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

Informed Consent Form Approval Date: 4/30/2024

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

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

Principal Investigator: Akshay Sharma, MBBS, MPH, PhD; Department of Health Behavior and Biological Sciences, University of Michigan School of Nursing

Co-Investigator: Erin Bonar, PhD; Department of Psychiatry, University of Michigan Medical School

Study Sponsor: National Institutes of Health (NIH) – National Institute of Allergy and Infectious Diseases (NIAID)

You are invited to take part in a research study. This form contains information that will help you decide whether to join the study.

1.1 Key Information

Things you should know about this study:

- The purpose of this study is to understand whether gay and bisexual men living with HIV are willing to collect and return their specimens for bacterial sexually transmitted infection (STI) testing when combined with live audio/video conferencing support.
- If you are eligible to participate, we will ask you to complete two online surveys, attend two live audio/video conferencing sessions, and collect and return a urine sample, a throat swab, a rectal swab, and a blood sample for bacterial STI testing. Later on, we may also ask you to attend an online interview to share your experiences. We expect all study activities to be completed over a period of 6 months. You could receive a total of up to $100 by the end of this study.
- Potential risks associated with this study are as follows:
    - Feeling concerned about others finding out that you are a participant
    - Feeling uncomfortable when answering sensitive survey questions
    - Feeling uncomfortable showing your face during the live audio/video conferencing sessions or the online interview
    - Experiencing mild physical discomfort when collecting some specimens
    - Experiencing emotional distress in case of one or more positive bacterial STI test results
    - Feeling concerned about a breach of confidentiality
- You may benefit from learning more about different bacterial STIs during the two live audio/video conferencing sessions and from receiving free kits to test for bacterial STIs.

Taking part in this study is voluntary. You do not have to participate, and you can stop at any time. Please take time to read this entire form and ask questions before deciding whether to take part in this study.

2. PURPOSE OF THIS STUDY

In the United States, gay and bisexual men living with HIV bear a heavy burden of bacterial STIs such as gonorrhea, chlamydia, and syphilis. It is important to diagnose and treat these infections in a timely manner to prevent health complications and to reduce their spread. The purpose of this study is to understand whether gay and bisexual men living with HIV are willing to collect and return their specimens for bacterial STI testing when combined with live audio/video conferencing support.

3. WHO CAN PARTICIPATE IN THE STUDY

3.1 Who can take part in this study?

Men who live in the United States, will be physically located in the United States when completing study activities, are 18 years of age or older, are of legal age to provide consent for taking part in research in the state or territory where they live, have been diagnosed with HIV, have had condomless sex with ≥2 men in the past year, are willing to provide their contact information, are able to attend live audio/video conferencing sessions, and are willing to receive a box that contains kits to collect a urine sample, a throat swab, a rectal swab, and a blood sample on their own for bacterial STI testing may be eligible to take part in this study. They should also provide valid contact information and complete the first online survey (called the baseline survey) in order to proceed.

3.2 How many people are expected to take part in this study?

75 gay and bisexual men living with HIV are expected to participate in Phase 1 of this study. Some participants (20 of 75) will be invited to attend an online interview in Phase 2 of this study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

Study procedures are described in detail in the following sections:

4.1.1 Procedures during the recruitment of participants

If you are interested in participating in this study, you will first need to provide consent. If you do not consent to participate, you will be referred to the CDC’s website on STIs so that you can learn more about protecting yourself and your sex partners. If you consent to participate, you will proceed to a brief survey (called the eligibility screener) so that we can determine whether you are eligible to participate in this study.

If you are not eligible, you will be referred to the CDC's website on STIs so that you can learn more about protecting yourself and your sex partners. If you are eligible, you will proceed to a contact information form that will ask you to provide your full name, email address, and mobile phone number (to receive study communications) and your mailing address (to receive a box that contains kits to collect specimens on your own for bacterial STI testing). Your contact information will be kept separate from the data collected during the study. We will not share it with anyone outside the study.

