Informed Consent

Protocol Title:

A Stigma Reduction Intervention at Time of Entry Into Antenatal Care to Improve PMTCT Services in Tanzania

NCT:

NCT03600142

Principal Investigator (United States):

Melissa Watt, PhD

Principal Investigator at KCMC (Tanzania):

Blandina Mmbaga, MD, PhD

Consent Version

November 27, 2018

KCMC-Duke University Kilimanjaro AIDS Program
A Collaborative Program between Duke University and Kilimanjaro Christian Medical Centre

Consent to Participate in a Research Study (Pilot Trial – Female Participants)
Postpartum HIV care engagement in the context of Option B+ in Tanzania
Version: 2
Version Date: 27 November 2018

Introduction:
You are being asked to participate in a research study that is seeking to support the implementation of the national guidelines for the prevention of HIV from mother to child. Under the national guideline, all pregnant women get tested for HIV, and those who have HIV initiate lifelong antiretroviral therapy during pregnancy, regardless of CD4 count or clinical staging. This phase of the study is testing a counseling intervention to support women through this process.

This form will give you an explanation of this research. I will read this consent form with you and allow you to take time making your decision. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are described in this form. Please ask if there are words or information that you do not clearly understand.

This study is being conducted together by Dr. Blandina Mmbaga at Kilimanjaro Christian Medical Centre in Tanzania and Dr. Melissa Watt at Duke University in the United States. It is funded by the National Institutes of Health in the United States.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to support the implementation of the national guidelines for the prevention of mother-to-child transmission (PMTCT) of HIV in clinics in the Kilimanjaro region. We are particularly interested in women's ability to remain engaged in HIV care after giving birth to a child, and in developing and testing an intervention to help women stay in care. In this phase of the study, we will be assessing whether the counselling program we developed, called *Maisha*, can be implemented in two clinics in the Kilimanjaro region, and how the counselling program affects the well-being of women who participate.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
In total, the study will involve over 1800 participants. Approximately 1000 female patients and 500 male participants will take part in this phase of the study. Female participants will be women over the age of 18, pregnant, and attending their first ANC appointment.

WHAT IS INVOLVED IN THE STUDY?

Participation in this study is entirely voluntary, and you are free to leave the study at any time. If you refuse to participate or withdraw from the study, this will not affect any present or future relationships you may have your medical care team. If you agree to be in this study, you will be asked to sign and date this consent form. If your partner accompanied you to the clinic for this visit, he may also be invited to participate in the study along with you.

After signing and dating this consent form, you will be asked to complete an interviewer-administered structured survey, conducted by a research nurse in a private space. The survey will take approximately 30 minutes.

After completing the survey, you will then receive (together with partner if you invited him) either: (1) the clinic's standard procedures related to HIV counselling; or (2) the clinic's standard of care counselling PLUS the *Maisha* intervention, which involves a video and brief discussion. Some participants will also be asked to complete up to two additional counselling sessions. We will decide this randomly, like when you toss a coin. You cannot choose which part of the study you will be selected into.

If you are assigned to receive the Maisha intervention**,** you will complete the survey and then receive (together with partner if you invited him) **Session 1 of the counselling intervention** (a video, followed by a brief discussion). You will then return to the waiting area to await the standard of care, which includes HIV testing and counselling.

If you are assigned to receive the Maisha intervention**,** you may also be selected to receive **another couple counselling session today** after the clinic's standard counselling session. You (alone) will then be invited and encouraged to attend a **third counselling session** at the clinic two weeks later. Each of these counselling sessions will last approximately 60 to 75 minutes.

You may be asked to complete a **follow-up survey in three months**. The survey will take place in a private room and will take approximately 60 minutes. At this time, you may also be asked to complete a **conversational interview** to talk about your experience with the intervention. The interview will be audio recorded with your permission and will last an additional 60 minutes.

