Peer PrEP referral + HIV self-test delivery for PrEP initiation among young Kenyan women

NCT04982250

Informed Consent Form for Peer Providers

Randomized Control Trial

Approved: January 29th, 2024

Fred Hutchinson Cancer Center and Jomo Kenyatta University of Agriculture and Technology

STUDY TITLE: Peer PrEP referral + HIV self-test delivery for PrEP initiation among young Kenyan women

Protocol v1.10, October 5, 2023

INVESTIGATORS:

Investigator	Role	Institution	Telephone
Katrina Ortblad, ScD, MPH	Principal investigator	Fred Hutchinson Cancer Research Center	001 206-667-7267
Kenneth Ngure, PhD, MPH, MSc	Co-investigator	Jomo Kenyatta University of Agriculture and Technology	067 2222561
Nelly Mugo, MBChB, MMed, MPH	Co-investigator	Kenya Medical Research Institute (KEMRI)	020 273 6744

24-hour emergency number: 0736464299
Study location: Thika, Kenya

Key Information for You to Consider

- **Voluntary Consent**. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There are no penalties and you will not lose anything if you decide not to join or if after you join, you decide to quit.
- **Purpose**. Studies have shown that the medications used to treat HIV infection can also be used to prevent passing the virus; this concept is called pre-exposure prophylaxis, or PrEP, and it is safe. Right now, PrEP uptake is low in Kenya, especially among young women at HIV risk. The purpose of this study therefore is to develop a model that uses peers and HIV self-testing to increase PrEP uptake among young women at HIV risk in Kenya.
- **Duration.** Your participation in the study will last about three months.
- **Procedures and Activities.** We will ask you to complete a survey when you join the study and three months later. These surveys will ask questions about your health behaviors and attitudes toward peer referral, HIV self-testing, and PrEP. We will also ask you to refer your peers to use PrEP. You may be asked to attend a training about referring your peers to PrEP.
- **Risks.** Most studies have some possible harms that could happen to you if you join. In this study, we expect that you may become embarrassed, worried, or anxious when talking about your health-seeking behaviors, PrEP use, and attitudes about peer referral, PrEP, and HIV self-testing to the study staff and your peers. It is possible that some social harms may come from discussing HIV self-testing and PrEP use with your peers, such as physical or emotional abuse from your peers and/or sexual partners.
- **Benefits**. We expect some benefits from this study, as well. You may get no direct benefit from answering the questions and referring your peers. However, you will contribute to developing new delivery models for HIV self-testing kits and PrEP in Africa, which will help others in the future.

- **Alternatives.** Participation is voluntary and the only alternative is to not participate.

INFORMED CONSENT

We are asking you to join a research study. The purpose of this form is to give you the information you need to help you decide if you want to take part. If you decide to participate in the research study, you will be asked to sign a copy of this consent form or make your mark in front of a witness. A signed copy of this form will be given to you to keep for future reference. Please read this form carefully. Please ask us to explain anything you may not understand to help you decide whether to join the study. The following is a more complete description of the study.

DESCRIPTION OF RESEARCH

The purpose of this study is to develop a model to increase PrEP uptake among young Kenyan women at HIV risk that uses peer referral and HIV self-testing. If you decide to take part, you will be asked to do several things, described below.

- We will ask you to complete a survey today and a follow-up survey in three months. These surveys aim to understand your health-related behaviors, mental health, your use of PrEP and HIV self-testing, and your attitudes about peer referral to health services. These surveys are short and should take about 30 minutes each. We will collect your contact information so we can connect with you in three months to complete the follow-up survey.
- We will ask you to identify 4 peers who could be at HIV risk and might be interested in using PrEP. We will ask you to refer them to the study and refer them to PrEP. We may encourage you to disclose your PrEP use to these peers and offer to escort them to a clinic to start PrEP, although that is optional.
- You may be randomly selected to join a one-time training session on how to do PrEP referral and given education materials and HIV self-test kits you can pass on during the referral process. This training will last a few hours.
- You may be randomly selected and given the option to join a WhatsApp group to support you during this study. Other participants may also be given this option and the group will be monitored by the staff. The WhatsApp group is a forum where the study team can answer questions, provide additional information, and promote discussion among other participants in this study who are referring their peers to PrEP. Participation in the WhatsApp group is optional.

YOUR PARTICIPATION IS VOLUNTARY

Before you agree to the study procedures, it is important that you know the following:

- You do not have to be in this study if you do not want to join.
- You may decide not to take part in this study, or to withdraw early from the study at any time, without penalty or loss of benefits to which they are otherwise entitled.
- If you decide not to take part in this study, you can still join another research study later, if one is available and you qualify.

USING YOUR DATA FOR FUTURE RESEARCH

The information that we obtain from you for this study might be used for future studies. We may remove anything that might identify you from the information. If we do so, that information may then be used for future research studies or given to another investigator without getting additional permission from you. It is also possible that in the future we may want to use or share study information that might identify you.

