

Study Title

An Economic and Relationship-strengthening Intervention to Reduce Alcohol Use in Malawi

NCT Number: NCT06367348

Informed Consent Form Document Approval Date: 12/11/2025



University of California  
San Francisco

**UNIVERSITY OF CALIFORNIA, SAN FRANCISCO  
CONSENT TO PARTICIPATE IN A RESEARCH STUDY**

Study Title	Mlambe: A randomized control trial of an economic and relationship-strengthening intervention with HIV-affected couples who drink alcohol in the Zomba district of Malawi.
Principal Investigator (Person in charge of this study)	University of California: Amy Conroy, PhD MPH Associate Professor <a href="mailto:amy.conroy@ucsf.edu">amy.conroy@ucsf.edu</a>  Invest in Knowledge: James Mkandawire, MPH Email Address: <a href="mailto:james3mkandawire@gmail.com">james3mkandawire@gmail.com</a> IKI Contact Number: 0888 77 20 93
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Clinicaltrials.gov National Clinical Trial (NCT) Number	NCT06367348

**1. Why have I been given this document?**

To see if you are interested in taking part in a research study. A research study is a planned project done to learn more about a topic.

**2. Do I need to take part in this research study?**

No. Taking part in research is voluntary. If you don't want to take part there will be no penalty and you will not lose your current benefits. The Principal Investigator, or another member of the study team, will explain the study to you. Please ask questions. Take your time deciding if you want to be in this study. You can talk with your health care team, your family, and friends before deciding. To participate, both you and your partner must agree to be in the study together.

### **3. This section describes key information to consider about this study**

#### **3.1 Why is this study being done?**

Many adults have HIV and drink alcohol. Both things can impact their relationships as well as their finances. This study will help us understand if providing financial and relationship education can help people reduce their alcohol use, improve their relationships, and help people take their HIV medications.

#### **3.2 How long would I be in this study? How many study visits are there?**

You would be in this study for about 20 months. If you agree to be in the study, you will come to the research site to complete a survey. You will also be asked to come back to be assigned to your study group. Once you are assigned to your study group, there will be three more follow up visits at 11, 15, and 20 months from now. Each follow up visit will last between 60-90 minutes. You may also be assigned to a study group that attends workshops that will take place once a month for ten months. The workshops would last between 2-4 hours each.

#### **3.3 What are the procedures with the most risk in this study?**

- Interview questions about sensitive topics
- Blood drawing (venipuncture)
- Blood drawing (finger prick)
- Loss of privacy
- Couple conflict

#### **3.4 What risks and discomforts are most severe? What risks and discomforts are most common?**

Possible risks and discomforts of this study that are most severe are:

- Blood drawing (venipuncture) risk

- Blood drawing (finger prick) risk
- Loss of privacy

Possible risks and discomforts of this study that are most common are:

- Interview questions about sensitive topics
- Loss of privacy risk
- Blood drawing (venipuncture) risk
- Couple conflict

We will tell you more about risks and discomforts later in this form.

### **3.5 Are there benefits to taking part in this study?**

You may or may not benefit from participating in the study. The information learned from this study may help others in the future.

### **3.6 What are my other options if I don't want to take part in this study?**

Your other options may include:

- Getting care without being in this study
- Taking part in another study if you are interested and one is available

### **3.7 What is the usual care for my condition?**

The usual care for your condition is regular HIV care plus brief advice on alcohol use.

## **4. How many people will take part in this study?**

About 250 couples (500 people) will take part in this study.

## **5. Who is paying for this study?**

This study is being paid for by the National Institutes of Health in the United States of America.

## **6. Do any UCSF researchers of this study have financial interests that I should know about?**

No

## 7. What are the research procedures of this study?

### Study procedures

If you qualify for the study, you will need to have the following exams, tests or procedures.

- You will complete a questionnaire. A trained interviewer will ask you questions and enter your answers directly into a tablet. Participation in the questionnaire will take about 60-90 minutes. You and your partner will be interviewed separately in private locations. Your partner will not know what you say.
- The questions on the questionnaire will ask about your relationship with your partner, your finances, your health and your partner's health, including HIV, and your alcohol use and your partner's alcohol use.

