assent they will be asked whether they would like to participate in the study or not, which is the documentation of their decision to enroll in the study. Once eligible participants have assented they will be sent an email containing a unique link to the baseline survey. To proceed to the main body of the survey, eligible participants will be required to click on that link. Participants will be reminded about assent parameters at the start of each follow-up assessment.

Retention Plan. Retention strategies include participant reminders, repeated contact, and compensation. Eligible participants who provide assent will be asked to provide an email address and phone number(s) for recontacting/tracking. REDCap will maintain an electronic system that will notify participants via email when they are due for an assessment and remind them up to 3 times within a 10-day period if they have missed an assessment. Participants will have the option to discontinue the study at any point by contacting study staff. Participants who wish to drop out of the study will be queried as to their reasons and attempts will be made to address their concerns. Participants will be compensated at the completion of the baseline survey ($15) and after each of the follow-up surveys ($25 for post-intervention, $35 for follow-up). Participants will be offered a bonus for the completion of all surveys ($20). Participants will be compensated via electronic gift cards.

See the Appendix 2 for the schedule of events.

10 Assessment of Safety and Data Safety Monitoring Plan (DSMP)

10.1 Definitions

The following definitions will be used in the assessment of safety:

Adverse Events (AEs) include any abnormal or harmful behaviors, increasing risk behaviors (e.g., sexual risk behaviors), suicidal behaviors, breach in the protection of participant data or breach of confidentiality whether or not consider related to the subjects participation in the research.

Serious Adverse Event (SAE) is any adverse event that

(1) results in death;
(2) is life-threatening;
(3) results in inpatient hospitalization or prolongation of existing hospitalization;
(4) results in a persistent or significant disability/incapacity;
(5) results in a congenital anomaly/birth defect; or
(6) based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition (examples of such events include allergic bronchospasm requiring intensive treatment in the emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse).

Life-threatening means that the event places the subject at immediate risk of death from the event as it occurred.

Unanticipated Problem is defined as an event, experience or outcome that meets **all three** of the following criteria:

- is unexpected; AND
- is related or possibly related to participation in the research; AND
- suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Table 2. Study Safety and Progress Monitoring

	Data Source / Frequency of Aggregation	Frequency of Review
Data Type	**Online Asessments/Website**	**PI**
Accrual, Retention, and Attrition	Daily	Daily
Adverse Events*	Daily	Daily
Missing data/data integrity	Twice a Week	Twice a Week
Intervention Integrity	Daily	Daily
*** Please note: serious adverse events will be reported within 24 hours to the IRB and to the sponsor (NIH) in accordance with their requirements.**		

Possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research

Unexpected means the nature, severity, or frequency of the event is not consistent with either:

- the known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in (a) the protocol–related documents, such as the IRB-approved research protocol, any applicable investigator brochure, and the current IRB-approved informed consent document, and (b) other relevant sources of information, such as product labeling and package inserts; or
- the expected natural progression of any underlying disease, disorder, or condition of the subject(s) experiencing the adverse event and the subject's predisposing risk factor profile for the adverse event.

10.2 Safety Review

Both the risks listed in Section 4.1 and unknown risks will be monitored as follows:

Study safety and progress will be monitored according to the schedule outlined in Table 2 (and more frequently, if needed). The PI (Dr. Nelson), will closely supervise all study activities on a day-to-day basis. The PI will personally monitor recruitment procedures, accrual and retention, and data integrity daily in order to take the necessary measures in a timely fashion. Participants will be instructed to notify the PI immediately if any symptoms occur during the online assessments or sexual health media literacy intervention. All AEs will be documented daily by the PI. AEs will be labeled according to severity, as 'mild' if the event does not have a major impact on the participant, 'moderate' if it causes the participant some minor inconvenience and 'severe' if it causes a substantial disruption to the participant's well-being. All AEs and SAEs will be labeled as definitely, probably, possibly or unrelated to the study intervention.

10.3 Reporting Plans

The Principal Investigator at BMC/BU Medical Campus will report Unanticipated Problems, safety monitors' reports, and Adverse Events to the BMC/BU Medical Center IRB in accordance with IRB policies:

- Unanticipated Problems occurring at BMC/BU Medical Campus will be reported to the IRB within 7 days of the investigator learning of the event.
- Reports from safety monitors with recommended changes will be reported to the IRB within 7 days of the investigator receiving the report.
- Adverse Events (including Serious Adverse Events) will be reported in summary at the time of continuing review, along with a statement that the pattern of adverse events, in total, does not suggest that the research places subjects or others at a greater risk of harm than was previously known.
- Reports from safety monitors with no recommended changes will be reported to the IRB at the time of continuing review.

The PI will promptly inform the NIH and the IRB of any changes in recruitment or in the protocol relevant to safety as the study is being performed. She will additionally notify the NIH promptly of any unanticipated problems or any actions taken by the IRB during continuing study review and any major changes in the status of the ongoing protocol which would only occur with IRB approval. Such changes would include but are not limited to: amendments to the protocol, temporary suspension of participant accrual, or of the protocol, any changes in informed consent or IRB approval status, termination of participant accrual or of the protocol, or other problems or issues that could affect the human subjects in the study.

10.4 Stopping Rules

Considering the low-risk of this study, no interim analyses are proposed and stopping rules have not been established. However, the study may be discontinued at any time by the IRB, the NIMH, the OHRP, or other government agencies as part of their duties to ensure that research participants are protected.

11 Data Handling and Record Keeping

11.1 Confidentiality

Confidentiality of study data will be maintained by numerically coding all data, by disguising identifying information, and by keeping all data in password-protected, encrypted computer files. All information obtained from participants will be accessible only to research staff. Study staff will maintain participant privacy by securing records using password-protected, encrypted databases. In meetings when study procedures are reviewed and issues of compliance are raised, participants will not be identified by name unless necessary, and if necessary only by first name. Project meetings will be held in private conference rooms.

Data will be obtained from electronic assessments completed by study participants and usage data from the study website. Personally identifiable information (PII), assessment responses, and usage data will be kept in separate datasets. They will be linked only with a randomly generated ID variable that is included in all data. Although the datasets will be housed on the same server (e.g., REDCap for assessment and self-report data, the intervention website for usage data and content review data), they will otherwise be completely separate. The PII dataset will be deleted upon completion of data collection and cleaning. AE reports and annual summaries will not include subject-identifiable material. Multiple levels of password protection will be utilized and access will be denied to non-study personnel. No identifiable information will be stored on laptops or transportable devices in this study. Further, REDCap and website servers will be physically stored in high security areas and study desktops will be located within a secured building.

If it is discovered that despite security precautions electronic data has been hacked, or if someone has illegally gained access to any data, the PI will determine to what extent the hacking has been successful. The PI will promptly inform the appropriate authorities to the extent of the hacking (e.g., BU, the IRB, NIH project officer, and, if appropriate, the police department). The PI in collaboration with the above authorities will determine what action, if any, is appropriate. In the unlikely event that hacking occurs, an attempt will be made to contact every participant potentially affected by the hacking to inform them that their data may have been accessed. Legal recourse will also be sought to

prevent further use or distribution of the data if we are able to identify the individual or agency who hacked the data. Upon reasonable suspicion that the data has been hacked, all data collection will be suspended until the incident has been reviewed and a secure means of continuing to obtain and store data has been re-established.

Because of the sensitive nature of the data we are collecting, we have received a Certificate of Confidentiality for this study to ensure that participants' data cannot be subpoenaed with a court order.

The study monitor or other authorized representatives of the sponsor may inspect all documents and records required to be maintained by the investigator. The study will permit access to such records.

