Official title: Improving HIV Care Engagement Among Ugandan Adolescent Girls and Young Women Through Reductions in Male Partner Alcohol Use and Intimate Partner Violence Risk: The Kisoboka Mukwano Intervention

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Makerere University School of Public Health / Arizona State University
INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY – Intervention

Title of the proposed study: Improving HIV Care Engagement Among Adolescent Girls and Young Women Living with HIV in Wakiso District Through Reductions in Male Partner Alcohol Use and Intimate Partner Violence Risk: The Kisoboka Mukwano Intervention

Sub-title: Improving Health for Couples

Investigators:

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Background and rationale for the study:

People living with HIV who have experienced marital/relationship conflict and stress have greater challenges in attending their clinic appointments and taking their HIV medication. When their partner drinks alcohol, it increases their risk of marital conflict and stress. This study aims to find the best ways to help young women living with HIV and their partners reduce marital/relationship conflict and stress and maintain and improve their health.

A description of sponsors of the research project and the organizational affiliation of the researchers:

Sponsors: National Institutes of Health (NIH)

Organizational Affiliation: Makerere University School of Public Health (MakSPH); Arizona State University, U.S.A.; San Diego State University, U.S.A.

Purpose:

The purpose of this study is to learn how we might help improve the health of couples. We want to know how living with HIV and partner alcohol use relates to marital relationships. We hope to find the best approaches to help couples maintain and improve their health.

This study involves experimentation: we will test a program for couples.

We are asking couples to join this study to help us test a new program to help people reduce their alcohol use and marital conflict and stress and be engaged in HIV care compared to

standard counseling and referrals. Half of the couples in this study will get the new program and the other half will get the standard counseling and referrals. Choosing who gets the new program is determined by chance. Each day it will be determined by chance, like flipping a coin, whether the new program or the standard counseling and referrals is offered that day. You and your partner will have an equal chance of getting the new program or the standard counseling and referrals.

The estimated duration the research participant will take to in the research project:

Your participation will last 6 months.

If you are chosen to get the standard counseling and referrals you will participate in 3 sessions/visits each lasting less than 75 minutes.

If you are chosen to get the new program you will participate in 8 sessions/visits. Each session/visit will last between 60-90 minutes. Some sessions/visits will be individual and others will involve your partner or other people participating in the study.

The investigators could take you out of the study at any time. This would happen if: They think it is in your best interest to stop being in the study; You are not willing or able to do all the things needed in the study; The whole study stops.

If you discontinue participating in this study, information collected before you stopped being in the study will be included in the analysis of study results. You have the right to request that your data be removed from the data set.

Procedures:

Before you take part in this study, the study must be explained to you and you must be given the chance to ask questions. You must read (or have it read to you) and sign this informed consent form. You will be given a copy of this consent form.

In this study, you will provide contact information so the researchers can reach you (phone numbers, secondary contacts, home location), answer questions in three interviews, have your blood taken and/or urine collected two or three times, and allow the researchers to access your medical files at health facilities in Wakiso District if you are a person living with HIV. Depending upon which group you are assigned to you may also participate in other activities. Each of these things are explained in more detail below.

Today you will provide contact information so that the researchers can reach you for this study. This information includes your phone number, phone numbers of two friends or relatives who know how to reach you, and the location of where you stay. This is so that we can contact you to schedule follow-up visits and to remind you about these visits. You only need to give the researchers phone numbers of people you are comfortable with the researchers contacting. Today an interviewer will ask you questions. That interview will last about 1 hour.

Approximately every 3 months during the study, if you are a person living with HIV, research staff will get information from your medical files at health facilities in Wakiso District. This is done to review your use of healthcare services, treatments, and medicines. This information will only be viewed by research staff, and will be recorded without your name. It will be recorded with your study identification number.

Today and about 6 months from today, research staff will take a small amount of blood (4mL, or 8mL if you are a person living with HIV) from your arm using a needle and/or ask you to provide a sample of your urine using a urine testing kit. Additionally, all women in the study and men who report taking Pre-exposure prophylaxis (PrEP) to prevent HIV infection will have their urine collected about 3 months from today.

