Informed Consent Form

Title:HealthMindr: Theoretically based mobile App

NCT Number:NCT03763942

IRB Approval Date: 3/31/2023

You Are Being Asked to Be in a Research Study

What Is a Research Study?

The main purpose of research studies is to gain knowledge. This knowledge may be used to help others. Research studies are not intended to benefit you directly, though some might.

Do I Have to Do This?

No. Being in this study is entirely your choice. If you decide to join this study, you can change your mind later on and withdraw from the research study.

Taking part in a study is separate from medical care. The decision to join or not join the research study will not affect your status as a patient.

What Is This Document?

This form is an informed consent document. It will describe the study risks, procedures, and any costs to you.

This form is also a HIPAA Authorization document. It will describe how your health information will be used and by whom.

Signing this form indicates you are willing to take part in the study and allow your health information to be used.

What Should I Do Next?

1. Read this form, or have it read to you.
2. Make sure the study doctor or study staff explains the study to you.
3. Ask questions (e.g., time commitment, unfamiliar words, specific procedures, etc.)
4. If there will be medical treatment, know which parts are research and which are standard care.
5. Take time to consider this, and talk about it with your family and friends.

Emory University
Consent to be a Research Subject / HIPAA Authorization

Title: HealthMindr: Theoretically based mobile App

Principal Investigator: Patrick Sullivan, DVM PhD

Sponsor: National Institutes of Health (NIH), National Institute on Drug Abuse

Sites: Emory University (Atlanta, GA), George Washington University (Washington, DC), and University of Mississippi Medical Center (Jackson, MS)

Introduction

You are being asked to be in a public health research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits.

Before making your decision:

- Please carefully read this form
- Please listen to the study staff explain the study to you in the online video
- Please ask questions about anything that is not clear

You can save a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This Web site will not include information that can identify you. At most the Web site will include a summary of the results. You can search this Web site at any time.

What is the purpose of this study?

The purpose of this study is to test a smartphone app designed to promote healthy behaviors to men who have sex with men through information, periodic screenings, testing and locator resources. We will ask participants to tell us about their thoughts on the app and its use. We will also ask participants about their sexual health and history, in order to determine whether using the app has an effect on sexual health outcomes.

What will I be asked to do?

If you choose to be in this study, we will ask you to complete a brief verification phone call and then participate in a series of activities over the course of 12 months. These activities will include downloading and interacting with a smartphone app and filling out surveys about your sexual health and behavior. The study activities include short 10-minute monthly surveys and quarterly surveys that last about 30-45 minutes.

You may also be asked to participate in an in-depth interview. If chosen, you will be asked to consent separately for the interview. The purpose of the interview will be to collect more information on your experiences as a participant on the study and the app.

You will be asked to participate in a randomized control trial. Randomization means that you will randomly be placed into one of two groups, like flipping a coin. The two groups will have different smartphone apps. One version of the app will have access to basic study procedures for surveys and the other version will have access to additional resources.

The version of the app with resource access will allow you to order condoms, lube, and HIV and STI testing kits at no cost to you. The STI home testing kits screen for syphilis and oral, urethral, and rectal chlamydia and gonorrhea. Ordering these services is optional. If you do choose to order an STI testing kit study staff will contact you to deliver results and refer you to treatment services if you test positive for an STI. If you have a positive test for HIV or an STI, state law requires us to report that positive test to the state health department for purposes of statistics and service planning. It is possible that the Health Department could contact you to offer referrals for care or help with getting your partners tested. These procedures are the same as if you were tested at a doctor's office or a clinic outside of this research study.

Specimen collection kits: If you choose to order HIV and/or STI test kits, you will also receive printed and video instructions on self-administered specimen collection methods, including urine collection, rectal and throat swabs, and finger-prick blood collection. You will be provided with a 24/7 call-in line to receive help with any unexpected problems. Collecting the specimens will take you at most one hour.

After collecting the samples, you will mail them to a certified laboratory in a prepaid mailer included in the kit. Your samples will be used to conduct tests for gonorrhea, chlamydia, and syphilis. Your STI test results will be returned by study staff. Urine samples you provide may be stored and used for additional tests for research purposes only. We will not sell your samples.

Our syphilis test is performed with a standard syphilis test and determines a preliminary positive result. It does not provide detailed results like a similar test from a doctor's office or health department. Therefore, if you test preliminary positive for syphilis, we will recommend that you seek additional testing from either your doctor or health department.

How many people will take part in this study?
If you decide to participate, you will be one of 680 people in this study.

Who owns my study information and samples?
If you join this study, you will be donating your samples and study information. You will not receive any compensation if your samples or information are used to make a new product. If you withdraw from the study, data and samples that were already collected may be still be used for this study. If you withdraw from the study and would like your data not to be used and your samples to be destroyed, inform the study staff.

