Zenyth: Motivational Interviewing-based Telehealth Intervention for Bacterial Sexually Transmitted Infection Screening

NCT Number: NCT06100250

University of Michigan Health Sciences and Behavioral Sciences Institutional Review Board (IRB-HSBS) ID: HUM00240181

Study Protocol and Statistical Analysis Plan Approval Date: 4/30/2024

SCIENTIFIC PROTOCOL

Study Title
Zenyth

Full Study Title
Zenyth – Feasibility and Acceptability of an MI-based Telehealth Intervention for Bacterial STI Screening

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Sponsoring Agency
National Institutes of Health (NIH) – National Institute of Allergy and Infectious Diseases (NIAID)

Section 1. Introduction

a. Background

In the United States (US), gay, bisexual, and other men who have sex with men living with HIV (GBMSM-LWH) bear a heavy burden of bacterial sexually transmitted infections (STIs) such as gonorrhea (GC), chlamydia (CT), and syphilis.[1] National surveillance data for 2020 from the Centers for Disease Control and Prevention (CDC) indicate that among GBMSM-LWH who presented for HIV medical care during the height of the COVID-19 pandemic, GC positivity was 14.2% (vs. 9.8% for GBMSM without HIV) and CT positivity was 6.5% (vs. 7.0% for GBMSM without HIV).[1] Additionally, 10.4% of GBMSM-LWH were diagnosed with primary and secondary syphilis (vs. 5.5% of GBMSM without HIV).[1] Left untreated, bacterial STIs may lead to serious health complications such as epididymitis, orchitis, prostatitis, seminal vesiculitis, and proctitis.[2-4] Inflammatory and ulcerative STIs can also facilitate the onward sexual transmission of HIV in the presence of inadequate viral suppression.[5-10] For example, new syphilis infections can increase HIV viral loads and decrease CD4 cell counts and syphilitic ulcers can aid the passage of HIV.[10] Therefore, the acquisition of bacterial STIs by GBMSM-LWH has profound individual and public health implications, underscoring the need for early diagnosis and treatment.

Sexually active GBMSM-LWH are recommended to be tested for GC, CT, and syphilis at least annually and at 3-6 month intervals if at elevated risk.[11] However, bacterial STI screening rates in GBMSM-LWH are suboptimal.[12-14] Data from the Medical Monitoring Project have revealed gradual increases in yearly testing for GC, CT, and syphilis among GBMSM-LWH engaged in HIV medical care,[15] but a 2020 study reported that only 49% had been tested for GC or CT and 68% had been tested for syphilis.[16] GC and CT infections at pharyngeal and rectal sites are often asymptomatic and remain undiagnosed.[17-21] Urine-only GC and CT testing can miss 70-75% of extra-urethral GC infections and 85-89% of extra-urethral CT infections.[22, 23] Recent estimates for the proportions of GBMSM-LWH being tested for extra-urethral GC or CT annually during routine clinic visits have ranged from 4-20%.[16, 24] Provider-related barriers to offering testing include limited time, fear of appearing judgmental, discomfort around discussing sexual behaviors, and being unsure of current testing guidelines.[25, 26] Patient-related barriers include perceptions of low risk for bacterial STIs, being unaware of the importance of triple-site GC and CT testing (i.e., using urine samples, throat swabs, and rectal swabs), fear of stigmatization by providers, and concerns about privacy and confidentiality.[27-29] Novel approaches are needed to reduce impediments to bacterial STI screening experienced by GBMSM-LWH in the US.

Home specimen self-collection has increasingly been used to test for bacterial STIs in studies conducted with diverse populations.[30-39] Self-collected specimens for bacterial STI screening are equally valid and reliable as those collected by a clinician.[40-53] Telehealth has also demonstrated promise in managing mental health[54, 55] and increasing antiretroviral therapy (ART) adherence in people living with HIV.[56-61] Only few studies have combined home specimen self-collection with live audio/video (AV) conferencing, all of which have been restricted to people without HIV.[62-67] None have focused on GBMSM-LWH or incorporated motivational interviewing (MI), a client-centered, strengths-based counseling approach that seeks to support individuals towards positive behavioral change.[68, 69] Integrating home specimen self-collection from different anatomical sites of possible exposure with MI delivered via live AV conferencing might offer a unique solution to engage GBMSM-LWH in bacterial STI screening. MI-guided discussions have the potential to increase participants' knowledge of bacterial STIs, enhance their intrinsic motivation to protect themselves and their sex partners, improve their self-efficacy for specimen self-collection, and problem-solve barriers to seeking treatment (if warranted) and repeat testing.

b. Objectives

To investigate the feasibility and acceptability of a novel MI-based telehealth intervention to engage GBMSM-LWH in GC, CT, and syphilis testing, we propose to conduct a 2-year sequential explanatory mixed-methods study.[70, 71] Our intervention is a package of 3 components: (i) a pre-test live AV conferencing session involving an MI-guided discussion to elicit awareness of bacterial STIs and fill any knowledge gaps, bolster the perceived importance of regularly testing for GC, CT, and syphilis, and improve self-efficacy for specimen self-collection, (ii) self-collecting at home and returning by mail a urine sample (for GC and CT testing), a throat swab (for GC and CT testing), a rectal swab (for GC and CT testing), and a finger-stick blood sample (for syphilis testing), and (iii) a post-test live AV conferencing session involving an MI-guided discussion to prepare participants for receiving test results and formulate personalized action plans for seeking treatment (if warranted) and repeat testing. Potential increases in participants' knowledge of GC, CT, and syphilis will be assessed by comparing their responses to the same set of questions on these STIs included in the baseline survey (to be administered before intervention delivery) and the satisfaction survey (to be administered after intervention delivery).

c. Specific aims

Guided by the main constructs of the Information-Motivation-Behavioral skills (IMB) model[72, 73] and the Theoretical Framework of Acceptability (TFA) of health interventions,[74] our specific aims are as follows:

Aim 1: Explore the feasibility and acceptability of a telehealth intervention for bacterial STI testing among 75 GBMSM-LWH in the US involving (i) a pre-test MI-guided live AV conferencing session, (ii) home specimen self-collection and return for GC, CT, and syphilis testing, and (iii) a post-test MI-guided live AV conferencing session.

Aim 2: Elucidate attitudes, facilitators, and barriers related to engaging in each intervention component via in-depth interviews with a purposive subsample of 20 participants who complete progressively smaller subsets of the pre-test session, specimen return for bacterial STI testing, and the post-test session to refine the intervention.

Section 2. Participant recruitment

a. Sample size

Pilot studies are well-suited to conducting exploratory research,[75, 76] for which sample sizes between 25 to 150 have been recommended.[77, 78] In Phase 1, we will enroll 75 GBMSM-LWH to collect data on the feasibility and acceptability of the intervention. Sample sizes between 10 to 30 have been recommended for in-depth interviews.[79, 80] In Phase 2, we estimate that collecting qualitative data on attitudes, facilitators, and barriers from a subsample of 20 participants will be sufficient to reach information power[81] and thematic saturation.[82]

b. Primary recruitment strategy – Social media advertising

Participants will primarily be recruited via social media advertising. According to a 2021 survey by the Pew Research Center, 7 in 10 Americans use social media.[83] Current internet usage is at 93% for non-Hispanic whites, 91% for non-Hispanic blacks, and 95% for Hispanics.[84] Smartphone usage has also increased, with 85% of non-Hispanic whites, 83% of non-Hispanic blacks, and

85% of Hispanics owning a smartphone in 2021.[85] Given the common use of social media by GBMSM to find sex partners,[86-91] we will enroll 75 GBMSM-LWH via advertisements placed on mobile dating apps (e.g., Grindr, Scruff) and social networking sites (e.g., Facebook, Instagram) to receive the intervention. Our goal is to enroll 25 non-Hispanic black participants, 20 Hispanic participants, 25 non-Hispanic white participants, and 5 participants of other races/ethnicities, mirroring the current racial/ethnic distribution of GBMSM-LWH in the US.[92] Our advertisements will include our study's name and logo, the University of Michigan logo, images of racially and ethnically diverse men holding hands, cuddling, or kissing, and call-to-action text. Similar to PI Sharma's recently completed Project Caboodle (HUM00153673), which successfully enrolled a diverse sample of GBMSM from across the US,[93-96] we will monitor the racial/ethnic distribution of our sample on an ongoing basis and tailor our advertising efforts to achieve our goal of diversity. For example, if we need to recruit additional non-Hispanic black participants, we will focus our social media advertising in US metropolitan areas that have large black populations (e.g., Atlanta, Chicago, Philadelphia).

