Study Title: Increasing HIV/STI Home Testing, Linkage to Care, and Linkage to PrEP via a Digital Intervention among Black Women in a Geographic Hotspot

NCT: NCT05390541

Date of Consent: October 2, 2024

JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH

ADULT INFORMED CONSENT
AND HIPAA PRIVACY AUTHORIZATION

Principal Investigator: Liesl Nydegger, PhD, MPH, Johns Hopkins

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IRB No.: IRB00030508

Sponsor/Supporter/Funded By: National Institute of Mental Health

PI Version Date: 10/4/2024

Key Information about the Study

- We ask you to volunteer for a study on HIV and STI self-testing. We want to see if a web-based program for Black women will boost self-testing and access to care and pre-exposure prophylaxis (PrEP).
- You do not have to join the study; it is your choice and there is no penalty for not joining. Ask as many questions as you need to help you make your decision. Please read the rest of this consent document before deciding.
- You may qualify for this study if you are a Black female, aged 18-59. You must also: 1. Have not tested for HIV/STIs in the past 12 months. 2. Live in a county around Austin, Dallas, Houston, or San Antonio. 3. Have a computer, tablet or smartphone.
- If you join, we will share your information with Kind Clinic Virtual Services. Kind Clinic Virtual Services provides virtual sexual healthcare across the state of Texas.
- If you join, you'll complete 5 online sessions and their tasks in 40 days. There are 2 groups, each with 5 sessions. You will be randomly assigned to one. Each of the 5 sessions will be online, self-paced and interactive. You will read information, view infographics, watch interviews, type responses, and answer questions. Each session will focus on a specific topic related to HIV/STI prevention and care. For example, one session will cover how people contract HIV. Another session is about how PrEP helps prevent HIV.
- You will have to complete a session to move onto the next session. If you do not complete a session, you will not move onto the next session. For example, you need to complete session 1 to move on to session 2.
- You will then have a virtual meeting with a Kind Clinic Virtual Services provider. Next, you'll do a self-test for HIV and STIs and mail it to the lab. After that, check your results and have a follow-up meeting with the provider.
- If you join the study, Kind Clinic Virtual Services will mail you a self-test. The self-test will test for HIV and STIs, including chlamydia, gonorrhea, and syphilis. You will get your test results.
    - If you need assistance while you wait for your results you can contact study staff or visit this website: https://www.hiv.gov/about-us/contact

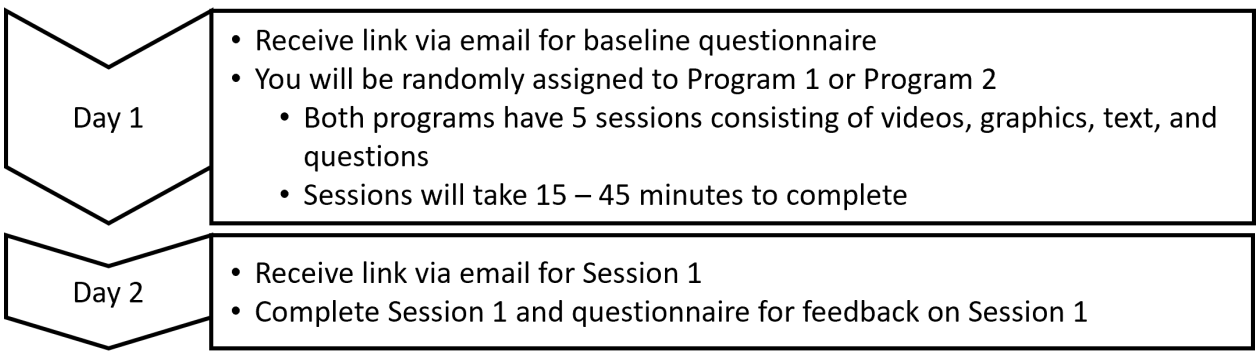
- The self-test will include a urine sample, oral swab, blood spot, and (optional) anal swab. We will provide instructions on how to do each of these tests. We will also provide contact information in case you need help with the tests.
- You will have a follow-up appointment with Kind Clinic Virtual Services after you get your results. If you test positive for HIV and/or any STIs, Kind Clinic Virtual Services will help you with treatment. If you test negative for HIV, the provider will discuss HIV prevention methods with you. They may recommend taking pre-exposure prophylaxis (PrEP).
- You might feel some discomfort during the sessions, the self-test, mailing the kit, or getting results. Two virtual meetings with Kind Clinic Virtual Services could be inconvenient. You might worry about the privacy of your information with the study and Kind Clinic Virtual Services. Our contact details will be in all our communications and on each session page. Please reach out with any questions or concerns. We will also provide Kind Clinic Virtual Services's number for health-related questions. To protect privacy, each participant gets an ID number. Your information links only to this number. A secure document connects your name and ID number, accessible only to key staff. Your personal information remains separate from study data. Study staff and Kind Clinic Virtual Services will send any information to each other via encrypted emails. You can leave the study anytime without penalty.
- You will receive compensation for participating. You will receive compensation via Tango. Tango is a website that will allow you to choose from over 1,000 gift cards. After the questionnaire, you will get $10 via Tango. You will choose a gift card on Tango. After completing the questionnaire after session 5, you will be sent $50 via Tango. Two weeks after your session 5 questionnaire, you will get an email. It will contain a follow-up assessment. After completing the 2-week follow-up questionnaire, we will send you $20 via Tango. The total amount of compensation you may receive is $80 via Tango. You will attend 2 virtual appointments with Kind Clinic Virtual Services. This will take time during your day to schedule and attend.

