MOSSIE-GO STUDY FOCUS GROUP DISCUSSIONS INFORMATION AND INFORMED CONSENT

STUDY TITLE: Evaluation of the protective efficacy of a spatial repellent to reduce malaria prevalence in Uganda: study protocol for a cluster-randomized double-blinded control trial

SHORT TITLE: The Mossie-GO trial

PRINCIPAL INVESTIGATORS: Dr Robert Jones (Arctech Innovation, UK) and Dr Jane Achan (Malaria Consortium, Uganda)

SPONSOR: Africa Power

STUDY-RELATED CONTACTS: If you have any questions, would like to withdraw or report a medical problem please contact a member of your Village Health Team or nearest health facility.

GENERAL INFORMATION ABOUT THIS STUDY

We wish to seek consent / assent from you to participate in a focus group discussion (FGD) for your opinions and experiences with the Mossie-Go device. Consent means agreeing to take part in this research study. You have the right to decide if you want to take part in the study or not. There will be no penalty or loss of benefits if you do not agree to participate or choose to leave the discussion at any point. Your participation in this FGD will not impact your access to the Mossie-Go device or current or future medical care. Throughout this process, please feel free to ask us if there is anything that is not clear or if you would like more information.

In order to complete this form, you must be a member of a community participating in the study (see Household ICF for full study overview). This form aims to obtain consent for community feedback on the Mossie-Go device.

What is malaria?
Malaria is an important cause of death and serious illness, particularly among children and pregnant women in Uganda. It is a disease transmitted by the bite of a mosquito infected with malaria parasites. Symptoms of malaria include fever, headache and vomiting, and if not treated quickly, it may lead to death. You can reduce but not completely remove the risk of malaria by sleeping under an insecticide-treated bed net.

What is the purpose of the study?
Spatial repellents have been demonstrated to provide protection against malaria infection by repelling the mosquito. The team behind this study, Africa Power, have developed a device that releases a spatial repellent called transfluthrin into the air. This device, called Mossie-GO, has a small battery that is charged by solar power so that it can actively release transfluthrin even if your house does not have electricity. This study will help us to determine if the Mossie-GO device and disc is effective in reducing malaria in the study sites selected in Uganda.

This part of the study will help us to determine if the Mossie-GO device is acceptable for users, used as intended and to understand how we can improve the device. We also aim to understand the willingness to pay for the device for future commercialization if the device is effective.

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS FOCUS GROUP DISCUSSION?

Why am I being asked to participate in this focus group discussion?

You are within a village / cluster which has been selected for this study. We intend to collect feedback on the device use and experience from a variety of groups that may include, but are not limited to, village health workers and community leaders.

What will happen if I take part?

If you consent to this part of the study, we will ask you to come to a central meeting venue in your community and contribute to questions regarding your opinions and experience with the device. We will also ask about your willingness to pay for the Mossie-Go device and for refills for the device. These discussions will aim to last no more than 90 minutes and you will be in a group of approximately 8-10 people from your community to get a comprehensive set of opinions on the Mossie-Go device. You will only need to participate once. The sessions will be recorded and transcribed for analysis.

What will I have to do?
You will need to participate in a focus group discussion and share your experiences and opinions on the Mossie-Go device.

Do I have to take part?
You are not required to participate in the focus group discussion. Your decision to participate or to withdraw your household from participation in the overall study will not affect the care they will receive at your local clinic in any way. You can withdraw from the focus group discussion at any time without giving reasons. If you chose not to participate, you will still have access to the device and the same level of clinical care.

WHAT ARE THE RISKS AND BENEFITS OF THIS FOCUS GROUP DISCUSSION?

What are the possible risks and disadvantages?
There is no increased risk or disadvantage from taking part in this study. You may feel uncomfortable discussing some issues such as willingness to pay, but you do not have to answer any questions if you choose not to.

What are the possible benefits?
We cannot promise the study will help you but the information we get from the study will help our knowledge and understanding of malaria control and use of the Mossie-GO device.

Compensation
You will be compensated fifty thousand Uganda shillings (50000 shs) for participation in the focus group discussions.

Confidentiality statement
The records concerning your participation are to be used only for the purpose of this research project Participants' names will not be used in any report resulting from this study. Any information obtained in connection with this study will be kept strictly confidential and locked away. Only authorized

members of the study team will have access to information linking your name with participant numbers. After completion of the collection of material, data will be anonymised and identifying information will be destroyed. Material and data from this study will then be kept for 10 years. This is a legal requirement of the funder. All data will be collected, processed, stored and handled in accordance to the Data Protection Act 2018.

Questions, adverse event reporting and freedom to withdraw from the study

Africa Power hold insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you may be eligible to claim compensation. If you have any question concerning this study, please contact a member of your Village Health Team or the Principal Investigator/Co-Investigator Contact Dr. Jane Achan or Dr. Asadu Sserwanga at the following numbers: +256-772-410183 or +256-782-429777. Results from the study will be communicated to your community.

In case you want to contact an independent person, not related to the study, about the research study itself or your rights as a research participant, you can contact the Chairman of Ethics Committee: Dr. Thomson Lakwo, Tel: +256772438311

An adverse event is any untoward medical occurrence that occurs whilst you are recruited in the study. This could be, for example, a cold, broken leg, or a reaction to the chemical repellent. Adverse events will be monitored at each study visit by a study staff member, however if you would like to report an adverse event at any other time, please contact your local Village Health Team, local health facility or the numbers listed above for study staff members.

Who has reviewed this study?

This study has been reviewed and approved by a panel of scientists at Arctech Innovation, Malaria Consortium, The Vector Control Division Research and Ethics Committee and the Uganda National Council for Science and Technology. These institutions consist of scientists and lay persons to protect your rights and wellbeing. The study has also been reviewed and approved by the Research Ethics Committee at Arctech Innovation.

FOCUS GROUP DISCUSSION INFORMED CONSENT FORM

Participant Name: _____

Participant Identification Number: |__|__|__|__|__|__|__|__|__|__|

☐ 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 focus group discussion and I am happy with the answers that have been provided,
- had enough time to think about whether I want to take part in this focus group,
- understand the focus group discussion procedures
- agree to take part in this focus group.

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

Printed name of participant _____

Participant signature/thumbprint* ☐

_____
Date (dd/mmm/yyyy) Time(24hr)

Printed name of witness* _____

Printed Name of Person obtaining consent _____

Signature of Person obtaining consent _____ _____
Date (dd/mmm/yyyy) Time(24hr)

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