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Evaluating the impact of an improved household flooring intervention on enteric and parasitic infections in rural settings in the counties of Bungoma and Kwale, Kenya.

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3. Abstract

Rudimentary floors are difficult to clean and often damp or dusty, providing an ideal environment for the survival of faecal pathogens and parasites. Resulting contamination of hands, feet and objects that encounter these surfaces may increase the risk of diarrhoea and parasitic infections. Cross-sectional surveys consistently show associations between household flooring and health outcomes, although there is little if any robust experimental evidence. This study will assess the contribution of household flooring to human health, through the evaluation of an improved household flooring and behaviour change intervention that will be delivered in two distinct settings in rural Kenya (Kwale county and Bungoma county). The study will evaluate the impact of the intervention on enteric infections, soil-transmitted helminthiasis, and tungiasis through implementation of a cluster randomised trial enrolling 440 households across the two sites. The feasibility, acceptability and durability of the

intervention will be assessed by an accompanying process evaluation adopting a mixed methods approach. This study will provide vitally needed evidence on the role of household floors as a remaining pathway for transmission of enteric and parasitic infections, as well as the feasibility and acceptability of providing improved floors as public health interventions.

4. Lay summary

Title

Does upgrading the floor in a home from earth to cement also improve the health of the people who live there?

Background

Clay, sand and earth floors inside and around homes can be difficult to keep clean and often remain damp or dusty, providing a good environment for the survival of parasites, bacteria and viruses that can harm human health. Resulting contamination of hands, feet, food, and objects that touch unclean floors may increase the risk of diarrhoea and parasitic infections among household members. In fact, many observational studies have suggested that clay, sand and earth floors may increase risk of childhood diarrhoea and jiggers and can harbour larvae and eggs for parasitic worms. Despite this, there are few studies that specifically investigate if and how providing an improved floor – that is, one that is solid and can be kept hygienically clean and dry – acts to improve health. This study aims to address the lack of evidence around flooring and health by running a research project in two sites in rural Kenya (Kwale county and Bungoma county).

What questions are we trying to answer?

We are aiming to uncover what impact household floors have on the number of parasitic worm infections, enteric infections, and jigger flea infections in our study communities. We want to know if having a cement floor makes a difference to people's happiness. As well as this we want to explore whether having a cement floor will change the way people carry out their daily routines and if it reduces the number of disease-causing microorganisms that can be found on the floor.

Where is the study taking place, how many people does it involve and how are they selected?

The study will take place in one or two villages in Kwale and Bungoma county and will involve 440 households (around 2640 individuals) across both sites. We aim to include all eligible households within selected study villages. To be eligible, households must have a child under the age of 5, have a home that only has an earthen floor, and have a home that is stable enough to have a new cement floor installed within. The study will involve a trial, where half of the recruited households will be randomly chosen to receive a new cement-based floor in their current home 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, after we have finished making our assessments, they will also receive a new floor.

What does the study involve for those who are taking part?

Before the new floors are installed, we will make a number of assessments in all of our study households. These will include a household survey – collecting data on household characteristics; a stool survey, to allow us to see 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 see if microorganisms can be found on the floor of the household. We will repeat these assessments again 12 months after the floor has been delivered. As well as this we will hold interviews and household observations with a small number of randomly selected participants at the end of the study. Throughout the 12 months following delivery of the intervention we will make unannounced visits to households to check the condition of the floor. Household members will also be offered treatment for parasitic worm infections after our assessments at the start and end of the project.

When households receive the new floor (either at the start of the project or at the end) they will have to move out of their house for a period of up to 7 days while the installation is ongoing. Household members will also be asked to attend some group meetings in the run up to and after the floor has been delivered – to discuss ways of taking care of the floor and keeping it clean.

What are the risks and benefits involved in taking part?

The benefits are that all households participating in the main part of the study will receive a new floor – either at the start or the end of the project. Household members will also receive free treatment for parasitic worm infections. The risks are that the installation may cause either cosmetic or structural damage to their homes. We will take every precaution to ensure that dwellings that are not suitable to have a new floor installed either make necessary improvements before the installation or are excluded from the trial. Additionally we will conduct thorough training with local fundis to make sure that the installation of the new floors is carried out to a very high standard.

How will the study benefit society?

This study will develop an acceptable and scalable flooring intervention that has the potential to have broad application for rural households across Kenya. Findings from this this research will improve our understanding of important social determinants of health, helping guide environmental health priorities in Kenya and beyond.

When does the study start and finish?

The study aims to start in February 2022 and will continue for 18 months.