11.2 Source Documents

There are two sources of data: (a) participant self-report and (b) usage data:

- Self-report data: will be collected via content ratings for each piece of intervention content and the assessments. Assessments for the pilot RCT will be conducted at baseline, post-intervention (3 week after baseline), and follow-up (15 weeks after baseline). Assessment data will be collected using a secure online survey software system, namely, REDCap.[60] Content ratings will be collected through the intervention website.
- Usage data: will include banner ad click-through rate, time spent on intervention content, and number of intervention website log-ins. Banner ad click-through rate will be acquired from the advertising websites. Time spent on each piece of intervention content and number of intervention website log-ins will be collected via the intervention website.

Only authorized study personnel will have access to the data.

Table 3. Measures: Purpose and Timing of Administration

Purpose	Construct or Behavior	Baseline	Intervention	Post Intervention	Follow-up
Descriptors / Moderators	Socio-demographics	x			
	Legal Guardians	x			
	Outness	x			x
	Healthcare access/use	x			x
	Substance Use	x			x
	Mental Health	x			x
	Sexual Abuse History	x			x
	Sexual Education Exposure	x			x
Feasibility	Study recruitment	x			
	Study retention			x	x
	Intervention metrics		x	x	
Acceptability	Webpage ratings		x		
	Satisfaction survey			x	
Exposure	SEOM exposure	x			x
Mediators	Identification with SEOM actors	x		x	x
	Perceived norms of SEOM behavior	x		x	x
	Expectancies about SEOM behavior	x		x	x
	Perceived consequences of SEOM behavior	x		x	x
Preliminary Efficacy	Sexual risk behaviors	x			x
	Antecedents to sexual risk	x		x	x
	Media literacy	x		x	x
	Sexual health knowledge	x		x	x

Self-report measures. An overview of the constructs and assessed behaviors is provided in Table 3.

Descriptive measures and moderators. *Socio-demographics*. Age, race/ethnicity, birth sex, gender identity, sexual orientation, education level, living situation, and zip code will be asked using standard formats. *Legal Guardians.* Participants will be asked questions about their legal guardians and how "out" they are about their sexual attraction to male partners.[15] *Outness.* Participants will also be asked about their overall degree of "outness."[37,87] *Healthcare access/use.* Access and use of healthcare services, including HIV/STI testing.[77] *Substance use.* The impact of participants' use of alcohol and other drugs will be assessed using the CAGE Adapted to Include Drugs (CAGE-AID).[88] Participants will also be asked about which drugs they used recreationally in their lifetime. *Mental Health*

will be assessed using the PHQ-4. *Sexual abuse history* will be assessed using the sexual abuse subscale of the Childhood Trauma Questionnaire (CTQ). *Sexual education exposure.* Sources of sexual education (e.g., parents, school, online) and coverage male-male sexual health-related topics will be assessed.[15]

Feasibility measures. To assess study feasibility, banner ad click-through rate, number of individuals recruited per week, and the percentage of individuals who were eligible; assented; dropped out and lost to follow-up will be calculated. To assess the feasibility of the media literacy intervention we will calculate intervention metrics (i.e., time spent on each piece of intervention content, percentage who complete all intervention content).

Acceptability measures. To assess acceptability, media literacy intervention participants will be asked to complete content ratings on each piece of intervention content using a 5-star rating system and an open text field. Participants will also be given the option of providing written feedback on each piece of content as well. All participants will also be asked to complete a satisfaction survey at the post-intervention follow-up.[48] Participants will be asked to report on study procedure acceptability (e.g., acceptability of recruitment, consent, assessment procedures). Intervention participants will be asked to report how informative, interesting, and helpful the intervention was; how likely they would be to recommend it to friends; and if they have suggestions for how it could be improved. Participants in the control group will be asked which website they went to, if any, and to report how informative, interesting, and helpful the website was; as well as how likely they would be to recommend it to friends. The satisfaction survey will include a combination of Likert scale and open-ended responses.

Exposure measure and mediators. Sexually explicit online media (SEOM) use will be established through a measure developed in a previous study of SEOM use among adult MSM[37] and adapted for use with ASMM.[26] This measure cover topics including: frequency and timing of usage; prevalence of viewing portrayed behaviors in SEOM; preferences for condoms use in SEOM; arousal during use; identification with SEOM actors; perceived norms of SEOM behaviors; expectancies about portrayed behaviors; perceived consequences of portrayed behaviors; and beliefs about the influence of SEOM on behaviors within the participant and on other MSM (i.e., perceived norms).

Preliminary Efficacy measures. To conduct exploratory assessments of intervention efficacy, we will measure three primary outcomes: sexual risk, media literacy, and sexual health knowledge. *Sexual risk.* Sexual risk behaviors and antecedents to sexual risk behaviors will be assessed. Participants will be asked aggregate information about the number of sex partners, gender of partners, HIV-status of partners, romantic/primary partner status, sexual activities and condom use, and substance use with sex in the prior 3 months. Participants will be asked to report only on voluntary sexual behavior (i.e., not forced). To optimize the accuracy of these reports, counts of behaviors will be asked in an open response format.[49–52] Antecedents to sexual risk-taking include intentions to have sex and for sexual communication (e.g., communication about HIV/STI status, condom use)[44,53] as well as condom attitudes.[54] *Media literacy skills* will be assessed using questions adapted from the two previous sexual health media literacy interventions, including awareness of SEOM myths, awareness of SEOM influence, and SEOM skepticism.[42–44] *Sexual health knowledge* will be determined by assessing HIV[55] and STI[56] transmission knowledge; HIV/STI prevention method knowledge;[57] and the levels of HIV/STI transmission risk (low, medium, high) associated with sexual behaviors (e.g., oral sex, anal sex).[53]

11.3 Case Report Forms

N/A

11.4 Study Records Retention

All study records will be retained in electronic form for at least seven years after completion of the study.

12 Statistical Plan

12.1 Study Hypotheses

We hypothesize that the YM&M intervention will be feasible and acceptable. We further hypothesize that sexual risk behaviors will decrease and media literacy skills and sexual health knowledge will increase by greater amounts in the intervention group compared to the control group at post-intervention and 3-month follow-up.

12.2 Sample Size Determination

Sexual health media literacy interventions have an overall effect size of 0.21 - 0.38 on antecedents to sexual risk behaviors.[42–44] For this exploratory study, we conservatively anticipate a Cohen's *d* = 0.20 between 2 groups. With the current sample size (*N* = 150) and a two-sided α = 0.05, we have 52% power to determine an effect size 0.20. With a two-sided α = 0.05 and 80% power (β = 0.20) we would require retention of a total sample size of 192. Considering the scope of the award, recruitment and retention of this sample size is not feasible. The proposed sample size is adequate to evaluate feasibility and acceptability of the intervention and gauge whether the intervention effects are encouraging.

12.3 Statistical Methods

Because this is a small pilot study, analyses are not powered to detect intervention effects or formally test mediation or moderation. To determine feasibility of conducting a RCT, we will calculate the percentage of individuals who were: eligible; assented; were randomized; and completed the post-intervention and 3-month follow-up. To determine feasibility of the intervention, we will calculate the total time spent on each intervention page as well as the percentage of individuals who complete the intervention. To determine acceptability of the intervention, we will calculate mean content ratings for the intervention pages and satisfaction surveys as well as inspect open-ended responses. As a secondary goal and to obtain preliminary evidence of efficacy of the online media literacy intervention, we will examine the within- and between-group differences at each follow-up for all three efficacy measures (i.e., sexual risk, media literacy, sexual health knowledge) using a series of longitudinal mixed effects models, controlling for baseline values, as well as any group differences.

13 Ethics/Protection of Human Subjects

This study is to be conducted according to applicable US federal regulations and institutional policies (which are based in federal regulations, guidance, and ICH Good Clinical Practice guidelines).

