Study title: Development of an Intervention to Reduce Heavy Drinking and Improve HIV Care Engagement Among Fisherfolk in Uganda

NCT03919695

Informed consent version date 11/23/2020

Makerere University School of Public Health / San Diego State University / Mildmay Uganda
INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY – Intervention
Consent form version date:
23 November 2020

IMPORTANT THINGS TO KNOW ABOUT THIS STUDY

We are inviting you to join this research study. The purpose of the research is to help improve the health of male fisherfolk living with HIV.

We are asking people who join this study to attend between 3 and 6 visits/ sessions in person/via phone over 6 months. The study involves an interviewer asking you questions about your behavior and health, taking a small amount of blood from you, and may include counseling and/or services which may help you to improve your health.

We do not know if the counseling and services offered will help improve the health of male fisherfolk living with HIV and it could make male fisherfolk's health worse.

You do not have to join this study. These are the reasons you might want to join this study: you may learn ways to overcome challenges to accessing health care services and to reduce your alcohol use. These are the reasons you might not want to join this study: the time commitment, potential for experiencing discomfort during interviews or counseling sessions which ask personal questions, potential breach in confidentiality of information you provide, and mild pain from taking a small amount of blood from your arm using a needle. The interviewer will be someone trained by Ministry of Health standards to do blood draws.

We will give you details about the purposes, procedures, risks and possible benefits related to this study. We will explain other choices you have. We will also give you any other information that you need to make an informed decision about joining this study.

The following information is a more complete description of the study. Please read this description carefully. We want you to ask us any questions that will help you decide whether you want to join this study. If you join the study, we will give you a signed copy of this form to keep for reference in the future.

WHO SHOULD I CONTACT IF I HAVE QUESTIONS?

Local Principal Investigator: Nazarius Mbona Tumwesigye
Makerere University School of Public Health (MakSPH)
Phone: 0782 447 771
Email: naz@musph.ac.ug

Co-Investigator: Barbara Mukasa
Mildmay Uganda
Phone: 0772 700 816
Email: barbara.mukasa@mildmay.or.ug

U.S. Principal Investigator: Susan M. Kiene, San Diego State University, U.S.A.

WE ARE INVITING YOU TO JOIN THIS RESEARCH 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, and you are a male fisherfolk. About 160 participants will be included in this study.

The directors of this study are Dr. Nazarius Mbona Tumwesigye from Makerere School of Public Health and Dr. Susan Kiene from San Diego State University in the U.S.A. The sponsor of this study is the National Institutes of Health in the U.S.A.

Research is not the same as treatment, or other medical or psychological care or therapy. The purpose of research is to answer scientific questions.

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.

WHY ARE WE DOING THIS STUDY?

The purpose of this study is to learn how we might help improve the health of male fisherfolk living with HIV. We want to learn what makes it difficult for people to reduce alcohol use, take their HIV medications, and attend their clinic appointments and to find the best approaches to help them maintain and improve their health.

This study will test a new program to help people reduce their alcohol use and be engaged in HIV care compared to standard counseling and referrals. Half of the people 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 will have an equal chance of getting the new program or the standard counseling and referrals.

WHAT IS THE TIME COMMITMENT IF I JOIN THIS RESEARCH STUDY?

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 6 sessions/visits. The first visit will last about 2 hours. The other sessions/visits will last between 25 minutes and one hour each. Everyday for the next 6 weeks you will keep a written diary. Completing the diary each day will take about 4 minutes.

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.

WHAT WILL I BE ASKED TO DO IN THIS RESEARCH STUDY?

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 and sign this informed consent form. You will be given a copy of this consent form.

You will provide contact information so the researchers can reach you (phone numbers, village), answer questions in three interviews, have your blood taken twice, and allow the researchers to access your medical files at the Mildmay-supported health facilities in Wakiso District. 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 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, research staff will get information from your medical files at the Mildmay-supported 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 from your arm using a needle. The blood will be transported to Mildmay laboratory where blood drops will be placed on a paper. The paper with the dried blood drops will be sent to a laboratory in the U.S. to perform a test which will tell the researchers if you have consumed alcohol during the prior month.

