



Consent form for cohort survey participants (Adult men)

Evaluation of the LINEA intervention

Name of researcher responsible for project:

Dr Joyce Wamoyi

National Institute for Medical Research, Mwanza Research Centre

Medical Street, Isamilo, P.O. Box 1462 Mwanza

Type of data collection:

- Cohort surveys
- In-depth interviews
- Focus group discussions

PART ONE: Participants information sheet

Introduction

We would like to invite you to take part in a research study. Joining the study is voluntary. Before you decide, you need to understand why the research is being done and what it would involve. One of our team members will go through this information sheet with you, and answer any questions you may have. Ask questions if anything you read is not clear or you would like more information. Please feel free to talk to others about the study if you wish. Take time to decide whether or not to take part.

What is the purpose of the study?

National Institute for Medical Research (NIMR), Amani Girls Home (AGH) and The London School of Hygiene and Tropical Medicine (LSHTM) are conducting research to improve the health and wellbeing of adolescent girls, men and their communities in Mwanza. We intend to get your thoughts and views on the radio drama program called Msichana wa Kati aired on the local radio station, and possibly what you have learnt from the LINEA curriculum sessions you might have participated in with a group of fellow men.

Why have I been asked to take part?

You have been invited because you live in one of the communities where this research study is planned to be implemented. Your community can be either one which will be reached by the radio drama called Msichana wa Kati on the local radio station, and possibly also one where the LINEA curriculum sessions will be implemented with groups of peers. We are inviting adult men aged 24 – 50 years and girls aged 13-15 years to take part in the study to understand their views towards the interventions.



Do I have to take part?

No, your participation is voluntary and confidential. This means you are allowed to not take part in this study, but your views and experiences are very important to us. Your decision will not affect the activities you have or will engage in as part of this research, or other activities happening in your community.

What will happen if I take part?

You will be invited to take part in one or two of the following activities: (i) two surveys (ii) three one-on-one interviews, and (iii) two group discussions with fellow men. These activities will take place in a location that is private and convenient for you, and your participation will depend on your willingness and availability. The surveys, interviews and group discussions will be conducted or led by a person of the same gender as you. We plan to conduct three surveys, this is the first, the second one will fall about a year later and the third will happen about a year after that. For the surveys and interviews, a researcher will ask you some questions regarding the health and wellbeing of men, adolescent girls and your community at large. They will also ask general questions about your sexual and reproductive health, including HIV status and relationships. The group discussions will involve a researcher leading a discussion to get you and your peer's views on a range of subjects including the Msichana wa Kati radio drama and the LINEA curriculum sessions in the case that your community was reached by these interventions.

In case you agree to participate in interviews or group discussions, we will ask for permission to record the discussions in order to capture all that you will have said and save time, as handwritten notes take longer. If you do not want to be recorded, you can choose not to participate. We will discuss the study together and give you a copy of this information sheet. If you agree to take part, we will then ask you to sign a consent form. Remember, agreeing to take part in on one of the mentioned research activities: survey, interview or group discussion does not mean that you will have to take part in future activities. We will invite you to take part in each before they begin, and like today you will have the opportunity to say no at any time.

What will I have to do?

Taking part in this research involves participating in some or all of the survey(s), interview(s) and group discussion(s) with fellow men where you will share views and opinions in response to questions asked by the researcher individually or in a group. Additionally, you will also need to participate in the LINEA curriculum sessions in case your community will be chosen for this particular intervention. The sessions will be 120 minutes each and occur every other week over 36 weeks.

For the surveys, interviews and group discussions, you will need to answer the questions the researcher asks to the best of your ability. Your views may not necessarily concur with others. We are interested in your personal views and therefore there are no right or wrong answers, all answers are correct, and you can share your opinions freely. Each survey will take about 60 minutes, an individual interview session will take about 1 hour to 1 hour and



half, and a group discussion will take about 1.5 to 2 hours. You will be offered a comfortable seat for the entire duration. The surveys, interviews and group discussion will be held in a private place where you cannot be overheard. You will also be offered a stipend of 5,000/Tanzanian Shillings to thank you for your time.

What are the possible risks and disadvantages?

We don't foresee this study having any major risks for you, your family or community. It is possible that some of the questions the researcher asks might make you feel uncomfortable, or make you remember difficult things about your past, in which case please share this with the researcher and they will be able to support you.

What are the possible benefits?

We cannot promise the study will help you individually. However, the information we get from the study will help us improve the health and wellbeing of men, girls and other people in your community, and other communities across Tanzania. You may find the Msichana wa Kati radio drama and LINEA curriculum educational and enjoyable.

What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If you remain unhappy and wish to make a formal complaint you can contact the Tanzanian National Health Research Ethics Committee (NathREC) at ethics@nimr.or.tz or +255 22 2121400.

Physical Address:
NIMR Headquarters
2448 Barack Obama Drive
Ground Floor, NathREC office

Post Address:
Chairperson, NathREC
National Institute for Medical Research
P.O. Box 9653
Dar es Salaam, Tanzania

NIMR and Amani Girls Home will work together to refer you to any help you might need from what you may share during this interview. This can be legal, protection or counseling assistance.

Can I change my mind about taking part?