If you are not assigned to receive the Maisha intervention**,** you will receive only the standard HIV testing and counselling services at the clinic. You may be asked to complete a **follow-up survey in three months**. The survey will take place in a private room and take approximately 60 minutes.

If you are selected to come for a follow-up survey at 3 months, we will also collect information from your medical record during the study period and up to 12 months from your first ANC date in order to record how often you come to the clinic and other information about your clinical care.

Whenever you are selected for a study activity (including counselling sessions, surveys, and interviews), the procedure for that activity will be clearly explained to you. You have the option to decline participation in any study activity at any time.

In order to keep in touch with you between the study activities, we will take your name, phone number and address. This information will be stored separately from study information we collect and will be kept private.

HOW LONG WILL I BE IN THIS STUDY?
The total length of time you will spend in the study is up to 3 months. We may review your medical records for up to 12 months. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled.

WHAT ARE THE RISKS OF THE STUDY?
The study procedures that have been selected have only minimal risk. Nevertheless, the protocol raises two general areas of human subjects concerns:

Discomfort. First, this study may make you feel uncomfortable as you talk about pregnancy, HIV, your health, and your personal life. You may feel embarrassed or shy, and sometimes it may bring up personal information that makes you feel emotional.

Confidentiality. Every effort will be made to keep your information confidential and protected, but this is something we cannot guarantee. No information will be shared with anyone outside of the study team, including your health care providers. We will not record your name during the conversation so no one will know what you said during the interview. Please see below for how we will aim to keep your information confidential.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you are assigned to the counselling intervention, you may get some benefit from the study by receiving the counselling sessions. If you do not receive the counselling intervention, you may not directly benefit from participating. However, research projects like these are done to gain scientific knowledge that will help others in the future. As an implementation science study, we expect that the results of this study will inform the delivery of HIV care services for women in Tanzania and similar settings. You will help us learn information that will help us improve services for pregnant women who are testing for HIV.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
All documents and audio-recordings will be stored in a locked filing cabinet or on a password protected computer. Your study information will be identified only by a number, not your name. The key to the code will be stored in a separate password protected document on a password protected computer, to which only essential study staff will have access. Any documents containing your name and personal information will be kept separate from other study records, and will be stored in a secure way.

Data will be securely stored in locked file cabinets in locked offices and in password protected documents on password protected computers and secure servers. Access to data storage areas will be restricted. If you are part of the conversational interview, we will use the audio recordings to write down our conversation, and then we will destroy the recording. If we write about this work, your identity will remain anonymous.

Information that you share with us will NOT be put in your medical record.

WHAT ARE THE COSTS?
There will be no additional costs to you as a result of being in this study.

WHAT ABOUT COMPENSATION?
You will not receive any compensation for your participation today. If you are asked to visit the clinic in one week for a follow-up counselling session, you will receive 5,000 TSh to compensate you for your transportation costs. If you participate in the three-month survey, you will receive 5,000 TSh to cover transportation. If you are selected to participate in the conversational interview at the time of your three-month survey, you will receive an additional 5,000 TSh.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes. Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at this clinic or at KCMC. If you do decide to withdraw, we ask that you contact Dr. Blandina Mmbaga in writing and let her know that you are withdrawing from the study. Her mailing address is Dr. Mmbaga, KCMC 3010, Moshi and her email is Blaymt@yahoo.com

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have complaints, concerns, or suggestions about the research, contact Dr. Blandina Mmbaga at KCMC 3010, Moshi or phone number +255-768-435116

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, you can call the Ethics Committee of KCMC at the phone number +255-27-53616.

STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to

be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Name of Subject	Signature	Date
_____	_____	_____
Signature of Person Obtaining Consent	Signature	Date

If the participant is unable to provide a signature, please include the thumbprint of the participant above and the signature of an impartial witness who observed the consent process below.