Individuals who click on our social media advertisements will be directed to our study's landing page programmed in Qualtrics that will provide a brief overview of the intervention. Those who are not interested can exit by closing their browser. Those who are interested can click on a link to the informed consent form that will include a detailed description of all study activities including (i) completing an eligibility screener, (ii) providing contact information to receive study communications and a specimen self-collection box if eligible, (iii) completing a baseline survey, each intervention component, and a satisfaction survey in Phase 1, and (iv) completing an in-depth interview in Phase 2 if selected. Individuals will have the option to download a copy of the informed consent form for their records. Because they will be using their own computers, tablets, or smartphones, informed consent will be obtained by them clicking on "I understand what this research study is about, and my questions so far have been answered. I agree to participate in this study" or "I do not wish to participate in this research study". The consent response, date, and IP address of the device will be recorded in Qualtrics. To minimize the potential for fraudulent activity, we will include a CAPTCHA verification question, enable the feature to prevent multiple submissions from the same IP address, and manually review the IP addresses on a regular basis to ensure that they are located within the US.

Individuals who do not consent will be directed to a terminal page with a link to the CDC's website on STIs so that they can learn more about protecting themselves and their sex partners. Those who consent will proceed to an eligibility screener that will assess whether they meet our study's inclusion criteria. Individuals who are not eligible will be directed to a terminal page with a link to the CDC's website on STIs so that they can learn more about protecting themselves and their sex partners. Those who are eligible will proceed to a contact information form that will request them to provide their full name, email address, and mobile phone number to receive study communications and their mailing address to receive a specimen self-collection box. Individuals who do not provide their contact information will be directed to a terminal page with a link to the CDC's website on STIs so that they can learn more about protecting themselves and their sex partners. Those who provide their contact information will be informed that a study team member will contact them to verify their full name, email address, mobile phone number, and mailing address. Individuals who do not provide valid contact information will be excluded from further consideration and their personally identifiable information will be deleted within 4 weeks. Individuals who cannot read English will be informally excluded.

Note: Qualtrics is approved by the University of Michigan (UM) Information and Technology Services (ITS) for sensitive identifiable human subjects research data regulated by the Federal Policy for the Protection of Human Subjects ("Common Rule"). Access to the Qualtrics account is

protected with a sufficiently complex password and requires Duo two-factor authentication for login. The data collected via the eligibility screener and the contact information form will be downloaded to a secure UM server. Only IRB-approved study team members, all of whom will have completed trainings on human subjects research protections offered by the UM Program for Education and Evaluation in Responsible Research and Scholarship (PEERRS), will have access to participants' data on an as-needed basis.

c. Inclusion criteria

(i) Individual self-reports identifying as a man (regardless of their sex assigned at birth) in the eligibility screener.
(ii) Individual self-reports residing in a US state or territory in the eligibility screener.
(iii) Individual self-reports being physically located in a US state or territory when completing study activities in the eligibility screener.
(iv) Individual self-reports being ≥18 years of age in the eligibility screener.
(v) Individual self-reports being of legal age to provide consent for research participation in their US state or territory of residence in the eligibility screener.
(vi) Individual self-reports having been diagnosed with HIV in the eligibility screener.
(vii) Individual self-reports having any kind of condomless sex (e.g., oral, anal) with ≥2 men in the past year in the eligibility screener.
(viii) Individual self-reports being willing to provide their contact information (full name, email address, mobile phone number, and mailing address) in the eligibility screener.
(ix) Individual self-reports being able to participate in live AV conferencing sessions using an internet-connected device (e.g., computer, tablet, smartphone) in the eligibility screener.
(x) Individual self-reports being willing to receive a box that contains kits to self-collect a urine sample, a throat swab, a rectal swab, and a blood sample for bacterial STI testing in the eligibility screener.
(xi) Individual provides valid contact information (full name, email address, mobile phone number, and mailing address).
(xii) Individual completes the baseline survey in order to receive the intervention.

d. Exclusion criteria

(i) Individual self-reports not identifying as a man (regardless of their sex assigned at birth) in the eligibility screener.
(ii) Individual self-reports not residing in a US state or territory in the eligibility screener.
(iii) Individual self-reports not being physically located in a US state or territory when completing study activities in the eligibility screener.
(iv) Individual self-reports not being ≥18 years of age in the eligibility screener.
(v) Individual self-reports not being of legal age to provide consent for research participation in their US state or territory of residence in the eligibility screener.
(vi) Individual self-reports not having been diagnosed with HIV in the eligibility screener.
(vii) Individual self-reports not having any kind of condomless sex (e.g., oral, anal) with ≥2 men in the past year in the eligibility screener.
(viii) Individual self-reports not being willing to provide their contact information (full name, email address, mobile phone number, and mailing address) in the eligibility screener.
(ix) Individual self-reports not being able to participate in live AV conferencing sessions using an internet-connected device (e.g., computer, tablet, smartphone) in the eligibility screener.

(x) Individual self-reports not being willing to receive a box that contains kits to self-collect a urine sample, a throat swab, a rectal swab, and a blood sample for bacterial STI testing in the eligibility screener.
(xi) Individual does not provide valid contact information (full name, email address, mobile phone number, and mailing address).
(xii) Individual does not complete the baseline survey in order to receive the intervention.

e. Secondary recruitment strategy – Peer referral

Individuals will be requested to share the link to our study's landing page with anyone in their social network who they believe might be interested in participating. The link will be provided at the end of the contact information form (which will be viewed by those who consent, are eligible, and provide their contact information) and on the terminal page (which will be viewed by those who do not consent, are not eligible, or do not provide their contact information).

Section 3. Phase 1 procedures

a. Baseline survey

Individuals whose contact information has been verified will be assigned a randomly generated participant ID number (e.g., ZEN618) and be sent a link to the baseline survey programmed in Qualtrics (with the participant ID number included as a metadata element) that will include questions on the following:

(i) *Sociodemographics:* Age, race and ethnicity, educational level, employment status, income level, health insurance coverage, sexual orientation, gender identity, sex assigned at birth, and relationship status.[97]
(ii) *Bacterial STI-related knowledge:* 22-item scale to assess participant's knowledge of GC, CT, and syphilis.[98]
(iii) *Awareness and use of home STI tests and commercial telehealth services:* Binary measures of whether the participant has heard of and used home STI tests sold online by companies and commercial telehealth services that offer STI treatment.
(iv) *Attitudes around "safer" sex:* 13-item subscale from the Sexual Risks Scale to assess the participant's attitudes around "safer" sex.[99]
(v) *Perceived risk of bacterial STIs:* Risk perception ruler from 1 (Extremely unlikely) to 10 (Extremely likely) to assess the participant's perceived likelihood of contracting a bacterial STI in the next 12 months.[98]
(vi) *"Safer" sex self-efficacy:* 7-item scale to assess the participant's confidence in practicing "safer" sex.[100]
(vii) *Specimen self-collection self-efficacy:* 5-point Likert items to assess the participant's perceived ease of self-collecting each type of specimen.
(viii) *History of HIV testing and management:* Timing of first positive HIV test, location of test, receipt of HIV medical care, ART use, HIV viral load, and CD4 count.[97, 101-103]
(ix) *History of bacterial STI testing and management:* Frequency of testing for GC, CT, and syphilis, timing of latest tests, location of latest tests, types of specimens provided, test results, and receipt of treatment.
(x) *Relationship and partner characteristics:* Relationship duration and type, partner's HIV status and use of ART or pre-exposure prophylaxis (PrEP), and partner's history of testing for GC, CT, and syphilis.

(xi) *Sexual behaviors:* Engagement in oral, anal, and vaginal or frontal sex in the past 12 months, and condom use.
(xii) *History of substance use:* Tobacco, alcohol, prescription medication, and other substance use using NIDA's TAPS screening tool.[104]

The baseline survey should take approximately 1 hour to complete, and it will allow participants to skip questions or indicate that they prefer not to answer a question. If participants do not complete the baseline survey within 1 week, up to 7 reminders will be sent at regular intervals over the next 7 weeks. The reminders will inform participants that non-completion of the baseline survey by the end of 8 weeks suggests that they are no longer interested and that they will not be able to proceed in the study after that time has elapsed (unless they request an extension). Participants who do not complete the baseline survey by the end of 8 weeks will be excluded from further consideration and their personally identifiable information will be deleted within 4 weeks. Those who complete the baseline survey will receive a $40 Amazon e-gift card and be considered "fully enrolled" participants (i.e., they will proceed to receive the intervention).

Note: Qualtrics is approved by the UM ITS for sensitive identifiable human subjects research data regulated by the "Common Rule". Access to the Qualtrics account is protected with a sufficiently complex password and requires Duo two-factor authentication for login. The data collected via the baseline survey will be downloaded to a secure UM server. Only IRB-approved study team members, all of whom will have completed trainings on human subjects research protections offered by the UM PEERRS, will have access to participants' data on an as-needed basis.

b. Intervention component I – Pre-test MI-guided live AV conferencing session

Once participants complete the baseline survey, they will be contacted to schedule a 30 min pre-test session to be conducted over Zoom with an interventionist who will have received training from PI Sharma and Co-I Bonar. Time slots will be offered in all US time zones and be flexible to meet their individual circumstances. If participants do not schedule a session within 1 week, up to 7 reminders will be sent at regular intervals over the next 7 weeks. The reminders will inform participants that not scheduling a session by the end of 8 weeks suggests that they are no longer interested and that they will not be able to proceed to the next intervention component (unless they request an extension). Once a time is confirmed, participants will be sent a password-protected Zoom link. They will be advised to join the session from a private location and be offered the option to reschedule if the original time no longer works or if they anticipate being in a situation where their privacy may be compromised.

