STUDY INFORMED CONSENT

Enhancing Mental Health Outcomes for Patients With Psychosis in Malawi Through Community-based Rehabilitation (ENHANCE)

NCT number NCT06080477
Document Date 10/17/2023

This consent form should be signed on
between 17/10/2023 and 16/10/2024
Approved by NHSRC, Malawi on 17/10/2023

University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants

Consent Form Version Date: Version 1.2, September 1, 2023
UNC IRB Study #: UNCPM 22311 **NHSRC Study #:**

Title of Study: UNCPM 22311- Enhancing post-acute mental health outcomes for patients with psychosis in Malawi through nurse-delivered community-based rehabilitation: Pilot Randomized Trial

Malawi Principal Investigators: Kazione Kulisewa, MBBS, MMed
US Principal Investigator: Brian Pence, PhD
UNC-Chapel Hill Department: Epidemiology

Funding Source and/or Sponsor: National Institute of Mental Health

Study Contact telephone number: +265 997 210 381

CONCISE SUMMARY
The purpose of this project is to enroll 180 participants to help evaluate the acceptability, fidelity, and effectiveness of a community-based treatment intervention for community dwelling individuals with psychosis in Malawi. Some participants will receive the intervention and some participants will receive care as usual.

Participation in this study has few risks. There is a risk of loss of confidentiality or of discussing uncomfortable things. Participation will help the investigators to better design treatments to help community-dwelling individuals with psychosis.

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 refuse to join, 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, Kamuzu University of Health Sciences, or the University of North Carolina Project, Lilongwe. If you are a patient with an illness, 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 given 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?
The purpose of this research study is to better understand if a community-based rehabilitation intervention for people with psychosis is feasible, acceptable, and able to be delivered to participants as planned. Another purpose of this study is to better understand if the intervention can improve participants' health and quality of life. Some enrolled participants will receive the intervention, some will receive care as normal. All participants will complete questionnaires at the beginning, middle (6-months), and end of the study (12 months).

You are being asked to be in the study because you are a person with psychosis or a caregiver or family member of a person with psychosis.

Are there any reasons you should not be in this study?
You should not be in this study if you are not comfortable discussing sensitive topics like psychosis.

How many people will take part in this study?
There will be approximately 60 people with psychosis and 120 caregivers or family members in this research study.

How long will your part in this study last?
Your participation will last approximately 1 year.

What will happen if you take part in the study?
If you take part in this study, you may be asked to interact with the intervention. This will include regular (weekly and eventually monthly) home visits with a psychiatric nurse. If you are not asked to interact with the intervention, you will continue to receive your medical care as usual. You will be asked to complete a total of three questionnaires that will ask about your experience with psychosis, psychosis recovery and care, and, if you receive the intervention, your experience with the intervention.

If you receive the intervention, the nurse may ask to record certain sessions so that they may be reviewed by a supervisor to check the quality. You may decline to have the session recorded and this will not affect your treatment or participation.

If you are a caregiver, and your family member with psychosis receives the intervention, you will participate in some intervention sessions with them. You will be asked to complete a total of three questionnaires that will ask about your experience of having a family member with psychosis, psychosis recovery and care, and, if you receive the intervention, your experience with the intervention.

You may choose not to answer a question for any reason. All questionnaires will be available in Chichewa.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. If you or your family member receive the intervention, you may benefit from the treatment visits. If you do not receive the intervention, there is little chance you will benefit from being in this research study. Your participation may contribute to improved efforts to manage psychosis and help in the recovery process for yourself and others in the future.

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

We do not anticipate any significant risks associated with this study. With research, there is always the possibility that your private information (in this case, information about your psychosis status) could be disclosed unintentionally. We will make every effort to protect your privacy and confidentiality while you are participating in this study. All the information you give will be kept confidential and all personal data will be kept secure. The information we collect will only be identified with a code or number, not with your name. We will not share the information you give us with anyone not involved in the study.

There may be uncommon or previously unknown risks that might occur. You should report any problems to the researchers.

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?

You will be identified by a code (a number), and personal information from your records will not be released without your written permission. All data will be kept in a locked cabinet at UNC project or on a secure server at UNC Project accessible only to approved study personnel. All study data will be destroyed 1 year after the completion of all study-related activities. You will not be personally identified in any publication about this study. However, your records may be reviewed, under guidelines of the sponsor of the study; the National Institutes of Mental Health (NIMH), the University of North Carolina Institutional Review Board (IRB), the National Health Sciences Research Committee in Lilongwe, Malawi, study staff, or study monitors.

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 we are concerned for your safety or the safety of someone else, we may share limited information to ensure your safety or the safety of that other person. 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.

Will you save my research data to use in future research studies?

Deidentified data from this study will be submitted to the National Institute of Mental Health Data Archive (NDA). NDA is a data repository run by the National Institute of Mental Health (NIMH) that allows researchers studying mental health to collect and share deidentified information with each other. A data repository is a large database where information from many studies is stored and managed. Deidentified information means that all personal information about research participants such as name, address, and phone number is removed and replaced with a code number. Researchers who want to access data from the NDA must file an application with the NIMH which will be carefully reviewed to minimize risks to your privacy. NIMH will report to the United States Congress and on its web site about the different studies that researchers are conducting using NDA data. However, you will not be contacted directly about the data you contributed to NDA.

