

ISSUES: The impact of tourism on sexual networks, health, and health system utilisation in The Gambia and the UK

SCC:	1638	Protocol:	
------	------	-----------	--

Sponsor & Funder:

What is informed consent?

You are invited to take part in a research study. Participating in a research study is not the same as getting regular medical care. The purpose of normal medical care is to improve one's health. The purpose of a research study is to gather information that may be useful in the future for the whole population. It is your decision to take part and you can stop at any time without giving any reason.

Before you decide you need to understand why the study is being done and what will happen in it. Please take time to read the following information or get the information explained to you in your language. Listen carefully. You can ask questions if there is anything that you do not understand. Ask for it to be explained until you are satisfied. You may also wish to speak to your spouse, family members or others before deciding to take part in the study.

If you decide to join the study, you will need to sign or thumbprint a consent form saying you agree to be in the study. You will receive a copy of the consent form.

Why is this study being done?

The aim of this study is to understand the sexual and reproductive health needs of different groups in The Gambia, and assess how well they are currently provided. For example, many people in the Gambia have sexually transmitted infections, often because people find it difficult to use condoms every time they have sex with someone else. We are trying to understand how people make choices in their personal lives, and whether they are able to access the healthcare that they need.

What does this study involve?

Participation in this study will involve taking part in a group discussion with around seven or eight others. The discussion will last about one hour. You have the right to refuse to answer any of the questions that you are asked. If you agree for us to do so, we will record the interview. We will keep all the information you tell us confidential. Taking part in this study will not affect the medical care you receive.

What harm or discomfort can you expect in the study?

We do not expect that you will encounter any harm as part of this study. The study will only involve taking part in an interview, where we will discuss topics regarding to your experience in accessing care. The only discomfort you may experience is if we discuss topics that are uncomfortable, or in sharing your personal data. We will keep all data confidential. However, if you feel any discomfort or wish to withdraw, you may do so at anytime without providing a reason for doing so.

What benefits can you expect in the study?

Taking part in this study will not benefit you directly. However, by taking part in this study you will contribute to improving the Gambian health system and the services that will be available in Gambia.

Will you be compensated for participating in the study?

We will give you 100 dalasi as compensation for your time and MRC will provide transport or give you back the money for your transport.

What happens if you refuse to participate in the study or change your mind later?

You are free to join the study or not and you are free to stop being in the study any time without giving a reason. If you do not want to continue in the study, we will not use the information already collected from you.

How will personal records remain confidential and who will have access to it?

All information that is collected about you in the study will be kept strictly confidential. Your personal information will only be seen by the study team members, the sponsor and if necessary the Ethics Committee and Government authorities.

Who should you contact if you have questions?

If you have any questions or are worried you can call Dr Melisa Martinez-Alvarez (+221 404 9586 /+220 203 4761) or Dr Matthew Quaife (+442079272669) and you can always call the personal numbers of the MRC workers given to you. Please feel free to ask any question you might have about the study.

Who has reviewed this study?

This study has been checked by scientists at the Medical Research Council, by the Gambia Government/MRC Joint Ethics Committee and Research Ethics Committee of the London School of Hygiene and Tropical Medicine. The Ethics Committees protect your rights and wellbeing, and has given permission for it to take place.

CONSENT FORM

Participant Identification Number: |_____|

(Printed name of participant)

 I have read the written information **OR** I have had the information explained to me by study personnel in a language that I understand, and I

- confirm that my choice to participate is entirely voluntarily,
- confirm that I have had the opportunity to ask questions about this study and I am happy with the answers that have been provided,
- understand that I allow access to the information about me by the persons described in the information sheet,
- had enough time to think about whether I want to take part in this study,
- agree to take part in this study.

 I agree for the discussion to be recordedParticipant's signature/
thumbprint*

Date (dd/mmm/yyyy)

Time (24hr)

Printed name of witness*

Printed name of person
obtaining consent

I attest that I have explained the study information accurately in _____ to, and was understood to the best of my knowledge by, the participant. He/she has freely given consent to participate *in the presence of the above named witness (where applicable).

Signature of person obtaining
consent

Date (dd/mmm/yyyy)

Time (24hr)

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