Pre-test sessions will be conducted from a private location and participants will have the option to mute their own video (i.e., use only audio from their end) if they prefer to remain discreet. Sessions will be audio-recorded using a digital voice recorder to allow for the ongoing monitoring of intervention fidelity. No audio or video will be recorded in Zoom. The audio recordings will be transferred to a secure UM server immediately after the session, and then deleted from the digital voice recorder. The recordings will not be transcribed, but IRB-approved study team members will listen to them on an ongoing basis to identify and discuss areas of potential improvement. The recordings will be deleted from the UM server upon study completion (i.e., when all study-related data have been collected and checked for accuracy and completeness). During the session, the interventionist will follow procedures described in the pre-test intervention outline. The session will begin with a conversation to initiate a collaborative partnership and build rapport (MI process: *Engaging*). Next, the interventionist will elicit participants' awareness of the epidemiology and transmission of bacterial STIs among GBMSM-LWH, provide new information to fill any knowledge gaps or address misconceptions around triple-site GC and CT or syphilis

testing, and elicit reactions to this new information. Open-ended questioning and reflective listening will be used to gain a better understanding of participants' perspectives on their own sexual risk and protective behaviors (MI process: *Focusing*). Subsequently, the interventionist will explore their history of bacterial STI testing, their motivations for testing or reasons for not testing, and their perceived benefits and challenges of regular testing (MI process: *Evoking*). To improve self-efficacy for specimen self-collection, the interventionist will demonstrate the contents of the specimen self-collection box, review step-by-step instructions for self-collecting each type of specimen, and address any questions or concerns. Participants who express an intent to test with their own provider or at a clinic will be encouraged to pursue that route. The session will end by summarizing the participants' strengths and goals with respect to protecting their own and their partners' sexual health and discussing their plans to test for GC, CT, and syphilis over the next month (MI process: *Planning*).

Participants who do not schedule or attend the pre-test session will be deemed not interested in this intervention component (unless they have contacted us to reschedule). Those who complete the session will proceed to the next intervention component. Although participants who express an intent to test with their own provider or at a clinic will be encouraged to pursue that route, they will still proceed to the next intervention component (i.e., they will be shipped a specimen self-collection box) upon completing the pre-test session unless they choose to withdraw from the study.

Note: Zoom is approved by the UM ITS for sensitive identifiable human subjects research data regulated by the "Common Rule". Access to the Zoom account is protected with a sufficiently complex password and requires Duo two-factor authentication for login. Only IRB-approved study team members, all of whom will have completed trainings on human subjects research protections offered by the UM PEERRS, will have access to participants' data on an as-needed basis.

c. Intervention component II – Home specimen self-collection and return

Once participants complete the pre-test session, they will be shipped a box in plain, unmarked packaging that contains kits to self-collect a urine sample, a throat swab, a rectal swab, and a finger-stick blood sample. Boxes will be assembled at the University of Michigan School of Nursing (UMSN) using specimen self-collection kits supplied by the Emory University Clinical Virology Research Lab (CVRL) located at Woodruff Memorial Research Building Room 7007, 101 Woodruff Circle, Atlanta, Georgia, 30322. CVRL has conducted HIV, GC, CT, or syphilis testing for >12 national studies with GBMSM,[105] including PI Sharma's recently completed Project Caboodle (HUM00153673).[93-96] The shipment and delivery of boxes to participants will be tracked by a study team member on a regular basis. Each box will include the following:

(i) *General information sheet:* This sheet will provide participants with a brief description of the box contents and information on how to package and return their self-collected specimens to CVRL in Atlanta, Georgia. It will also instruct participants to not include any sort of personally identifiable information (e.g., full name, mailing address) on the lab requisition form.

(ii) *Urine sample self-collection kit:* This kit will include materials for participants to self-collect a urine sample of 3 milliliters (which is less than 1 teaspoon of urine). These include a collection cup, a transfer pipette, and a transport tube containing a buffer to stabilize DNA until specimen preparation. The transport tube will be affixed with a unique specimen ID number (e.g., URN327) to enable specimen identification upon return and to document GC and CT test results. The kit will also include written instructions with color images and a QR code that links to video instructions.

Participants will be instructed to not urinate for at least 1 hour before urine collection, collect the first part of their urine stream into the collection cup up to the marked line, use the transfer pipette to transfer urine from the collection cup to the transport tube and fill it between the minimum and maximum lines, secure the lid of the transport tube, place the transport tube in the plastic biohazard bag, and dispose of the collection cup and the transfer pipette in their home garbage.

(iii) *Throat swab self-collection kit:* This kit will include materials for participants to self-collect a throat swab. These include a sterile specimen collection swab and a transport tube containing a buffer to stabilize DNA until specimen preparation. The transport tube will be affixed with a unique specimen ID number (e.g., THR327) to enable specimen identification upon return and to document GC and CT test results. The kit will also include written instructions with color images and a QR code that links to video instructions. Participants will be instructed to open their mouth wide in front of a mirror, wipe the specimen collection swab along the back of their throat on both sides several times and then remove, insert the swab into the transport tube and break off its top portion, secure the lid of the transport tube, place the transport tube in the plastic biohazard bag, and dispose of the swab wrapper and the unused portion of the swab in their home garbage.

(iv) *Rectal swab self-collection kit:* This kit will include materials for participants to self-collect a rectal swab. These include a sterile specimen collection swab, two lubricant packets, and a transport tube containing a buffer to stabilize DNA until specimen preparation. The transport tube will be affixed with a unique specimen ID number (e.g., REC327) to enable specimen identification upon return and to document GC and CT test results. The kit will also include written instructions with color images and a QR code that links to video instructions. Participants will be instructed to lubricate their rectum, gently insert the specimen collection swab into their rectum about 1.5 inches, gently move the swab in a circular motion and then remove, insert the swab into the transport tube and break off its top portion, secure the lid of the transport tube, place the transport tube in the plastic biohazard bag, and dispose of the swab wrapper and the unused portion of the swab in their home garbage.

(v) *Finger-stick blood sample self-collection kit:* This kit will include materials for participants to self-collect a finger-stick blood sample of 500 microliters (which is equal to 10 drops of blood). These include an alcohol wipe, two safety lancets, two gauze pads, two bandages, and a transport tube containing a buffer to stabilize DNA until specimen preparation. The transport tube will be affixed with a unique specimen ID number (e.g., BLD327) to enable specimen identification upon return and to document syphilis test results. The kit will also include written instructions with color images and a QR code that links to video instructions. Participants will be instructed to clean their middle or ring finger from their non-dominant hand using the alcohol wipe, stimulate blood flow by shaking their hand below their waist, prick their finger using the safety lancet, massage from the base of their finger using a squeeze-release motion, wipe away the first drop of blood with the gauze pad, wipe subsequent drops of blood onto the inside of the transport tube and fill it to top line, wipe the remaining blood off their finger using the gauze pad, apply the bandage, secure the lid of the transport tube, gently mix the blood in the transport tube by inverting it and moving it around, place the transport tube in the plastic biohazard bag, and dispose of the alcohol wipe, the gauze pad(s), and the wrappers in their home garbage. The Occupational Safety and Health Administration's Bloodborne Pathogens Standard (29 CFR 1910.1030(b)) as amended pursuant to the 2000 Needlestick Safety and Prevention Act defines regulated waste as "liquid or semi-liquid blood or other potentially infectious materials (OPIM); contaminated items that would release blood or OPIM in a liquid or semi-liquid

state if compressed; items that are caked with dried blood or OPIM and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or OPIM". The amount of blood or OPIM released from a finger-stick is not enough to saturate the gauze pads to the point of caking them or releasing these materials if compressed during handling. Unsaturated gauze pads do not meet the definition of regulated waste and can therefore be placed in one's home garbage for disposal. The safety lancets being provided to participants are sterile, contact-activated, single-use devices that enable the collection of up to 500 microliters of blood from a single puncture. Their contact-activation design facilitates a consistent puncture depth and minimizes the likelihood of having to repeat the puncture. They consist of a stainless-steel needle/blade in a thick plastic casing that retracts automatically and permanently after the puncture. Participants will be instructed to follow procedures described by SafeNeedleDisposal.org, the nation's leading information resource for home-generated medical sharps disposal, to safely dispose of their used lancet(s) in their locality.

(vi) *Plastic biohazard bag:* This bag will be used by participants to enclose the transport tubes containing their self-collected specimens.

(vii) *Lab requisition form:* This form will be used by participants to write down the date on which they self-collected their specimens and the unique specimen ID numbers affixed to the transport tubes.

(viii) *Prepaid bubble mailer with a category B sticker:* This bubble mailer will be used by participants to return their self-collected specimens and the completed lab requisition form to CVRL.