What are the possible risks and discomforts?
There are minor risks associated with this study. Some of the questions in the surveys are personal, and may make you uncomfortable. We hope you will answer all questions to the best of your ability. You can choose not to answer any question that makes you uncomfortable. We will keep information about your HIV and STI testing, and your responses to the survey questions. Although we will take steps to reduce the chance, there is a small chance that someone other than study staff might see your study information. More information about how we will protect your confidentiality is below.

There is a possibility that someone may see the mobile app on your device. Because this app provides information about STIs and HIV, there is a risk of breach of privacy. To prevent this, we recommend closing out of the app and/or locking your mobile phone when you are not interacting with the app.

If you choose to order an STI or HIV home testing kit through the mobile app, you may find out you that you have HIV or other STIs. This may be upsetting to you. However, study staff will provide testing and treatment resources located in your community.

New Information

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Will I benefit directly from the study?

This study is not designed to benefit you directly. However, you may benefit from participating because the mobile app may provide information and links to resources about HIV and STIs. The app may allow you to order condoms, lube, and HIV and STI testing kits at no cost to you.

This study may also indirectly benefit you because we may learn about how to promote prevention services that can help reduce the health burden of HIV among men who have sex with men.

Will I be compensated for my time and effort?

You will receive compensation for completing surveys. You will receive $50 for the first survey, $40 for surveys at months 3 and 6, $50 for month 9 survey, and $60 for month 12 survey. The expected total compensation is $240. If you do not finish the study, we will compensate you only for the surveys you have completed.

Some participants may be asked to complete additional steps depending on responses to the surveys. Participants may be asked to submit photo verification of prescription labels and/or dried blood spot (DBS) specimen collection for additional analysis. Additional one-time compensation for prescription photo verification will be $15 and for DBS collection will be $40.

What are my other options?

If you decide not to enter this study, there are services available to you outside of this research study. You should discuss this with the researchers if you have concerns or want to know about other options. You may wish to research other study options at websites like clinicaltrials.gov and ResearchMatch.org.

How will you protect my private information that you collect in this study?

Any information about you obtained from this research will be kept as confidential as possible.
Your personal information may be disclosed if required by law. Any publication of this study's results will not use your name or identify you personally in any way. The study staff may use your personal information to verify that you are not in any other research studies. Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents. Your records may be reviewed by:

- Study monitors
- Study staff
- Emory University employees
- The Office for Human Research Protections, the Emory Institutional Review Board, the Emory Office of Research Compliance and the Office for Clinical Research.

Additional For Mississippi Participants:

Protected health information is any personal health information through which you can be identified. The information collected in this study includes: your name, age, date of birth, address, phone number, laboratory test results for sexually transmitted infections (chlamydia, gonorrhea, syphilis, and HIV), prescription information, and alcohol and

substance use, and PrEP drug levels. By signing this consent document, you authorize Dr. Mena and his study staff to collect this information and use your records as necessary for this study.

The information collected for this study will be kept indefinitely and may be combined with information collected through other research studies or used in other studies but no information will identify you. While this study is ongoing you may not have access to the research information, but you may request it after the research is completed.

Your medical information and records, once disclosed, may be re-disclosed and may no longer be protected by the Privacy Standards of the Health Insurance Portability and Accountability Act (HIPAA), which is a federal regulation designed to protect medical information, including medical information and records created through research.

You have the right to cancel this authorization at any time by providing Dr. Mena (601-984-5560) with a written request to cancel the authorization. If you cancel this authorization medical information and records about you that were created before the authorization was cancelled will still be used and disclosed as needed to preserve the integrity of the study.

This authorization has no expiration date. If you do not sign this consent document, you will not be allowed to participate in this study.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.

Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Storing and Sharing your Information

De-identified data from this study may be shared with the research community at large to advance science and health. Data from this study may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Costs

There will be no costs to you for participating in this study. You will not be charged for any of the research activities, including the postage costs of mailing any specimens you provide.

Withdrawal from the Study

You have the right to leave a study at any time without penalty. If you leave the study before the final planned study visit, the researchers may ask you to have some of the final steps done. The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

Contact Information

Contact Jeb Jones at [redacted]

- if you have any questions about this study or your part in it,
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at [redacted]

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

Consent and Authorization

Being in this study is entirely your choice. You have the right to refuse to participate or to stop taking the survey at any time. Please print a copy of this form for your records.

If you agree to the above information and would like to be in the study, please sign your name using mouse or touch pad, and then type in your name below. *

I understand that checking this box constitutes a legal signature confirming that I have read the consent form, and agree to participate in the HealthMindr study. *

- ○ Legally sign document
- ○ Do NOT legally sign document