This protocol and any amendments will be submitted to the Boston Medical Center and Boston University Medical Campus IRB, for formal approval of the study conduct. The decision of the IRB concerning the conduct of the study will be made in writing to the investigator. A copy of the initial IRB approval letter will be provided to NIMH before commencement of this study.

All subjects for this study will be provided assent material describing this study and providing sufficient information for subjects to make an informed decision about their participation in this study. The assent material will be submitted with the protocol for review and approval by the IRB. The assent of a subject, using the IRB-approved assent material, must be obtained before that subject is submitted to any study procedure. Assent will be documented as required by the IRB.

14 Literature References

1. Centers for Disease Control and Prevention. HIV Surveillance Report, 2017; vol 29 [Internet]. Atlanta, GA: Centers for Disease Control and Prevention; 2018 [cited 2018 Dec 17]. Available from: http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html
2. Centers for Disease Control and Prevention. HIV and Youth Fact Sheet [Internet]. Atlanta, GA: Centers for Disease Control and Prevention; 2018 [cited 2018 Jun 8]. Available from: https://www.cdc.gov/hiv/pdf/group/age/youth/cdc-hiv-youth.pdf
3. Everett BG, Schnarrs PW, Rosario M, Garofalo R, Mustanski B. Sexual orientation disparities in sexually transmitted infection risk behaviors and risk determinants among sexually active adolescent males: results from a school-based sample. Am J Public Health 2014;104(6):1107–12.
4. Mustanski BS, Newcomb ME, Du Bois SN, Garcia SC, Grov C. HIV in young men who have sex with men: a review of epidemiology, risk and protective factors, and interventions. J Sex Res 2011;48:218–53.
5. Ybarra ML, Prescott TL, Phillips GL, Bull SS, Parsons JT, Mustanski B. Pilot RCT results of an mHealth HIV prevention program for sexual minority male adolescents. Pediatrics 2017;140(1):e20162999.
6. Bauermeister JA, Pingel ES, Jadwin-Cakmak L, et al. Acceptability and preliminary efficacy of a tailored online HIV/STI testing intervention for young men who have sex with men: the Get Connected! program. AIDS Behav 2015;19(10):1860–74.
7. Martos AJ, Nezhad S, Meyer IH. Variations in Sexual Identity Milestones Among Lesbians, Gay Men, and Bisexuals. Sex Res Soc Policy 2015;12(1):24–33.

8. Floyd FJ, Bakeman R. Coming-Out Across the Life Course: Implications of Age and Historical Context. Arch Sex Behav 2006;35(3):287–96.
9. Pedlow CT, Carey MP. Developmentally appropriate sexual risk reduction interventions for adolescents: rationale, review of interventions, and recommendations for research and practice. Ann Behav Med Publ Soc Behav Med 2004;27(3):172–84.
10. Buhi ER, Goodson P. Predictors of adolescent sexual behavior and intention: a theory-guided systematic review. J Adolesc Health Off Publ Soc Adolesc Med 2007;40(1):4–21.
11. Rimal RN, Real K. How Behaviors are Influenced by Perceived Norms A Test of the Theory of Normative Social Behavior. Commun Res 2005;32(3):389–414.
12. Brown JD. Media literacy has potential to improve adolescents' health. J Adolesc Health Off Publ Soc Adolesc Med 2006;39(4):459–60.
13. Brown JD, Halpern CT, L'Engle KL. Mass media as a sexual super peer for early maturing girls. J Adolesc Health Off Publ Soc Adolesc Med 2005;36(5):420–7.
14. Collins L, Murphy S, Bierman K. A conceptual framework for adaptive preventive interventions. Prev Sci 2004;5:185–96.
15. Glick SN, Golden MR. Early male partnership patterns, social support, and sexual risk behavior among young men who have sex with men. AIDS Behav 2014;18(8):1466–75.
16. Wong CF, Schrager SM, Chou C-P, Weiss G, Kipke MD. Changes in Developmental Contexts as Predictors of Transitions in HIV-Risk Behaviors Among Young Men Who Have Sex with Men (YMSM). Am J Community Psychol 2013;51(3–4):439–50.
17. Friedman SR, Cooper HL, Osborne AH. Structural and social contexts of HIV risk Among African Americans. Am J Public Health 2009;99:1002–8.
18. Viner RM, Ozer EM, Denny S, et al. Adolescence and the social determinants of health. The Lancet 2012;379(9826):1641–52.
19. Kachur R, Mesnick J, Liddon N, et al. Adolescents, technology, and reducing risk for HIV, STDs, and pregnancy. Atlanta, GA: Centers for Disease Control and Prevention; 2013.
20. Flores DD, Blake BJ, Sowell RL. "Get them while they're young": reflections of young gay men newly diagnosed with HIV infection. J Assoc Nurses AIDS Care JANAC 2011;22(5):376–87.
21. Kubicek K, Beyer WJ, Weiss G, Iverson E, Kipke MD. In the dark: young men's stories of sexual initiation in the absence of relevant sexual health information. Health Educ Behav 2010;37:243–63.
22. Rothman EF, Kaczmarsky C, Burke N, Jansen E, Baughman A. "Without Porn … I Wouldn't Know Half the Things I Know Now": A Qualitative Study of Pornography Use Among a Sample of Urban, Low-Income, Black and Hispanic Youth. J Sex Res 2015;52(7):736–46.
23. Arrington-Sanders R, Harper GW, Morgan A, Ogunbajo A, Trent M, Fortenberry JD. The role of sexually explicit material in the sexual development of same-sex-attracted Black adolescent males. Arch Sex Behav 2015;44(3):597–608.
24. Nelson KM, Pantalone DW, Carey MP. Sexual health education for adolescent males who are interested in sex with males: An investigation of experiences, preferences, and needs. J Adolesc Health 2019;64(1):36–42.
25. Nelson KM, Carey MP. Media Literacy Is an Essential Component of HIV Prevention for Young Men Who Have Sex With Men. Arch Sex Behav 2016;45(4):787–8.
26. Nelson KM, Perry NS, Carey MP. Sexually explicit media use among 14–17-year-old sexual minority males in the U.S. Arch Sex Behav [Internet] 2019 [cited 2019 Sep 12];Available from: http://link.springer.com/10.1007/s10508-019-01501-3
27. Raifman J, Beyrer C, Arrington-Sanders R. HIV education and sexual risk behaviors among young men who have sex with men. LGBT Health 2018;5(2):131–8.
28. Rasberry CN, Condron DS, Lesesne CA, Adkins SH, Sheremenko G, Kroupa E. Associations between sexual risk-related behaviors and school-based education on HIV and condom use for adolescent sexual minority males and their non-sexual-minority peers. LGBT Health 2018;5(1):69–77.