If you do not provide your contact information, you will be referred to the CDC's website on STIs so that you can learn more about protecting yourself and your sex partners. If you provide your contact information, you will be contacted by a study team member to verify your full name, email address, mobile phone number, and mailing address. You will be offered time slots in all time zones to schedule a 10 min live audio/video conferencing session over Zoom. Once you schedule a session, you will be sent a password-protected Zoom link. You will need to keep your camera on during the session, but no audio or video will be recorded. If you do not provide valid contact information, you will not be able to proceed in the study.

4.1.2 Procedures during Phase 1 of the study

Once your contact information has been verified, you will be assigned a randomly generated participant ID number and be sent a link to the first online survey (called the baseline survey) programmed in Qualtrics. It will include some sensitive questions about yourself and your behaviors, as well as your partner's HIV status and history of testing for bacterial STIs (if you are in a relationship). The survey should take approximately 1 hour to complete, and it will allow you to skip questions or indicate that you prefer not to answer a question. We will send you reminders to complete the survey. If you do not complete the survey by the end of 8 weeks, we will assume you are not interested. You will not be able to proceed in the study (unless you have requested an extension), and your name and other information that can directly identify you will be deleted within 4 weeks. If you complete the survey, you may be contacted by a study team member to verify your contact information over Zoom. If your contact information cannot be verified, you will not receive a $40 Amazon e-gift card and will not be able to proceed in the study. Once your contact information is verified, you will receive a $40 Amazon e-gift card and proceed in the study.

Once you complete the survey, you will be contacted to schedule the first 30 min live audio/video conferencing session over Zoom. Time slots will be offered in all time zones, and you will have the option to reschedule if you wish. We will send you reminders to schedule the session. If you do not schedule a session by the end of 8 weeks, we will assume you are not interested (unless you have requested an extension). Once you schedule a session, you will be sent a password-protected Zoom link. You can mute your own video (i.e., use only audio from your end) if you prefer to remain discreet. The session will be audio-recorded using a digital voice recorder. No audio or video will be recorded in Zoom. During the session, a study team member will review step-by-step instructions

on how to collect different specimens on your own and answer your questions. If you do not attend the session, we will assume you are not interested (unless you have contacted us to reschedule). If you complete the session, you will proceed in the study.

Next, you will be shipped a box in plain, unmarked packaging that contains kits with instructions to collect a urine sample, a throat swab, a rectal swab, and a blood sample on your own for bacterial STI testing. You will be asked to return your specimens to the Emory University Clinical Virology Research Lab (CVRL) using a pre-paid shipping box. You can choose to return all, some, or none of the four specimens. Your urine sample, throat swab, and rectal swab will be tested for gonorrhea and chlamydia, and your blood sample will be tested for syphilis. If the screening test for syphilis is reactive (i.e., abnormal), it will be followed by a confirmatory test at the Emory Medical Laboratory (EML). 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 you return within 8 weeks will be destroyed immediately after lab testing. Any specimens you return after 8 weeks will be destroyed without being tested (unless you have requested an extension). Your test results will be shared with us by lab personnel at CVRL via a secure Dropbox folder. We will send you reminders to return your specimens. If you do not return any specimens by the end of 8 weeks, we will assume you are not interested (unless you have requested an extension). If you return some or all specimens by the end of 8 weeks, you will proceed in the study.

Once we receive your test results back from CVRL (approximately 2 weeks after you return your specimens), you will be contacted to schedule the second 30 min live audio/video conferencing session over Zoom. Time slots will be offered in all time zones, and you will have the option to reschedule if you wish. We will send you reminders to schedule the session. If you do not schedule a session by the end of 8 weeks, we will assume you are not interested (unless you have requested an extension). Once you schedule a session, you will be sent a password-protected Zoom link. You can mute your own video (i.e., use only audio from your end) if you prefer to remain discreet. The session will be audio-recorded using a digital voice recorder. No audio or video will be recorded in Zoom. During the session, a study team member will screen share a copy of your lab test results form. If you receive one or more positive bacterial STI test results, they will offer to talk with you about how you are feeling and work with you to develop a linkage to care plan. After the session, a copy of your lab test results form and an information sheet on how to identify local STI clinics will be shared with you via a secure Dropbox folder. A study team member will also follow up via phone at 2 weeks and at 4 weeks to see if you have received treatment and offer you additional assistance as requested. During each of these interactions, they will complete a case report form programmed in Qualtrics. If you do not attend the session, we will assume you are not interested (unless you have contacted us to reschedule). However, a copy of your lab test results form and an information sheet on how to identify local STI clinics will be shared with you via a secure Dropbox folder.

