Malawi-Liverpool-Wellcome Trust
Clinical Research Programme
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Title: Creating demand for Fishermen's schistosomiasis and HIV services (FISH): piloting and delivery of a 3-arm cluster randomized control trial (cRCT) in Malawi

Participant ID

Principal Investigator: Dr. Augustine Choko
Funder: Wellcome Trust, UK and National Institute for Health Research
Sponsor: Liverpool School of Tropical Medicine
Study site: Mangochi, Malawi

[The following text must be read to the participant, who must have their own copy to take home]

Introduction

Hello. My name is ……, and I am working with Malawi Liverpool Wellcome Trust (MLW) on behalf of Dr. Augustine Choko and colleagues. We thank you for accepting to participate in this endline survey. In this component of the study, we are interested in understanding what happened since you enrolled in the study. Therefore, we will ask you some questions and do some biological measurements. As you may recall, this study is taking place in fishing communities here in Mangochi to investigate best approaches to increase demand for HIV and schistosomiasis services.

Request for your Voluntary Participation

I would like to ask you to voluntarily participate in this endline survey. Please note that you were not selected to participate in this endline survey because you are HIV positive or negative, or that because you have schistosomiasis. We consider that your participation in this project would help us understand the best ways to serve fishing communities with HIV and schistosomiasis services. This is very important because the Ministry of Health may consider implementing successful strategies studied here nationally.

Procedure / what the study involves

Please note that we are carrying out these procedures on everyone who accepts to participate in this endline survey. All participants are asked a few questions about themselves and/or their social and sexual networks. All participants are asked to give 10 mls of urine sample for us to test for genital schistosomiasis. Some participants are asked to give two more urine samples on two consecutive days as part of quality assurance. Participants who self-report an HIV positive self-test will undergo confirmatory HIV testing with 7 mls of blood taken by finger-prick.

Note that we are able to give you treatment for schistosomiasis as part of the study even when the test is negative if you need the treatment as part of the national guidelines. All

participants with a positive confirmatory HIV test will be referred to the nearest ART clinic.

Your participation is entirely voluntary. If you decide to take part, you may withdraw from any interview or procedure in this study any time. You also have a right not to answer any particular question or questions that will be asked or to give a urine or blood sample. Declining to participate in this study will not affect any health services that you or any person related to you may be currently receiving or may require in future.

Confidentiality

All personal information collected in this study will be kept strictly confidential. I will not share the information you provide with anyone who is not part of this research. But it may be shared with fellow researchers and may also be published through meetings or journals in a manner that does not reveal your identity. Before sharing in this manner, the information from you will be combined with that from other research participants. Information which could identify you or anyone related to you will never be released. This also means that names of study participants, including your own will not be included when sharing the data. Data collection equipment and the data collected will be kept with identifiers, locked, and only accessible to people that have authorised access. All data will be handled in accordance with the applicable laws in Malawi.

The blood and urine samples that you provide will be used only for the purposes that have been stated in this document. Any samples that remain during tests or after completion of all tests will be destroyed.

Risks

You may be uncomfortable with some of the questions that I will ask. You may also feel slight pain during the finger prick although this is a normal procedure in most diagnoses with rapid tests. You are perfectly entitled to refuse to discuss issues that you do not want to or not to give a blood or urine sample.

Benefits

There are no direct benefits to you in your taking part in this study. However, what we learn from this study would help the Ministry of Health to make important decisions regarding how best to serve fishing communities with HIV and schistosomiasis services. It is not yet known if services including the offer of HIV self-test kits would increase demand for HIV and schistosomiasis services. Therefore, your participation would benefit many others in the future.

Compensation

You will not receive payment for participating in the study. You will however, be compensated for your time and the minor procedures that you will undergo amounting to MWK4,000.

Contact details

This research has been approved by the College of Medicine Research Ethics Committee (COMREC), and the Liverpool School of Tropical Medicine Research Ethics Committee. If you have any questions regarding your rights as a research participant, or concerns on how you have been treated in the study, please feel free to contact **Dr. Augustine Choko** [+265 (0) 999 577 452] or [achoko@mlw.mw]. If you have any questions regarding your rights as a research participant, or concerns on how you have been treated in the study, please feel free to contact COMREC Secretariat, College of Medicine, Private Bag 360, Chichiri, Blantyre 3 or call on 01871911 ext 334.

Consent Declaration

If you agree to voluntarily participate in the study, please sign or write your initial or your thumb print below to show that you understand the information above and that your consent is given voluntarily.

		Participant Initials / thumb print
1	I have received and read or had read to me the information sheet C03a: Participant Information and Consent Form for endline Interview - Eng v1.3 of 26 Aug 2020 provided by the Researcher that explains in detail the reasons for the study.	----------
2	I have understood the purpose of the research.	----------
3	I have asked all the questions that I have about the purpose of the research and feel that I have enough information about it.	----------
4	I understand the reasons for this study.	----------
5	I am willing to take part in the study.	----------
6	I understand what I will be required to do if I participate in the study.	----------
7	I know that I have the right to leave the study at any time or to refuse to answer any questions.	----------
8	If I do not agree to take part in this study, I understand that I will not be penalized for doing so by the researcher nor by any medical service providers in the future.	----------
9	I am willing to give 10 mls of urine for genital schistosomiasis testing	
10	**[ONLY APPLIES TO PEOPLE WITH POSITIVE HIV SELF-TESTS]** I am willing to give 7 mls of finger-prick blood for confirmatory HIV testing.	
11	**I voluntarily agree to take part in this study**	----------

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Participant name Date Signature or thumb print

If the participant gave verbal consent, please enter the name of person who witnessed the consent here, and their signature:

Name of Witness (BLOCK CAPITALS)	Date	Signature or thumb print
Name of person obtaining consent	Date	Signature