STUDY INFORMED CONSENT

Aligning Facility Leadership and Climate to Advance Mental Health Services Integration in Malawi (ALIGN)

NCT number NCT06399991
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This consent form should be signed on between 07 Feb 2025 and 09 Jan 2026
Approved by NHSRC, Malawi on 07 Feb 2025

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

Consent Form Version Date: Version 2.3, January 24th, 2025
UNC IRB Study #: 23-2722
NHSRC Study #: 23/10/4209

Title of Study: UNCPM 22320 - Trial Phase: Aligning facility leadership and climate to advance mental health services integration in Malawi (ALIGN)

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 compare the success of two implementation strategies in achieving successful integration of evidence-based mental health treatment into general medical care.

Participants in this study will complete 4 visits either at the clinic or by phone, including today, over the next year. Participation in this study has few risks. There is a risk of loss of confidentiality or of emotional distress caused by discussing uncomfortable things. There may be one finger stick or blood draw that could cause some discomfort; this will be similar to what might be done in a standard clinic visit.

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 project is to compare the success of two strategies for integrating mental health treatment into general medical care.

You are being asked to be in the study because you had symptoms of anxiety or depression at a clinic visit today or recently.

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 mental health symptoms.

How many people will take part in this study?
There will be approximately 1,440 individuals with mental health symptoms in this research study.

How long will your part in this study last?
Your participation will last approximately 12 months.

What will happen if you take part in the study?
You will be asked to complete questionnaires that will ask about symptoms of anxiety and depression, other health problems, and use of alcohol or drugs. All participants will complete questionnaires at the beginning of the study and then again after 3, 6 and 12 months. You may choose not to answer a question for any reason. Each of these visits will take approximately one hour.

The 3 and 12 month interviews may be by phone. The 6 month interview will be in person. At the 6-month visit, we will collect additional clinical measures. If you are a patient at the ART clinic, an HIV RNA viral load by dried blood spot will be collected by finger stick. If you are a hypertension patient at the NCD clinic, blood pressure will be measured. If you are a diabetes patient at the NCD clinic, HbA1c will be collected by blood draw. If you are a patient at the tuberculosis clinic, sputum for AFB smear microscopy will be collected. These biomarker collections are specifically for the study but are similar to what might occur during a normal clinical visit. The biomarker collection will take approximately 5 minutes.

We may also collect certain information from your health passport and from your medical record at the clinic, including measures of depression and anxiety symptoms, medications prescribed, and treatment plans.

What are the possible benefits from being in this study?
Research is designed to benefit society by gaining new knowledge. Your participation may

contribute to improved efforts to provide mental health treatment and help in the recovery process for yourself and others in the future. There are no expected benefits to individuals who take part in the study.

What are the possible risks or discomforts involved from being in this study?
We do not anticipate any significant risks associated with this study. Some parts of the questionnaire may cause emotional distress. You do not have to answer any questions that you do not want to.

There may be one finger stick or blood draw that could cause some discomfort; this will be similar to what might be done in a standard clinic visit.

With research, there is always the possibility that your private information 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 with identifiers 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. De-identified data from this study may be used in future research without additional consent.

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.

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 website at any time.

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 with 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 study visit completed, up to a total of US $40

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 Evelyn Chitsa Banda- +265999936937.

SIGNATURE PAGE

UNC IRB Study #: 23-2722
NHSRC Study #: 23/10/4209

Title of Study: UNCPM 22320 - Aligning facility leadership and climate to advance mental health services integration in Malawi (ALIGN) Trial

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

Participant's Agreement:

PART A: LITERATE PARTICIPANT

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.

Participant is literate: ☐

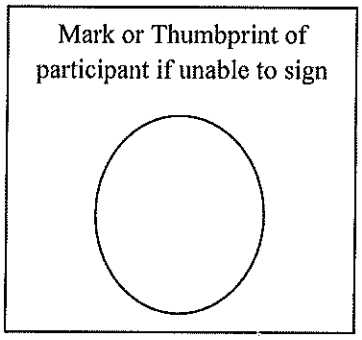
Participant Name (print)	Participant Signature	Date
Study Staff Conducting Consent Discussion (print)	Study Staff Signature	Date

PART B : ILLITERATE PARTICIPANT

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.

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