Participants will be requested to self-collect their specimens, enclose the transport tubes in the plastic biohazard bag, complete the lab requisition form, place the bag and the form in the prepaid bubble mailer, and return the bubble mailer to CVRL. Specimen return will be voluntary, and participants can choose to return all, some, or none of the four specimens. However, if no specimens have been received by CVRL within 3 weeks of box delivery (which will be confirmed by contacting lab personnel at CVRL and providing them the unique specimen ID numbers), up to 5 reminders will be sent at regular intervals over the next 5 weeks. The reminders will inform participants that not returning any specimens by the end of 8 weeks suggests that they are no longer interested and that they will not be able to proceed to the next intervention component (unless they request an extension). The reminders will also inform participants that any specimens received by CVRL after 8 weeks will not be tested and will be destroyed (unless they have requested an extension).

Urine samples, throat swabs, and rectal swabs returned by participants will be tested for GC and CT using the Abbott Real Time PCR Assay. Finger-stick blood samples returned by participants will be tested for syphilis using the ASI rapid plasma reagin (RPR) Card Test reported as a titer of antibodies. If the screening test for syphilis is reactive (i.e., a titer of ≥1:8), it will be followed by a confirmatory test (i.e., a treponemal enzyme immunoassay to detect IgG antibodies) at the Emory Medical Laboratory (EML) which is located in the same building as CVRL. Both CVRL and EML are certified under CLIA (Clinical Laboratory Improvement Amendments). CLIA regulations establish quality standards for lab testing performed on specimens from humans. Any specimens returned by participants within 8 weeks will be destroyed immediately after lab testing. Any specimens returned after 8 weeks will be destroyed without being tested (unless they are from participants who have requested an extension). Lab personnel at CVRL or EML will only be able to connect the participants' test results to the unique specimen ID numbers affixed to the different transport tubes. They will not have access to either the participant ID numbers or to the participants' contact information (full name, email address, mobile phone number, and mailing

address). Only IRB-approved study team members at the UM will have access to the data on which unique specimen ID numbers are assigned to a particular participant ID number, and which participant ID number corresponds to a particular participant's contact information. These data will be stored in a password-protected file on a secure UM server. Before sending a link to the baseline survey to an individual whose contact information has been verified, a study team member will update the file containing participants' contact information with a corresponding participant ID number (e.g., ZEN618). Before shipping a specimen self-collection box to this participant, a study team member will further update the file with information on which unique specimen ID numbers affixed to the different transport tubes (e.g., URN327, THR327, REC327, BLD327) are assigned to their participant ID number. This file will be deleted from the UM server upon study completion (i.e., when all study-related data have been collected and checked for accuracy and completeness). GC, CT, and syphilis test results will be shared with us by lab personnel at CVRL via a secure Dropbox folder and will be stored on a secure UM server. Once we receive all the test results, lab personnel at CVRL will no longer have access to the folder.

Participants who do not return any specimens by the end of 8 weeks will be deemed not interested in this intervention component (unless they have requested an extension). Those who return some or all specimens within 8 weeks will proceed to the next intervention component.

Note: Dropbox is approved by the UM ITS for sensitive identifiable human subjects research data regulated by the "Common Rule". Access to the Dropbox account is protected with a sufficiently complex password and requires Duo two-factor authentication for login. Only IRB-approved study team members, all of whom will have completed trainings on human subjects research protections offered by the UM PEERRS, will have access to participants' data on an as-needed basis.

d. Intervention component III – Post-test MI-guided live AV conferencing session

Once we receive participants' GC, CT, and syphilis test results back from CVRL (approximately 2 weeks after they return their specimens), they will be contacted to schedule a 30 min post-test session to be conducted over Zoom with the same interventionist who conducted the pre-test session, whenever possible. Time slots will be offered in all US time zones and be flexible to meet their individual circumstances. If participants do not schedule a session within 1 week, up to 7 reminders will be sent at regular intervals over the next 7 weeks. The reminders will inform participants that not scheduling a session by the end of 8 weeks suggests that they are no longer interested (unless they request an extension). Once a time is confirmed, participants will be sent a password-protected Zoom link. They will be advised to join the session from a private location and be offered the option to reschedule if the original time no longer works or if they anticipate being in a situation where their privacy may be compromised.

Post-test sessions will be conducted from a private location and participants will have the option to mute their own video (i.e., use only audio from their end) if they prefer to remain discreet. Sessions will be audio-recorded using a digital voice recorder to allow for the ongoing monitoring of intervention fidelity. No audio or video will be recorded in Zoom. The audio recordings will be transferred to a secure UM server immediately after the session, and then deleted from the digital voice recorder. The recordings will not be transcribed, but IRB-approved study team members will listen to them on an ongoing basis to identify and discuss areas of potential improvement. The recordings will be deleted from the UM server upon study completion (i.e., when all study-related data have been collected and checked for accuracy and completeness). During the session, the interventionist will follow procedures described in the post-test intervention outline. The session will incorporate the four MI processes of *Engaging*, *Focusing*, *Evoking*, and *Planning*. It will begin with a conversation to initiate a collaborative partnership and build rapport. The

interventionist will discuss the meaning of negative and positive bacterial STI test results and assess participants' emotional response to each possible outcome via open-ended questioning and reflective listening. Test results will be delivered via screen sharing the lab test results form (that will only include the unique specimen ID numbers and corresponding test results). The interventionist will have completed online training courses on GC, CT, and syphilis offered by the Michigan Department of Health and Human Services (MDHHS). For participants receiving negative GC, CT, and syphilis test results, the interventionist will use affirmations to acknowledge their engagement in protective behaviors and jointly formulate a plan to prevent the acquisition of bacterial STIs. For participants receiving a positive GC, CT, or syphilis test result, the interventionist will offer emotional support, discuss the benefits of timely antibiotic treatment, and jointly formulate a linkage to care plan. Barriers to accessing treatment (e.g., lack of insurance, limited personal transportation, reluctance to visit one's own provider) will be elicited and the interventionist will work with participants to find practical solutions. For example, if someone lacks insurance, screen sharing will be used to give information on local STI clinics that provide free or low-cost services identified using site locators on the CDC's "GetTested: National HIV, STD, and Hepatitis Testing" and Planned Parenthood's "STD Testing, Treatment & Vaccines" websites. If someone has limited personal transportation, the interventionist will assist in creating a commute plan that uses public transportation options. If someone is reluctant to visit their own provider, the interventionist will assist in finding other STI clinics or identifying commercial telehealth services that offer STI treatment (e.g., GoodMDs, PlushHealth, CallonDoc). Participants will be encouraged to notify their sex partners of their positive test results so that they can seek testing. Open-ended questioning and reflective listening will be used to engage them in a discussion on sexual risk reduction. Next, elicit-provide-elicit will be used to find out what participants already know about the current national recommendations for bacterial STI testing among GBMSM and to fill any knowledge gaps or address misconceptions around the recommended frequency of testing. The interventionist will also explore whether and how home STI tests sold online by companies (e.g., NURX, myLAB Box, LetsGetChecked) might fit into the participants' testing routines. The session will end by reviewing the participants' personalized action plans formulated based on their test results and summarizing their strengths and goals with respect to reducing sexual risk behaviors and regularly testing for bacterial STIs. After the session, a copy of the lab test results form will also be shared with participants via a secure Dropbox folder that is only accessible to them and the study team members. The folder will also include a supplemental information sheet on using site locators on the CDC's "GetTested: National HIV, STD, and Hepatitis Testing" and Planned Parenthood's "STD Testing, Treatment & Vaccines" websites to identify local STI clinics to seek treatment (if warranted) and repeat testing. The link to the folder will expire after 4 weeks and the folder will be deleted, following which participants will need to contact us to obtain a new link.

For participants receiving a positive GC, CT, or syphilis test result, a study team member will review their state and local statutory reporting requirements and procedures and make up to 3 attempts to notify the relevant public health authorities. Reporting of these bacterial STIs can be performed without providing isolates. Participants' contact information will be reported. This notification may result in participants being contacted by their public health authorities for follow up and possible contact tracing. A study team member will also follow up via phone at 2 weeks and at 4 weeks to determine their treatment status. During each of these interactions, the study team member will complete a case report form programmed in Qualtrics documenting whether the participant has initiated treatment, completed treatment, has not yet initiated treatment but has made an appointment with a provider, or has not yet made an appointment with a provider. Those who have not yet made an appointment with a provider will be encouraged to do so as soon as possible and offered additional assistance as requested. The data entered into the case report forms will be downloaded to a secure UM server.

Participants who do not schedule or attend the post-test session will be deemed not interested in this intervention component (unless they have contacted us to reschedule). However, a copy of the lab test results form and the supplemental information sheet on using site locators to identify local STI clinics will be shared with these participants via a secure Dropbox folder that is only accessible to them and the study team members. The link to the folder will expire after 4 weeks and the folder will be deleted, following which participants will need to contact us to obtain a new link.