**Randomization:** This study has different groups. You will be put into a group by chance. How your group is chosen is like flipping a coin or rolling dice. You will have an equal chance of being in either group. You must be willing to be in either group to be in the study. You will need to come to the research center to be randomized into one of the two groups. A study staff person will tell you which group you are in and this cannot be changed.

**If you are in group 1** you will receive a short talk on alcohol and antiretroviral therapy (ART) use shortly after being randomized.

- If you are assigned to the group that receives a short talk about alcohol, you will be asked to come back in 11 months and again at 15 months and 20 months to answer another questionnaire.
- If you drink alcohol, you will also be asked to give us a few drops of blood so that we can study your alcohol use. We will send a card with spots of your blood to a laboratory in the United States where they test the amount of alcohol you have had over the past four weeks.
- If you are living with HIV, you will also be asked to provide a small tube of blood for an HIV viral load test. A lab here in Malawi will test whether you have detectable virus in your blood. If they can detect virus, we will report that to you HIV care provider. There is more information about the blood tests later in this form.

- If your blood sample is lost or damaged due to unforeseen circumstances (eg. power outage at the lab in Malawi), we will request a second sample from you. You will be reimbursed for providing a second sample according to the visit schedule amount. We will tell you more about what you will be paid later in this form.

**If you are in group 2** you will be in a study group that receives economic and relationship-strengthening workshops.

- If you are assigned to the group that receives the workshops, you will be asked to come in with your partner for approximately 10 sessions over the next 10 months. Two of these sessions will be just you and your partner and the counselor, and the others will be done in a group with other couples. Some of the workshops will focus on alcohol, some will focus on your relationship, and some will focus on financial education. In these groups, there you will have the chance to share your opinions and experiences about relationships, banking, finances, and alcohol. You do not have to share any personal information in the group sessions; it is up to you.
- Both you and your partner must attend the workshop sessions. If one of you decides not to participate, neither of you can participate. You may be able to continue completing study surveys, though.
- After each of the group sessions, we will provide a meal and you will have the opportunity to socialize with other couples in the group.
- If you are assigned to the group that receives the workshops, you will be assigned a financial counselor who will work with you and your partner to make a savings plan. Every month that you are in the study, for 10 months, you will be asked to put money in a savings account. For every kwacha that you save, up to \$10 USD per month, the study will put a matching amount into your savings account. You will not be able to access the matched money until later in the study, and only if you successfully attend at least 8 of the 10 workshop sessions. You will have access to the matched savings for 10 more months after the matching stops to start a business or income-generating activity.
- If you are assigned to the group that receives the workshops, we would like your permission to record the workshops so that we can document accurately what is being said. We will also record the sessions with just you, your partner, and the counselor. The recordings will be transcribed and translated. All records of your personal details will not be linked to any information you give us. Both the recordings and the paper transcript of the workshops will be stored safely and securely with access only by research staff from IKI and the study investigators. After 5 years all the data will be destroyed.

- If you are assigned to the group that receives the workshops, you will be asked to come back in 11 months and again at 15 months and 20 months to answer another questionnaire.
- If you drink alcohol, you will also be asked to give us a few drops of blood so that we can study your alcohol use. We will send a card with spots of your blood to a laboratory in the United States where they test the amount of alcohol you have had over the past four weeks.
- If you are living with HIV, you will also be asked to provide a small tube of blood for an HIV viral load test. A lab here in Malawi will test whether you have detectable virus in your blood. If they can detect virus, we will report that to your HIV care provider. There is more information about the blood tests later in this form.
- If your blood sample is lost or damaged due to unforeseen circumstances (eg. power outage at the lab in Malawi), we will request a second sample from you. You will be reimbursed for providing a second sample according to the visit schedule amount. We will tell you more about what you will be paid later in this form.

**Blood drawing (venipuncture or finger prick):** As part of the study, we will draw a small amount of blood to test your HIV viral load (if you are living with HIV) and your alcohol use (if you drink alcohol). These tests are part of the study for people in both groups.

If you drink alcohol, you will be asked to give a small blood sample at the start of the study and again when you come back for the 11, 15, and 20 month follow up visits. If you are living with HIV, you will be asked to give a small blood sample at the start of the study and then again at the 15 month follow up visit. The blood will be drawn by a trained-health care worker who will put a needle into a vein in your body or prick your finger. Each sample will be about 10 mL. A total of about 25 mL will be taken for the whole study.

