Brief Title: Efficacy Testing of a Culturally Relevant Stigma Intervention With WLWH in Tanzania

Official Title: Efficacy Testing of a Culturally Relevant Stigma Intervention With Women Living With HIV in Tanzania

NCT#: NCT05033002

Informed consent IRB Reference Date: 9/13/2023

Consent to Participate in a Research Study

Participant Unique ID #:

Efficacy testing of a culturally relevant stigma intervention in WLWHIV in Tanzania

Consent Form of: 21/02/2022 English
Research Name: Efficacy testing of a culturally relevant stigma intervention in WLWHIV in Tanzania
Principal Investigators: Mrema Kilonzo (Tanzania), Michael Relf (U.S) and Laura Nyblade (U.S)
Key Research Department: Department of Psychiatry and Mental Health, MUHAS, Tanzania.
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Financial Source/Donor: National Institute of Health (NIH)

IMPORTANT INFORMATION YOU NEED TO KNOW REGARDING THIS STUDY

You are being asked to take part in this research study because you are a woman living with HIV.

Research studies are voluntary and include only individuals who choose to take part. Please read this consent form carefully and take your time making your decision.

Mr. Mrema Kilonzo, clinical psychologist and faculty member in the Department of Psychiatry and Mental Health in the College of Medicine at the Muhimbili University of Health and Allied Sciences or a member of his research team, will discuss this consent form with you. Please ask to have any words or information that you do not clearly understand explained to you. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

If you have further questions about participating in this study, you may contact:

> Chairperson of the Senate Research and Publications Committee of Muhimbili University of Health and Allied Science at +255 22 2152489.

This document will inform you of the study details and your potential role in it, you will also get a copy of the document. If you have questions at any time please ask our researcher or contact person mentioned above.This study was registered with clinicaltrials.gov and assigned ID# NCT05033002.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to assess an intervention designed to ease the effects of stigma associated with HIV and being a woman living with HIV. This study will collect information about internalized stigma, ability to cope, self-esteem, hope, depressive

symptoms, intimate partner violence, disclosure, engagement in care, adherence, sexual risk behaviors, and quality of life among women living with HIV.

If you agree to be in this study, you will be asked to give your written consent. Only women living with HIV will be included in this study.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 160 women living with HIV in Tanzania will take part in this study.

WHO ARE THE PEOPLE CONDUCTING THIS STUDY?

Mr. Mrema Kilonzo, a clinical psychologist, from Muhimbili University of Health and Allied Sciences in Tanzania. He will follow all national and university guidelines to decrease the chance of discomfort to you and for those who will take part.

Additionally, Dr. Michael Relf, a nurse scientist from Duke University in the United States; and Dr. Laura Nyblade a demographer from Research Triangle International in the United States will also collaborate on this study.

WHAT IS INVOLVED IN THE STUDY?

If you agree to be in this study, you will be asked to sign this consent form.

If you agree to participate, you will be randomized to receive treatment as usual or to participate in a 5-session intervention. Regardless of your random assignment, you will be asked to complete a set of questions upon enrolling in the study, 30 days after enrolling or completing the intervention and at 90 and 180 days. An electronic tablet will be used to present the questions and capture your response to each question. A member of the research team will be available to assist you in you need assistance.

A member of the research team will work with you to schedule a time and a location convenient for you, if you decide to participate. Some possible locations to answer the questions would be at the Muhimbili University of Health and Allied Sciences School of

Medicine or a local health center or community meeting place. Other public venues where you feel most comfortable might also be arranged. Participating in this study is voluntary, and if you decide not to participate or to respond to a certain question, there is no penalty or loss of benefits that you are already entitled to.

HOW LONG WILL I BE IN THIS STUDY?

You will participate in this study for 180 days. You can choose to stop participating at any time.

WHAT ARE THE RISKS OF THE STUDY?

There are no physical risks associated with this study. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

When answering some of the questions, you might feel uncomfortable. You may refuse to answer any of the questions or stop participating at any time.

Once you are finished answering the questions, a member of the research team will submit your responses to RTI who review and clean the data and will then transmit data to Duke University. The data from the questionnaires will be input into the study's database, which is on a secured, protected server. Access to the database will require a password. No identifying information will be included in this database.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there is no direct benefit to you. There may be some indirect benefit to study participation. We hope the information learned from this study will help other women living with HIV to learn new skills to adapt to stigma and living with HIV.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Study records that identify you will be kept confidential in accordance with international standards for conducting research on human subjects. Privacy Regulations provide safeguards for privacy, security, and authorized access. Except when required by law, you will not be identified by name, national identification number, address, telephone number, or any other direct personal identifier in study records.

Your information will be given a code number, and this number will be used on all documents so as not to reveal your identity to the data entry personnel. The list linking your name and code number will be kept in a locked file cabinet in a locked office at the Muhimbili University of Health and Allied Sciences, and on a sensitive electronic data (SED) folder on the Duke University School of Nursing secure server. All paper documents that could identify you, as well as all data that just has your code number on it, will be kept in a locked file cabinet in a locked office at the Muhimbili University of Health and Allied Sciences.

All electronic data will be kept in a sensitive electronic data (SED) folder on the Duke University School of Nursing secure server. Your research related records may be reviewed in order to comply with national and international guidelines. Reviewers may include representatives of the Muhimbili University of Health and Allied Science Institutional Review Board. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by the federal privacy regulations.

Additionally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others. If we learn in the course of this study that you pose a serious danger to yourself (for example, you are planning on attempting suicide) or to others (for example, you are planning to hurt someone else), we may refer you for an emergency evaluation, or may be required to alert appropriate authorities. If this happens, your participation in the study would no longer be confidential.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information will be destroyed.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your identity will not be revealed.

WHAT ARE THE COSTS?

There are no financial costs associated with participation.

WHAT ABOUT COMPENSATION?

If you chose to voluntarily participate in this study, you will receive 20,000 Tanzanian Schillings for the baseline and 30 days visits and for each intervention session if you are randomized to participate in the intervention. For the 90 and 180 follow-up study visits, you will receive 30,000 Tanzanian Schillings.

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 this 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 other than data needed to keep track of your withdrawal.

Your decision 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. If you do decide to withdraw, we ask that you contact Mr. Mrema Kilonzo. You will be given a card with their phone number.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

If you want to talk to a mental health counselor or are in need of counseling and support as a result of participating in this study, please telephone Mr. Mrema Kilonzo +255 685077786 during regular business hours for a referral to a psychologist or other mental health providers.

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, contact the Chairperson of the Senate Research and Publications Committee of Muhimbili University of Health and Allied Sciences at +255 22 2152489.

SHARING OF RESEARCH FINDINGS

At the end of the study, we will be sharing what we have learned with the participants. We will do this by inviting participants to attend a meeting where we will share results of the study. We will also publish the results in order that other interested people may learn from our research.

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."

_____	_____	_____
Signature or Thumbprint of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time