29. Hall KS, Sales JM, Komro KA, Santelli J. The state of sex education in the United States. J Adolesc Health 2016;58(6):595–7.
30. Mustanski B, Lyons T, Garcia SC. Internet use and sexual health of young men who have sex with men: a mixed-methods study. Arch Sex Behav 2011;40(2):289–300.
31. Downing MJ, Schrimshaw EW, Antebi N, Siegel K. Sexually explicit media on the internet: a content analysis of sexual behaviors, risk, and media characteristics in gay male adult videos. Arch Sex Behav 2014;43(4):811–21.
32. Grudzen C, Elliott M, Kerndt P, Schuster M, Brook R, Gelberg L. Condom Use and High-Risk Sexual Acts in Adult Films: A Comparison of Heterosexual and Homosexual Films. Am J Public Health 2009;99:S152–S156.
33. Hurley R. Bareback to basics: How gay porn undermines safe sex campaigns. BMJ 2009;338:b910.
34. Rosser BRS, Grey JA, Wilkerson JM, et al. A commentary on the role of sexually explicit media (SEM) in the transmission and prevention of HIV among men who have sex with men (MSM). AIDS Behav 2012;16(6):1373–81.
35. Stein D, Silvera R, Hagerty R, Marmor M. Viewing pornography depicting unprotected anal intercourse: are there implications for HIV prevention among men who have sex with men? Arch Sex Behav 2012;41(2):411–9.
36. Rosser BRS, Smolenski DJ, Erickson D, et al. The effects of gay sexually explicit media on the HIV risk behavior of men who have sex with men. AIDS Behav 2013;17(4):1488–98.
37. Nelson KM, Simoni JM, Morrison DM, et al. Sexually explicit online media and sexual risk among men who have sex with men in the United States. Arch Sex Behav 2014;43(4):833–43.
38. Schrimshaw EW, Antebi-Gruszka N, Jr MJ. Viewing of Internet-based sexually explicit media as a risk factor for condomless anal sex among men who have sex with men in four U.S. cities. PLOS ONE 2016;11(4):e0154439.
39. Whitfield THF, Rendina HJ, Grov C, Parsons JT. Sexually explicit media and condomless anal sex among gay and bisexual men. AIDS Behav 2018;22(2):681–9.
40. Albury K. Porn and sex education, porn as sex education. Porn Stud 2014;1(1–2):172–81.
41. Jeong S-H, Cho H, Hwang Y. Media Literacy Interventions: A Meta-Analytic Review. J Commun 2012;62(3):454–72.
42. Pinkleton BE, Austin EW, Cohen M, Chen Y-CY, Fitzgerald E. Effects of a peer-led media literacy curriculum on adolescents' knowledge and attitudes toward sexual behavior and media portrayals of sex. Health Commun 2008;23(5):462–72.
43. Pinkleton BE, Austin EW, Chen Y-C "Yvonnes", Cohen M. Assessing Effects of a Media Literacy-Based Intervention on US Adolescents' Responses to and Interpretations of Sexual Media Messages. J Child Media 2013;7(4):463–79.
44. Scull T, Malik C, Kupersmidt J. A Media Literacy Education Approach to Teaching Adolescents Comprehensive Sexual Health Education. J Media Lit Educ 2014;6(1):1–14.
45. Nelson KM, Carey MP, Fisher CB. Is guardian permission a barrier to online sexual health research among adolescent males interested in sex with males? J Sex Res 2019;56(4–5):593–603.
46. Nelson KM, Underhill K, Carey MP. Consent for HIV Testing Among Adolescent Sexual Minority Males: Legal Status, Youth Perceptions, and Associations with Actual Testing and Sexual Risk Behavior. AIDS Behav 2019;
47. Norris AL, Nelson KM, Carey MP. HIV testing intentions and behaviors among 14-17-year-old sexual minority males. AIDS Care 2019;1–5.
48. Larsen DL, Attkisson CC, Hargreaves WA, Nguyen TD. Assessment of client/patient satisfaction: Development of a general scale. Eval Program Plann 1979;2(3):197–207.
49. Weinhardt LS, Carey MP, Maisto SA, Carey KB, Cohen MM, Wickramasinghe SM. Reliability of the timeline follow-back sexual behavior interview. Ann Behav Med Publ Soc Behav Med 1998;20(1):25–30.
50. Weinhardt LS, Forsyth AD, Carey MP, Jaworski BC, Durant LE. Reliability and validity of self-report measures of HIV-related sexual behavior: progress since 1990 and recommendations for research and practice. Arch Sex Behav 1998;27(2):155–80.
51. Schroder KEE, Carey MP, Vanable PA. Methodological challenges in research on sexual risk behavior: II. Accuracy of self-reports. Ann Behav Med Publ Soc Behav Med 2003;26(2):104–23.
52. Schroder KEE, Carey MP, Vanable PA. Methodological challenges in research on sexual risk behavior: I. Item content, scaling, and data analytical options. Ann Behav Med Publ Soc Behav Med 2003;26(2):76–103.
53. Mustanski B, Greene GJ, Ryan D, Whitton SW. Feasibility, Acceptability, and Initial Efficacy of an Online Sexual Health Promotion Program for LGBT Youth: The Queer Sex Ed Intervention. J Sex Res 2014;

54. Sacco WP, Levine B, Reed DL, Thompson K. Attitudes about condom use as an AIDS-relevant behavior: Their factor structure and relation to condom use. Psychol Assess J Consult Clin Psychol 1991;3(2):265–72.
55. Carey MP, Schroder KEE. Development and psychometric evaluation of the brief HIV Knowledge Questionnaire. AIDS Educ Prev Off Publ Int Soc AIDS Educ 2002;14(2):172–82.
56. Jaworski BC, Carey MP. Development and psychometric evaluation of a self-administered questionnaire to measure knowledge of sexually transmitted diseases. AIDS Behav 2007;11(4):557–74.
57. Frost JJ, Lindberg LD, Finer LB. Young Adults' Contraceptive Knowledge, Norms and Attitudes: Associations with Risk Of Unintended Pregnancy. Perspect Sex Reprod Health 2012;44(2):107–16.
58. Mustanski B. Ethical and regulatory issues with conducting sexuality research with LGBT adolescents: a call to action for a scientifically informed approach. Arch Sex Behav 2011;40(4):673–86.
59. Macapagal K, Bettin E, Matson M, Kraus A, Fisher CB, Mustanski B. Measuring discomfort in health research relative to everyday events and routine care: An application to sexual and gender minority youth. J Adolesc Health Off Publ Soc Adolesc Med 2019;64(5):594–601.
60. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform 2009;42(2):377–81.
61. Palmer NA, Kosciw JG, Greytak EA, Ybarra ML, Korchmaros JD, Mitchell KJ. Out Online: The experiences of lesbian, gay, bisexual, and transgender youth on the Internet. New York, NY: Gay, Lesbian, & Straight Education Network; 2013.
62. Sullivan PS, Grey JA, Simon Rosser BR. Emerging technologies for HIV prevention for MSM: what we have learned, and ways forward. J Acquir Immune Defic Syndr 1999 2013;63 Suppl 1:S102-107.
63. Bowen AM, Daniel CM, Williams ML, Baird GL. Identifying multiple submissions in Internet research: preserving data integrity. AIDS Behav 2008;12(6):964–73.
64. Mustanski BS. Getting wired: Exploiting the internet for the collection of valid sexuality data. J Sex Res 2001;38(4):292–301.
65. Sullivan PS, Khosropour CM, Luisi N, et al. Bias in online recruitment and retention of racial and ethnic minority men who have sex with men. J Med Internet Res 2011;13(2):e38.
66. Mustanski B. Ethical and regulatory issues with conducting sexuality research with LGBT adolescents: a call to action for a scientifically informed approach. Arch Sex Behav 2011;40(4):673–86.
67. Fisher CB, Mustanski B. Reducing Health Disparities and Enhancing the Responsible Conduct of Research Involving LGBT Youth. Hastings Cent Rep 2014;44(s4):S28–31.
68. Schrager SM, Steiner RJ, Bouris AM, Macapagal K, Brown CH. Methodological considerations for advancing research on the health and wellbeing of sexual and gender minority youth. LGBT Health 2019;6(4):156–65.
69. Santelli JS, Smith Rogers A, Rosenfeld WD, et al. Guidelines for adolescent health research. A position paper of the Society for Adolescent Medicine. J Adolesc Health Off Publ Soc Adolesc Med 2003;33(5):396–409.
70. Amercian Psychological Association. APA resolution on Support for the Expansion of Mature Minors' Ability to Participate in Research [Internet]. Washington, DC: American Psychological Association; 2018 [cited 2019 Mar 1]. Available from: https://www.apa.org/about/policy/resolution-minors-research.pdf
71. Du Bois SN, Emerson E, Mustanski B. Condom-related problems among a racially diverse sample of young men who have sex with men. AIDS Behav 2011;15(7):1342–6.
72. Newcomb ME, Ryan DT, Garofalo R, Mustanski B. The effects of sexual partnership and relationship characteristics on three sexual risk variables in young men who have sex with men. Arch Sex Behav 2014;43(1):61–72.
73. Torres HL, Delonga K, Lee S, et al. Sociocontextual Factors: Moving Beyond Individual Determinants of Sexual Risk Behavior Among Gay and Bisexual Adolescent Males. J LGBT Youth 2013;10(3):173–85.
74. Rosario M, Schrimshaw EW, Hunter J. A model of sexual risk behaviors among young gay and bisexual men: longitudinal associations of mental health, substance abuse, sexual abuse, and the coming-out process. AIDS Educ Prev 2006;18:444–60.
75. Ybarra ML, Prescott TL, Ii GLP, Bull SS, Parsons JT, Mustanski B. Iteratively Developing an mHealth HIV Prevention Program for Sexual Minority Adolescent Men. AIDS Behav 2015;1–16.

