STUDY INFORMED CONSENT

Uptake of Voluntary Medical Male Circumcision among Men Attending a Sexually Transmitted Infections Clinic in Lilongwe Malawi

NCT number NCT04677374
Document Date 12/11/2020

University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants (In-depth Interview)

Consent Form Version Date: v1.1 dated December 11, 2020
Wits REC study # M200328
UNC IRB Study # 19-2559
NHSRC Study # 19/10/2412

Title of Study: UNCPM 21920 - Uptake of Voluntary Medical Male Circumcision among Men attending a Sexually Transmitted Infections Clinic in Lilongwe Malawi.

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Funding Source and/or Sponsor: The National Institutes of Health through the Malawi HIV Implementation Scientist Training (MHIRST) and the Fogarty International Center

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CONCISE SUMMARY

The purpose of this study is to evaluate the impact of using transport reimbursement, intensified health education, cell phone tracing and clinic escort in increasing the uptake of voluntary medical male circumcision at this clinic. We are interested in assessing the acceptability and feasibility of this intervention at this clinic. Participants will include uncircumcised men ≥ 18 years attending the Bwaila STI clinic (BSC). Participants will participate in in-depth interview, which will focus on your opinion on whether or not you find the intervention being tried in this study acceptable or feasible at this clinic. The questions are not a test, so there is no right or wrong answer.

There are minimal risks associated with participation in this study since we will only be performing in-depth interviews. You may choose not to answer any questions if you are uncomfortable with answering any of them. There is no direct benefit to you for participating in this study.

If you are interested in learning more about this study, please continue to read below.

What are some general things you should know about research studies?
You are being asked to take part in a research study. To join the study is voluntary. You may choose not to participate, or you may withdraw your consent to be in the study, for any reason,

without penalty.

Research studies are designed to obtain new knowledge that may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care providers, or your employer. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study. If you decide that you would like to take part in this study, we will ask you to sign or thumbprint this consent form.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
The purpose of this study is to evaluate the impact of using transport reimbursement, intensified health education, cell phone tracing and clinic escort in increasing the uptake of voluntary medical male circumcision at this clinic. We are interested in assessing the acceptability and feasibility of this intervention at this clinic.

Are there any reasons you should not be in this study/interview?
You should not be in this study if you are not willing to participate in the interview process.

How many people will take part in this study/interview?
If you decide to be in this study, you will be one of about 20 people from this clinic to participate in this study.

How long will the interview last?
The interview is expected to last between 30 minutes and 45 minutes.

What will happen if you take part in the study?
If you agree to take part, you will ask you questions concerning your opinion on whether or not you find the intervention being tried in this study acceptable or feasible at this clinic. The questions are not a test, so there is no right or wrong answer. The role of the interviewer is to listen and to respect your point of view. You may refuse to answer any questions that you do not feel comfortable answering. You may also say that you do not know the answer to a question.

Note Taking

The interviewer will take notes during the interview process. The notes will be for some of the important things you will say during the interview. Identifiable information will not be included in the notes or in any written data or report resulting from the study.

Recording the interview

We would like to request your permission to record the interview because we cannot write down all your answers quickly enough and might miss some important things that you will say in response to some of the questions that you will be asked if we do not record them. It is essential for you to know that the recording and notes will remain confidential and your identity will not be disclosed. The tape may be listened to by supervisors, the investigator and qualitative researchers at the University of North Carolina (UNC) Project Malawi and the University of Witwatersrand School of Public Health whose offices. Recordings of interviews will be transcribed and transcripts of interviews will not bear any identifiable information. Recordings and notes will be kept under a double-locked system. The information will then be coded and written up as part of my PhD thesis.

Check the line that best matches your choice:

_____ OK to record me during the study

_____ Not OK to record me during the study

What are the possible risks and benefits from being in this study?

Research is designed to benefit by gaining new knowledge. There is little change your will benefit from being in this research study. Information gathered from this study may help in the implementation of this intervention. There will be no direct benefits to anyone who participates in the interviews. Similarly there will be no negative consequences for individuals who do not want to be interviewed. You will not be compensated for taking part in the interview.

How will information about you be protected?

The information that you provide during the interview will be kept confidential. All interviewees will be assigned a participant identification number (PID) and PID will be used on interview notes and transcriptions. The PIDs will only be known to the researchers. We undertake that all information provided by you will be used only for the purpose of the study. Everything that you say when answering the questions will be treated as private and confidential to the extent permitted by law. This means that apart from the person who asks you the questions, no one will know how you answered. Identifiable information will not be revealed in any written data or report resulting from the study. The answers given by participants will be combined and analysed to look for common themes and experiences. The combined information will be written up in my PhD thesis. Participants' de-identified data will not be used or distributed for any future research without additional consent.