5. Background

Access to adequate, safe and affordable housing is highlighted in the UN Sustainable Development Goals as vital to ensuring all people can fulfil their potential in a healthy environment. The need for better, healthier homes is pronounced in sub-Saharan Africa, where upwards of 840 million people are estimated to live in inadequate housing [1]. Structurally deficient housing can expose residents to multiple health risks, including many important infectious diseases [2, 3]. Rudimentary household flooring (earth, sand or clay) that is difficult to clean and is often damp can provide an ideal environment for the survival of many faecal pathogens and parasites such as the off-host stages of *Tunga penetrans* (jiggers/sand fleas) and hookworm larvae.

Diarrhoeal diseases are one of the leading causes of global paediatric morbidity and mortality – accounting for 446,000 deaths and 40 million disability adjusted life years (DALYs) annually in children-under-five [4]. Commonly resulting from a viral, bacterial or parasitic infection transmitted via the faecal-oral route, the burden of disease for diarrhoea is disproportionally carried by communities based in low-resource settings, where coverage of safe water, sanitation and hygiene services is often poor and effective healthcare is not widely accessible. Evidence suggests that homes with rudimentary floors can have high levels of bacterial contamination [5], and can also be host to diarrhoea-causing viruses and protozoa [6, 7]. Widespread contamination of the domestic floor environment with these pathogens puts infants and children at particularly heightened risk of exposure as they explore environments with their hands and commonly perform hand-to-mouth actions [8-10]. Many previous studies have shown that prevalence of childhood diarrhoea and infections with diarrhoea-causing pathogens are more common in households with rudimentary floors compared to those with cement-based or other improved types of floor [11-13], especially when local environmental contamination is high due to inadequate sanitation or living in close proximity to animals [5, 14, 15].

Rudimentary household floors can also host soil-transmitted helminth (STH) species [16-18]. Soil-transmitted helminths are one of the world's most common infections, affecting around 1.5 billion people and causing considerable morbidity through a wide variety of health outcomes including abdominal pain, anaemia, stunting and delayed cognitive development in children [19, 20]. Human infection can occur through the fecal-oral route (*A. lumbricoides, T. trichiura*) or through larvae directly penetrating the skin (hookworm), making rudimentary household floors an ideal setting for transmission. A study in western Kenya identified high concentrations of STH eggs on the floors of areas used for food preparation, cooking, and bathing [16]. Cross-sectional and cohort studies have routinely demonstrated significant and meaningful associations between rudimentary household flooring and increased prevalence of STH infections among children [21-23].

Tungiasis is an inflammatory skin condition caused by parasitic sand fleas (*Tunga penetrans*). It is responsible for considerable morbidity and poor quality of life in numerous tropical and sub-tropical areas of the Americas and Sub-Saharan Africa, including parts of Kenya [24]. The disease is chronically under researched and there is a subsequent paucity of data on prevention, treatment, and burden of disease for which there are no accurate regional or global estimates. The home environment is known to be a key domain of transmission and previous research has linked rudimentary flooring with increased rates of tungiasis [25, 26].

Observational studies consistently show associations between flooring and the health outcomes outlined above. Evidence from experimental studies involving flooring interventions is very limited but from what is available they demonstrate tangible benefits to health and wellbeing [27]. In 2005, an evaluation of a major programme in Mexico that provided more than 34,000 households with cement flooring revealed that replacing mud with cement floors in households with children under five resulted in a 19.6% reduction in parasite infections, 12.8% reductions in diarrhoea and 20.1% in anaemia prevalence, and improvements in cognitive development [28]. The study also reported a notable reduction in mothers' depression and perceived stress levels, possibly attributed to less time spent cleaning and repairing floors [28]. A forthcoming study in Bangladesh found even greater

impacts on health, with pilot data suggesting a 75% reduction in childhood diarrhoea [29]. This limited evidence suggests that while flooring interventions may be able to deliver significant improvements in community health, there is an urgent need for high-quality experimental data that can accurately and reliably quantify the impact of such interventions.

5.1. Formative research

In 2021 formative research was carried out in study villages in Kwale county, Bungoma county, and Narok county to help inform the development of a flooring intervention for these communities (IRB protocols: KEMRI SERU Reference 4157 and LSHTM Ethics Ref 22916). Specifically, this work aimed to identify current housing conditions, map daily routines, and explore household development priorities.

Our observations revealed that while building culture varied between sites in terms of dwelling layout and use of building materials, all study villages had extremely low coverage of improved household floors (Kwale 20%, Bungoma 23%, Narok 10%). Dwelling environments were observed to be vulnerable to contamination with enteric and parasitic pathogens through close contact with livestock (most notably poultry), lack of consistent access to sanitation (Narok), and inability to effectively remove pathogens from earthen floors through sweeping alone.