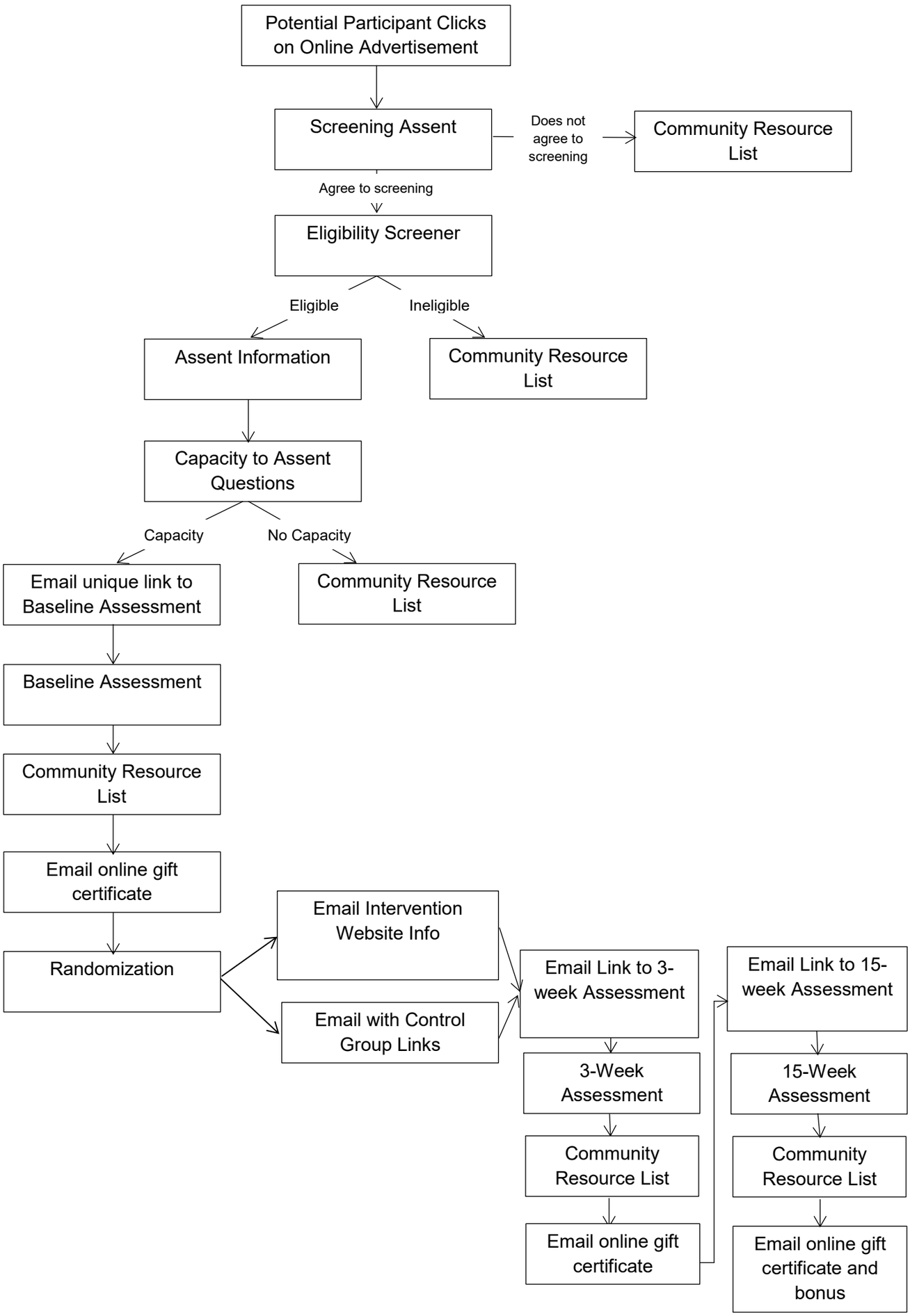
76. Fisher CB, Mustanski B. Reducing Health Disparities and Enhancing the Responsible Conduct of Research Involving LGBT Youth. Hastings Cent Rep 2014;44(s4):S28–31.
77. Fisher CB, Arbeit MR, Dumont MS, Macapagal K, Mustanski B. Self-consent for HIV prevention research involving sexual and gender minority youth: Reducing barriers through evidence-based ethics. J Empir Res Hum Res Ethics JERHRE 2016;11(1):3–14.
78. Macapagal K, Coventry R, Arbeit MR, Fisher CB, Mustanski B. "I won't out myself just to do a survey": Sexual and gender minority adolescents' perspectives on the risks and benefits of sex research. Arch Sex Behav 2017;46(5):1393–409.
79. Fisher CB, Fried AL, Ibrahim Puri L, Macapagal K, Mustanski B. "Free Testing and PrEP without Outing Myself to Parents:" Motivation to participate in oral and injectable PrEP clinical trials among adolescent men who have sex with men. PloS One 2018;13(7):e0200560.
80. Jeffries WL, Gelaude DJ, Torrone EA, et al. Unhealthy environments, unhealthy consequences: Experienced homonegativity and HIV infection risk among young men who have sex with men. Glob Public Health 2015;1–14.
81. Martinez G, Abma, Joyce C., Copen, Casey E., National Center for Health Statistics (U.S.). Educating teenagers about sex in the United States. Hyattsville, MD: U.S. Department of Health and Human Services; 2010.
82. Guttmacher Institute. An overview of consent to reproductive health services by young people [Internet]. Washington, DC: Guttmacher Institute; 2019 [cited 2019 Apr 5]. Available from: https://www.guttmacher.org/state-policy/explore/overview-minors-consent-law
83. Santelli JS, Smith Rogers A, Rosenfeld WD, et al. Guidelines for adolescent health research. A position paper of the Society for Adolescent Medicine. J Adolesc Health Off Publ Soc Adolesc Med 2003;33(5):396–409.
84. Amercian Psychological Association. APA resolution on Support for the Expansion of Mature Minors' Ability to Participate in Research [Internet]. Washington, DC: American Psychological Association; 2018 [cited 2019 Mar 1]. Available from: https://www.apa.org/about/policy/resolution-minors-research.pdf
85. Dunn LB, Jeste DV. Enhancing informed consent for research and treatment. Neuropsychopharmacol Off Publ Am Coll Neuropsychopharmacol 2001;24(6):595–607.
86. The University of California at San Diego Task Force on Decisional Capacity. Procedures for determination of decisional capacity in persons participating in research protocols. San Diego, CA: The University of California; 2003.
87. Thiede H, Jenkins R, Carey J, et al. Determinants of recent HIV infection among Seattle-area men who have sex with men. Am J Public Health 2009;99 Suppl 1:S157-64.
88. Brown RL, Rounds LA. Conjoint screening questionnaires for alcohol and other drug abuse: criterion validity in a primary care practice. Wis Med J 1995;94(3):135–40.

