

Agricultural Intervention for Food Security and HIV Health Outcomes in Kenya

Consent Form
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NCT02815579

SHAMBA MAISHA

An agricultural intervention for food security and HIV health outcomes

Consent to Participate in a Research Study

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Researchers' Statement: This is a study being conducted by researchers from the Kenya Medical Research Institute (KEMRI) and the University of California, San Francisco (UCSF).

The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. You may ask any questions about the purpose of the research, what happens if you participate, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called 'informed consent.'

You are being asked to participate in this study because you are

- HIV-positive
- Between 18 to 60 years old
- Are using antiretroviral therapy
- Either belong to a patient support group or demonstrate willingness to join a support group
- Have access to farming land and available surface water
- Have poor access to food and/or are malnourished based on your medical records during the last year
- Are willing to save no more than 2,000 KSH as a down payment for a small loan

Why is this study being done?

The purpose of the study is to learn whether helping people living with HIV improve their farming improves health, nutrition, and family income.

Who pays for this study?

This study is being paid for by the U.S. National Institutes of Health.

How many people are taking part in this study?

Up to 1040 people will be asked to participate in this study.

Study groups

There are two study groups. If you decide to take part in the study, you will be placed in one of the two groups based on the HIV clinic you attend. Your group will be chosen "by lot", for example, like flipping a coin to be in one of these two groups. You cannot choose your group, and the study staff cannot choose your group for you. You have an equal chance of being placed in one of the two groups. Once you are in a group, you cannot change to another group.

Participants in one of the groups will receive training on finances and farming. Participants in this group will be asked to pay a down payment of no more than 2,000 KSH to receive a small loan to purchase a human powered water pump, hosing, fertilizer, and certified seeds. Participants will be expected to repay the loan in full by sixteen months, starting with a four-month grace period of no-payment, followed by twelve months of monthly payments. Participants who do not save the down payment by the end of the finance training will be withdrawn from the study and will not receive the small loan.

Participants in the second group will receive standard of care at the clinic. At the end of this 2-year study, participants in this study group will be eligible for the finance training and those who pay the down payment of no more than 2,000 KSH will be eligible for a small loan to purchase a human powered water pump, hosing, fertilizer, and certified seeds.

What will happen if I take part in this study?

Here is what will happen if you agree to take part in the study:

- **Interview:** You will be interviewed by a staff member from our study. Over the next 2 years, a staff member will interview you five times at the clinic in a private room, usually on the day of your regular clinic visit. Each interview at the clinic will last about one hour and thirty minutes. A staff member will also visit your home or farm approximately five times to interview you there. Interviews at your home or farm will last about an hour and thirty minutes. Interview topics will include questions about your physical and mental health, diet, farming, income, relationships, sexual activity and substance use.
- **Adherence:** You will receive a bottle to record each time you open your bottle of antiretroviral (ARV) pills to measure how well you take your ARVs.
- **Body measurements:** We will measure your height, weight, and arm circumference five times at the clinic.
- **Blood tests:** A nurse or lab technician will collect blood samples from you three times at the clinic to measure the amount of HIV in your blood. The results of the blood tests will be available to you and to your healthcare provider.
- **Collecting information from medical records:** In addition to talking to you, research staff will gather information from your medical chart about your HIV illness, medications you take, and medical history for up to two years from the time you enroll in this study. Information will only be available to members of the research team and healthcare providers involved in your care.
- **Training & small loan:** If your study group is chosen to receive the finance and farming training and the small loan, you will attend these trainings and be required to save no more than 2,000 KSH for the small loan. If you do not save this money, you will not be able to continue in the study or get the small loan.

How long will I be in the study?

Participation in the study will last up to two years. There will be five study visits (today and every six months up to two years) at the clinic, approximately five home or farm visits for interviews (today and every six months up to two years). Each interview at the clinic and at home will last about one hour and thirty minutes.

Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study researcher 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, if you do not follow the study rules, or if the study is stopped.

What risks can I expect from being in the study?

- Social Risks. One potential risk of study participation includes social risks (e.g., risks to reputation) if information you reveal during the interview were to be disclosed outside of the research team. We will do our best to ensure that your personal information is kept private.
- Risk of discomfort. Some of the questions in the interviews may make you uncomfortable or upset. You are free to refuse to answer any questions you do not wish to answer, or stop the interview at any time without effecting your participation in the study.
- Potential loss of privacy or confidentiality. One potential risk of study involvement is loss of privacy. Your information will be handled with as much privacy as possible. In order to protect your name, only your ID number will be used. Information identifying you will be kept in a secure location. All identifying information will be omitted from any data distributed to others, or any publications to result from this study.
- Blood drawing risks: Drawing blood may cause temporary discomfort from the needle stick, bruising and infection. To minimize this risk, we will employ experienced phlebotomists or clinician to draw your blood.
- For more information about risks, please ask the study staff who is reading this form to you.

Are there benefits to taking part in this study?

Participants in both groups will be able to get free tests to show how much HIV is in their blood and their CD4 count. This may help their healthcare provider improve their care.

This study will help doctors learn more about how a farming intervention affects you and your medical condition, and it is hoped that this information will help in the treatment of future patients with conditions like yours.

What other choices do I have if I do not take part in this study?

You are free to decide whether or not to participate in this study. If you choose not to participate, you can still receive the usual care provided at the clinic.

Will my medical information be kept private?

We will do our best to ensure that your personal information is kept private, but we cannot guarantee total privacy. Your personal information may be given out if required by law. Information identifying you will be kept in a secure location. If study information is published or presented at scientific meetings, your name and other personal information will not be used. Organizations that may look at and/or copy your research records for study purposes include: KEMRI, UCSF, & UCSF's Committee on Human Research.

What are the costs of taking part in this study?

You will not need to pay anything for any of the study activities. However, if you are chosen to be in the study group that receives the finance and farming trainings, you will be required to pay no more than 2,000 KSH as down payment for your loan.

Will I be paid for taking part in this study?

You will be reimbursed for your time and travel expenses related to your participation in each interview for this study. For clinic based interviews, you will receive up to 800 Kenyan Shillings depending on the distance from your home to the clinic. You will receive up to 400 Kenyan Shillings for each interview conducted at your home or farm. You will be paid in cash immediately after you complete the interview.

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

Taking part in this study is your choice. You may choose whether or not to take part in this study. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care.

Who can answer my questions about the study?

You can talk to the researchers about any questions, concerns, or complaints you have about this study. Contact the study staff at 0732 390 992. You may also contact the secretary of the Ethics Review Committee, KEMRI at 020-272-2541 or 020-272-6781 or the *Committee on Human Research* at the University of California, San Francisco at 000-1-415-476-1814. Or you may write to: Committee on Human Research, Box 0962, University of California, San Francisco (UCSF), San Francisco, CA 94143. These committees are concerned with the protection of volunteers in research projects

Consent You have been given a copy of this consent form.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You can decide not to participate or to withdraw from the study at any point in time without penalty or loss of benefits to which you are entitled. If you decide not to take part in this study, there will be no penalty to you and you will not lose your regular medical care. **If you wish to participate in this study, you should sign below.**

Do you provide consent to participate in the study? ☐ Yes ☐ No _____ DATE

GIVEN BY:

NAME OF PARTICIPANT

SIGNATURE OF PARTICIPANT

BY:

NAME OF STAFF MEMBER

SIGNATURE OF STAFF MEMBER

WITNESSED BY:

NAME OF WITNESS

SIGNATURE OF WITNESS