_____	_____
Signature of Witness	Date and Time

KCMC-Duke University Kilimanjaro AIDS Program
A Collaborative Program between Duke University
and Kilimanjaro Christian Medical Centre

Consent for Male Partners to Participate in a Research Study
Postpartum HIV care engagement in the context of Option B+ in Tanzania
Version: 1
Version Date: 27 November 2018

Introduction:
You are being asked to participate in a research study that is seeking to support the implementation of the national guidelines for the prevention of HIV from mother to child. Under the national guideline, all pregnant women get tested for HIV, and those who have HIV initiate lifelong antiretroviral therapy during pregnancy, regardless of CD4 count or clinical staging. This phase of the study is testing a counseling intervention to support women through this process.

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HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
In total, the study will involve over 1800 human subjects. Approximately 1000 female patients and 500 male participants will take part in this phase of the study. Male participants will be men over the age of 18, accompanying their pregnant partner to her first ANC appointment.

WHAT IS INVOLVED IN THE STUDY?

Participation in this study is entirely voluntary, and you are free to leave the study at any time. If you refuse to participate or withdraw from the study, this will not affect any present or future relationships you and your partner may have with your medical care team. If you agree to be in this study, you will be asked to sign and date this consent form.

After signing and dating this consent form, you will be asked to complete an interviewer-administered structured survey, conducted by a research nurse in a private space. The survey will take approximately 30 minutes.

After completing the survey, you will then together with your partner receive either: (1) the clinic's standard procedures related to HIV counselling; or (2) the clinic's standard of care counselling PLUS the *Maisha* intervention, which involves a video and brief discussion. Some couples will also be asked to complete one additional counselling sessions. We will decide this randomly, like when you toss a coin. You cannot choose which part of the study you will be selected into.

If you and your partner are assigned to receive the Maisha intervention**,** you will complete the survey and then together with your partner receive **Session 1 of the counselling intervention** (a video, followed by a brief discussion). You will then return to the waiting area to await the standard of care, which includes HIV testing and counselling.

If you and your partner are assigned to receive the Maisha intervention**,** you may also be selected to receive **another couple counselling session today** after the clinic's standard counselling session. The counselling session will last approximately 60 to 75 minutes.

You may be asked to complete a **follow-up survey in three months**. The survey will take place in a private room and will take approximately 60 minutes. At this time, you may also be asked to complete a **conversational interview** to talk about your experience with the intervention. The interview will be audio recorded with your permission and will last an additional 60 minutes.

If you and your partner are not assigned to receive the Maisha intervention**,** you will receive only the standard HIV testing and counselling services at the clinic. You may be asked to complete a **follow-up survey in three months**. The survey will take place in a private room and take approximately 60 minutes.

Whenever you are selected for a study activity (including counselling sessions, surveys, and interviews), the procedure for that activity will be clearly explained to you. You have the option to decline participation in any study activity at any time.

In order to keep in touch with you between the study activities, we will take your name, phone number and address. This information will be stored separately from study information we collect and will be kept private.

HOW LONG WILL I BE IN THIS STUDY?
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Discomfort. First, this study may make you feel uncomfortable as you talk about pregnancy, HIV, your health, and your personal life. You may feel embarrassed or shy, and sometimes it may bring up personal information that makes you feel emotional.

Confidentiality. Every effort will be made to keep your information confidential and protected, but this is something we cannot guarantee. No information will be shared with anyone outside of the study team, including your health care providers. We will not record your name during the conversation so no one will know what you said during the interview. Please see below for how we will aim to keep your information confidential.

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Information that you share with us will NOT be put in your medical record.

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WHAT ABOUT COMPENSATION?
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WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes. Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at this clinic or at KCMC. If you do decide to withdraw, we ask that you contact Dr. Blandina Mmbaga in writing and let her know that you are withdrawing from the study. Her mailing address is Dr. Mmbaga, KCMC 3010, Moshi and her email is Blaymt@yahoo.com

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Name of Subject	Signature	Date
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If the participant is unable to provide a signature, please include the thumbprint of the participant above and the signature of an impartial witness who observed the consent process below.

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Signature of Witness	Date and Time