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Does providing a sealed, washable domestic floor to households in rural Kenya improve health?

Submission date
12/06/2023

Recruitment status
No longer recruiting

Registration date
14/06/2023

Overall study status
Completed

Last Edited
12/06/2023

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The aim of this study is to learn about the impact of household flooring on health in rural Kenya, and test whether providing an improved (cement-stabilised, washable) floor improves the health of children and their care providers.
The main questions the study aims to answer are:
1. What is the effect of providing a sealed, washable floor on the prevalence of infections that cause diarrhoea, intestinal worms and sand flea infections?
2. To what extent does the intervention reduce contamination of floors with pathogens within the home?
3. What is the effect of the intervention on the wellbeing of caregivers and children?
4. Over the course of a year, do the new floors remain undamaged, with no cracks?
5. Do participants living with the new floors, and the masons that helped to install the floors, like them and feel they are practical and affordable?

Who can participate?
This study is being conducted in villages in Bugoma and Kwale counties in Kenya. Members of households with unimproved earthen floors within these villages will be able to participate if they have a resident child under 5 years of age. Household dwellings must also be structurally sound so that laying the floor does not cause damage, and participants will need to be willing to move out of their homes for a week whilst the floors are laid.

What does the study involve?
Half of the recruited households will be randomly chosen to receive the new floor in addition to some support on how to care for the floor and keep it clean. The other half of households will not receive anything at first, but at the end of the research project will also receive a new floor. Before the new floors are installed, the investigators will make several assessments in all study households. These will include a survey to measure household characteristics; a stool survey, to measure how many people are infected with diarrhoea-causing microorganisms and parasitic worms; a jigger flea examination among children; wellbeing assessments among children and caregivers; and soil sampling to identify microorganisms on the floor of the household.

When households receive the new floor, participants will have to move out of their house for up to 7 days during installation. Participants will also be asked to attend some group meetings to discuss ways of taking care of the floor and keeping it clean.
Assessments will be repeated 12 months after the floor has been delivered, and additional interviews will be held with a small number of randomly selected participants. Throughout the 12 months following the delivery of the intervention, investigators will make unannounced visits to households to check the condition of the floor. Participants will also be offered treatment for parasitic worm infections after assessments have been completed at the start and end of the study.

What are the possible benefits and risks of participating?
The main benefit of taking part will be receiving a new cement-stabilised floor. Participants will additionally be offered treatment for parasitic worm infections and tungiasis infection. Trained builders will oversee the installation of the floors however it is possible that installing the floor may cause some superficial or structural damage to the existing building. Participating in group meetings may also take up time and will require a household member to travel to a central location within the village.

Where is the study run from?
The study is run by a collaboration based in Kenya (the Kenya Medical Research Institute [KEMRI]; the Jomo Kenyatta University of Agriculture & Technology [JKUAT], and the International Centre of Insect Physiology & Ecology [icipe]) and the UK (London School of Hygiene & Tropical Medicine [LSHTM]). The study is being conducted in villages in Bugoma and Kwale counties in Kenya, and is implemented in participants' homes.

When is the study starting and how long is it expected to run for?
September 2022 to December 2024

Who is funding the study?
This work was supported by UK Research and Innovation (UKRI) Global Challenges Research Fund (GCRF) grant number MR/T029811/1, as supported by Research England

Who is the main contact?
1. Dr Charles Mwandawiro
2. Dr Rachel Pullan, rachel.pullan@lshtm.ac.uk
3. Dr Ulrike Fillinger

Contact information

Type(s)
Principal investigator

Contact name
Dr Rachel Pullan

ORCID ID
https://orcid.org/0000-0001-9844-1362

Contact details
London School of Hygiene & Tropical Medicine, Keppel Street
London

United Kingdom
WC1E 7HT
+44 (0)7772241148
rachel.pullan@lshtm.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
MR/T029811/1

Study information

Scientific Title
Evaluating the impact of an improved household flooring intervention on enteric infections in children under 5 years of age and parasitic infections amongst all household members in rural settings in the counties of Bungoma and Kwale, Kenya

Acronym
SABABAU

Study objectives
The main questions the study aims to answer are:
1. What is the effect of providing a sealed, washable floor on the prevalence of infections that cause diarrhoea, intestinal worms and sand flea infections?
2. To what extent does the intervention reduce contamination of floors with pathogens within the home?
3. What is its effect of the intervention on the wellbeing of caregivers and children?

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 16/02/2023, LSHTM ethics committee (Keppel Street, London, WC1E 7HT, United Kingdom; +44 (0)20 7927 2221; ethics@lshtm.ac.uk), ref: 28307

Study design
Multicentre interventional open-label two-arm household cluster randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of enteric infections and tungiasis in children and soil-transmitted helminthiasis in all ages living in rural Kenya

Interventions
The flooring intervention will involve retrofitting a cement-stabilised floor that is sealed, washable and durable and that covers the total interior floor space of a household dwelling. The intervention will additionally include a behaviour change component aiming to promote sustained adoption of appropriate domestic hygiene behaviours.