Note: Qualtrics, Zoom, and Dropbox are approved by the UM ITS for sensitive identifiable human subjects research data regulated by the "Common Rule". Access to the Qualtrics, Zoom, and Dropbox accounts is protected with a sufficiently complex password and requires Duo two-factor authentication for login. Only IRB-approved study team members, all of whom will have completed trainings on human subjects research protections offered by the UM PEERRS, will have access to participants' data on an as-needed basis.

e. Satisfaction survey

Upon completion of the intervention delivery, all 75 "fully enrolled" participants (regardless of their level of engagement in the pre-test session, specimen return for bacterial STI testing, and the post-test session) will be sent a link to the satisfaction survey programmed in Qualtrics (with the participant ID number included as a metadata element) that will include questions on the following:

(i) *Pre-test live AV conferencing session experience:* 4-item subscale from the Telehealth Usability Questionnaire to assess the participant's quality of interaction with the interventionist,[106] 12-item Counselor Rating Form Short to assess the participant's perceptions of the interventionist,[107] 5-point Likert items to assess the participant's satisfaction with, willingness to repeat, and likelihood to recommend the session.

(ii) *Urine sample self-collection experience:* 5-point Likert items to assess the participant's experience with, willingness to repeat, and likelihood to recommend self-collection.[66]

(iii) *Throat swab self-collection experience:* 5-point Likert items to assess the participant's experience with, willingness to repeat, and likelihood to recommend self-collection.[66]

(iv) *Rectal swab self-collection experience:* 5-point Likert items to assess the participant's experience with, willingness to repeat, and likelihood to recommend self-collection.[66]

(v) *Finger-stick blood sample self-collection experience:* 5-point Likert items to assess the participant's experience with, willingness to repeat, and likelihood to recommend self-collection.[66]

(vi) *Specimen packaging and return experience:* 5-point Likert items to assess the participant's experience with packaging and returning specimens.

(vii) *Post-test live AV conferencing session experience:* 4-item subscale from the Telehealth Usability Questionnaire to assess the participant's quality of interaction with the interventionist,[106] 12-item Counselor Rating Form Short to assess the participant's perceptions of the interventionist,[107] 5-point Likert items to assess the participant's satisfaction with, willingness to repeat, and likelihood to recommend the session.

(viii) *Bacterial STI-related knowledge:* 22-item scale to assess the participant's knowledge of GC, CT, and syphilis[98] for comparison with the baseline survey responses.

(ix) *Likelihood of testing for bacterial STIs in the future:* 5-point Likert items to assess the participant's likelihood of testing for bacterial STIs at least annually and likelihood of using home STI tests sold online by companies.

The satisfaction survey should take approximately 30 min to complete, and it will allow participants to skip questions or indicate that they prefer not to answer a question. If participants do not complete the satisfaction survey within 1 week, up to 7 reminders will be sent at regular intervals over the next 7 weeks. The reminders will inform participants that non-completion of the satisfaction survey by the end of 8 weeks suggests that they are no longer interested (unless they request an extension). Those who complete the satisfaction survey will receive a $20 Amazon e-gift card.

Note: Qualtrics is approved by the UM ITS for sensitive identifiable human subjects research data regulated by the "Common Rule". Access to the Qualtrics account is protected with a sufficiently complex password and requires Duo two-factor authentication for login. The data collected via the satisfaction survey will be downloaded to a secure UM server. Only IRB-approved study team members, all of whom will have completed trainings on human subjects research protections offered by the UM PEERRS, will have access to participants' data on an as-needed basis.

Section 4. Phase 2 procedures

To gain a deeper understanding of attitudes, facilitators, and barriers related to engaging in each component of the intervention, we will conduct in-depth interviews with a subsample of 20 participants. Purposive sampling will be used to select a mix of participants who complete progressively smaller subsets of the pre-test session, specimen return for bacterial STI testing, and the post-test session.[108]

Participants will be contacted to schedule a 1-hour interview with a study team member to be conducted over Zoom or phone (depending upon their preference). Time slots will be offered in all US time zones and be flexible to meet their individual circumstances. If participants do not schedule an interview within 1 week, up to 7 reminders will be sent at regular intervals over the next 7 weeks. The reminders will inform participants that not scheduling an interview by the end of 8 weeks suggests that they are no longer interested (unless they request an extension). Participants who prefer being interviewed over Zoom will be sent a password-protected Zoom link. They will be advised to join the interview from a private location and be offered the option to reschedule if the original time no longer works or if they anticipate being in a situation where their privacy may be compromised.

Interviews will be conducted from a private location and participants on Zoom will have the option to mute their own video (i.e., use only audio from their end) if they prefer to remain discreet. Interviews will be audio-recorded using a digital voice recorder to allow for verbatim transcription. No audio or video will be recorded in Zoom. The audio recordings will be transferred to a secure UM server immediately after the interview, and then deleted from the digital voice recorder. During the interview, the study team member will ask participants open-ended questions outlined in the semi-structured in-depth interview guide. Informed by the TFA of health interventions[74], the interviews will focus on a range of participants' experiences including factors influencing their attendance (e.g., discuss specimen self-collection procedures, receive bacterial STI test results) or non-attendance (e.g., concerns about session length, scheduling conflicts) of the pre-test or the post-test sessions, and reasons for returning specimens (e.g., confirm bacterial STI status, limited access to testing) or choosing not to return specimens (e.g., lack of confidence, preference for clinic-based testing). The audio recordings will be transcribed by IRB-approved study team members, all of whom will have completed trainings on human subjects research protections offered by the UM PEERRS. Each transcript will only be connected to the participant ID number and saved on a secure UM server. The recordings will be deleted from the UM server upon study

completion (i.e., when all study-related data have been collected and checked for accuracy and completeness). Only IRB-approved study team members will have access to participants' data on an as-needed basis.

Participants who do not schedule or attend the interview will be deemed not interested (unless they have contacted us to reschedule). Those who attend the interview will receive a $40 Amazon e-gift card.

Section 5. Data analyses

a. Phase 1 analyses

Descriptive statistics (e.g., means, medians and ranges for continuous variables, counts and proportions for categorical variables) and progression ratios (i.e., proportions who sequentially progress through different intervention components) will be calculated using software for quantitative data analysis (e.g., SAS, Excel). Intervention feasibility outcomes include the number of participants who (i) schedule a pre-test session, (ii) join the pre-test session within 15 min of the start time, (iii) return each type of specimen, (iv) provide specimens of adequate quality for lab testing, (v) schedule a post-test session, and (vi) join the post-test session within 15 min of the start time. Intervention acceptability outcomes include (i) satisfaction with the different intervention components, (ii) willingness to repeat the different intervention components, (iii) willingness to recommend the different intervention components to friends or sex partners, (iv) quality of interactions with and perception of the interventionist, and (v) comparison of bacterial STI testing experience in the study with the last testing experience. Potential impact of the intervention on IMB model constructs will be assessed by calculating (i) improvement in bacterial STI-related knowledge, (ii) willingness to test for bacterial STIs at least annually, and (iii) improvement in self-efficacy for specimen self-collection. Because our study is inherently exploratory, we do not plan on using probability-based statistical inference techniques in line with current best practices.[109, 110] Instead, potential variations in our intervention's feasibility and acceptability across selected participant characteristics, and its potential impact on IMB model constructs will be numerically summarized and graphically visualized (e.g., side-by-side boxplots, scatter plots), as recommended for exploratory data.[111, 112] Proportions of participants who test negative or positive for GC, CT, and syphilis (using our specimen self-collection kits or with their own provider or at a clinic), and proportions who initiate treatment (with their own provider or at a clinic or via commercial telehealth services) within 2 weeks or 4 weeks of receiving a positive test result will also be calculated.

b. Phase 2 analyses

In-depth interview transcripts will be imported into software for qualitative data analysis (e.g., NVivo, Dedoose). Thematic analysis will be used to identify, analyze and report patterns in the qualitative data.[113-116] This approach is being chosen as it allows for flexibility within both post-positivist and constructivist paradigms, which is consistent with mixed-methods research.[116] We will follow Braun & Clarke's 6 stages of thematic analysis: (i) becoming familiar with the data, (ii) generating initial codes, (iii) searching for themes, (iv) reviewing themes, (v) defining and naming themes, and (vi) writing up the results.[116] Trustworthiness and authenticity of the qualitative analysis will be enhanced through multiple mechanisms, including double coding a subset of transcripts independently, regular meetings among the study team members to discuss and resolve discrepancies, and maintaining documentation for auditing purposes.

c. Integration of quantitative and qualitative data[117]

Integration at the design level will be achieved by our use of a sequential explanatory mixed methods design wherein we will first collect quantitative data on the feasibility and acceptability of our intervention, and then collect qualitative data on attitudes, facilitators, and barriers related to engaging in different intervention components. Integration at the methods level will be achieved via (i) connecting (i.e., when one form of data links with the other form through the sampling frame) as we will select a purposive subsample of 20 participants for the qualitative phase from 75 participants in the quantitative phase, and (ii) building (i.e., when results from the first phase inform data collection in the second phase) as we will use information on participants' level of engagement in different intervention components to guide our in-depth interviews. Integration at the interpretation level will be achieved through a comparison of our quantitative findings (i.e., potential variations in our intervention's feasibility and acceptability across selected participant characteristics) with our qualitative findings (i.e., themes describing attitudes, facilitators, and barriers related to engaging in each intervention component), including a consideration of how results from each study phase converge, diverge, and expand our understanding of these issues. Integration at the reporting level will be achieved by representing comparisons through combined written descriptions of the quantitative and qualitative data (e.g., statistics-by-themes) and visual representations (e.g., joint displays). Results from our study will be contextualized by and compared to the extant literature on home specimen self-collection and telehealth-delivered MI in other sexual and gender minority populations in the US.