Blood samples will be transported to a laboratory where blood drops will be placed on a paper. The paper with women's dried blood drops will be sent to a laboratory in Uganda to perform an HIV viral load test that will tell the researchers the amount of HIV in your blood during the prior month. Additionally, blood samples of men and women who drink alcohol will be transported to a laboratory where blood drops will be placed on a paper and sent to a laboratory in the U.S. to perform a test that will tell the researchers if you have consumed alcohol during the prior month. Urine samples will be tested shortly after collection to tell the researchers if you have taken your HIV (women) or HIV prevention (men taking PrEP) medication during the prior 2 weeks.

You may or may not get different parts of a new program to help people reduce their marital/relationship conflict and stress and alcohol use and remain engaged in HIV care. We don't know if the new program is better than the standard counseling and referrals.

Usual Referrals

If you are chosen to get the usual referrals you and your partner will participate in these things:

1) Today: The interviewer will ask you questions about your health, risk behaviors, and about your use of health services. The interview will last about 60 minutes. If you are identified as a person living with HIV, the interviewer will take down information from your health record card. The interviewer will also take a small amount of blood (4mL, or 8mL if you are a person living with HIV) from your arm using a needle and may collect a urine sample. You will also provide your contact information. **Female partners**: A counselor will discuss about your relationship, adherence, and clinic attendance with you and provide referrals for other services as appropriate. This counseling will last about 15 minutes. **Male partners**: A counselor will discuss about your alcohol use and relationship with you and provide referrals for other services as appropriate. If living with HIV, the counselor will also discuss adherence and clinic attendance. This counseling will last about 15 minutes.

2) 3 months: In about 3 months, an interviewer will ask you questions about your health, risk behaviors, and about your use of health services. The interview may take place at the clinic or another location of your choosing in this area.. The interview will last about 60 minutes. Some will have the option of completing the interview by phone, if no urine sample

is needed. **Female partners**: The interviewer will also ask you to provide a urine sample and test it using a urine testing kit. **Male partners.** If taking PrEP medication to prevent HIV infection, the interviewer will ask you to provide a urine sample and test it using a urine testing kit.

3) 6 months: in about 6 months, an interviewer will ask you questions about your health, risk behaviors, and about your use of health services. The interview may take place at the clinic or another location of your choosing in this area. The interviewer will also take a small amount of blood (4mL, or 8mL if you are a person living with HIV) from your arm using a needle and ask you to provide a urine sample and test it using a urine testing kit. The interview will last about 60 minutes.

4) Approximately every 3 months during the study: As described above, if you are identified as a person living with HIV, research staff will get information from your medical files at health facilities in Wakiso District.

New Program

If you and your partner are chosen to get the new program, you will participate in these things:

1) Today: The interviewer will ask you questions about your health, risk behaviors, and about your use of health services. The interview will last about 60 minutes. If you are identified as a person living with HIV, the interviewer will take down information from your health record card. The interviewer will also take a small amount of blood (4mL, or 8mL if you are a person living with HIV) from your arm using a needle and ask you to provide a urine sample and test it using a urine testing kit. You will also provide your contact information. **Female partners:** A counselor will discuss about your relationship, adherence, and clinic attendance with you and provide referrals for other services as appropriate. **Male partners:** A counselor will discuss about your alcohol use and relationship with you and provide referrals for other services as appropriate. If living with HIV, the counselor will also discuss adherence and clinic attendance. Counseling sessions will last about 70 minutes. Total time today: 2 hours and 10 minutes.

2) At least once a week during the 6 months of the study the researchers will call or send you a text message reminding you of the healthy living goals you discussed with the counselor in the first session. Text messages will not be about marital/relationship conflict and stress, HIV, or alcohol.