15 Appendix

	DESCRIPTION
1	Schematic of study design and participant flow
2	Schedule of events
3	Intervention website content
4	Resource list

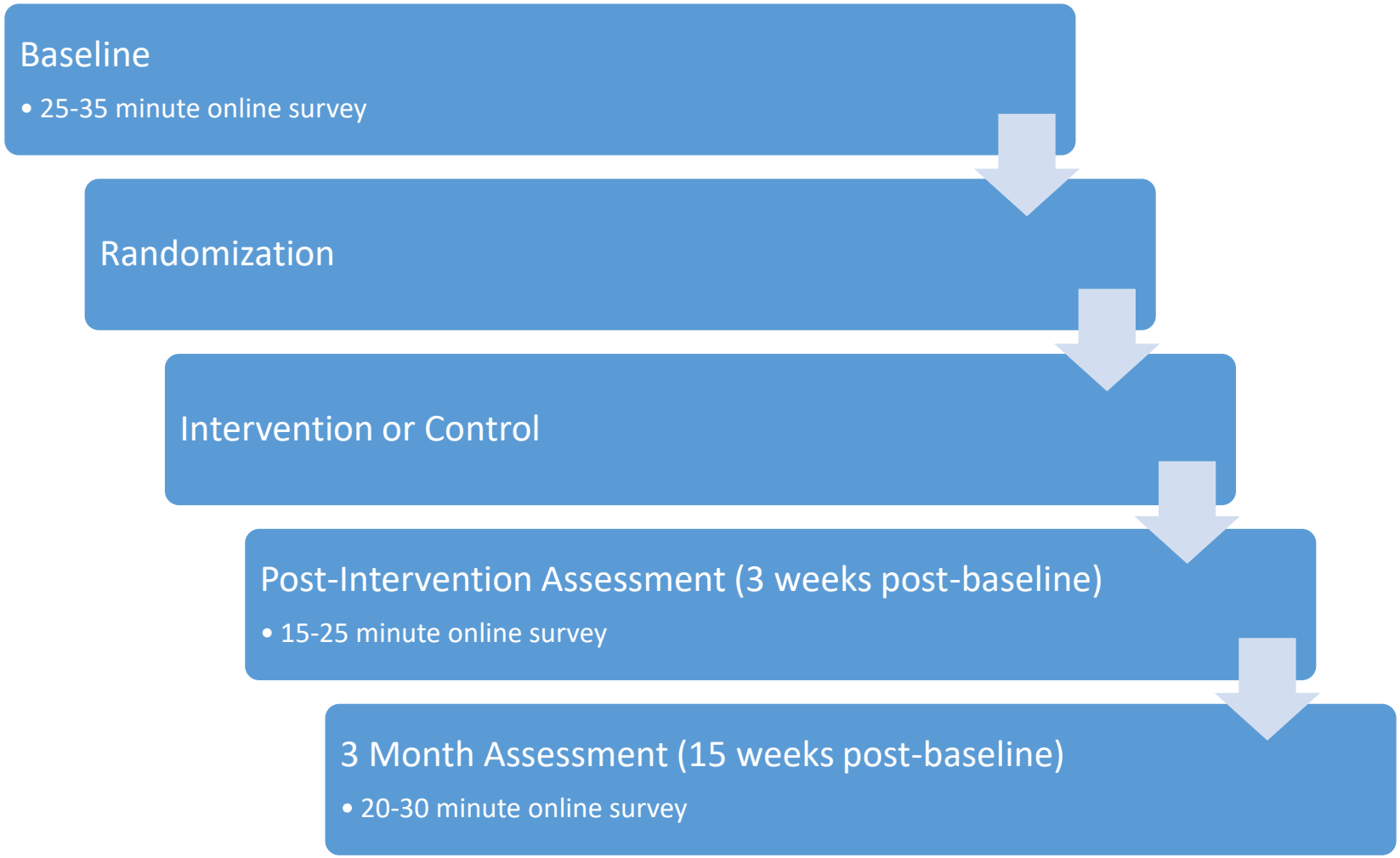
Appendix 1

Schematic of study design and participant flow


Potential Participant Clicks on Online Advertisement
Screening Assent
Does not agree to screening
Community Resource List
Agree to screening
Eligibility Screener
Eligible
Ineligible
Assent Information
Community Resource List
Capacity to Assent Questions
Capacity
No Capacity
Email unique link to Baseline Assessment
Community Resource List
Baseline Assessment
Community Resource List
Email online gift certificate
Randomization
Email Intervention Website Info
Email with Control Group Links
Email Link to 3-week Assessment
3-Week Assessment
Community Resource List
Email online gift certificate
Email Link to 15-week Assessment
15-Week Assessment
Community Resource List
Email online gift certificate and bonus

Appendix 2

Schedule of events


Baseline
• 25-35 minute online survey
Randomization
Intervention or Control
Post-Intervention Assessment (3 weeks post-baseline)
• 15-25 minute online survey
3 Month Assessment (15 weeks post-baseline)
• 20-30 minute online survey

Appendix 3

Intervention Website Content

A. Website Address:

a. www.youngmenandmedia.com

B. Landing Page:

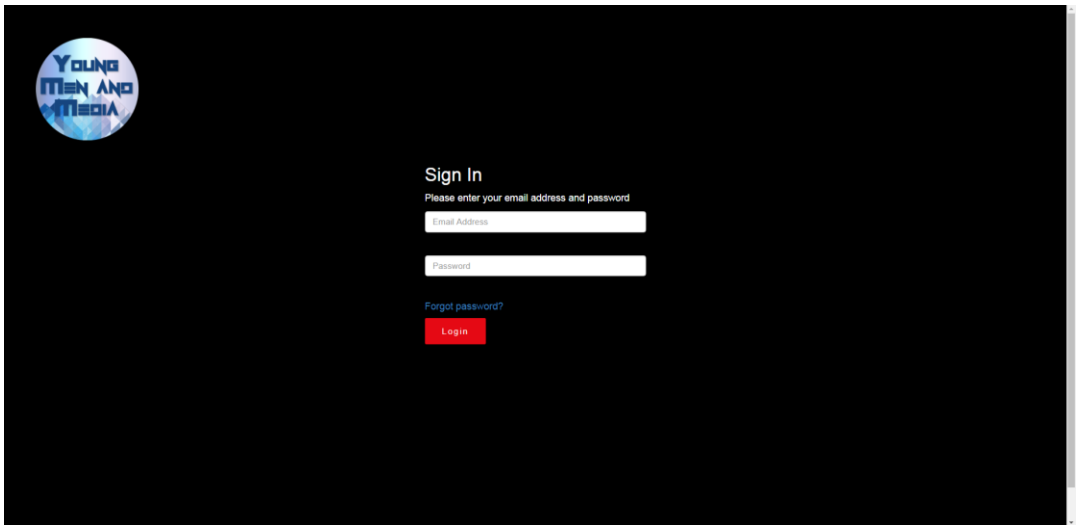
a. Description: The landing page is basic with no information to indicate the target population or anyway to enter the page without a sign in.

b. Screenshot:

C. Sign in page:

a. Description: The sign in page is basic with no information to indicate the target population or anyway to enter the page without an assigned sign in.

b. Screenshot:

