Intervention Arm Consent Form

Partners-based HIV/PrEP services for sero-discordant couples attending antenatal care: A randomized trial to increase family-based support for PrEP adherence among discordant couples through storytelling

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Intervention Arm Participants
PI: Audet
Title: Partners-based HIV/PrEP services for sero-discordant couples attending antenatal care: A randomized trial to increase family-based support for PrEP adherence among discordant couples through storytelling
Institution: Vanderbilt University Medical Center
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KEY ELEMENTS OF THE STUDY

1. This consent form contains information about a new study to provide a storytelling intervention to serodiscordant expectant couples.

2. Couples who are in the intervention group of this study will have the opportunity to listen to three stories that will educate and help support them to stay adherent to their medication and will complete two interview surveys.

3. Couples in the control group will complete two interview surveys, but otherwise will enroll in PrEP and HIV care and treatment as they would normally.

4. You have been selected to receive three storytelling sessions, along with any family members (being a confidante) you want to include.

5. If you agree to participate in the study, a study staff person will conduct a survey now and again at three to four months after you start medication.

6. If you are an eligible female and you agree to participate in the study, when you come to pick up your PrEP, a study staff person will do a simple urine test monthly for three (3) months from the first month after starting PrEP to check for the presence of the PrEP drug in your body.

7. You can stop participating in the study at any time without penalty.

This informed consent document applies to adults 18 years or older. This document is to be read aloud to the participants in the intervention arm.

Age of participant: _____

Introduction

This consent form contains information about a new study to provide couples-based PrEP medication that will help prevent someone being infected with HIV and HIV care and treatment for discordant pregnant couples.

You both have been selected because you both attended antenatal care visit; and one tested HIV-negative while the other is HIV-positive; and you are 18 years or older.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits

of this study, you will be told so that you can decide whether or not you still want to be in this study.

This form describes your rights as a participant. It is meant to answer your questions. We will read this form to you. Please feel free to ask any questions you may have about this.

If you both agree to participate in this program, I will ask you to sign the form or make your thumbprint mark. Even if you agree to participate, you can stop participating at any time. I will give you a copy of this form. This form might contain some words that you do not know. Please ask me to explain anything you do not understand.

Purpose of this study

This study is being done by staff from Vanderbilt University Medical Center (VUMC) and Friends in Global Health (FGH). We want to try a new way to offer PrEP and HIV care and treatment to couples where one person is HIV-positive and the other HIV-negative who are expecting a child. Right now, couples can receive PrEP and HIV care together in HIV treatment services, but their counseling and education is limited to short education sessions and does not engage their families.

Couples who are in the intervention group of this study will have the opportunity to listen to three stories that will educate and help support them to stay adherent to their medication. Couples in the control group will complete two surveys, but otherwise will enroll in PrEP and HIV care and treatment as they would normally. We want to see if couples who get the additional storytelling sessions are better at staying on treatment compared to couples in regular care.

Procedures to be followed and approximate duration of the study

You have been selected to receive the storytelling sessions.

This study will begin today and last for the next 6 months. If you and your partner agree to be part of this study, we will enroll you both into PrEP / HIV care and treatment. All future clinical visits, drugs, and tests to assess medication levels in your body will be given to you at the ANC or CCR clinics.

Our study assistant will arrange a meeting with you and the storytellers in the next two weeks. Your storytellers will arrange three times to come to the family home (or a location of your choice) to tell each story to you and to any family members that you would be willing to disclose your treatment to and who also provide consent to participate.

If you consent, we will record this storytelling session and the discussion that follows on an audiotape. The audio recording will be kept in a secure file at the FGH office in Quelimane. We will write out the recording into a document in the computer. The information will be analyzed to understand what people think about the storytelling and to improve this program. Before we use this data, all of your identifying information will be removed. It will not be possible for anyone to

know it is your words or information. These data will only be accessible by study staff and the principal investigator at Vanderbilt University Medical Center. After 6 years, the transcript files will be destroyed.

We will access your and your baby's medical records to see what medications you are taking, medical data about your health (drug levels, CD4 cell count and viral load), and the dates you pick up your medications.

A study staff person will also conduct two surveys at the beginning of your treatment and at three to four months after you start treatment. You do not need to answer all the questions in the surveys if you do not want to. If a question makes you feel uncomfortable or you do not know the answer, it is ok to tell the interviewer that you do not want to answer the question. You can also stop the surveys at any time without any penalty.

A study staff person will also do a simple urine test with all the women enrolled in the study to measure the presence of the PrEP drug in your body. This will be done for three (3) months, starting the first month after you begin PrEP, when you come to pick up your PrEP from the health facility. You will be asked to collect a small amount of urine in a clean container. Then the trained study staff person will use a testing instrument to dip into the urine to test how much PrEP drug is present in your body. If a PrEP pick-up appointment is missed, or if you are not able to come for any reason, the study staff person will do a home visit. The study staff person will complete the same urine test on the home visit as needed.

This urine test has been validated for use in research but has not yet been approved for commercial use. This means that the results can only be used for the study. Therefore, they will not be part of your clinical record, and we cannot share these results with participants or health care providers.