You may or may not get different parts of a new program to help people reduce their 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 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. The interviewer will take down information from your health record card. The interviewer will also take a small amount of blood from your arm using a needle. You will also provide your contact information. A counselor will discuss your alcohol use, adherence, and clinic attendance with you and provide referrals for other services as appropriate. 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, another location of your choosing in this area, or by phone. The interview will last about 60 minutes.

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 from your arm using a needle. The interview will last about 60 minutes.

4) Approximately every 3 months during the study: As described above research staff will get information from your medical files at the Mildmay-supported health facilities in Wakiso District.

New Program

If you 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. The interviewer will take down information from your health record card. The interviewer will also take a small amount of blood from your arm using a needle. You will also provide your contact information. A counselor will discuss your alcohol use, adherence, clinic attendance, healthy living and savings goals with you and teach you about ways to manage your finances and save money. This counseling will last about 70 minutes. Total time today: 2 hours and 10 minutes.

2) Everyday for the next 6 weeks you will keep a written diary of money you spent and money you saved and what leisure activities you did when you were not working. Completing the diary each day will take about 4 minutes.

3) Two times each week during the 6 months of the study the researchers will send you a text message reminding you of the healthy living and savings goals you discussed with the counselor in the first session. These messages will not be about HIV or alcohol.

4) During the 6 months of the study you will receive you work payments via mobile money instead of cash. The researchers will help you make these arrangements with your employer.

5) 2 weeks: In two weeks the counselor will call you to discuss your alcohol use, adherence, clinic attendance, healthy living and savings goals. This will last about 25 minutes.

6) 4 weeks: You will attend a counselor-led group discussion about healthy living and savings goals. About 5-8 male fisherfolk will be in the group. The group discussion will last less than one hour. The group discussion will take place in a private place in the community such as a community center or in the clinic.

7) 6 weeks: You will attend a counselor-led group discussion about healthy living and savings goals. About 5-8 male fisherfolk will be in the group. The group discussion will last less than one hour. The group discussion will take place in a private place in the community such as a community center or in the clinic.

8) 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 private location of your choosing in this area, or by phone. The interview will last about 60 minutes.

9) 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 private location of your choosing in this area. The interviewer will

also take a small amount of blood from your arm using a needle. The interview will last about 60 minutes.

10) Approximately every 3 months during the study: As described above research staff will get information from your medical files at the Mildmay-supported 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.

WHAT ARE THE RISKS OR DISCOMFORTS INVOLVED IN THE STUDY?

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 sexual behavior, 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 counsellor about your 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 medical files are not kept private. This is unlikely because this information will not include your 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 "Will My Information Be Private" 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.

If you are chosen to participate in the new program there is also the risk that by receiving work pay by mobile money your employer may learn private information about you. This risk is low however because if the researchers help you to set up mobile money payments with your employer we will only share the fact that you are in a study involving mobile money payments. We will not disclose that the study is related to HIV or alcohol.

Finally, this study involves taking a small amount of blood 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 same as if you had your blood taken for any medical test.

WHAT IF I HAVE A PROBLEM FROM THINGS IN THIS STUDY?

We do not expect that you will be physically hurt from having your blood taken. If you do have an injury from this you will be given treatment free of charge at any public health facility.

We do not expect that you have any psychological problems from being in this study. If you do have a psychological problem from things like experiencing prejudice and discrimination because you have HIV study staff can give you information to help you get services that may be able to help you.

ARE THERE ANY BENEFITS TO PARTICIPATION?

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 alcohol use. However, we cannot promise that you will get any benefits from this study.

WILL MY INFORMATION BE PRIVATE?

Information gathered 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 ethics boards at Makerere University, Mildmay Uganda, and San Diego State University 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, your name and personal information will remain private.