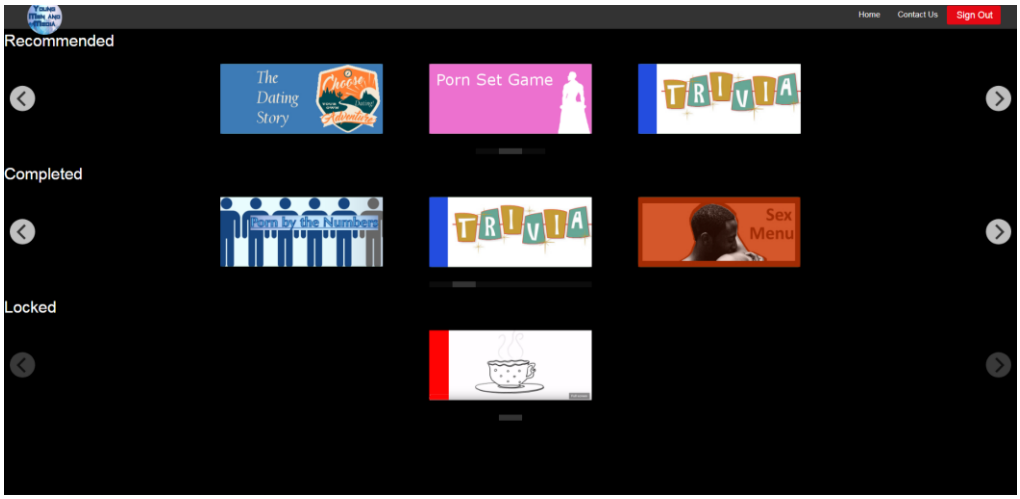


D. Website Design:

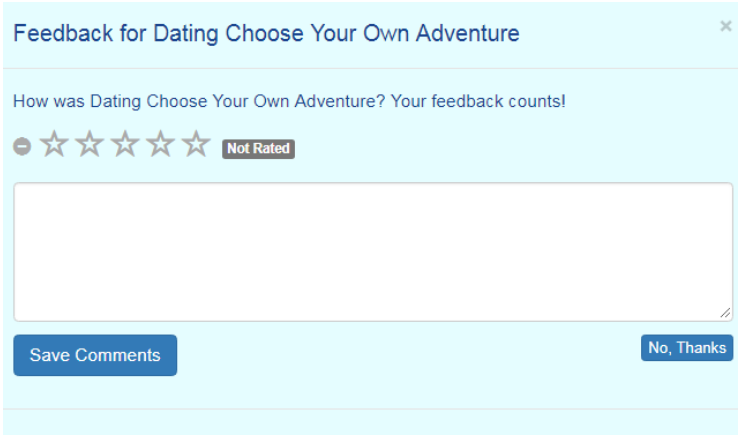
a. Description: The website is designed to mimic the flow and formatting of Netflix. It is adaptive so that it can be used on a mobile phone or a computer. There are tiles to represent the various parts of the intervention. There are three rows of tiles: recommended, completed, and locked. Once a participant has completed

recommended content, the tile for that content will move to the completed row and locked content will be unlocked and moved to recommended. Participants can complete pieces of content more than once and will be asked to rate each piece of content on a 5-star scale and provide additional comments about content (that can only be seen by them and our staff) upon their completion.

b. Screenshot of Site:



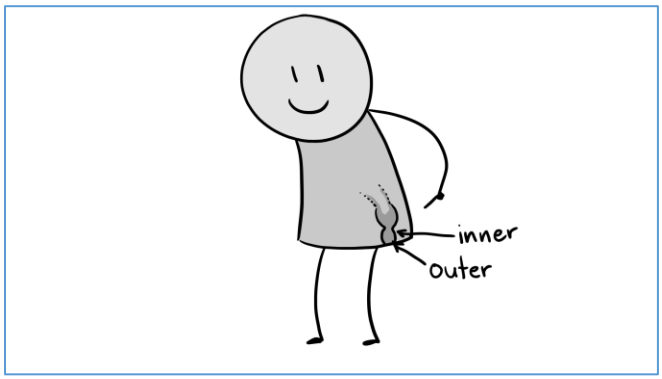
c. Screenshot of Example Feedback Panel:



d. Intervention Content

Topics	Intervention Content (Detailed Descriptions Below)
Male-Male Sex Ed 101	
Anatomy	
Penis	Sexual Health/Anatomy Animation by Blue Seat Studios
Anus/Prostate	Sexual Health/Anatomy Animation by Blue Seat Studios
HIV/AIDS and STIs Prevention	
HIV transmission 101	HIV/STI Jeopardy
STI transmission 101	HIV/STI Jeopardy
How to use a condom	Sexual Health/Anatomy Animation by Blue Seat Studios
How to talk with sexual partners about STIs/HIV	Choose Your Own Dating Adventure Game
How to access services (e.g., testing, doctors)	HIV/STI Jeopardy
General Sexual Health	
The types of sex you can have with a male partner	Sex Menu
How to pick partners	Choose your own adventure communication overview
Anal health	Interview with Dr. Bryan Kutner
Fiber/Anal douching	Interview with Dr. Bryan Kutner
How to safely and comfortably have anal sex	Interview with Dr. Bryan Kutner
How to use lubrication or lube (e.g., K-Y, bodyglide)	Interview with Dr. Bryan Kutner
Communication with partners	Choose Your Own Dating Adventure Game
Consent	Tea Consent Animation by Blue Seat Studios
How to talk with sexual partners about what you would/wound NOT like to do sexually	Choose Your Own Dating Adventure Game
Sex-seeking website/app etiquette/protection	Choose Your Own Dating Adventure Game
Porn Literacy	
What's omitted	Porn Matching Game
Behind the scenes	
Author and purpose	Porn Set Scavenger Hunt Game
Political/Economic Context	Porn Set Scavenger Hunt Game
Porn Addiction	Porn by the Numbers Infographic

e. Sexual Health/Anatomy Animation by Blue Seat Studios
   i. Description: This animated video uses humor to cover basic anatomy of the penis, anus, and prostate as well as how to correctly put a condom on, the importance of talking with partners, and a brief introduction to anal health.
   ii. Screenshot:

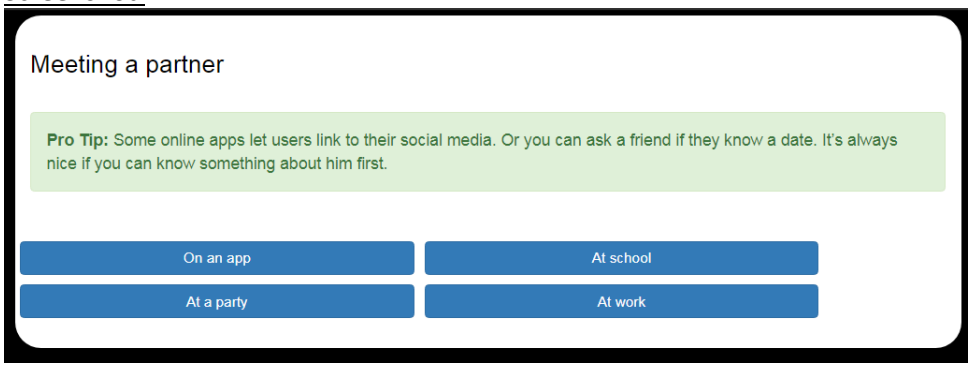


f. HIV/STI Jeopardy
   i. Description: This game is based on traditional jeopardy (5 columns with 5 questions in each column). The five columns are: (1) HIV 101, (2) HIV Testing, (3) STI 101, (4) STI Testing & Symptoms, and (5) Final Review. Each question is given a dollar value and there is a "Daily Double" after all questions have been answered. The questions cover the basics of HIV/STI transmission, how to prevent HIV/STIs, and how to access services. Example questions include: "What does HIV stand for?" "What are ways you can protect yourself from getting HIV and other sexually transmitted infections?"
   ii. Screenshot:

g. Sex Menu
    i. Description: This infographic goal is to expand what participants consider male-male sex. It covers a wide range of behaviors including hand holding, cuddling, licking, masturbation, oral sex, and anal sex. All images imply the sexual behaviors that are being highlighted in an artistic manner. They do not show anything that could be considered pornographic (e.g., no exposed genitalia, penetration) and are in accord with what youth would be able to see in standard magazine and TV advertisements.

