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An Economic and Relationship-strengthening Intervention for HIV affected Couples Who Drink Alcohol in Malawi
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UNIVERSITY OF CALIFORNIA, SAN FRANCISCO / INVEST IN KNOWLEDGE INITIATIVE
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: An Economic and Relationship-Strengthening Intervention for HIV-affected Couples who use Alcohol in Malawi

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Hello, I am from the Invest in Knowledge Initiative (known as IKI) in Zomba. We are conducting a research study with married couples who are living with HIV and drink alcohol. We want to know if providing couples with financial and relationship workshops can help reduce alcohol use, improve their relationships, and help people take their HIV medications.

In this study, researchers are conducting questionnaires, offering savings and microfinance workshops, helping couples open a saving account and start an income-generating activity, offering workshops on relationships and communication, and collecting blood samples to learn more about HIV and alcohol use.

This is a research study, and you are not required to take part. This paper tells you about the study. A counselor will also talk about the study with you today. Please take your time to make your decision about participating. If you have any questions, you may ask the researchers.

You are being asked to take part in this study because you, or the person you are married to, is living with HIV and uses alcohol.

Why is this study being done?
Many adults have HIV and also drink alcohol. Both of these 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.

Who pays for this study?
This study is paid for by the National Institutes of Health in the United States of America.

How many people will take part in this study?
About 80 couples will take part in this phase of the study.

What will happen if I take part in this study?
If you take part in this study, you will:

1. Complete a questionnaire. A trained interviewer will ask you questions and enter your answers directly into a computer. 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.
2. Be assigned to either receive a short talk on alcohol and antiretroviral therapy (ART) use or to be in the study group that receives the economic and relationship-strengthening workshops. This assignment will be done at random, like rolling a dice. You will have an equal chance of being in either group. A study staff person will tell you which group you have been assigned to and this cannot be changed. You must be willing to be in either group to be in the study.
3. ***If you are assigned to the group that receives the short talk about alcohol***, you will be asked to come back in 10 months and again at 15 months to answer another questionnaire.
4. ***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. Some of these sessions will be just you and your partner and the counselor, and some 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.
5. ***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 5 more months after the matching stops to start a business or income-generating activity.
6. ***If you are assigned to the group that receives the workshops***, you will be asked to come back in 10 months and again at 15 months to answer another questionnaire.
7. ***If you are assigned to either group*** **and you are the main drinker of alcohol or are living with HIV,** you will be asked to give a small blood sample when you come back for the 10 month follow up questionnaire at *one of three clinic locations:* Matawale Health Center, Tisungane clinic at Zomba Central Hospital, or Pirimiti Community Hospital. This will be the clinic you attend for your HIV care visits. The blood will be drawn by a trained health care worker who will put a needle into a vein in your arm. One small tube of blood will be taken. This will take about five minutes.
8. ***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. The recording 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.

Storage for Future Testing:
We will store the blood at a laboratory for up to 4 years. We will use the blood to do tests to find out about the amount of HIV and HIV medications in the blood, and the nature of your alcohol use; these samples will only be used for our study. Your name will not be used to identify the blood sample – instead we will use confidential study numbers. You will not be contacted with any test results.

Optional future studies
At the end of this form, we will ask you if you would like to provide consent for us to keep your contact information so that we may contact you about any future research studies for which you may be eligible.

How long will I be in the study?
Participation in the study will take about 15 months. It will take about 2 hours to complete this consent and the questionnaire. You will be asked to come back for an hour long visit in order to be assigned to your study group. The follow-up visits at 10 months and 15 months to complete the questionnaire will each last around 60-90 minutes. The blood draw at 10 months will take about five minutes. If you are in the group that receives the workshops, you will spend an addition 2-4 hours per month for 10 months doing study workshops.

Can I stop being in the study?
Yes. You can decide to stop at any time. Just tell the study researcher or staff person right away if you wish to stop being in the study. Also, the study researcher may stop you from taking part in this study at any time if he or she believes it is in your best interest or if you do not follow the study rules.

What side effects or risks can I expect from being in the study?
There may be some risk or discomfort from doing this study.