3) 2 weeks: You will attend a counselor-led group discussion about healthy living and marriage/relationship goals. About 5-8 persons of your same gender will be in the group. The group discussion will last about 90 minutes. The group discussion will take place in a private place in the community such as a community or health center.

4) 4 and 6 weeks: A counselor will meet with you and your partner together to discuss about healthy living and marital/relationship goals. This discussion will last about one hour. The

discussion will take place in a private place in the community such as a community or health center.

5) 8 and 10 weeks: You will attend a counselor-led group discussion about healthy living and marriage/relationship goals. About 3-5 other couples will be in the group. The group discussion will last about 90 minutes. The group discussion will take place in a private place in the community such as a community or health center.

6) 3 months: In about 3 months, an interviewer will ask you questions about your health, risk behaviors, and about your use of health services. The interview may take place at the clinic, another location of your choosing in this area, or by phone (if no urine sample is needed). The interview will last about 60 minutes. **Female partners:** The interviewer will also ask you to provide a urine sample and test it using a urine testing kit. **Male partners.** If taking PrEP medication to prevent HIV infection, the interviewer will ask you to provide a urine sample and test it using a urine testing kit.

7) 6 months: in about 6 months, an interviewer will ask you questions about your health, risk behaviors, and about your use of health services. The interviewer may also ask you questions about your experience in the program. The interview may take place at the clinic or another location of your choosing in this area. The interviewer will also take a small amount of blood (4mL, or 8mL if you are a person living with HIV) from your arm using a needle and ask you to provide a urine sample and test it using a urine testing kit. The interview will last about 60-75 minutes.

8) Approximately every 3 months during the study: As described above, if you are identified as a person living with HIV, research staff will get information from your medical files at health facilities in Wakiso District.

The individual and group counseling sessions will be audio-recorded so that the researchers can review the counselor's performance.

Who will participate in the study:

This study is being done in Wakiso District. We are inviting you to take part in this study because you live in Wakiso District, you are living with HIV or your partner is living with HIV, you drink alcohol or are married to or living with a partner who drinks alcohol. About 40 couples (80 people) will be included in this study.

The estimated duration of active participation will vary depending on whether you are chosen to receive the new program or standard counseling and referral. If you are chosen to get the usual referrals, it will take approximately 3 hours and 15 minutes of your time over the 6 months. If chosen to get the new program, it will take approximately 10 hours and 55 minutes of your time over the 6 months.

You do not have to be in this study. You are free to say "yes" or "no", or to drop out of the study after joining.

Risks/Discomforts:

There are no physical risks that will result from the interviews. Some of the questions, however, may be personal. For example, the interviewer may ask you about how much alcohol you use, your marital/ relationship conflict, or if you went to the clinic when the doctors told you to. Since these questions are personal, you might feel some discomfort during the interview. If you feel uncomfortable you may choose not to answer any questions that make you feel uncomfortable, or you may stop your participation in this study with no negative outcomes. The information taken will not be shared with hospital/clinic members or anyone outside of the research staff.

The risks from individual counseling sessions include feeling discomfort when you talk with the counselor about your marital/relationship conflict and stress, alcohol use, and HIV care. If you feel uncomfortable, you may choose not to talk about things that make you feel uncomfortable, and you may stop your involvement in this study with no negative outcomes at any time.

There is the risk that the information you give and the information that we take from your and/or your partner's medical files are not kept private. This is unlikely because this information will not include your or your partner's name. It will only include your study identification number. While it is unlikely, there is also the risk that your personal contact information will not be kept private. The "Confidentiality" section below explains how the researchers will protect your privacy.

If you are chosen to participate in the new program, there are risks associated with the group discussions. Because other people are also participating in the group discussion, there is a chance that what you say may be told to others outside the group. In signing this form, you are promising to keep what is said in the group discussion to yourself. However, we cannot guarantee that all will follow their agreement to keep the discussion private. Therefore, you can choose not to participate in this study. You can also choose not to discuss personal information that you would feel uncomfortable or at risk if people outside of this group knew this information.