Finally, you will be sent a link to the second online survey (called the satisfaction survey) programmed in Qualtrics (even if you chose to not attend the two live audio/video

conferencing sessions or return specimens for lab testing). It will include questions about your satisfaction with study participation. The survey should take approximately 30 min to complete, and it will allow you to skip questions or indicate that you prefer not to answer a question. We will send you reminders to complete the survey. If you do not complete the survey by the end of 8 weeks, we will assume you are not interested (unless you have requested an extension). If you complete the survey, you may be contacted by a study team member to verify your contact information over Zoom. If your contact information cannot be verified, you will not receive a $20 Amazon e-gift card. Once your contact information is verified, you will receive a $20 Amazon e-gift card.

4.1.3 Procedures during Phase 2 of the study

Some participants (20 of 75) will be invited to attend an online interview to share their experiences. If you are selected, you will be contacted to schedule a 1-hour interview over Zoom or phone (depending upon your preference). Time slots will be offered in all time zones, and you will have the option to reschedule if you wish. We will send you reminders to schedule the interview. If you do not schedule an interview by the end of 8 weeks, we will assume you are not interested (unless you have requested an extension). Once you schedule an interview, you will be sent a password-protected Zoom link (if you prefer being interviewed over Zoom). You can mute your own video (i.e., use only audio from your end) if you prefer to remain discreet. During the interview, we will ask questions related to your participation in this study, including collecting specimens on your own. The interview will be audio-recorded using a digital voice recorder. No audio or video will be recorded in Zoom. If you do not attend the interview, we will assume you are not interested (unless you have contacted us to reschedule). If you attend the interview, you will receive a $40 Amazon e-gift card.

4.2 How much of my time will be needed to take part in this study?

The total amount of time you will devote to this study is approximately 4 hours (if you are not selected for an online interview) or approximately 5 hours (if you are selected for and attend an online interview). We expect all study activities to be completed over a period of 6 months.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

Potential risks associated with this study and the steps we will take to protect you against these risks are as follows:

- You may feel concerned about others finding out that you are a participant. This could happen if someone else reads the emails or texts that we send or opens the box that contains the kits to collect specimens for bacterial STI testing when it arrives in the mail. To minimize this possibility, none of the study communications

will make any reference to the nature of the study. We encourage you to delete any emails, call logs, or texts received as part of the study. The box will be shipped in plain, unmarked packaging with no reference to the nature of its contents to the mailing address you provide.

- You may feel uncomfortable when answering sensitive survey questions. The first online survey (called the baseline survey) will include questions on history of HIV testing and management, history of bacterial STI testing and management, sexual behaviors, and history of substance use. To reduce the possibility of discomfort, you will input responses yourself and the survey will allow you to skip questions or indicate that you prefer not to answer a question.
- You may feel uncomfortable showing your face during the live audio/video conferencing sessions or the online interview. To reduce the possibility of discomfort, you will be sent password-protected Zoom links and be advised to join the sessions and the interview from a private location. You will also have the option to reschedule if the original time no longer works or if you think you might be in a situation where you do not have privacy. The sessions and the interview will be conducted from a private location, and you can mute your own video (i.e., use only audio from your end) if you prefer to remain discreet.
- You may experience mild physical discomfort when collecting some specimens. Although collecting a urine sample of 3 milliliters (which is less than 1 teaspoon of urine) is not expected to cause any physical discomfort, collecting a throat swab and a rectal swab may cause mild physical discomfort. Collecting a blood sample by pricking your 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). To help you properly collect each type of specimen on your own, a study team member will review step-by-step instructions and answer your questions during the first live audio/video conferencing session. Each kit will include written instructions along with color images and a QR code that links to video instructions. You can choose to return all, some, or none of the four specimens.
- You may experience emotional distress in case of one or more positive bacterial STI test results. To minimize this possibility, a study team member will offer to talk with you about how you are feeling and work with you to develop a linkage to care plan during the second live audio/video conferencing session. A study team member will also follow up via phone at 2 weeks and at 4 weeks to see if you have received treatment and offer you additional assistance as requested.
- You may feel concerned about a breach of confidentiality. Because this study collects information about you, one of the risks is a breach of confidentiality. See “Section 8. Protecting and Sharing Research Records and Specimens” for more information on how we will protect your confidentiality.