1. The needle stick may hurt. There is a small risk of bruising and fainting, and a rare risk of infection. Only trained community health workers will collect the blood to ensure that the experience is as comfortable as possible.
2. The questionnaire includes personal questions about HIV, alcohol use, and other behaviors. This can make you feel embarrassed. If any question makes you feel uncomfortable, you can choose not to answer that question. You can also end the interview at any time you choose.
3. People in your community might find out that you are in the study, so they may assume you have HIV or use alcohol. But the study answers are secret and we do all we can to keep what you say private.
4. It is possible that your information is seen by someone else, accidentally. We will do our best to ensure that does not happen.
5. It is also possible that your partner may ask you about your responses to certain questions that come up in the interview. This may cause you some discomfort or distress when talking about difficult issues with your partner. Should you experience any difficulties resolving disagreements or conflict with your partner, you can consult with one of our counselors at IKI. In addition, all participants will receive a list of community-based resources, including mental health counseling, general health services, and other services for couples.
6. The study involves periodic in-person meetings and therefore poses some risk to infection from Covid-19. We have developed and will follow a Covid-19 Risk Management Plan to minimize the risk to Covid-19. We will also monitor the Malawi Ministry of Health and the World Health Organization for changes in Covid-19 guidance.

Are there any benefits from taking part in this study?
If you choose to be in this study, you can receive free information about how alcohol affects HIV and how to reduce your alcohol use. You and your partner may benefit from the financial and relationship-strengthening workshops if you are assigned to that group. There is also a benefit to your community because the information you give us will help us improve programs in your community. There is also the possibility that you will not receive any benefit from the study.

What other choices do I have if I do not take part in this study?
You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you. You can continue to receive care as you normally would at your local clinic.

How will my specimens and information be used?
Researchers will use your specimens and information to conduct this study. Specimens and information gathered during this research study will only be used for this study. They will not be shared with other researchers outside of the research team.

Will my medical and other information be kept private?
We will do our best to make sure that the personal information gathered for this study is kept private, although we cannot guarantee absolute confidentiality. Your questionnaire information and blood sample will use a study ID number, not your name. This consent form will be stored in a locked room. The computer that is used for entering the information is protected with a password. If researchers publish or present findings from this study, no personal information will be used.

The researchers will not give out your personal information unless required by law. Authorized individuals from the following organizations may look at our research records: the United States National Institutes of Health, the University of California, and the National Health Sciences Research Committee in Malawi.

Are there any costs or payments?
There are no costs to you for taking part in this study. You will receive a small incentive for your time and participation in each survey (1500 Malawi Kwatcha per partner). You will also be reimbursed for travel expenses for each study assessment. Study assessments will occur at baseline, 10-months, and 15-months after baseline. Each couple will be eligible to receive a total of 3000 MK x 3 = 9000 MK 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 (around 7500 MK). To receive the matched savings, you are required to attend at least 8 of the 10 Mlambe sessions. We will also provide you with a travel stipend to attend each session.

What happens if I am injured because I took part in this study?

It is important that you tell the study investigators if you feel that you have been injured because of taking part in this study. You can tell the investigators in person or call Mr. Mkandawire at Invest in Knowledge at 0888 77 20 93.

If you are injured as a result of being in this study, treatment will be provided at a local health care site per the recommendation of IKI, the local implementing partner. The costs of the treatment may be billed to you just like any other medical costs, or covered by the University of California or the implementing partner, IKI, depending on a number of factors. The University and the implementing partner do not normally provide any other form of compensation for injury. For further information about this, you may call the office of the National Health Sciences Research Committee at 0999 39 79 13.

What are my rights if I take part in this study?
Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to participate in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way.

Who can answer my questions about the study?

If you have questions regarding your participation in the study, please contact IKI at 0888 37 00 81. If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the NHSRC at 0999 39 79 13. 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.

Interviewer: Answer the participant's questions about the study before proceeding to the informed consent authorization.

INFORMED CONSENT AUTHORIZATION

You have been given a copy of this consent form to keep.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this study, or to withdraw from it at any point without any penalty or loss of benefits to which you are otherwise entitled.

1. Do you agree to participate in part or all of the study or do you decline participation?
   - ☐ 1 YES, agree to participate in part or all of the study. Initial: _____
   - ☐ 0 NO, decline to participate. Initial: _____

   If declined:
   We're interested in knowing why people do not want to participate in this study. Would you tell me which of the following best describes the reason you do not want to do this study?

I don't have time	☐ 1
I don't want to talk about these topics	☐ 2
Some other reason; Specify_____	☐ 3
I would rather not say why	☐ 9

Please tick the box to show your decision, and initial or make your mark on the line next to the response you choose.

1. Would you like to be contacted by this research group about other research studies in the future for which you may be eligible?
   - ☐1 YES, agree. Initial: _____
   - ☐0 NO, decline. Initial: _____

If you have read this document or had the document read to you, have been given the chance to ask any questions, and agree to participate in any of the above procedures (as marked), please sign below.

Signature or mark of participant: _____ Date: _____

I have explained to the participant the study purpose and procedures and we have discussed all the risks that are involved. I have answered questions to the best of my ability that the participant had.

Name of person obtaining consent: _____

Signature of person obtaining consent: _____ Date: _____