CONSENT TO PARTICIPATE IN RESEARCH

The University of Mississippi Medical Center

Study Title: Telemedicine for PrEP throughout Mississippi:

Principal Investigator: Leandro Mena, M.D., M.P.H.

Site: University of Mississippi Medical Center

Introduction

PrEP is a medication that is taken daily to prevent HIV infection. You are being invited to be in this research study because you presented to the clinic for HIV testing. Please ask us about anything in this document or that we tell you that you do not understand.

Purpose

We are doing this study to develop and test a program that may help increase access to PrEP for at-risk individuals in rural areas and reduce the rate of HIV infection. This program will use telemedicine, or the use of a computer to receive healthcare services. We want opinions on what features people think this program should have and how the program may be helpful to individuals in rural areas.

Procedures

If you agree to participate in this study:

You will complete three online survey assessments at enrollment, 3-month, and 6-months. These survey assessments will discuss:

- Patient needs and resources,
- Risk behaviors,
- Knowledge and beliefs about PrEP,
- Medical mistrust,
- Stigma, and
- Telemedicine experience.

If you schedule a telemedicine appointment after you are enrolled in the study, we will check to see if you attended your appointment and if you received a prescription for PrEP.

Length of Participation

Your participation in this study will last for six months.

Risks

- Although every effort will be made to keep your information confidential, there is the risk of breach of confidentiality. A breach of confidentiality could occur if information about your identity is given to a third party. To protect your identity, we will keep personal information about you private.
- Some of the questions in the survey assessments can be personal and you may feel uncomfortable talking about them. You can always choose not to answer questions or discuss a topic that makes you too upset. You may also request a referral for additional mental health services should you feel the need for evaluation or treatment.

Benefits

You will not receive a direct benefit from being in this research study. We hope to learn information that may help others in the future.

Alternatives

The alternative is not to participate in this study.

Costs

There will not be any additional costs to you if you participate in this study.

Compensation

You will receive a $25 electronic gift card for completing the baseline survey assessment. You will receive a $30 electronic gift card for each follow-up survey assessment you complete (at 3-month and at 6-month).

The University of Mississippi Medical Center will receive money from the NIH to cover some of the costs of doing this study.

The Principal Investigator receives compensation from Gilead, the manufacturer of the drug Truvada that is used for PrEP, as a speaker and member of its Community Advisory Board on PrEP.

Voluntary Participation

Your participation is voluntary. If you decide not to participate in this study you will not suffer a penalty or loss of benefits to which you are otherwise entitled.

Withdrawal

You may choose to stop your participation in this study at any time. If you decide to withdraw, the information already collected about you may still be used in this study but additional information will not be collected. Your decision to stop your participation will have no effect on the quality of medical care you receive at the University of Mississippi Medical Center or Open Arms Healthcare Center.

Confidentiality

Every effort will be made to keep the information we learn about you private. Study personnel, the study sponsor, the National Institute of Mental Health, the Food and Drug Administration (FDA), study collaborators, Brown University, Bradley Hospital and Rhode Island Hospital/Lifespan, the Office for Human Research Protections (OHRP) and the University of Mississippi Medical Center's Institutional Review Board (IRB) and Office of Integrity and Compliance, and Grants and Contracts may review the study records. If study results are published your name will not be used.

This study has a Certificate of Confidentiality from the National Institutes of Health which will help us protect the privacy of our research participants. The Certificate is intended to protect against the involuntary release of participant information collected during this study.

The Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider or other person gets your written authorization to receive research information UMMC will not use the Certificate to withhold that information.

The Certificate will not protect against mandatory reporting by the researchers to local, state or federal agencies of information on suspected child abuse, reportable communicable diseases and/or possible threat of harm to self or others.

Protected Health Information

Protected health information is any personal health information through which you can be identified. The information collected in this study includes: your name, demographics (date of birth and age), information related to risk behaviors, and PrEP visit date(s) and prescription information, if applicable. By signing this consent document, you authorize Dr. Mena and his staff to collect this information and use it as necessary for this study.
If the study results are published, your name or other information that could be used to identify you will not be released beyond the purposes of conducting this study.

Number of Participants

We expect to enroll approximately 240 participants in this part of the study.

Questions

If you have questions about this study or need to report any problems, please call 601-984-5560 Dr. Leandro Mena at 601-984-5560, 24hrs -7 days a week.

You may discuss your rights as a research participant with the Chairman of the University of Mississippi Medical Center's Institutional Review Board, 2500 North State Street, Jackson, Mississippi 39216; telephone, 601 984-2815; facsimile, 601 984-2961. The Institutional Review Board is a group of people not involved with this study who have reviewed the study to protect your rights.
You will be given a copy of this consent document for your records after it has been signed.

Statement of Participation

I have been told about this study and the possible risks and benefits. My participation is voluntary and I may withdraw at any time without any penalty or loss of benefits to which I am entitled.

By signing this form, I am not giving up any legal rights I may have.

_____
Participant's Printed Name

_____
Participant's Signature

_____
Date

_____
Printed Name of Person Obtaining Consent

_____
Signature of Person Obtaining Consent

_____
Date

I acknowledge that the participant identified above has been entered into this study, with properly obtained informed consent.

_____
Signature of Investigator

_____
Date