Why is this research being done?

This study is about promoting HIV and STI self-testing. We seek feedback on each of the program sessions, program instructions, and questionnaires. After getting participants' feedback, we will revise the programs, instructions, and questionnaires. Then, we will do a second study with more participants. This will test which of the two programs better promotes HIV and STI self-testing and, if applicable, links to treatment or PrEP.

What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things:



Days 3 – 6	• Receive link via email from Kind Clinic Virtual Services to complete clinic forms and schedule a virtual appointment • Attend virtual appointment with Kind Clinic Virtual Services
Day 7	• Receive link via email for Session 2 • Complete Session 2 and questionnaire for feedback on Session 2
Days 8 – 9	• Use HIV/STI self-testing kit
Day 10	• Receive link via email for Session 3 • Complete Session 3 and questionnaire for feedback on Session 3
Days 11 – 12	• Mail HIV/STI self-testing kit in pre-paid packaging with the United States Postal Service (USPS)
Days 13 – 18	• Wait for HIV/STI test results
Day 19	• Receive link via email for Session 4 • Complete Session 4 and questionnaire for feedback on Session 4
Days 20 – 26	• Receive email informing you that your test results are ready to check in your Kind Clinic Virtual Services patient portal **and/or** • Receive a phone call from Kind Clinic Virtual Services with results from your HIV/STI self-testing kit
Day 27	• Receive link via email for Session 5 • Complete Session 5 and questionnaire for feedback on Session 5
Days 28 – 29	• Attend virtual follow-up appointment with Kind Clinic Virtual Services • Discuss test results, obtain treatment (if applicable), and discuss PrEP (if applicable)

Day 40	• Receive link via email to complete follow-up questionnaire

Will research test results be shared with you?

This study involves HIV and STI tests that will produce clinical information that could be useful to you. Kind Clinic Virtual Services will share this information with you and our primary study research team. The results of your HIV and STI self-tests will be shared with you via the Kind Clinic Virtual Services patient portal.

What happens to data that are collected in the study?

The data we collect from you will help advance science and public health. As a participant, you will not own your research data. You will not benefit financially from any new product or idea that might arise from our work. Sharing of research data is often done to increase what scientists can learn. The data you provide us might be shared

- directly with other researchers, funders, government agencies, publishers of papers
- through government or other databases/repositories

We will do our best to protect your data. We will only share it anonymously. That means it won't be linked to your name, address, date of birth, or any other identifying info. If you are not okay with us using your data in future research, you may not want to join this study.

