ISRCTN62801024 https://doi.org/10.1186/ISRCTN62801024

Developing low-cost house floors to control sand flea disease (jiggers) in Kenya

Submission date
29/06/2023

Recruitment status
No longer recruiting

Registration date
07/07/2023

Overall study status
Completed

Last Edited
13/12/2023

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Tungiasis is a neglected tropical skin disease caused by sand fleas, the adult female of which burrows into the skin of the feet. The parasite rapidly expands its body size by a factor of 2000. The growth causes inflammation with immense itching, pain and debilitation. With no good treatment available people cut out the fleas using plant thorns and dirty blades causing more damage and suffering. The embedded flea lays eggs out of the skin into the soil where they develop into larvae and 3 weeks later adults emerge from pupae ready to infect the same person or another person. Several studies have shown that the main source of infection is inside people's homes since they have floors of sand or soil. The best way to control tungiasis is to enable people to build houses with sealed, hard floors in which the flea larvae cannot live. In this project we aim to develop and test a hard floor that is affordable for the poorest families, who are the ones most affected by tungiasis.

Who can participate?
The study enrolled households in Kilifi county in Kenya with an earthen floor and at least two tungiasis cases.

What does the study involve?
Houses were randomly allocated to have either a low-cost floor, a concrete floor, or no additional floor.
Floors were installed in houses in December 2019 and children in all houses monitored for infection once a month for 10 months.

What are the possible benefits and risks of participating?
The benefits of participating in the study were receiving a hard sealed floor in the house and all infected children were treated for tungiasis. The main risk was exposure of the infection status of family members to neighbours.

Where is the study run from?
International Centre of Insect Physiology and Ecology (Kenya)

When is the study starting and how long is it expected to run for?
April 2019 to February 2023

Who is funding the study?
The study was funded with a pump-prime grant from UKRI-MRC through the BOVA Network

Who is the main contact?
Dr Ulrike Fillinger of the International Centre for Insect Physiology and Ecology, Nairobi, Kenya; ufillinger@icipe.org

Contact information

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Principal investigator

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Protocol serial number
KEMRI-SERU-NON-KEMRI 652

Study information

Scientific Title
Developing low-cost house floors to control Tungiasis in Kenya

Study objectives
Sealing house floors will prevent development of off-host stages of Tunga penetrans and therefore transmission

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 08/02/2019, KEMRI-SERU (PO Box 54840, Nairobi, 00200, Kenya; +254 722205901; ddrt@kemri.go.ke), ref: NON-KEMRI-652

Primary study design
Interventional

Study design
Feasibility study

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of tungiasis among children under 18 years

Interventions
A low-cost floor retro-fitted into 12 houses of families with at least two cases of tungiasis. A second intervention group of 12 houses received a local standard concrete floor and the control group received no floor until the end of the study. The heads of households were randomized to study arms through a public lottery event.
Floors were installed in 24 houses in December 2019 and children in all 36 houses monitored for infection once a month for 10 months.

Intervention Type
Other

Primary outcome(s)
Proportion of participating children with live fleas embedded in their feet as detected by eye at midline (4 months) and endline (10 months).

Key secondary outcome(s)
1. Infection intensity of infected children measured by counting the number of all embedded fleas in both feet of participants at midline (4 months) and endline (10 months).
2. Acute symptom scores of infected children measured by counting the number of zones (9 in

each foot) exhibiting each symptom (thermographic hotspot, desquamtation, fissures, ulcers, abscess) at midline (4 months) and endline (10 months).

Completion date
12/02/2023

Eligibility

Key inclusion criteria
1. Households with at least two children infected with tungiasis and having at least 5 embedded fleas each
2. House with an unsealed floor
3. Houses with a maximum floor area of 36m²
4. Head of household willing and able to move out of the house while the floor is installed and provide informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 Months

Upper age limit
18 Years

Sex
All

Total final enrolment
36

Key exclusion criteria
1. Households with a concrete sealed floor
2. Houses larger than 36m²
3. Household not willing or able to move out of the house while the floor is installed

Date of first enrolment
09/10/2019

Date of final enrolment
22/11/2019

Locations

Countries of recruitment
Kenya

Study participating centre
Dabaso Tujengane
P.O. Box 770
Watamu
Kenya
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Sponsor information

Organisation
International Centre of Insect Physiology and Ecology

ROR
https://ror.org/03qegss47

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during the current study will be stored in a publicly available repository associated with the publication.

IPD sharing plan summary

Stored in publicly available repository, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		12/12/2023	13/12/2023	Yes	No
Participant information sheet			04/07/2023	No	Yes