UNCPM 22325 - Supporting oral and long-acting pre-exposure prophylaxis decision making among pregnant women in Lilongwe, Malawi: a feasibility pilot study

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University of North Carolina at Chapel Hill
Consent to Participate in a Study
Adult participant – Study 2

Consent Form Version Date: October 31, 2024
IRB Study: UNC # 24-0511, NHSRC # 23/10/4310

Title of Study: UNCPM 22325 - Supporting oral and long-acting pre-exposure prophylaxis decision making among pregnant women in Lilongwe, Malawi: a feasibility pilot study
Principal Investigator: Dr. Lauren M Hill
Principal Investigator Department: Health Behavior
Principal Investigator Phone number: (919) 966-3761
Principal Investigator Email Address: hilllm@email.unc.edu

Funding Source and/or Sponsor: National Institutes of Health

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Study Contact Email: tphanga@unclilongwe.org

CONCISE SUMMARY

The purpose of this research study is to find the best way to help pregnant women make personally appropriate decisions about HIV prevention during pregnancy and breastfeeding. This part of the study focuses on a counseling discussion to help women like you decide what HIV prevention method(s), if any, they would like to use for HIV prevention. These HIV prevention methods include oral and injectable pre-exposure prophylaxis (PrEP) and male and female condoms. All participants must be willing to take part in this counseling discussion and complete up to two follow-up visits and one pharmacy visit. Participants who are interested in using PrEP following this counseling discussion will not receive PrEP from the study but will be referred to government services to receive PrEP. Participation in this study lasts 2 months.

Individuals could benefit from the study if this counseling session helps them identify an HIV prevention method they want to use. There are minimal potential risks to participating in this study that are described in this document. Primary risks include breach of confidentiality, emotional discomfort, and discomfort in discussing issues related to HIV risk or HIV prevention methods with study staff.

If you are interested in learning more about this study, please continue reading below.

What are some general things you should know about research studies?

You are being asked to take part in a research study. To join the study is voluntary. You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the local clinic. You do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can

make an informed choice about being in this research study.

You will be offered a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

Women who become infected with HIV during pregnancy and breastfeeding have a high chance of transmitting the infection to their babies. There are a growing number of HIV prevention options available to pregnant and breastfeeding women, but knowing which option is the best for each individual is dependent on each woman's needs and preferences. The purpose of this research study is to find the best way to help pregnant women make personally appropriate decisions about HIV prevention during pregnancy and breastfeeding. This part of the study focuses on a counseling discussion to help women like you decide what HIV prevention method(s), if any, they would like to use for HIV prevention. These methods include male and female condoms and oral and injectable pre-exposure prophylaxis (PrEP), a daily pill for people who are HIV-negative to protect them against HIV. In this study, we want to find out if this counselling approach can help women make choices about the available HIV prevention methods is acceptable and feasible. We also want to understand if other study procedures like recruitment and interviews are acceptable and feasible so we can plan for a future study.

Are there any reasons you should not be in this study?

You should not be in this study if you are younger than 18 years old, are living with HIV, do not plan on staying in this area for the next 3 months, or if you have concerns that your partner may harm you.

How many people will take part in this study?

A total of approximately 50 women from this facility will take part in this study.

How long will your part in this study last?

Participation in the study is for 2 months. This includes the visit today and 2 additional follow-up visits (one and two months from now). If you choose to participate, today's enrollment visit will take about 1 ½ hours. The follow-up visits at months 1 and 2 will take about 1 hour, depending on which group of the study you are assigned.

What will happen if you take part in the study?

If you agree to take part in this study, at today's visit we will complete a counseling session to discuss the HIV prevention options available to you. We will also ask questions about yourself (including medical history), your partners, your home environment, and some of your opinions and behaviors. Half of the women in this study will receive enhanced Shared Decision-Making Counseling at this first visit. The counseling is designed to help you understand the available HIV prevention options and identify which one(s) may be most appropriate for you. Following this conversation, if you are interested in using condoms, we will provide them to you. If you are interested in using oral or injectable PrEP, we will refer you to government services to receive it. The length of these sessions will depend on your particular circumstances and how much you already know about the methods that will be discussed but are expected to be approximately 45 min to 1 hour. These sessions will be audio-recorded, so we can make sure the counseling is performed correctly. These audio-recordings will be identified by your study number and not your name. The choice about who receives the Shared Decision-Making Counseling who does not will happen at random/by chance (like flipping a coin). Neither you nor the study staff will be able to choose which group you are placed in.

In addition to the counseling session, in today's visit and follow-up visits you will be asked to:

- Answer questions about your experience with the counseling, your opinions and behaviors, and information about your partners and medical history

- You may also be invited to complete in-depth interviews to share more about your experiences with the study

What are the possible benefits from being in this study?
Research is designed to benefit society by gaining new knowledge. You may not benefit personally from being in this research study. Individuals could benefit from the study if the counseling session helps them identify an HIV prevention method they want to use.

What are the possible risks or discomforts involved from being in this study?

It is possible that you may experience embarrassment or discomfort discussing issues related HIV risk and HIV prevention methods including PrEP. If there any questions that you are uncomfortable answering, you can ask to skip any question at any time.

There is also the risk of breach of confidentiality. The study staff will take precautions to ensure the confidentiality of all study data. All participants will be assigned a unique study ID number, and this number will be used on all study documents and specimens. Consent forms will be kept in a locked cabinet.