Section 6. Human subjects protections

a. Potential risks

Our study poses no more than minimal risk to participants. The risks that could arise are detailed as follows:

Participants may have concerns about the risk of disclosure of their participation in our study: Some participants may be concerned that their participation in our study could be disclosed if someone else reads our emails or texts or opens the specimen self-collection box when it arrives in the mail.

Participants may feel uncomfortable when answering sensitive survey questions: Our baseline survey includes questions on history of HIV testing and management, history of bacterial STI testing and management, sexual behaviors, and history of substance use. Because these topics are of a sensitive nature, some participants may feel uncomfortable.

Participants may feel uncomfortable revealing their faces over Zoom during the pre-test or the post-test sessions, or during the in-depth interview: The pre-test and the post-test MI-guided live AV conferencing sessions in Phase 1 will be conducted over Zoom. The in-depth interviews in Phase 2 will be conducted with a purposive subsample of participants over Zoom or phone (depending upon their preference). The prospect of revealing their faces over Zoom could make some participants feel uncomfortable.

Participants may experience mild physical discomfort when self-collecting some specimens: Our intervention involves self-collecting at home and returning by mail a urine sample (for GC and CT testing), a throat swab (for GC and CT testing), a rectal swab (for GC and CT testing), and a finger-stick blood sample (for syphilis testing). Although self-collecting a urine sample of 3

milliliters (which is less than 1 teaspoon of urine) is not expected to cause any physical discomfort, self-collecting a throat swab and a rectal swab may cause mild physical discomfort. Self-collecting a finger-stick blood sample by pricking one's own finger to obtain 500 microliters (which is equal to 10 drops of blood) can also cause some physical discomfort. However, the risks associated with this procedure are minimal (e.g., mild bruising at the puncture site).

Participants who test positive for one or more bacterial STIs may experience emotional distress after learning of their health condition: The receipt of one or more positive bacterial STI test results may cause emotional distress in some participants, especially if they were expecting all of their test results to be negative.

Participants may have concerns about a breach of confidentiality: Because participants will be providing their contact information (full name, email address, mobile phone number, and mailing address) as well as quantitative and qualitative data during Phases 1 and 2 of our study, some may be concerned that the details they share could be unintentionally disclosed to someone who is not authorized to access the data.

b. Protections against risks

The procedures that we will undertake to protect participants in our study against risks are detailed as follows:

Protections during recruitment: Participants will be recruited via social media advertising and peer referral. Our study's landing page will provide a brief overview of the intervention. Individuals who are interested can click on a link to the informed consent form that will include a detailed description of all study activities including (i) completing an eligibility screener, (ii) providing contact information to receive study communications and a specimen self-collection box if eligible, (iii) completing a baseline survey, each intervention component, and a satisfaction survey in Phase 1, and (iv) completing an in-depth interview in Phase 2 if selected. The informed consent form will be in plain English and use simple, non-technical terms. It will describe the expectations of participation, the voluntary nature of participation, and the potential risks and benefits of participation, such that individuals are fully aware of the nature of our study. It will also provide the study team members' contact information to discuss any questions or concerns prior to deciding on participation. Individuals will have the option to download a copy of the informed consent form for their records.

Protections against the risk of disclosure of participation in our study: To minimize the risk of disclosure of participation (i) none of the study communications will make any reference to the nature of our study, (ii) participants will be encouraged to delete any emails, call logs, or texts received as part of our study, and (iii) the specimen self-collection box will be shipped in plain, unmarked packaging with no reference to the nature of its contents to the mailing address provided by participants in the contact information form.

Protections against potential discomfort when answering sensitive survey questions: To reduce potential discomfort when answering questions on sensitive topics (e.g., history of HIV testing and management, history of bacterial STI testing and management, sexual behaviors, history of substance use) in the baseline survey, these data will be collected via a self-completed survey programmed in Qualtrics that will allow participants to skip questions or indicate that they prefer not to answer a question.

Protections to safeguard participants' privacy during the pre-test and the post-test sessions, and during the in-depth interviews: Participants will be sent password-protected Zoom links and be advised to join the pre-test and the post-test sessions, and the in-depth interview from a private location. They will also be offered the option to reschedule if the original time no longer works or if they anticipate being in a situation where their privacy may be compromised. The pre-test and the post-test sessions, and the in-depth interviews will be conducted from a private location and participants on Zoom will have the option to mute their own video (i.e., use only audio from their end) if they prefer to remain discreet.

Protections to aid the proper self-collection and safe return of specimens: To assist participants in correctly self-collecting a urine sample, a throat swab, a rectal swab, and a finger-stick blood sample, and appropriately packaging them for return by mail, the interventionist will demonstrate the contents of the specimen self-collection box, review step-by-step instructions, and address any questions or concerns during the pre-test session to be conducted over Zoom. The specimen self-collection box shipped to participants will include a general information sheet that will provide participants with a brief description of the box contents and information on how to package and return their specimens to CVRL in Atlanta, Georgia. It will also instruct participants to not include any sort of personally identifiable information (e.g., full name, mailing address) on the lab requisition form. Each specimen self-collection kit included in the box will include written instructions along with color images and a QR code that links to video instructions. Participants will be requested to enclose the transport tubes containing their self-collected specimens in the plastic biohazard bag, complete the lab requisition form, place the bag and the form in the prepaid bubble mailer, and return the bubble mailer to CVRL. Specimen return will be voluntary, and participants can choose to return all, some, or none of the four specimens.

Protections to ensure the quality of specimen testing: CVRL is one of two primary labs of the Virology and Molecular Biomarkers Core of the Emory University Center for AIDS Research (CFAR). Urine samples, throat swabs, and rectal swabs returned by participants will be tested for GC and CT using the Abbott Real Time PCR Assay. This test targets a region of the Opa gene of *Neisseria gonorrhea* and a region of the cryptic plasmid of *Chlamydia trachomatis*. It can also detect the Sweden (nvCT) variant strain. For GC, its sensitivity is 97.5% and its specificity is 99.7%. For CT, its sensitivity is 95.2% and its specificity is 99.3%.

Finger-stick blood samples returned by participants will be tested for syphilis using the ASI RPR Card Test reported as a titer of antibodies. This is a semiquantitative nontreponemal flocculation test to detect reagin antibodies in human serum and plasma with a sensitivity of 97.7% and a specificity of 99.5%. If the screening test for syphilis is reactive (i.e., a titer of ≥1:8), it will be followed by a confirmatory test (i.e., a treponemal enzyme immunoassay to detect IgG antibodies) at EML which is located in the same building as CVRL. EML is a fully accredited and licensed clinical lab operating within the Emory Healthcare Department of Pathology & Laboratory Medicine. Both CVRL and EML are certified under CLIA. CLIA regulations establish quality standards for lab testing performed on specimens from humans. The physical and environmental conditions of the labs are adequate and appropriate for the types of testing performed. Extensive safety and biohazard requirements are followed at CVRL and EML to keep lab personnel safe from physical, chemical, and biological hazards. Lab personnel wear appropriate personal protective equipment such as gloves, goggles, and masks, and follow practices to reduce their risk of exposure (e.g., handling all blood and other body fluids as if they are infectious, being cautious of exposure to mucous membranes such as the eyes, nostrils, and mouth, disposing of any used sharps properly in puncture-proof sharps containers, participating in trainings related to infection prevention). During the testing process, the biohazard bags and sharps containers used for disposal of contaminated materials are as close to the immediate testing area as possible,

kept upright throughout use, replaced routinely, and prevented from being overfilled. Containers for contaminated waste are constructed to contain all contents and prevent leakage of fluids during handling, storage, and transport, are labeled or color-coded to indicate biohazard material, and are closed prior to removal to prevent spillage or protrusion of contents during handling. Lab personnel at CVRL and EML are appropriately educated, experienced, and trained to perform lab tests and report test results in accordance with written duties and responsibilities.

Protections to securely return test results to participants: Once we receive participants' GC, CT, and syphilis test results back from CVRL (approximately 2 weeks after they return their specimens), they will be scheduled for a post-test session to be conducted over Zoom with the same interventionist who conducted the pre-test session, whenever possible. The interventionist will discuss the meaning of negative and positive bacterial STI test results and assess participants' emotional response to each possible outcome via open-ended questioning and reflective listening. Test results will be delivered via screen sharing the lab test results form (that will only include the unique specimen ID numbers and corresponding test results). The interventionist will have completed online training courses on GC, CT, and syphilis offered by the MDHHS. After the session, a copy of the lab test results form will also be shared with participants via a secure Dropbox folder that is only accessible to them and the study team members. The folder will also include a supplemental information sheet on using site locators on the CDC's "GetTested: National HIV, STD, and Hepatitis Testing" and Planned Parenthood's "STD Testing, Treatment & Vaccines" websites to identify local STI clinics to seek treatment (if warranted) and repeat testing. The link to the folder will expire after 4 weeks and the folder will be deleted, following which participants will need to contact us to obtain a new link. Participants who do not schedule or attend the post-test session will also be provided a copy of the lab test results form and the supplemental information sheet on using site locators to identify local STI clinics via a secure Dropbox folder that is only accessible to them and the study team members.