Yes. You can withdraw from the study at any time. You just need to tell one of the researchers that you don't want to be in the study anymore and this will not affect you in anyway. We may still use the data collected up until your withdrawal, unless you ask us to delete it.

What will happen to information collected about me?

All information collected about you will be kept private. Only the study staff from NIMR, AGH, and the authorities who checks that the study is being carried out properly will be allowed to look at information about you. Data will also be sent to study staff at the London School of Hygiene and Tropical Medicine, but this will be anonymised. This means that any information about you will have your name and address removed so that you cannot be recognised.



Your personal details will be kept in a different safe place to the other study information, and will be destroyed within 10 years of the end of the study. The data may be made available to other researchers worldwide for research and to improve knowledge and the health and wellbeing of men, girls and their communities. Your personal information will not be included and there is no way that you can be identified. The audio recordings of the interviews and focus group discussions will be deleted once the transcription has been verified.

What will happen to the results of this study?

The study results will be published in journals and shared at conferences so that other researchers, implementers and policy makers can learn from them. Your personal information will not be included in the study report and there is no way that you can be identified from it. We may describe your responses along with others who take part, but only without your name or personal information attached to them.

Who is organising this study?

The National Institute for Medical Research is the sponsor for the research and they have full responsibility for the project including the collection, storage and analysis of your data.

Who has checked this study?

All research involving human participants is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and approved by The London School of Hygiene and Tropical Medicine Research Ethics Committee. The Ethics Committee at the National Institute of Medical Research (NIMR) in Tanzania has also reviewed the study and has agreed that it is safe for us to ask people to take part.

Further information and contact details

Thank you for taking time to read this information leaflet. If you think you will take part in the study I will review the comprehension list of questions with you and later you will sign the consent form.

If you would like any further information, please talk to the NIMR staff member who is showing you the information sheet, who can answer any questions you may have about the study. You can also contact the supervisor of the study.

Study Principal Investigator: Dr Joyce Wamoyi

Address: P.O. Box 1462, Mwanza

Phone number: +255 752 145 910



PART TWO: Comprehension assessment

The researcher obtaining informed consent from an adult participant or an adolescent girl should also complete this short questionnaire.

Ask the participant the following questions to check they understand everything on the information sheet. If there are any questions that the participant cannot answer, return to the information sheet to help explain it to the participant.

Can you tell me in your own words what this research is about?

[Interviewer: ensure participant understands that this research is about men and girl's health and wellbeing. If they do not understand this, please clarify.]

Do you have any questions about the research?

[Interviewer: answer any questions from the participant.]

Can you tell me in your own words what you will need to do to take part?

[Interviewer: ensure participant understands that to take part in this research they will need to participate in one or two of the following: surveys each takes about 60 minutes, one-on-one interviews each takes 1 hour to an hour and half, group discussions each take 1.5 hours to 2 hours, and participating in the LINEA curriculum sessions every other week for 36 weeks in case his/her community is involved].

Do you understand that it is ok to stop taking part at any time?

[Interviewer: ensure participant understands that they can stop participating in any study activity at any time.]

Can you describe in your own words the possible consequences (negative and positive) of taking part in the research?

[Interviewer: ensure the participant understands that there are likely no negative consequences of taking part in this research. While we cannot promise an individual gain, their participation will also likely benefit their community. In the unlikely event that they do experience any negative consequences, they will be referred to someone who can help.]

Can you tell me what will happen to the data collected about you if you choose to take part in this study?

[Interviewer: ensure the participant understands that all information collected about them will be kept private and confidential. Information about what they have said in the survey may be used in publications, but their name and any information linking their responses back to them will be excluded. Their information will be destroyed within 10 years.]

Do you know who to contact if you have any questions or concerns?

[Interviewer: ensure participant understands that they can contact the study supervisor Dr Joyce Wamoyi if they have any questions or concerns. Her contact information is on the information sheet provided to them.]

Are you happy to take part in the research study?

[Interviewer: ensure participant is happy to take part in the research study before proceeding.]



PART THREE: Consent form

Statement	Participant: please initial or thumbprint* each box
I have had the information explained to me by study personnel in a language that I understand. I have had the opportunity to consider the information, ask questions and the questions have been answered satisfactorily.	
I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my access to services or legal rights being affected.	
I understand that data collected during the study may be looked at by authorised individuals from the National Institute for Medical Research, Amani Girls Home and the London School of Hygiene and Tropical Medicine. I give permission for these individuals to have access to information I will provide.	
I agree for my conversations during the interviews or group discussions to be audio recorded.	
I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers.	
I agree that my answers without my name attached can be used for future studies.	
I am happy to receive updates on the study during the study	
I agree to take part in this study	
I confirm I have not participated in another LINEA survey recently called the cross-sectional survey. <i>Your data collector will explain further.</i>	

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Printed full name of participant

Signature of participant

Date

Thumb print of participant*



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Printed full name of impartial witness*

Signature of impartial witness*

Date

The researcher to collect the contact number of the participant:

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Printed full name of participant

Contact number

I attest that I have explained the study information accurately in Kiswahili and was understood to the best of my knowledge by the participant, and that he/she has freely given their consent* in the presence of the above named impartial witness who is literate; able to read and understand Kiswahili (where applicable).

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Printed name of person obtaining consent

Signature of person obtaining consent

Date

[*Only required if the participant is unable to read or write]