If we do, a review board will decide whether or not we need to get additional permission from you. You may choose to opt-out of the future use or sharing of your identifiable data below.

RISKS AND/OR DISCOMFORTS
You may become embarrassed, worried, or anxious when talking about your health-related behaviors and use of PrEP and HIV self-testing to the study staff and your peers. It is possible that some social harms may come from discussing HIV self-testing and PrEP use with your peers, such as physical or emotional abuse from your peers and/or sexual partners. If you are given the option to join the WhatsApp group and you decide to join, your name and phone number will be visible to other participants and there is a risk your information won't remain private. The study team will be monitoring the group and answering your questions. To ensure additional privacy, the study team will delete old messages and encourage everyone to keep the group's information confidential.

BENEFITS
You may get no direct benefit from being in this study. However, you will contribute to developing new delivery models for HIV self-testing kits and PrEP in Kenya, which will help others in the future.

COSTS TO YOU
There is no cost to you for being in this study.

SOURCE OF FUNDING AND RESEARCH COLLABORATORS
The study is funded by the National Institute of Mental Health which is part of the National Institutes of Health in the United States of America. This study is conducted in partnership with Fred Hutchinson Cancer Center, Jomo Kenyatta University of Agriculture and Technology, and the Partners in Health and Research Development.

REIMBURSEMENT
You will receive transportation reimbursement and an additional 300 KES for your time and effort spent for study participation. You will receive 150 KES for each peer client you recruit that calls the study line.

CONFIDENTIALITY
Your information will be kept private and any publication of this study will not use your name or identify you personally. A risk of study participation is that your identity might become known despite our best efforts. To help ensure privacy, you will be given a study identification code that will be used by researchers – only a few select researchers will have access to your identifying information. Some organizations may need to look at your research records for quality assurance or data analysis. These include:

- Agencies or data monitoring boards, who needs it to check and assess the research.
- To the funding agency and groups involved in the research, if they need the information to make sure the research is being done correctly.
- Institutional Review Boards (IRB) or Ethics Review Boards. An IRB is a group that reviews the study to protect your rights as a research participant.

A description of this study will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. 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.

RESEARCH-RELATED INJURY
We do not anticipate any research related injury. However, if you feel you are injured from participating in this study, we will refer you to the nearest health clinic for treatment. You will be financially responsible

for treatment of injuries, although usually these health clinics are free or have only a minimal charge.

PROBLEMS OR QUESTIONS

If you ever have any questions about this research, or if you have a research-related injury you should contact Njeri Wairimu at 0736464299. If you have questions about your rights as a participant, contact the secretary of the KEMRI Scientific and Ethics Review Unit, P.O. Box 54840-00200, Nairobi, Telephone number 020272-2541, 0722205901, 0733-400003, 0717719477. Email address: seru@kemri.org. You can also contact the Director of the Fred Hutch Institutional Review Office at 001 206-667-5900 or email irodirector@fredhutch.org.

STATEMENT OF CONSENT AND SIGNATURES

I have read this form or had it read to me. I have discussed the information with study staff and my questions have been answered. I permit Fred Hutchinson Cancer Center, and their research collaborators, to use my health information in this study as described above. I allow my de-identified survey responses to be used for future research studies or distributed to another investigator for future research studies without additional informed consent. I understand that my decision whether or not to take part in the study is voluntary. I understand that if I decide to participate in this study I may withdraw at any time. By signing this form, I do not give up any rights that I have as a research participant.

_____	_____	_____
Participant Name (print)	Participant Signature/Thumbprint	Date
_____	_____	_____
Study Staff Conducting Study Consent Discussion (print)	Staff Signature	Date
_____	_____	_____
Witness Name (print)	Witness Signature	Date

PERMISSION TO HAVE MY FINGERPRINT TAKEN FOR PURPOSES OF BIOMETRIC IDENTIFICATION
Please initial and date one option

_____ I DO agree to have my fingerprint taken.

_____I DO NOT agree to have my fingerprint taken.

PERMISSION TO USE AND SHARE MY IDENTIFIABLE DATA FOR FUTURE STUDIES

Please initial and date one option:

_____ I DO agree that my identifiable data can be used and shared for future research into HIV, HIV- related diseases, and other sexually transmitted diseases.

_____ I DO NOT agree that my identifiable data can be used and shared for future research into HIV, HIV- related diseases, and other sexually transmitted diseases.

PERMISSION TO BE CONTACTED FOR FUTURE STUDIES
Please initial and date one option

_____ I DO agree to be contacted for future studies.

_____I DO NOT agree to be contacted for future studies.

Participant Name (print).	Participant Signature/Thumbprint	Date
Staff Name (print).	Staff Signature	Date
Witness Name (print)	Witness Signature	Date

Copies to: 1. Investigators, 2. Study participant