Protections to safeguard participants who test positive for one or more bacterial STIs and link them to medical care: For participants receiving a positive GC, CT, or syphilis test result, the interventionist will offer emotional support, discuss the benefits of timely antibiotic treatment, and jointly formulate a linkage to care plan during the post-test session to be conducted over Zoom. Barriers to accessing treatment (e.g., lack of insurance, limited personal transportation, reluctance to visit one's own provider) will be elicited and the interventionist will work with participants to find practical solutions. For example, if someone lacks insurance, screen sharing will be used to give information on local STI clinics that provide free or low-cost services identified using site locators on the CDC's "GetTested: National HIV, STD, and Hepatitis Testing" and Planned Parenthood's "STD Testing, Treatment & Vaccines" websites. If someone has limited personal transportation, the interventionist will assist in creating a commute plan that uses public transportation options. If someone is reluctant to visit their own provider, the interventionist will assist in finding other STI clinics or identifying commercial telehealth services that offer STI treatment (e.g., GoodMDs, PlushHealth, CallonDoc). Participants will be encouraged to notify their sex partners of their positive test results so that they can seek testing. Open-ended questioning and reflective listening will be used to engage them in a discussion on sexual risk reduction. A study team member will follow up via phone at 2 weeks and at 4 weeks to determine participants' treatment status. During each of these interactions, the study team member will complete a case report form programmed in Qualtrics documenting whether the participant has initiated treatment, completed treatment, has not yet initiated treatment but has made an appointment with a provider, or has not yet made an appointment with a provider. Those who have not yet made an appointment with a provider will be encouraged to do so as soon as possible and offered additional assistance as requested.

Protections to safeguard confidentiality: To minimize risks to confidentiality, we will provide all of the appropriate protections to participants' data collected as part of our study. UM has signed Business Associate Agreements with Qualtrics, Zoom, and Dropbox. These resources are approved by the UM ITS for sensitive identifiable human subjects research data regulated by the "Common Rule". Access to the Qualtrics, Zoom, and Dropbox accounts is protected with a sufficiently complex password and requires Duo two-factor authentication for login. Duo protects applications by using a second source of validation, like a phone or token, to verify user identity before granting access. Individuals whose contact information has been verified will be assigned a randomly generated participant ID number to be included as a metadata element in subsequent baseline and satisfaction surveys programmed in Qualtrics. Participants' contact information (full name, email address, mobile phone number, and mailing address) will be kept separate from the quantitative and qualitative data collected during Phases 1 and 2 of our study in a password-protected file stored on a secure UM server. Only IRB-approved study team members, all of whom will have completed trainings on human subjects research protections offered by the UM PEERRS, will have access to participants' data on an as-needed basis. Any specimens returned by participants within 8 weeks will be destroyed immediately after lab testing. Any specimens returned after 8 weeks will be destroyed without being tested (unless they are from participants who have requested an extension). Lab personnel at CVRL or EML will only be able to connect the participants' test results to the unique specimen ID numbers affixed to the different transport tubes. They will not have access to either the participant ID numbers or to the participants' contact information. Only IRB-approved study team members at the UM will have access to the data on which unique specimen ID numbers are assigned to a particular participant ID number, and which participant ID number corresponds to a particular participant's contact information. The data collected via the eligibility screener, contact information form, baseline survey, case report form, and satisfaction survey will be deleted from Qualtrics upon study completion (i.e., when all study-related data have been collected and checked for accuracy and completeness). The audio recordings from our pre-test sessions, post-test sessions, and in-depth interviews will be deleted from the UM server upon study completion (i.e., when all study-related data have been collected and checked for accuracy and completeness). The file containing participants' contact information will also be deleted from the UM server upon study completion (i.e., when all study-related data have been collected and checked for accuracy and completeness). All other data collected as part of our study (i.e., survey responses, case report form data, in-depth interview transcripts) will be stored on a secure UM server for subsequent analyses and reporting, and the only link between them will be the participant ID numbers (i.e., none of the files will contain any sort of personally identifiable information except ZIP code). Results from our study will be described in a manner such that no individual participants can be identified. Our study is funded by the NIH and holds a Certificate of Confidentiality.

c. Potential benefits

Participants in our study may benefit from having the opportunity to learn more about bacterial STIs during the pre-test and the post-test live AV conferencing sessions and receiving free specimen self-collection kits to test for GC or CT at three different anatomical sites of possible exposure and for syphilis. Others may benefit because our study will provide new information on the feasibility and acceptability of a novel MI-based telehealth intervention to engage sexually active GBMSM-LWH in bacterial STI screening. Our potentially scalable intervention is unique in integrating home specimen self-collection and return for GC, CT, and syphilis testing with MI-guided discussions over live AV conferencing and has a high likelihood of advancing the field in an area of critical need.

d. Importance of the knowledge to be gained

GBMSM-LWH bear a heavy burden of GC, CT, and syphilis. Left untreated, bacterial STIs may lead to serious health complications. Inflammatory and ulcerative STIs can also facilitate the onward sexual transmission of HIV in the presence of inadequate viral suppression. Timely diagnosis and treatment are key to prevention. Sexually active GBMSM-LWH engaged in HIV medical care are not being tested for GC, CT, and syphilis at least annually, as recommended by the CDC. Home specimen self-collection has increasingly been used to test for bacterial STIs in studies conducted with diverse populations. Telehealth has also demonstrated promise in managing mental health and increasing antiretroviral therapy adherence in people living with HIV. Only few studies have combined home specimen self-collection with live AV conferencing, all of which have been restricted to people without HIV. None have focused on GBMSM-LWH or incorporated MI, a client-centered, strengths-based counseling approach that seeks to support individuals towards positive behavioral change. Integrating home specimen self-collection from different anatomical sites of possible exposure with MI delivered via live AV conferencing might offer a unique solution to engage GBMSM-LWH in bacterial STI screening. Our sequential explanatory mixed-methods study seeks to explore the feasibility and acceptability of a novel MI-based telehealth intervention to engage GBMSM-LWH in GC, CT, and syphilis testing. Our intervention is a package of 3 components: (i) a pre-test live AV conferencing session involving an MI-guided discussion to elicit awareness of bacterial STIs and fill any knowledge gaps, bolster the perceived importance of regularly testing for GC, CT, and syphilis, and improve self-efficacy for specimen self-collection, (ii) self-collecting at home and returning by mail a urine sample (for GC and CT testing), a throat swab (for GC and CT testing), a rectal swab (for GC and CT testing), and a finger-stick blood sample (for syphilis testing), and (iii) a post-test live AV conferencing session involving an MI-guided discussion to prepare participants for receiving test results and formulate personalized action plans for seeking treatment (if warranted) and repeat testing. Our study advances multiple goals of the *2021-2025 STI National Strategic Plan for the United States* (prevent new STIs, accelerate progress in STI research, technology, and innovation, and reduce STI-related health disparities). Data on attitudes, facilitators, and barriers related to engaging in each intervention component from in-depth interviews will guide refinements to our intervention prior to assessing its impact in improving GC, CT, and syphilis testing rates among sexually active GBMSM-LWH in a future study.

Section 7. Researchers' qualifications

a. Akshay Sharma, MBBS, MPH, PhD

PI Sharma is an Assistant Professor in the Department of Health Behavior and Biological Sciences at the UMSN. He is educated as a physician, an infectious disease epidemiologist, and an HIV prevention counselor. He has extensive experience in conducting online studies with GBMSM[118-128] and in research methods.[129-134] He was recently the PI of an NIH-funded sequential explanatory mixed-methods study evaluating the return of 5 self-collected specimens for HIV, GC, CT, and potential PrEP adherence testing among GBMSM without HIV (Project Caboodle)[93-96] and a Co-I on telehealth studies among transgender youth without HIV[62-64] and seroconcordant HIV-negative male couples.[65-67]

b. Erin Bonar, PhD

Co-I Bonar is an Associate Professor in the Department of Psychiatry at the UM Medical School. She is a licensed clinical psychologist with experience in both quantitative and qualitative research.[135-141] She has expertise in telehealth[142-144] and MI (e.g., MI Network of Trainers trained)

and has led MI training, fidelity, and supervision on several collaborative trials focused on HIV and substance use prevention.[145-155] She is the PI of multiple NIH-funded studies to evaluate interventions to reduce substance use and concomitant sexual risk behaviors in vulnerable populations, all of which deliver MI via telehealth. Several of these studies pair in-depth interviews with quantitative data to inform implementation.