With an easier way to share, researchers hope to learn new and important things about mental illnesses more quickly than before. However, you will not benefit directly from allowing your information to be shared with NDA.

You may decide now or later that you do not want to share your information using NDA. If so, contact Kazione Kulisewa, Malawi PI, at +265 997 210 381 However, NDA cannot take back information that was shared before you changed your mind. If you would like more information about NDA, this is available on-line at http://data-archive.nimh.gov.

What will happen if you are injured by this research?

All research involves a chance that something bad might happen to you. It is unlikely that you will be injured as a result of study participation. If you are injured, the UNC Project will give you immediate necessary treatment for your injuries. You will not have to pay for this treatment. You will be told where you can get additional treatment for your injuries. There is no program to pay money or give other forms of compensation for such injuries either through this institution or the United States NIH. You do not give up any legal rights by signing this consent form.

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, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

Will you receive anything for being in this study?
You will receive the equivalent of US $10 for each of three research interviews at baseline, 6, and 12 months. You will not receive any payment for intervention visits.

Will it cost you anything to be in this study?
It will not cost you anything to be in this study.

Who is sponsoring this study?
This research is funded by the National Institute of Mental Health from the United States. This means that the research team is being paid by the sponsors 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.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research.

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact the study doctor Dr Kulisewa at +265 997 21 03 81.

What 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 participant, or if you would like to obtain information or offer input, you may contact the NHSRC Director, Dr. Collins Mitambo at +265 999 39 79 13.

SIGNATURE PAGE

UNC IRB Study #: 22-1507; NHSRC Study #:

Title of Study: UNCPM 22209 - Enhancing post-acute mental health outcomes for patients with psychosis in Malawi through nurse-delivered community-based rehabilitation: Pilot Randomized Trial

Malawi Principal Investigator: Kazione Kulisewa, MBBS, MMed
US Principal Investigator: Brian Pence, PhD

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 print and sign your name and write the date** in the signature area below.

PART A: LITERATE PARTICIPANT

Participant is literate: ☐

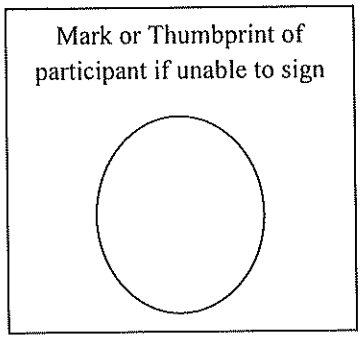
_____	_____	_____
Participant Name (print)	Participant Signature	Date
_____	_____	_____
Study Staff Conducting Consent Discussion (print)	Study Staff Signature	Date

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 make your mark or place your thumbprint** in the signature area below.

PART B : ILLITERATE PARTICIPANT

Participant is illiterate: ☐

The study staff must complete this section, ONLY if an impartial witness is available.
The **study staff must write participant's name and date of consent below.**



Participant Mark or Thumbprint

Participant Name (print)	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

Participant's/Legal Authorized Representative's (LAR) 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, make your mark or place your thumbprint** in the signature area at the bottom of this page.

PART C: LITERATE PARTICIPANT/LAR

Participant/LAR is literate: ☐

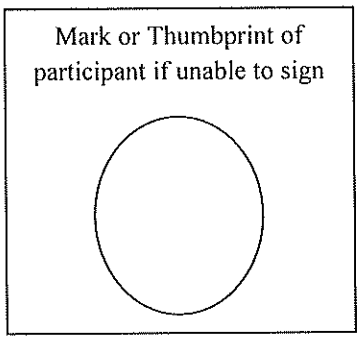
Participant Name (print)	Participant Signature	Date
LAR Name (print) (If applicable)	LAR Signature	Date
Study Staff Conducting Consent Discussion (print)	Study Staff Signature	Date

PART D : ILLITERATE PARTICIPANT/LAR

Participant/LAR is illiterate: ☐

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

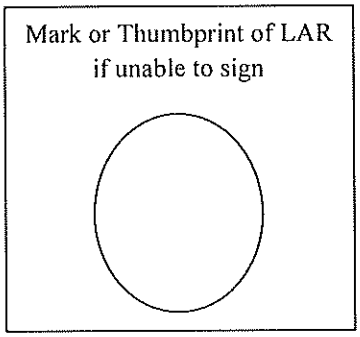
The **study staff must write participant's name and date of consent below.**



Participant Mark or Thumbprint

Participant Name (print)

Date



LAR Mark or Thumbprint

LAR Name (print)
(If applicable)

Date

Participant/LAR Name and Date Written By.....on.....

Study Staff Conducting Consent Discussion (print)

Study Staff Signature

Date

Impartial Witness Name (print)

Impartial Witness Signature

Date