What are the risks or discomforts of the study?

Study Item	Risks	Addressing Risks
Questionnaire	• Discomfort answering personal questions about your sexual health and/or medical history	• All participants will be assigned an ID number • All questionnaire responses will be linked to your ID number (not your name) • Only 1 document will link your ID number and name, which will be password protected and only accessible by the primary research team • You can refuse to answer any question that you are uncomfortable answering • If you feel distressed by any questions, please contact the research team ASAP via phone, text, or email
Program Sessions	• Being interrupted by someone near you while doing the session	• We recommend completing all sessions and questionnaires when you are alone for 15 – 20 minutes • We recommend using headphones/earbuds so others cannot hear the sessions

		• If you cannot complete a session or questionnaire in one sitting, you will be able to return and complete it later
Virtual Appointment with Kind Clinic Virtual Services	• Discomfort answering some person questions	• All questions asked by Kind Clinic Virtual Services are to provide you with the best possible care • Let the Kind Clinic Virtual Services provider know if you experience any discomfort—they will respond appropriately • You can always contact the research team ASAP via phone, text, or email

	• Being interrupted by someone near you while doing your Kind Clinic Virtual Services appointment	• Only schedule your Kind Clinic Virtual Services appointment when you will be alone
		• If someone interrupts your appointment, please stop speaking
		  ○ Try to find a private space where no one can hear you or your provider
		  ○ If this is not possible, find a time to reschedule your appointment with Kind Clinic Virtual Services

Using the HIV/STI Self-Testing Kit	• Someone in your home seeing the self-testing kit	• The self-testing kit will arrive in an unmarked package addressed only to you • Once the package arrives, you can hide it to prevent others in your home from opening it • Find a time when you are alone for about 20 – 30 minutes to complete the self-testing kit
	• Discomfort when using the urine sample, oral swab, blood spot, or anal swab (optional)	• Ensure to watch all videos in Session 2 that demonstrate the self-testing procedures • Read all of the provided instructions that come with the self-testing kit • Call Kind Clinic Virtual Services with any questions
	• Administering the blood spot may cause discomfort, bleeding, and/or bruising at the needle site	• The discomfort should be minimal (similar to checking blood sugar if someone has diabetes) • If you have any concerns about the self-test, contact Kind Clinic Virtual Services
Mailing the HIV/STI Self-Testing Kit	• Inconvenience by traveling to USPS to mail the pre-paid self-testing kit	• The return package will be unmarked and pre-paid. It will fit in a USPS drop box • Session 3 will provide details for mailing the self-testing kit including how to find USPS drop boxes and schedule a pick-up
	• Discomfort in sending your biospecimens to the lab in the mail	• Take a picture of your mailing label with the tracking number • If dropping package at USPS, ask for a receipt, which will include the tracking number

Checking Your HIV/STI Test Results	• Feel anxious or afraid while waiting for your HIV/STI test results	• Session 4 will provide ideas on how to ease your anxiety or fear • Contact our study team by phone, text, or email to discuss your anxiety or fear • Contact Kind Clinic Virtual Services by phone or email to discuss your anxiety or fear • Contact someone in your support system who will provide positive feedback and support
Providing Identifiable Private Information	• There is a risk that someone outside of the study will see your private information	• Your private information you provide electronically will be stored in password-protected files on a password protected computer that can only be access by the primary research team • All participants will be assigned an ID number • All questionnaire responses will be linked to your ID number (not your name) • Identifiable data will be destroyed within 1 year of the study closing • If we share your data with other researchers, we will not include any identifiable information, and ask them the use the same precautions mentioned above

How will the confidentiality of your data be protected?

We have steps to protect your personal information.

Before Starting the Program:

- After you completed the screener questionnaire in Qualtrics, we assigned you an ID number.
- One document links participants' names and identifiable information. It's in a password-protected file only accessible to senior study staff.
- All study data in sessions and questionnaires are collected via Qualtrics and saved with participant ID numbers.
    - Therefore, your identifiable data will never be connected to your name.
    - All data will be stored in password-protected files on OneDrive.

