

Information Leaflet for Households

Low Cost Floors to Control Tungiasis

Institution	Investigators
ICIPE	Ulrike Fillinger,
KIRDI	Paul Mwitari
Dabaso Tujengane	Shadrack Nyawa, Lynne Elson

Introduction

Tungiasis is also known as Jiggers. These are a flea which burrows into the skin of people's feet and grows rapidly causing much pain and itching.

Who is carrying out this study?

This study is being carried out by ICIPE in collaboration with KIRDI and Dabaso Tujengane. ICIPE is an international organization based in Kenya to study insects that are important to humans. Kenya Industrial Research and Development Institute (KIRDI) is a Kenyan research institute developing industrial goods. Dabaso Tujengane is a CBO based in the Watamu-Mida area attempting to control jiggers in the community.

What is this study about?

The study is trying to develop a new hard floor for houses which does not allow jiggers to survive and is cheap enough for everyone to use in their home.

Some of the questions we will try to answer:

1. What are the traditional methods that were or are used to make floors hard?
2. Can the new floor protect people from getting new jiggers after we treat them?
3. Can the new floor prevent jiggers from living on the house floor?
4. Is the new floor acceptable to people living in the house?
5. Is the new floor affordable for the people who need it most?

Procedures

To do this we will hold some small meetings with people from the community to ask them about traditional methods used to harden the floor, those that are used now, or were in the past. After we have designed a new floor that we think will be good, we will put this floor in the houses of some families here to test if they protect from jiggers. The families will be selected carefully as those living in a house with a dirt floor and having at least 2 people with jiggers. They will be assigned to receive either, the new floor, a concrete floor or no floor. Before we put the floor in the house we will ask some questions of the family members and the house. We will examine the feet of all family members for jiggers and will ask each of them questions about how the jiggers affect them. All members with jiggers will be treated according to the County standard. After we have put the floors, we will return every month for 4 months to examine everyone again. At the end of 4 months we will ask the family some questions about the floor and if it made any difference to their lives. At the end, the families who did not receive a floor, will be given either the new floor or a concrete floor.

Why do you want to talk to us and what does it involve?

- Your family has been chosen to participate in the study through a random process which ensures all families in the area with a dirt floor and 2 cases of jiggers have the same chance of participating, without preference. We will be including 36 families/houses in the watamu-Mida area.

Are there any risks or disadvantages to taking part?

- The interviews will take about 1 hour and the examinations of feet for jiggers will take about 10 minutes for each person.
- The main risk from participating is that your neighbours will probably find out that your family have jiggers.

Are there any advantages to taking part?

- You will be donated a hard floor for your house for free. This may be a floor of concrete or a new floor. You may receive this floor at the beginning of the study or after 4 months, decided by the random process that we will use.

Who will have access to the information you give?

- All of our documents will be stored securely in locked cabinets and on password protected computers. The knowledge gained from this research will be shared in summary form, without your name, with the Ministry of Health.
- In future, information collected or generated during this study may be used to support new research by other researchers in Kenya and other countries. In all cases, we will only share information with other researchers without including your name and where you live, and will replace this information with number codes. Any future research using information from this study must first be approved by a local or national expert committee to make sure that the interests of participants and their communities are protected.
- This study has many scientists working together to understand jiggers and we will need to share the information we collect with them. They are at ICIPE in Nairobi and Mbita, Kenya, in KIRDI in Nairobi, at Dabaso Tujengane in Dabaso and in Durham University, England. We will do this in ways that do not reveal your name.
- When the study is finished we will need to share the results and the information we collected with other scientists around the world, health and education officers. This will only be done in a way that does not share your name and has been approved by the KEMRI Scientific and Ethics Review Unit. Some of this will be in special storage places on the internet.

Who has allowed this research to take place?

Before any work begins, all research at ICIPE has to be approved by a national committee who look carefully at planned work. They must agree that the research is important, relevant to Kenya and follows nationally and internationally agreed research guidelines. This includes ensuring that all participants' safety and rights are respected.

What will happen if I refuse to participate?

All participation in research is voluntary. You are free to decide if you want to take part or not. If you do agree you can change your mind at any time without any consequences.

What if I have any questions?

You are free to ask me any question about this research. If you have any further questions about the study, you are free to contact the research team using the contacts below:

Dr. Ulrike Fillinger, International Centre of Insect Physiology and Ecology, Kenya (**ICIPE**), Duduville Campus, Nairobi 00100. ufillinger@icipe.org, mobile: 0791-845259.

If you want to ask someone independent anything about this research please contact:

The Head, KEMRI Scientific and Ethics Review Unit, P. O. Box 54840-00200, Nairobi;
Telephone numbers: 0717 719477; 0776 399979 Email address: seru@kemri.org

16.7 Head of Household's Consent Form

Low Cost floors to control tungiasis

Village _____

I have had the study explained to me. I have understood all that has been read/explained and had my questions answered satisfactorily.

☐ **Yes please tick I agree to allow my family take part in this research**

☐ **Yes please tick I agree for the interview/discussion to be recorded**

I understand that I can change my mind at any stage and it will not affect me or my child in any way.

Adult's Signature/thumb print: _____ **Date:** _____ **Time:** _____

Adult's name: _____

study ID no. _____

Where the adult cannot read, a witness* may observe consent process and sign below if needed:

I attest that the information concerning this research was accurately explained to and apparently understood by the subject and that informed consent was freely given by the subject.

Witness' signature: _____ **Date** _____

Witness' name: _____ **Time** _____

**A witness is a person who is independent from the study team or a member of staff who was not involved in gaining the consent.*

[Following section is recommended, and where verbal consent is obtained, must be signed by person undertaking informed consent.]

I have followed the study SOP to obtain consent from the [participant/guardian]. S/he apparently understood the nature and the purpose of the study and consents to the participation [of the child] in the study. S/he has been given opportunity to ask questions which have been answered satisfactorily.

Designee/investigator's signature: _____ **Date** _____

Designee/investigator's name : _____ **Time** _____

(Please print name)

THE PARENT SHOULD NOW BE GIVEN A SIGNED COPY TO KEEP