What is a Certificate of Confidentiality?

Most people outside the research team will not see your name on your research information. This includes people who try to get your information using a court order in the United States. One exception is if you agree that we can give out research information with your name on it or for research projects that have been approved under applicable rules. Other exceptions are for information that is required to be reported under law, such as information about child or disabled abuse or neglect or certain harmful diseases that can be spread from one person to another.

Personnel of a government agency sponsoring the study may also be provided information about your involvement in the research study.

What if you want to stop before your part in the study is complete?
You can withdraw from this study at any time, without penalty. You can inform the investigator or any member of the study team about your decision to discontinue participation in this study. Your decision to discontinue the study will not affect your ability to access care and services at this clinic. The study team member is obliged to assist you with the appropriate care or service. You have the right to report a study team member to the Bwaila Hospital management if you are denied service due to study discontinuation. The investigators also have the right to stop your participation at any time if they feel that the interview is not going accordingly.

Will you receive anything for being in this study?
You will not receive anything for your participation in this study.

Will it cost you anything to be in this study?
It will not cost you anything to be in this study.

Who is sponsoring this study?
This research is funded by The National Institutes of Health through the Malawi HIV Implementation Scientist Training (MHIRST) and the Fogarty International Center. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may, anonymously if you wish, the Head of Secretariat for the Malawi Health Sciences Research Committee Dr. Collins Mitambo at +265 999 39 79 13

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Title of Study: UNCPM 21920 - Uptake of Voluntary Medical Male Circumcision among Men attending a Sexually Transmitted Infections Clinic in Lilongwe Malawi.

Principal Investigator: Mitch Matoga, MBBS, MS

I have been given the information sheet on the study entitled: Uptake of voluntary medical male circumcision among men attending a sexually transmitted infections clinic in Lilongwe Malawi.

I have read and understood the Information Sheet and all my questions have been answered satisfactorily.
I understand that it is up to me whether or not I would like to participate in the interview and that there will be no negative consequences if I decide not to participate.

I also understand that I do not have to answer any questions that I am uncomfortable with and that I can stop the interview at any time.

I understand that I can decide whether or not the interview should be audio recorded and that there will be no consequences for me if I do not want the interview to be recorded.

I understand that information from the recording will be transcribed and transcripts will no identifiable information. I understand that if the interview is recorded, the audio files will be destroyed after the PhD degree is conferred.

I understand that I can ask the person interviewing me to stop the recording, and to stop the interview altogether, at anytime.

I consent voluntarily for the researcher/ PhD student to record the interview.

I understand that the researcher/PhD student involved in this study will make every effort to ensure confidentiality and that my name will not be used in the study reports, and that comments that I make will not be reported back to anybody else. I consent voluntarily to participate in the interview for this study.

I have been given telephone numbers that I may call if we have any questions or concerns about the research.

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Principal Investigator: Mitch Matoga, MBBS, MS

Participant's Agreement:
If you have read this informed consent, or have had it read and explained to you, and understand the information, and you voluntarily agree to participate in this research study, **please sign your name, make your mark or place your thumbprint** in the signature area at the bottom of this page**.**

PART A: LITERATE PARTICIPANT

Participant is literate: ☐

_____	_____	_____
Participant Name (print)	Participant Signature	Date
_____	_____	_____
Study Staff Conducting Consent Discussion (print)	Study Staff Signature	Date

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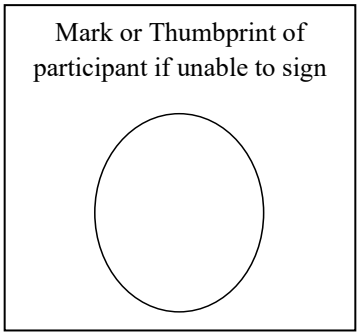
PART B : ILLITERATE PARTICIPANT

Participant is illiterate: ☐

The study staff must complete this section, ONLY if an impartial witness is available.

The **study staff must write participant's name and date of consent below.**



_____ Participant Mark or Thumbprint _____
Participant Name (print) Date

Participant Name and Date Written By…….on…...……

_____ _____ _____
Study Staff Conducting Consent Discussion (print) Study Staff Signature Date

_____ _____ _____
Impartial Witness Name (print) Impartial Witness Signature Date