Finally, this study involves taking a small amount of blood (4mL, or 8mL if you are a person living with HIV) from your arm. You may feel mild pain from the needle. The pain should stop soon after your blood is taken. There is a small chance the needle will cause bleeding, a bruise, or an infection. These risks are the same as if you had your blood taken for any medical test.

Benefits:

The benefit of taking part in this study is that you may learn ways to overcome challenges to accessing health care services and to reduce your marital/relationship conflict and stress and alcohol use. However, we cannot promise that you will get any benefits from this study.

Confidentiality:

Information collected for this study is private. We will do our best to keep the privacy of the information we gather from you but we cannot promise 100% privacy. The sponsor, the National Institutes of Health in the U.S.A., and the local Research Ethics Committee (REC) at Makerere University School of Public Health (SPH-REC), Uganda National Council for Science and Technology (UNCST), and Arizona State University Institutional Review Board may review study files to make sure that the study is being done correctly. The information we collect will only be looked at in summary and if the results of the study are made public through reports, presentations, or publications, your name and personal information will remain private. Your name will never be used.

The following steps will be used to protect the privacy of your data. Your name will not be connected with the information you say during the group discussions or interviews. The study staff (directors, managers, study assistants, etc.) will keep all study files in a locked room. The electronic audio recordings of the group discussion will be transcribed within 6 months of the session and the audio recordings will be destroyed once the information from the recordings is written down and double-checked for accuracy. The electronic audio recordings and transcriptions of the recordings will at all times be locked with a password and will have special protection. This special protection means that the information in the computer file will be locked in such a way that even if someone who is not allowed tries to access it, they would not be able to see any information. Any computer with such files will also have a password lock to stop anyone from using it who should not be. Only staff that are allowed to work on this project, the sponsor, and organizations that monitor that the study is being done correctly will have the ability to see your information.

Regarding your blood and urine samples, extracted medical record data, and interview data, we will never include your name on these data. Instead, all data will be labeled with a study identification number only. The study identification number will be a random 5-digit code number. A master key that links names and study identification numbers will be kept in a secure file separate from the data. The master key will be destroyed 1 year after the end of the study.

All data will be collected electronically and will at all times be locked with a password and will have special protection. This special protection means that the information in the computer file will be locked in such a way that even if someone who is not allowed tries to access it, they would not be able to see any information. Any computer with such files will also have a password lock to stop anyone from using it that should not be.

This consent form will be destroyed 10 years after the end of the study.

Alternatives:

An alternative is to not join the research study.

Your participation in this study is voluntary. You do not have to participate in this study. If you choose not to participate there is no loss of benefits that you normally get. You may choose to stop participating at any time without loss of benefits, which you normally get. Not

participating or deciding to quit the study, will not affect the health care services you normally get.

Whether you are eligible or not for the study, you will receive referrals to health and relationship services.

Cost:

The only cost of participation is the time you will be asked to give to the study. The time it will take for the group discussions, counselor sessions, blood draws, and urine sample collections, are detailed above in the "The estimated duration the research participant will take in the research project" section. There may be costs associated with transportation to and from the facilities where study visits/sessions will take place.

Compensation for participation in the study:

We do not expect study participation will lead to injury or permanent damage. However, by signing this consent form, you will not waive any of your legal rights or release the parties involved in this study from liability for negligence.

Reimbursement:

You will be paid for your time and possible transportation costs involved in participating in different parts of the study as follows: 15,000 Shillings for completing the interview today, 30,000 Shillings for completing the 3-month interview, and 35,000 Shillings for completing the 6-month interview.

If you are chosen to receive the new program if you complete the following activities you will be paid for your time and possible transportation costs: 25,000 Shillings for participating in the counseling session today and 35,000 Shillings each for the 2, 4, 6, 8, and 10 week sessions. Additionally, refreshments will be provided at each group session.

Questions about the study:

If you have any questions about taking part in this study, or if you think you may have been injured because of the study, call Dr. Janet Nakigudde at +256772407885.