Interactions with Kind Clinic Virtual Services:

- You will complete forms about your sexual health for Kind Clinic Virtual Services.
- To keep your name and study data private, we will use only names with Kind Clinic Virtual Services. Only the study staff will see your participant ID. This way participant names will not be linked to study data. All emails with Kind Clinic Virtual Services will be encrypted.

What is a Certificate of Confidentiality?

Your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we must report by law, such as child abuse or some infectious diseases. The Certificate does not stop us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing it for this study or future research. Disclosures that you make yourself are also not protected.

HIPAA Authorization for Disclosure of Protected Health Information

What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree to two things. One, your health care providers will share your private health information with us. Two, the study team will use any information it needs to conduct the study. Your private information will include things learned from this consent form. Kind Clinic Virtual Services will inform study staff when you complete clinic forms and attend your first virtual appointment. They will tell study staff when they mail the self-testing kit and when they receive the self-testing kit back after you have used it. Kind Clinic Virtual Services will inform us of your test results from using the self-testing kits. This includes test results for chlamydia, gonorrhea, syphilis and HIV. They will also inform study staff when you attend your second virtual appointment, if your doctor prescibed medication for any positive tests and if your doctor prescribed you PrEP.

Who will see, use or share the information?
Researchers may request, receive or use your private health information. We may share your information with other people at Johns Hopkins. We would share your information if needed for your clinical care or study oversight. Some study information will be in your medical record. It will help coordinate your research and clinical care. By signing this form, you allow the research team to share your information with others outside of Johns Hopkins. This may include the study's sponsor, its agents, contractors, and outside providers. It also includes safety monitors, government agencies, other study sites, data managers, and contractors used by the study team. We will try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee it. If your health care providers or the research team disclose your information, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you will not be eligible to join the study.

How long will your information be used or shared?
Your permission to collect, use, and share your information does not expire. Also, you agree that your information may be used for similar future research.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must inform the Principal Investigator in writing. Use the contact information in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

What are the potential benefits to being in the study?

The benefits of this study are that you will be provided with an HIV/STI self-testing kit, receive your test results, and follow-up care for no charge. In addition, you have the opportunity during the questionnaires to provide invaluable feedback to the study team to improve the intervention.

Will you be paid if you join this study?

If you choose to join this study, you will be compensated $10 for completing the baseline questionnaire. After completing Session 5 (Day 27), you will be compensated $50. When you complete the follow-up questionnaire (Day 40), you will be compensated $20. If you complete all portions of the study, you will be compensated a total of $80. All compensation will occur through Tango where you can select a gift card of your choice.

Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

If you leave the study early, Johns Hopkins may use or share your health information that it has already collected if the information is needed for this study or any follow-up activities.

Why might we take you out of the study early?

You may be taken out of the study if:

- The study is cancelled
- If you do not complete session 3 and its deliverables
- There may be other reasons to take you out of the study that we do not know at this time

If you are taken out of the study early, Johns Hopkins University may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

What other things should you know about this research study?

What is the Institutional Review Board (IRB) and how does it protect you?

An Institutional Review Board (IRB) reviewed this study. It is a group of scientists and community members who review human research studies. The IRB can help you with questions about your rights as a research participant. It can also address any concerns or complaints about this study. You may contact the IRB at 410-955-3193 or bsph.irboffice@jhu.edu.

What should you do if you have questions about the study, or are injured or ill as a result of being in this study?

Call the principal investigator, Liesl Nydegger at 667-306-9763. If you wish, you may contact the principal investigator by letter. The address is on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3193.

Documenting Participant Choices

Future Contact

We would like your permission for our research team to contact you in the future. Please note that your decision below does not prevent other researchers at Johns Hopkins from contacting you about other research. Please indicate your decision below by checking the appropriate box.

YES NO

What does your signature on this consent form mean?

Your signature means you have reviewed this form, you have had a chance to ask questions, and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

_____

Signature of Participant (Print Name) Date/Time

_____

Signature of Person Obtaining Consent (Print Name) Date/Time