There may be uncommon or previously unknown risks. You should report any problems to the researcher.

What if we learn about new findings or information during the study?
You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will information about you be protected?
Every effort will be made to keep your personal information confidential. It will be your decision whether you share any information about this study with others in your home or community. We will not do so. Your study information will be identified by a code to protect your privacy. Any publication about the results will not use your name or identify you personally.

Your records may be reviewed by representatives of the ethical and regulatory committees in Malawi-National Health Sciences Research Committee (NHSRC) and the University of North Carolina Institutional Review Board, the study sponsor (NIH), the U.S. Office for Human Research Protections, study staff, or study monitors. This is for quality control and safety purposes.

The recordings of the counseling sessions will be deleted after they have been transcribed (written down), and any identifying information will be deleted.

What is a certificate of confidentiality?
Most people outside the research team will not see your name on your research information. This includes people who try to get your information using a court order in the United States. One exception is if you agree that we can give out research information with your name on it or for research projects that have been approved under applicable rules. Other exceptions are for information that is required to be reported under law, such as information about child or disabled abuse or neglect or certain harmful diseases that can be spread from one person to another. Personnel of a government agency sponsoring the study may also be provided information about your involvement in the research study.

What if you want to stop before your part in the study is complete?
You can withdraw from this study at any time, for any reason. The investigators also have the right to stop your

participation at any time.

Will you receive anything for being in this study?
You will be receiving a reimbursement equivalent to US$10 for transport/travel cost refund for each study visit you complete.

Will it cost you anything to be in this study?
Participants will not have any out-of-pocket costs for participating in the research.

Who is sponsoring this study?
This research is funded by the National Institutes of Health in the United States. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

For further information or questions
If you have any questions about this research, please contact the Investigator named at the top of this form by emailing hilllm@email.unc.edu or by calling UNC Project-Malawi at +265 1 755 056.

If you have questions about your rights as a research participant
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may, anonymously if you wish, contact the Head of Secretariat for the Malawi Health Sciences Research Committee Dr. Evelyn Chitsa Banda at +265 999 936 937.

University of North Carolina-Chapel Hill
Consent Addendum for Unencrypted Communication
Title of Study: UNCPM 22325 - Supporting oral and long-acting pre-exposure prophylaxis decision making among pregnant women in Lilongwe, Malawi: a feasibility pilot study

Principal Investigator: Dr. Lauren M Hill
Principal Investigator Department: Health Behavior
Principal Investigator Phone number: (919) 966-3761
Principal Investigator Email Address: hilllm@email.unc.edu

Funding Source and/or Sponsor: National Institutes of Health

Study Contact Telephone Number: +265 1 755 056
Study Contact Email: tphanga@unclilongwe.org

The following information is regarding un-encrypted communication (e,g., texting or email) by study staff and should be read as an addition to the consent information you have already been provided. All information previously provided is still true and remains in effect. Your participation continues to be voluntary. You may refuse to participate or may withdraw your consent to participate at any time, and for any reason, without jeopardizing your future care at this institution or your relationship with your study team.

The study team would like to message you by text messaging or e-mail, however you may say "no" to receiving these messages and still participate in this study. If you say "yes", messages may contain personal information about you and may be sent or received by the study team's personal electronic devices or in a method that is not able to be encrypted (protected) and there is the risk your information could be shared beyond you and the study team. This information may include information such as reminders and notifications to contact the study team.

If you wish to stop receiving unprotected communication from the study team or have lost access to your device, please notify the study team using the study contact information on the first page of this addendum to the consent. After the study is complete and all research activities finished, or you withdraw from the study or request to stop receiving unprotected communication, you will no longer receive un-encrypted (un-protected) messages specific to this study.

_____ Yes, I consent to the study team utilizing the following (insert mechanism; e.g. cell phone number, email) to send communication: (List e-mail, cell-phone #)_____

_____ No, I do not consent to receive un-protected communication from the study team.

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Principal Investigator: Dr. Lauren M Hill

Participant's Agreement:

If you have read this informed consent, or have had it read and explained to you, and understand the information, and you voluntarily agree to participate in this research study, **please sign your name or place your thumbprint** in the signature area at the bottom of this page**.**

PART A: LITERATE PARTICIPANT

Participant is literate: ☐

_____	_____	_____
Participant Name (print)	Participant Signature	Date

_____	_____	_____
Study Staff Conducting Consent Discussion (print)	Study Staff Signature	Date

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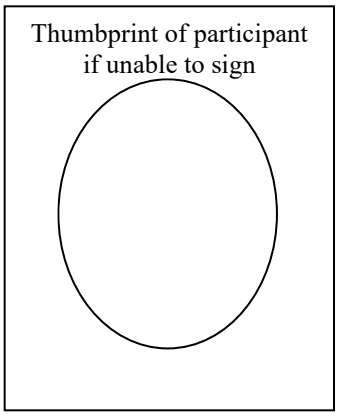
Principal Investigator: Dr. Lauren M Hill

PART B : ILLITERATE PARTICIPANT

Participant is illiterate: ☐

The study staff must complete this section, ONLY if an impartial witness is available.

The **impartial witness must write participant's name and date of consent** on the **SHADED AREA.**



Participant Name (print) Participant Thumbprint Date

Participant Name and Date Written By…….on…...……

Study Staff Conducting Consent Discussion (print)	Study Staff Signature	Date
Impartial Witness Name (print)	Impartial Witness Signature	Date