    ii. Screenshot:

h. Choose your own dating adventure game
    i. Description: In the tradition of choose your own adventure books, this game allows participants to play out different dating scenarios including choices related to where to meet partners, using alcohol or drugs on a date, whether to have sex or not, talking about HIV/STIs with partners, and talking about what you do and do not want to do sexually with partners. With each choice participants are given feedback about the pros and cons of the choice they have made. At the end participants are given a summary of their choices and how they choices relate to their HIV/STI risk and safety.
    ii. Screenshot:



i. Interview with Dr. Bryan Kutner, anal health specialist
    i. Description: Dr. Bryan Kutner, an anal health specialist and clinical psychologist, is interviewed in this video and discusses topics related to anal health including

anatomy, fiber/douching, how to safely and comfortably have anal sex, how to use lube, and how to effectively communicate with partners.

ii. Screenshot:

j. Tea Consent Animation by Blue Seat Studios

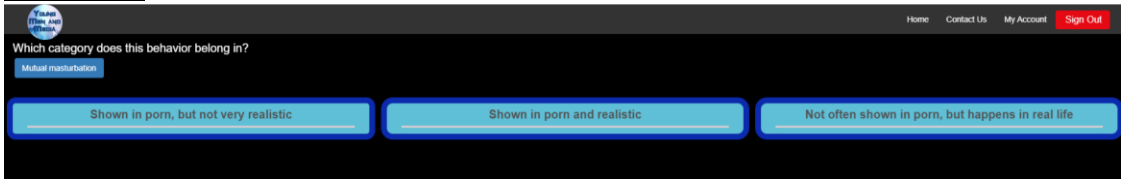
i. Description: This animated video uses humor to convey what does and does not constitute consent between sexual partners.

ii. Screenshot:

k. Porn Matching Game

i. Description: Participants are given a list of sexual and relationship behaviors and asked to sort them into three buckets: (1) Shown in porn, but not very realistic (e.g., rapid/rough anal sex); (2) Shown in porn and realistic (e.g., mutual masturbation); (3) Not often shown in porn, but happens in real life sexual relationships (e.g., talking with partners, eye contact).

ii. Screenshot:

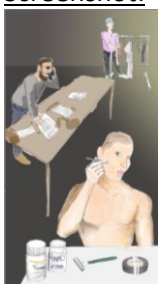


l. Porn Set Scavenger Hunt Game

i. Description: In this game participants are asked to find all of the items that are "clickable" on an illustrated porn set (which does not depict any sexual acts). When they click on an item (e.g., the producer, STI test results, the lighting rig)

they are given a description of the item and why it is there. The goal of this game is to help participants to understand that what they see on the screen when they are viewing pornography is not representative of what is actually happening on the set and to illustrate the roles and motives of the people who are involved in making the porn.

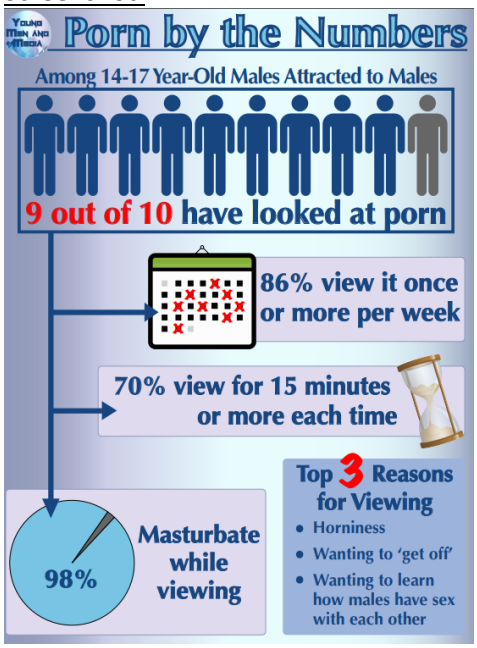
ii. Screenshot:



m. Porn by the Numbers Infographic

i. Description: To help youth understand the typical way porn is used by other ASMM their age, this infographic (using data from Phase 2 of this study) provides basic statistics about how many 14-17 year old ASMM report viewing porn, how often they view, how many are masturbating while they are viewing, and the top three reasons for viewing

ii. Screenshot:



Appendix 4

Resource List

The Young Men & Media Study

For those who are ineligible:

Thank you for your time! Check out these youth-friendly national community resources.

For those who are completed a baseline assessment:

Thank you for completing the first survey!

Once we have determined that you are eligible and have not taken the survey more than once, we will email you a $15 Amazon.com gift certificate code. You will also receive a second email with either a link, username, and temporary password for our developed website or some links to other HIV/STD related websites.

For those who are completed a 3-week assessment:

Thank you for completing the second survey!

We will email you a $25 Amazon.com gift certificate code. Also, don't forget that there is one more survey that will be sent to you in about three months.

For those who are completed a 15-week assessment:

Thank you for completing the last survey!

We will email you a $35 Amazon.com gift certificate code. Also, if you completed all three surveys, we will email you an additional $20 Amazon.com gift certificate code.

For everyone:

If you have any questions or comments about our study or have experienced any distress as a result of this study, please feel free to contact the study investigator, Dr. Kimberly Nelson, 617-358-1482, ymnm@bu.edu.

Additionally, we have compiled a list of youth-friendly national community resources below that you may find useful.

The Trevor Project
The Trevor Project is the leading national organization providing crisis intervention and suicide prevention services to LGBTQ young people ages 13-24, including a 24-hour helpline.
Address:PO Box 69232 West Hollywood, CA 90069
Phone:(866) 488-7386
Email:info@thetrevorproject.org
Website:http://www.thetrevorproject.org/

GLBT National Youth Talkline
The GLBT Youth Talkline provides telephone and online private, one-to-one chat and email peer-support, as well as factual information and local resources for cities and towns across the United States. The talkline is open Monday - Friday from 4pm to 12am and Saturday 12pm to 5pm.
Address: 511 East Pike Street Seattle, WA 98122
Phone: (800) 246-7743
Email: help@GLBThotline.org
Website:http://www.glbthotline.org/talkline.html

PRIDE Institute
The PRIDE Institute specializes in treatment of substance abuse, sexual health, and co-occuring mental health issues for LGBTQ+ clients. Their phone line is open 24 hours a day.
Phone: (800) 547-7433
Website:https://pride-institute.com/

The National Alliance on Mental Illness
The National Alliance on Mental illness (NAMI) provides information about how mental health conditions affect the LGBTQ community as well as ways to find LGBTQ-inclusive mental health treatment.
Phone:(800) 950-NAMI
Email: info@nami.org
Website:https://www.nami.org/Find-Support/LGBTQ

Genders & Sexualities Alliance (GSA) Network
GSA Network operates the GSA Network of California, which connects over 900 clubs across the state, the National Association of GSA Networks, which unites 40 statewide networks of GSA clubs, and GSAs Unite (unite.gsanetwork.org), an online campaign and petition platform supporting youth organizers across the country.
Phone:(415) 552-4229
Email: info@gsanetwork.org
Website:https://gsanetwork.org/