The first two activities will be conducted in the intervention arm at month 0, and in the control arm at the end of the study after all data collection is complete:
1. A low-cost, cement-stablised floor shall be installed in each room of the dwelling (including the kitchen area) to meet the following requirements: (i) non-absorbent, durable and smooth; (ii) possess good wear resistance; (iii) acceptable appearance; (iv) be affordable. The proposed structure will consist of a base layer made from compacted cement-stabilized murram and a final sand and cement mortar finish. All materials required to build the floor will be provided by the study. Floors will be installed by trained masons supervised by the investigators, with the support of additional laborers. Household members will not be expected to contribute to labour or costs of laying floors, but they will need to vacate their dwellings for up to 7 days whilst floors are laid and cured. The logistics around this will be discussed in detail with community leaders, and trial participants, during initial community engagement activities.
2. Group meetings facilitated by the investigators will be held periodically post-intervention to allow households to provide peer support on routines or challenges relating to living with the new floor and to give space to allow mutually accepted norms and standards around floor cleaning and maintenance to be established among intervention households. These group meetings will be complemented by individual household meetings which will take place at 4 weeks and 8 weeks post-intervention, which will serve to help households develop and adhere to plans around floor hygiene, personal storage, livestock housing, and cooking arrangements.
3. Annual mass treatment for STH infections (400 mg albendazole) and treatment of tungiasis in those affected by heavy infections (at 0 and 12 months) according to county DoH recommendations will be provided in both study arms.

This study will take place in two study sites; one within Kwale county (Dzombo ward) and the other in Bungoma county (South Bukusu ward and Kabula ward). Randomisation is by household using a simple random lottery and will be conducted after the baseline assessments.

Intervention Type
Other

Primary outcome(s)
1. Enteric infections: Prevalence of enteric infections in children under 5 years old measured using PCR analysis of stool at baseline and 12 months after receiving the floors. Pathogens identified from those observed at baseline using a multipathogen panel on a subset of 100 samples.
2. Tungiasis infections: Prevalence of tungiasis (detected through clinical examination of hands and feet) in children under 15 years old at baseline and 12 months after receiving the floors.
3. STH infections: Prevalence of at least one STH infection (hookworm, acsaris and trichuris infections; detected through Kato Katz of stool samples) in all household members 12 months and older at baseline and 12 months after receiving the floors.

Key secondary outcome(s))
1. Gastrointestinal illness measured using caregiver-reported symptoms at baseline and 12 months

2. Severity of acute and chronic tungiasis-associated pathology in children <15 years assessed using clinical severity scores at baseline and 12 months
3. Quality of life for children aged 8 to 14 years assessed using the standardised EQ5D-Y tool at baseline and 12 months
4. Quality of life in primary caregivers assessed using the standardised EQ5D tool at baseline and 12 months
5. Prevalence of Ascaris lumbricoides infection in all household members >1 year assessed using Kato Katz at baseline and 12 months
6. Prevalence of hookworm infection in all household members >1 year assessed using Kato Katz at baseline and 12 months
7. Prevalence of Trichuris trichiura infection in all household members >1 year assessed using Kato Katz at baseline and 12 months
8. Contamination of floors with eggs, larvae, pupae and adults of T. penetrans, assessed through entomology soil surveys at 6 months

Completion date
31/12/2024

Eligibility

Key inclusion criteria
1. Resident in a household with a child under 5 years of age
2. Dwelling where child under 5 sleeps meet structural criteria (unimproved earthen flooring throughout, structurally sound)
3. All household members willing to temporarily relocate whilst floors are laid

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
All

Sex
All

Key exclusion criteria
1. No child under 5 years of age resident in the household
2. Dwelling where a child aged under 5 years sleeps has improved floor (i.e. cement or tiled) or is not structurally sound
3. Household is intending to move within the next 12 months

Date of first enrolment
12/04/2023

Date of final enrolment
31/08/2024

Locations

Countries of recruitment
Kenya

Study participating centre
Dzombo ward
Kwale
Kenya
-

Sponsor information

Organisation
London School of Hygiene & Tropical Medicine

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Government

Funder Name
UK Research and Innovation (UKRI) Global Challenges Research Fund (GCRF) through the Medical Research Council (MRC)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository (https://datacompass.lshtm.ac.uk/)
The type of data stored: deanonymized individual-level quantitative data (basic attributes and outcome data)
Data in this repository are publicly available
Date of availability will be 31/12/2025
Consent from participants for data sharing was obtained
Data will be anonymised by removal of personally identifiable information (names, age, address, SES information etc summarised to asset scores)

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.3	30/01/2023	12/06/2023	No	No