Some couples enrolled in the study will be asked to participate in an interview to describe their experience with the program and costs related to your and your family's health care. This interview will occur at least four months after enrollment. You do not need to answer the questions if you do not want to. If a question makes you feel uncomfortable or you do not know the answer, it is ok to tell the interviewer that you do not want to answer the question. You can also stop the interview at any time without penalty.

If you consent, your responses to this interview will be recorded on an audio recording. Just like the storytelling session recordings, the interview recording will be kept in a secure audio file at the FGH office in Quelimane. The recording will be transcribed to an electronic document (Word). We will use these transcribed data to do a data analysis at the end of this study. Before we use this data, all of your identifying information will be removed. It will not be possible for anyone to know if it is your answers or information. The transcripts will be kept and stored securely on servers and computers protected by a password at the FGH office in Quelimane. These data will

only be accessible by study staff and the principal investigator at VUMC. After 6 years, the transcript files will be destroyed.

Alternative Treatments Available

Our study is only studying the impact of our storytelling intervention on medication adherence. We are not providing any medication as part of our study.

Expected Costs:

None.

Possible Risks

The idea of providing stories to education and motivate discordant couples (and their families) expecting a baby is new and untested. While we will provide support, there is a chance that you and your partner will not agree on ways to take medication or talk together. This could make more problems in your relationship. If you feel any discomfort or have relationship problems, please contact us as soon as possible so we can work to resolve it together.

We know that talking about your personal experiences with HIV with your partner or health care workers can be uncomfortable. We will try to have a comfortable, honest, and relaxed discussion. Still we know that some of the questions we ask might make you feel uncomfortable. We will try to limit embarrassment as much as possible. No study staff will tell anyone else your responses to the survey questions.

Possible Benefits

The information you share may help us to offer better services for serodiscordant couples who come for ANC services. This could benefit Mozambican society by improving health programs for people living with HIV. If the project is successful, you may have better communication and trust with your partner after our counseling sessions.

Unforeseeable Risks

In any research study there are the possibility of unforeseeable risks. We try to minimize these by employing trained personnel to conduct our interviews to make you comfortable and to identify any potential problems. We are also partnering with a Ministry of Health supported health facility to ensure everyone has access to the free health services they need.

What happens if you choose to withdraw from study participation?

Nothing. You are free to stop participating at any point without problem. You only need to say that you would like to stop being in the study. You can tell this to us at any time.

Confidentiality

We will make every effort to keep your personal information confidential. However, it is not possible to guarantee total confidentiality. The clinical information obtained during this study will be kept with your medical record and stored securely at the health facility in locked areas and on a protected database. Only trained medical and study staff will have to access this clinical information.

The information related to the study activities will be kept at the health facility and at FGH offices in locked secure areas. Only trained study staff will have access to this study information.

Privacy Information

Your information may only be shared if you or someone else is in danger, or if we are required to do so by law. If this occurs, your information may be shared with VUMC, or the U.S. and/or Mozambican government. This includes, for example, the VUMC IRB board, U.S. Federal Government Office for Human Research Protections, or the Mozambican Ministry of Health.

Study Results

We will gather former participants and community members within one year of the study ending to tell you the results. You are welcome to attend this meeting to learn if storytelling was a useful strategy.

Clinical Trials Registry

A description of this clinical trial will be available on 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 Web site at any time.

Contact Information for Questions

If you should have any questions about study or wish to have additional counseling related to your care, please feel free to contact the study manager, Almiro Emilio, at the FGH office in Quelimane at +258 24217593, or the local co-investigator, Caroline De Schacht, at the FGH office in Maputo by calling +258 21328310, or Principal Investigator, Carolyn Audet, at the Vanderbilt University Medical Center, by calling +1-615-343-2418.

For more information about giving consent or your rights, please feel free to contact the Secretary of the National Committee for Bioethics of Health (CNBS) in Mozambique at +258 824066350. You may also contact the Vanderbilt University Medical Center Institutional Review Board (IRB) office in the U.S. at +001-615-322-2918 or toll free at +001-866-224-8273.

Do you have any questions?

This form has been read and explained to me. I have been given an opportunity to ask questions I have about the study. I understand that I may decide at any time that I do not want to continue participating in the study. I understand that I will receive a copy of this consent form. By saying

yes, you agree to participate in the study for 6 months. If you are a female and saying yes, you are agreeing to participate in the monthly PrEP urine tests. You are agreeing to participate in our interviewer-administered surveys and that we can look at your medical records, and that of your unborn child. You are agreeing for the storytelling sessions and interview to be recorded. By saying no, you decline to participate in all parts of the study.

Moderator: Answer the participant's questions before proceeding to the next question.

I give my consent to participate in the study. ☐ Female partner ☐ Male Partner

I agree to participate in the storytelling/discussion session

[ ] YES [ ] NO

I agree that the storytelling/discussion session can be recorded

[ ] YES [ ] NO

I agree to participate in the interview [ ] YES [ ] NO

I agree that the interview can be recorded [ ] YES [ ] NO

_____ _____

Printed Name of Participant Date

Thumbprint of Participant

_____ _____

Signature of Participant Date

_____ _____

Signature of Witness (if thumbprint used) Date

_____ _____

Signature of Person Who Explained This Form Date

I have explained to the participant the study purpose and procedures and we have discussed all the risks that are involved. I have answered questions to the best of my ability.