Section 8. References

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Ame00143150

Section 1.b: We have made minor additions to the introduction section to clarify how the feasibility and acceptability of the intervention will be assessed. The amended text reads as follows:

To investigate the feasibility and acceptability of a novel MI-based telehealth intervention to engage GBMSM-LWH in GC, CT, and syphilis testing, we propose to conduct a 2-year sequential explanatory mixed-methods study.[70, 71] Our intervention is a package of 3 components: (i) a pre-test live AV conferencing session involving an MI-guided discussion to elicit awareness of bacterial STIs and fill any knowledge gaps, bolster the perceived importance of regularly testing for GC, CT, and syphilis, and improve self-efficacy for specimen self-collection, (ii) self-collecting at home and returning by mail a urine sample (for GC and CT testing), a throat swab (for GC and CT testing), a rectal swab (for GC and CT testing), and a finger-stick blood sample (for syphilis testing), and (iii) a post-test live AV conferencing session involving an MI-guided discussion to prepare participants for receiving test results and formulate personalized action plans for seeking treatment (if warranted) and repeat testing. Feasibility will be assessed by documenting participants' levels of engagement in the pre-test session, specimen return for bacterial STI testing, and the post-test session. Acceptability will be assessed by documenting overall intervention satisfaction, interventionist perceptions, usability of the pre-test and the post-test

sessions, willingness to repeat the intervention, and likelihood of recommending the intervention to friends or sex partners. Potential increases in participants' knowledge of GC, CT, and syphilis will be assessed by comparing their responses to the same set of questions on these STIs included in the baseline survey (to be administered before intervention delivery) and the satisfaction survey (to be administered after intervention delivery). Potential increases in participants' self-efficacy for specimen self-collection will be assessed by comparing their responses to similar sets of questions on the ease or difficulty of self-collecting each specimen in the baseline survey and the satisfaction survey.

Section 5.a: We have made minor revisions to the description of outcome measures in the data analyses section to clarify which outcomes are primary and which outcomes are secondary, in alignment with the information registered on ClinicalTrials.gov. The amended text reads as follows:

Descriptive statistics (e.g., means, medians and ranges for continuous variables, counts and proportions for categorical variables) and progression ratios (i.e., proportions who sequentially progress through different intervention components) will be calculated using software for quantitative data analysis (e.g., SAS, Excel).

Primary outcome measures:

Outcomes to measure the feasibility of our intervention include the following:
(i) Number of participants that schedule a pre-test session.
(ii) Number of participants that join the pre-test session within 30 min of the start time.
(iii) Number of participants that return each type of specimen within 6 weeks of box delivery.
(iv) Number of participants that provide specimens of adequate quality for lab testing.
(v) Number of participants that schedule a post-test session.
(vi) Number of participants that join the post-test session within 30 min of the start time.

Outcomes to measure the acceptability of our intervention include the following:
(i) Overall intervention satisfaction: Participants' satisfaction with the pre-test session, urine sample self-collection, throat swab self-collection, rectal swab self-collection, finger-stick blood sample self-collection, and the post-test session will be assessed using six 5-point Likert items included in the satisfaction survey. Response values will be summed to obtain a total score ranging from 6-30, with higher scores indicating greater overall intervention satisfaction.
(ii) Interventionist perceptions: Participants' perceptions of the interventionist conducting the pre-test and the post-test sessions will be assessed using two 12-item Counselor Rating Form Short scales included in the satisfaction survey. Response values will be summed to obtain a total score ranging from 24-168, with higher scores indicating more positive interventionist perceptions.
(iii) Usability of the pre-test and the post-test sessions: Participants' usability of the pre-test and the post-test sessions will be assessed using two 4-item subscales from the Telehealth Usability Questionnaire on the quality of interactions with the interventionist during each session included in the satisfaction survey. Response values will be summed to obtain a total score ranging from 8-56, with higher scores indicating greater usability of the pre-test and the post-test sessions.

(iv) Willingness to repeat the intervention: Participants' willingness to repeat the pre-test session, urine sample self-collection, throat swab self-collection, rectal swab self-collection, finger-stick blood sample self-collection, and the post-test session will be assessed using six 5-point Likert items included in the satisfaction survey. Response values will be summed to obtain a total score ranging from 6-30, with higher scores indicating greater willingness to repeat the intervention.

(v) Likelihood of recommending the intervention to friends or sex partners: Participants' likelihood of recommending the pre-test session, urine sample self-collection, throat swab self-collection, rectal swab self-collection, finger-stick blood sample self-collection, and the post-test session to friends or sex partners will be assessed using six 5-point Likert items included in the satisfaction survey. Response values will be summed to obtain a total score ranging from 6-30, with higher scores indicating greater likelihood of recommending the intervention to friends or sex partners.

Secondary outcome measures:

Outcomes to measure the potential impact of our intervention on IMB model constructs include the following:
(i) Improvement in STI-related knowledge: Potential increases in participants' knowledge of GC, CT, and syphilis will be assessed by comparing responses to the same set of 22 items included in the baseline survey and the satisfaction survey. Response values will be summed to obtain separate total scores ranging from 0-22, with higher scores indicating greater STI-related knowledge.
(ii) Likelihood of testing for bacterial STIs at least annually: Participants' likelihood of testing for bacterial STIs at least annually will be assessed using a single 5-point Likert item included in the satisfaction survey. Response values will range from 1-5, with higher values indicating greater likelihood of testing for bacterial sexually transmitted infections at least annually.
(iii) Improvement in self-efficacy for specimen self-collection: Potential increases in participants' self-efficacy for urine sample self-collection, throat swab self-collection, rectal swab self-collection, and finger-stick blood sample self-collection will be assessed by comparing responses to similar sets of four 5-point Likert items included in the baseline survey and the satisfaction survey. Response values will be summed to obtain separate total scores ranging from 4-20, with higher scores indicating greater self-efficacy for specimen self-collection.

Outcomes to measure the prevalence of bacterial STIs and receipt of treatment include the following:
(i) Number of participants that test negative or positive for GC, CT, and syphilis (using our specimen self-collection kits or with their own provider or at a clinic).
(ii) Number of participants that initiate treatment (with their own provider or at a clinic or via commercial telehealth services) within 1 week of receiving a positive test result.

Because our study is inherently exploratory, we do not plan on using probability-based statistical inference techniques in line with current best practices.[109, 110] Instead, potential variations in our intervention's feasibility and acceptability across selected participant characteristics, and its potential impact on IMB model constructs will be numerically summarized and graphically visualized (e.g., side-by-side boxplots, scatter plots), as recommended for exploratory data.[111, 112]

Ame00145753

Instead of using a bubble mailer for participants to return their specimens, we will be using a shipping box made of cardboard as the outer shipping package. This change is to promote compliance with the Hazardous Materials Regulations for the safe transportation of hazardous materials, including Category B infectious substances, that recommend the use of "rigid outer packaging" (HMR; 49 CFR §173.199). To reflect this change, we have replaced the phrase "bubble mailer" with "shipping box" in the informed consent form and have updated the general information sheet that includes packaging instructions for participants. We have also included our contact details in the general information sheet and the supplemental information sheet so that

participants can readily contact us via phone or email if they have any questions. We have updated the lab test results form to include the Emory University Clinical Virology Research Lab's CLIA ID (11D1069803), so that participants can look up detailed information about the lab on the Centers for Medicare & Medicaid Services website. We have also changed the study's start date from 11/1/23 to 3/1/24. Per our correspondence with HSIP, we have checked the option for cash and unchecked the option for HSIP issued gift cards to disburse participant incentives. Study team members who have taken the TME103 training may pick up cash in the form of a prepaid Visa card from Wolverine Tower and use it to purchase e-gift cards from Amazon, which is an approved third-party vendor for HSIP.

Ame00147334

In an effort to reach a greater number of potential participants, we will also place advertisements on Adam4Adam, Jack'd, and Sniffies. We have added their Web addresses (URLs) to the application. Our advertisements will include content that has been previously approved by the IRB. We have also checked the option for Study Coordinator/Research Assistant in the fields for who will provide study information and instructions to the participants beyond what is included in the informed consent form, obtain informed consent, and monitor subjects and identify adverse events. Additionally, we have added the names and areas of expertise of the Data and Safety Monitoring Board (DSMB) members and uploaded a copy of the signed DSMB charter.

Ame00147802

To minimize the potential for fraudulent activity, we will schedule a 10 min live audio/video conferencing session over Zoom to verify a potential participant's contact information. Time slots will be offered in all US time zones and be flexible to meet their individual circumstances. Once a time is confirmed, potential participants will be sent a password-protected Zoom link. They will need to keep their camera on during the session, but no audio or video will be recorded. During the session, a study team member will verify their full name, email address, mobile phone number, and mailing address. Based on a review of the baseline and satisfaction survey metadata in Qualtrics, we will undertake a similar verification process before disbursing participant incentives on as as-needed basis. To reflect these changes, we have added this information to the informed consent form, created a new Qualtrics survey to seek re-consent, and drafted correspondence scripts for scheduling a Zoom session and for re-consenting previously enrolled participants.