5.2 How could I benefit if I take part in this study? How could others benefit?

You may benefit from learning more about different bacterial STIs during the two live audio/video conferencing sessions and from receiving free kits to test for bacterial STIs.

Others may benefit from the knowledge gained from this study. The results will provide new information on procedures to engage gay and bisexual men living with HIV in bacterial STI screening.

5.2.1 Will the researchers provide information to me about what they learn from analyzing my specimens?

Yes, we will inform you about your gonorrhea, chlamydia, and syphilis test results during the second live audio/video conferencing session. We will also share a copy of your lab test results form and an information sheet on how to identify local STI clinics via a secure Dropbox folder.

6. ENDING THE STUDY

6.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. If you decide to leave the study before it is finished, please inform a study team member listed in “Section 9. Contact Information”. If you choose to tell us why you are leaving the study, your reasons may be kept as part of the study record. Any specimens you return for lab testing will be destroyed. However, we will keep the information that we collect about you during this study, including your survey responses, test results, and interview responses for research purposes unless you ask us to delete it from our records. If we have already used your information for a research analysis it will not be possible to remove your information.

7. FINANCIAL INFORMATION

7.1 Will I be paid or given anything for taking part in this study?

You will not be paid for completing the brief survey (called the eligibility screener) that will help us determine whether you are eligible to participate in this study or for completing the contact information form. You will only be eligible to receive payments once your contact information has been verified by a study team member over Zoom.

If you complete the first online survey (called the baseline survey) in Phase 1 of the study, you will receive a $40 Amazon e-gift card. If you complete the second online survey (called the satisfaction survey) in Phase 1 of the study, you will receive a $20 Amazon e-gift card. Therefore, you could receive a total of up to $60 by the end of Phase 1.

If you are selected for and attend an online interview in Phase 2 of the study, you will receive an additional $40 Amazon e-gift card. Therefore, you could receive a total of up to $100 by the end of Phase 2.

8. PROTECTING AND SHARING RESEARCH RECORDS AND SPECIMENS

8.1 How will the researchers protect my information and specimens?

To minimize risks to confidentiality, we will provide all of the appropriate protections to your data collected as part of this study. The University of Michigan has signed business agreements with Qualtrics, Zoom, and Dropbox allowing these resources to be used for sensitive identifiable human subjects research data. Access to the accounts is protected with a sufficiently complex password and requires Duo two-factor authentication for login. Once your contact information has been verified, you will be assigned a randomly generated participant ID number. Your contact information will be kept separate from the data collected during Phases 1 and 2 of the study in a password-protected file stored on a secure University of Michigan server. We will not share it with anyone outside the study. Only IRB-approved study team members, all of whom will have completed trainings on human subjects research protections, will have access to your data on an as-needed basis. Any specimens you return within 8 weeks will be destroyed immediately after lab testing. Any specimens you return after 8 weeks will be destroyed without being tested (unless you have requested an extension). Lab personnel at CVRL or EML will only be able to connect your test results to the unique specimen ID numbers affixed to the different transport tubes. They will not have access to either your participant ID number or to your contact information. Your test results will be shared with us by lab personnel at CVRL via a secure Dropbox folder. A copy of your lab test results form and an information sheet on how to identify local STI clinics will be shared with you via a secure Dropbox folder. The password-protected file containing your contact information will be deleted upon study completion (i.e., when all study-related data have been collected and checked for accuracy and completeness). All other data will be stored on a secure University of Michigan 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 this study will be described in a manner such that you cannot be identified.