### **7.1 Where do the procedures happen?**

Study procedures will be done at a clinic or community location that is convenient for you.

### **7.2 Will clinically relevant research results be shared with me?**

If the blood test for your viral load shows that you have a detectable amount of HIV, we will share that information with your HIV care provider at the clinic you go to. We will not share the results of the test that tells us about your alcohol use with you or with your provider.

## 8. What are the risks of this study?

Risks and side effect related to this study include:

**Blood drawing (venipuncture) risks:** Drawing blood may cause discomfort from the needle stick. It may cause bruising, infection, and fainting.

**Blood drawing (finger prick) risks:** Drawing blood may cause discomfort from the finger prick. It may cause bruising, infection, and fainting.

**Questionnaire risks:** The questionnaire includes personal questions about HIV, alcohol use, and other behaviors. This can make you feel embarrassed.

**Randomization risks:** You might be put into a group that is not as effective as another group.

### Loss of privacy risks:

- People in your community might find out that you are in the study, so they may assume you have HIV or use alcohol.
- If you are assigned to the group that attends workshops with other couples, others might repeat what you say. We will ask everyone to protect the privacy of others, but we cannot guarantee it.
- It is possible that your partner may ask you about your responses to some questions that come up in the interview. This may cause you some discomfort or distress when talking about difficult issues with your partner.
- If you are assigned to the group that saves money, it is possible that you and your partner will disagree about how to use the money. This disagreement could cause distress.
- It is possible that your information is seen by someone else, accidentally. This may cause you some discomfort, distress, or embarrassment.

## 9. Will I be paid if I take part in this study?

In return for your time and effort, you will be paid the equivalent of \$10 US for your time and transportation for each of the four study assessments. Each couple will be eligible to receive a total of the equivalent of \$20 US x 4 = \$80 US for participation in the study assessments.

If you are in the group that receives the workshops, we will “match” every kwacha you are able to save, up to \$10 USD per month (up to \$100 USD total). To receive the matched savings, you are required to attend at least 8 of the 10 Mlambe sessions.

### **9.1 Will I share in any profits from this study?**

No. Your specimens or information obtained from your specimens may be used for commercial use. If this happens, you will not share in any profits.

### **10. Will I be reimbursed for expenses if I take part in this study?**

You will be reimbursed for expenses if you take part in this study.

You will be reimbursed for travel expenses for each study assessment. You will be paid in cash at the end of each study assessment.

If you are in the group that receives the workshops, you will be reimbursed for travel expenses to attend each session. You will be paid in cash at the end of each study session.

### **11. How will my information be used?**

Researchers will use your information to do this study to help us understand if providing financial and relationship education can help people reduce their alcohol use, improve their relationships, and help people take their HIV medications.

Data from this study will also be submitted to the National Institute on Alcohol Abuse and Alcoholism Database (NIAAADA) at the National Institutes of Health (NIH). NIAAADA is a large database where deidentified study data from many NIAAA studies is stored and managed. Deidentified study data means that all personal information about you (such as name, address, birthdate and phone number) is removed and replaced with a code number. Sharing your deidentified study data helps researchers learn new and important things about alcohol problems more quickly than before.

During and after the study, the study researchers will send your deidentified data about to the NIAAADA. Other researchers across the world can then request your deidentified study data for other research. Every researcher must promise to keep your data safe and promise not to try to learn your identity. Experts at the NIH who know how to keep your data safe will review each request carefully to reduce risks to your privacy. Sharing your study data does have some risks, although these risks are rare. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. The study researchers will make every attempt to protect your identity.

## **12. How will information about me be kept confidential?**

If you take part in this study, there may be some loss of privacy. We will do our best to make sure information about you is kept confidential. But we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

If you are in the group that receives the workshops, the researchers will ask you and the other people in the group to use only first names during the group session. They will also ask you not to tell anyone outside the group what any particular person said in the group. However, the researchers cannot guarantee that everyone will keep the discussions private.