The following steps will be used to protect the privacy of your data. Your name will not be connected with your answers to the questions in the interviews or to laboratory test results. The study staff (directors, managers, study assistants, etc.) will keep all study files in a locked room. Study files, including the information you give in the interview will be labelled with a study identification number only. The study identification number will be a random 5 digit 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 6 months after the end of the study. Paper files will be kept in locked study offices. Electronic audio recordings of individual and group counselling sessions 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. All computer files (e.g., interview data, audio recordings, lists, etc.) including personal information 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. 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 while it is stored with your personal information. Data that will be shared with others will be coded as described above to help protect your privacy. This consent form will be destroyed 3 years after the end of the study.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any U.S, federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a U.S. federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by National Institute on Alcohol Abuse and Alcoholism which is funding this project. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of harm to self or others.

DO I HAVE TO JOIN THIS STUDY?

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.

The National Institutes of Health, the sponsor of this study, and the ethics boards of Makerere University, Mildmay Uganda, and San Diego State University may choose to end the study at any time, for reasons that do not have to do with your healthcare.

WILL I BE TOLD ABOUT THE STUDY RESULTS?

We will share the results of the study through community meetings after the study ends.

WILL IT COST ME ANYTHING IF I JOIN THE STUDY?

The only cost of participation is the time you will be asked to give to the study. The time it will take for the interviews and the new program are detailed above in the “What will I be asked to do in this research study” section. There may be costs associated with using mobile money services.

WILL I BE PAID IF I JOIN THIS STUDY?

You will be paid for your time involved in participating in different parts of the study as follows: 15,000 Shillings for completing the interview today, 20,000 Shillings for completing the 3 month interview and 25,000 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: 15,000 Shillings for participating in the counseling session today (cash), 10,000 Shillings for the 2 week phone session, 20,000 Shillings each for the 4 and 6 week group sessions, 7,500 per week for 6 weeks for completing the daily savings and spending diary. We will also pay you 20,000 Shillings if by the 4 week session you have: (a) established a savings account (mobile or bank) and (b) transferred money to the savings account at least 3 times. Finally, we will provide you with a 10,000 transportation reimbursement per session to attend the 4 and 6 week sessions. Other than where noted above payments will be made by deposit into your mobile money account.

If you stop participation, you will only get payment for the activities you have done.

FUTURE STUDIES

With your permission the researchers may contact you about future studies that you may participate in.

WHAT IF I HAVE QUESTIONS ABOUT THIS STUDY?

If you have any questions about the study now, please ask. If you have questions later about the study, you may contact Dr. Nazarius Mbona Tumwesigye (0782 447 771). If you have any questions about your rights as a participant in this study, or if you face a study related injury, you may contact the Makerere School of Public Health IRB 0414-532207. At any time during the study you can contact the IRB for questions about study rights, problems, or to give your thoughts about the study.

CONSENT TO PARTICIPATE:

The Makerere School of Public Health, Mildmay Uganda, and San Diego State University Institutional Review Boards have approved this consent form, as signified by the Boards' stamps. The IRB must review the consent form yearly. The IRB approval expires on the date indicated by the stamp in the upper right-hand corner of this document.

Your signature below shows that you have read the information in this document and have had a chance to ask any questions you have about the study. Your signature also shows that you agree to be in the study and have been told that you can change your mind and take back your consent to participate at any time. The program director or a member of his/her study team has given you a copy of this consent form with information about whom to contact in case you have questions.

_____

Name of Participant (please print) Date

_____

Signature of Participant Date

_____
Signature of Research Staff Obtaining Consent Date

***If participant cannot write, in have him place their thumb print here _____ in place of a signature. _____ date*

_____
Signature of Witness to Consent for Participants Who Had Consent Form Read Aloud Date

CONTINUED MONITORING AFTER STUDY DROP-OUT:

If you decide to stop your participation in the study, it would still be useful to us to know how you do over the 6 months. We'd appreciate it if you would allow us to continue to take information about your use of healthcare services, treatments, and medicines from your medical files at the Mildmay-supported health facilities in Wakiso District.

___ If I drop out of the study, I allow you to take this information from my medical files.

___I do not allow for you to continue to take this information from my medical files if I stop participating in the study.

_____
Signature of Participant Date