Questions about participants' rights:

If you have any questions about your rights as a research subject, you can call the Chair of the Higher Degrees, Research and Ethics Committee (HDREC), Dr. Joseph Kagaayi on +256773785333.

Statement of voluntariness:

Your participation in the study is voluntary. You may join on your own free will. You do not have to participate, even if your partner has already consented. You have a right to withdraw

from the study at any time without penalty or loss of benefits to which you are otherwise entitled.

Dissemination of results:

We will not contact you with results of this study after this study is completed. However, results will be made available to healthcare providers in the Wakiso Health District.

Storage, sharing, and future research using the information collected for this study:

We may share your coded data with other researchers through the a data repository, specifically the National Institute of Mental Health (NIMH) Data Archive (NDA) system. A data repository holds research data and makes that data available for future use by the broader research community. Many data repositories have restrictions on who can add and access data.

If you allow us to share your coded research data with the NIMH data repository, other researchers can apply to this data repository to receive a copy of your research data for their own research.

If you allow your coded research data to be shared with other researchers, there are risks. There are researchers who may attempt to learn your identity without your consent. In addition, researchers who receive a copy of your research data may use your information for purposes you do not intend, including scientific research that you do not agree with or sharing it with others you do not know.

Your coded research in the NIMH data repository will be destroyed upon your request (see below). However, *once shared with other researchers*, the shared copy of your research data cannot be destroyed. You will likely not benefit directly by allowing your research data to be shared with the NIMH data repository.

You do not have to make any decisions right now. Sharing your research data with the NIMH data repository is **optional** and not required to participate in this study.

You may ask the research team to share or stop sharing your research data with the NIMH data repository at any time by contacting [Dr. Janet Nakigudde at +256772407885 or janet.nakigudde@mak.ac.ug)]. The research team will let you know if it is still possible to share your data with the NIMH data repository (for example, sharing may not be possible if the study has ended).

I give permission for my de-identified (coded) data to be shared with the NIMH data repository for future research as described above.

_____ Yes _____ No
Initials Initials

MAKERERE UNIVERSITY
SCHOOL OF PUBLIC HEALTH
APPROVED
VALID UNTIL
★ 08 MAY 2026 ★
RESEARCH & ETHICS COMMITTEE
P. O. BOX 7072, KAMPALA

Makerere University School of Public Health / Arizona State University
INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY – Intervention

Agreement to be Contacted for Participation in Future Research

We may contact you in the future about new research on HIV, marital conflict/stress, or alcohol use. If you are contacted, you can decide at that time whether or not you are interested in participating in the study. Being included in this study does not mean you will be enrolled in future studies; rather, you are only agreeing to be contacted about future research studies.

If you agree to be contacted for future research, we will retain your name and contact information (phone numbers, secondary contacts, home location). Additionally, we may contact you following this study to confirm that your contact information is updated.

I give permission to be contacted by the researchers of this study for participation in future research as described above.

_____ Yes _____ No
Initials Initials

Ethical approval:

The Makerere University School of Public Health Research and Ethics Committee (SPH-REC) and the Arizona State University Institutional Review Board has approved this consent form, as signified by the Boards' stamps. The IRB approval expires on the date indicated by the stamp on this document.

Consent:

..... has described to me what is going to be done, the risks, the benefits involved and my rights regarding this study. I understand that my decision to participate in this study will not alter my usual medical care. In the use of this information, my identity will be concealed. I am aware that I may withdraw at anytime. I understand that by signing this form, I do not waive any of my legal rights but merely indicate that I have been informed about the research study in which I am voluntarily agreeing to participate. A copy of this form will be provided to me.

_____ _____
Study Participant (signature or thumbprint) Date

_____ _____
Print Participant's Name Date

Makerere University School of Public Health / Arizona State University
INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY – Intervention

Witness Signature Date

_____ _____
Witness' Name Date

_____ _____
Signature of person obtaining informed consent Date

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★ 08 MAY 2026 ★
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