### **12.1 Who may review my research information?**

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the University of California
- Representatives of the National Institutes of Health
- Representatives of the Office of Human Research Protections (OHRP)
- Representatives of the National Health Sciences Research Committee in Malawi
- Representatives of Invest in Knowledge, Malawi

## **13. Does this study involve testing of diseases and conditions that must be reported to the public health department?**

No, this study does not involve testing for reportable diseases and conditions. If you are living with HIV, the viral load test will be identified only by your number and will not be reported to any public health department.

#### **14. What happens if I am injured or feel harmed because I took part in this study?**

It is important to tell the Principal Investigator if you feel you have been injured or harmed because you took part in this study. The contact information for this person is on the first page of this form.

##### **14.1 Treatment and Compensation for Injury**

If you get hurt because of this study, you can seek treatment at your regular health clinic. For example, if your finger becomes infected and you need antibiotics, you can seek care at your regular clinic. If there are costs because of the treatment, please let a member of the study staff know. We may be able to reimburse you for costs and transportation, depending on the nature of the injury. You can contact Nancy Mulauzi at 0888 77 20 93.

#### **15. Are there any costs to me for taking part in this study?**

There will be no costs to you for being in this study.

#### **16. Can I stop being in the study if I want to?**

Yes. You can decide to stop at any time. If you are thinking about stopping, tell the study team so they can discuss any risks of stopping with you. They can tell you what follow-up care and testing could be most helpful. The study team will help you stop your participation safely.

If you stop being in the study, any data or specimens we have already collected will remain part of the study records. The study team may still get information from your medical records if it is important to the study. This information may include information like laboratory results, treatment courses, or health outcomes. If you do not want this information to be collected after you decide to stop being in the study, you must tell the study team.

If you are in the study group that attends workshops, both members of the couple must attend the workshops together. If your partner does not want to continue in the study,

you will not be able to attend the workshops alone, but you may be able to continue completing study assessments.

**17. Can I be removed from the study by the Principal Investigator?**

Yes. The Principal Investigator may stop you from taking part in this study at any time. This could happen without your permission. It could be because it is in your best interest, if you did not follow the study rules, or the study has been stopped.

**18. What are my rights if I take part in this study?**

You may choose to take part or not to take part in this study. It's your choice. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

**19. Who can answer my questions about this study?**

You can contact the study team with any questions, concerns, or complaints you have about this study. The contact information is on the first page of this form.

Malawi has an office that can answer questions about your rights as a research participant. The office is called the National Health Sciences Research Committee (NHSRC). The NHSRC is available to talk about any problems or concerns you have about the study. The NHSRC number is 0999 39 79 13. The NHSRC chairperson's number is 0999 936937 (Dr. Chitsa Banda).

Additionally, UCSF has an office that can answer questions about your rights as a research participant. This office is called the Institutional Review Board (IRB). The IRB is available to talk about any problems or concerns you have about the study. The UCSF IRB's phone number is 01-415-476-1814.

**19.1 Where can I get more information about this study?**

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. 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.

The National Clinical Trial (NCT) number for this study will be listed on the first page of this form. If the NCT number is not yet available, the study team will give it to you when it is available.

## 20. Consent

You will be given a copy of this form to keep.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to say “No” to this study now or at any point without penalty.

If you wish to take part in this study, please sign or mark below.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of participant

Fingerprint of participant if they cannot read.



(NOTE: If the participant is not literate, the consent will be read out loud by the person obtaining consent in the presence of an independent witness.)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Person Obtaining Consent

Date

Witness

## 21. Additional Optional Research

This section of the informed consent form is about future research studies done with people who are taking part in the main study. You may take part in these optional future studies if you want to. You can still be a part of the main study even if you say "no" to taking part in any future studies.

Your contact information (name, phone number if you have one, and address) will be stored in a locked room at IKI.

Would you like to be contacted by this research group about other research studies in the future for which you may be eligible?

YES	NO
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\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of participant

Fingerprint of participant if they cannot read.

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(NOTE: If the participant is not literate, the consent will be read out loud by the person obtaining consent in the presence of an independent witness.)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Person Obtaining Consent

Informed Consent Form  
Mlambe RCT

\_\_\_\_\_  
Date

\_\_\_\_\_  
Witness