8.1.1 Special protections

This research holds a Certificate of Confidentiality from the National Institutes of Health (NIH). This means that we cannot be forced to disclose any research information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. In general, we will use the Certificate to resist any demands for information that would identify you, except as described below.

There are some important things that you need to know:

- The Certificate does not stop reporting or information-sharing that you agreed to in this consent form. For example, we may share information with appropriate authorities if we think you may harm yourself or others. We may also share your de-identified data with other researchers.
- The Certificate does not stop reporting that federal, state, or local laws require. All 50 states require reporting positive results of any of the three STIs for which you are testing (gonorrhea, chlamydia, and syphilis). If you receive a positive test

result, a study team member will review your state and local statutory reporting requirements and procedures and make up to 3 attempts to notify the relevant public health authority. Your contact information will be reported. This notification may result in you being contacted by your public health authority for follow up and possible contact tracing.

- The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs.
- We may also release information about you to others when you say it is okay. For example, you may give us permission to release information to insurers, medical providers, or anyone else.
- The Certificate does not stop you from personally releasing information about your involvement in this study if you wish. For example, you may choose to tell your healthcare provider about your bacterial STI test results.

More information about Certificates of Confidentiality and the protections they provide is available at https://grants.nih.gov/policy/humansubjects/coc.htm

8.2 Who will have access to my research records?

There are reasons why information about you may be used or seen by the study team members or others during or after this study. For example, the university, government officials, study sponsors or funders, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.

8.3 What will happen to the information and specimens collected in this study?

We will keep the information that we collect about you during this study, including your survey responses, test results, and interview responses for research purposes unless you ask us to delete it from our records. Any specimens you return for lab testing will be destroyed. Your name and other information that can directly identify you will be stored securely and separately from the research information we collect about you and deleted upon study completion (i.e., when all study-related data have been collected and checked for accuracy and completeness). Results from this study could be presented at a conference or published in an article but will be described in a manner such that you cannot be identified.

8.4 Will my information and specimens be used for future research or shared with others?

We may use or share the information that we collect about you during this study, including your survey responses, test results, and interview responses for future research unless you ask us to delete it from our records. If we share your information with other researchers, it will be de-identified, which means that it will not contain your name or other information that can directly identify you. The future research may be similar to this study or completely different, and we will not ask for your additional informed consent. Any

specimens you return for lab testing will be destroyed and will not be used for future research or shared with other researchers.

8.4.1 Special Requirements

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by the National Institutes of Health (NIH). This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

9. CONTACT INFORMATION

Who can I contact about this study?

Please contact a study team member listed below to:

- Obtain more information about the study
- Ask a question about the study procedures
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Akshay Sharma
Email: akshaydr@umich.edu
Phone: 734-647-0151

If you have questions about your rights as a research participant, or wish to obtain information, ask questions, or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

University of Michigan
Health Sciences and Behavioral Sciences Institutional Review Board (IRB-HSBS)
2800 Plymouth Road
Building 520, Room 2144
Ann Arbor, MI 48109-2800
Phone: 734-936-0933 (Toll-free number: 1-866-936-0933)
Fax: 734-936-1852
E-mail: irbhsbs@umich.edu

You can also contact the University of Michigan Compliance Hotline at 1-866-990-0111.

10. YOUR CONSENT

Consent to participate in the research study

Please click on one of the choices below to tell us if you are interested in participating. You may download a copy of this form for your records. If you have any questions about the study after you consent, you can contact a study team member listed in “Section 9. Contact Information”.

- ☐ I understand what this research study is about, and my questions so far have been answered. I agree to participate in this study.

- ☐ I do not wish to participate in this research study.