In Kwale and Bungoma, communities demonstrated a strong demand for sealable, washable floors, that was derived from anticipated health benefits, improvements in social status, and time-saved on housekeeping routines. In Narok, demand for new floors was less explicit with community stakeholders citing other developments, such as sanitation provision, as possibly more important. In addition to this, a large majority of the traditional dwelling types in Narok were deemed to be unsuitable for the retrofitting of new floors.

As a result of this research, villages in Bungoma and Kwale County were deemed to be appropriate for inclusion in this trial, and an intervention package was developed (section 9 of this protocol). In Narok a flooring intervention was judged to have likely limited acceptability or feasibility, and as such has not been included as a study site in this protocol.

6. Problem statement

Despite large-scale implementation of targeted public health programmes, including deworming and community-led total sanitation (CLTS), infectious diseases associated with environmental contamination of the domestic environment continue to represent important causes of morbidity and mortality in Kenya. Notably;

- **Enteric infections:** Diarrhoeal disease remains a leading cause of paediatric morbidity and mortality in Kenya with the global burden of disease study estimating over 6000 child deaths per year in 2016 [4]. Control of enteric infections is currently centred around ensuring access to improved WASH, however the failure of recent large-scale, high fidelity WASH interventions to achieve meaningful reductions in childhood diarrhoea demonstrate the need for additional control strategies to be explored [30].

- **Tungiasis:** Tungiasis is known to be endemic across many counties within Kenya, causing severe acute and chronic morbidity among children and adults [31-34]. National prevalence is currently unknown; an on-going national survey of primary school children, however, will

provide much needed evidence on the burden of disease associated with this condition. Despite its proliferation across large parts of Sub-Saharan Africa and Central and South America [35, 36], there is currently no global road map for the control of tungiasis [37] and evidence on effective prevention and control strategies remains weak.

- **Soil transmitted helminths:** Despite notable declines in recent years, STH continue to persist across Kenya, causing significant morbidity among at-risk populations [38, 39]. Recent evaluation of the national school-based deworming programme reveals important inter-county heterogeneities in risk remain, with few counties achieving a target of 90% reduction in infection prevalence despite multiple rounds of mass treatment. Globally, evidence suggests that complimentary interventions in addition to preventative chemotherapy (PC) may be required to accelerate and sustain elimination as a public health problem [39].

It has been suggested that improvements in domestic flooring that lead to reduced domestic environmental contamination with faecal pathogens and parasites may represent a novel complementary strategy to support reduction in disease prevalence [22]. As for much of Africa, over 70% of rural households in Kenya have a rudimentary floor [40], and could potentially benefit from such an intervention. However evidence on the health impact for housing improvement interventions relevant to poor rural settings remains woefully inadequate [41].

7. Justification for the study

Results from large-scale WASH intervention trials conducted in Kenya, Zimbabwe, and India all failed to see reductions in childhood diarrhoea, suggesting an insufficient reduction in faecal-oral pathogen exposure [42-46]. This has led an urgent call for the development of transformative interventions to reduce the level of faecal contamination in the domestic environment [30, 43]. Sustainable reductions in STH and tungiasis transmission will also require improvement in environmental conditions and a change in risk behaviours. Despite this, WHO guidelines for STH control focus almost exclusively on targeted treatment, and trials of alternative intervention strategies for STH, tungiasis, and diarrhoeal diseases have not considered environmental improvements (beyond sanitation) to enhance impact. In contrast, the Ministry of Health (MoH) in Kenya is thinking more broadly, and in 2019 launched a comprehensive “Breaking Transmission Strategy” for NTDs including STH that calls for implementing strategies beyond preventive chemotherapy. Tungiasis has also been identified as a priority health problem.

The proposed study would be a two-arm household cluster randomised controlled trial (RCT) evaluating the impact of an improved household flooring intervention on enteric and parasitic infections among participating households in two contrasting settings in western and coastal Kenya. The flooring intervention will involve retrofitting a cement-based floor that is sealed, washable and durable and that covers the total interior floor space of a household dwelling. A key pathway through which an improved floor is expected to reduce exposure to enteric and parasitic infections is facilitating a more hygienic domestic environment. As such the proposed intervention would also include a behaviour change component aiming to promote sustained adoption of appropriate domestic hygiene behaviours. This proposed trial would be the first of its kind to comprehensively assess the effects of combining improved flooring technologies with tailored behaviour change

programming on a wide range of parasitic and enteric outcomes, providing an important step towards the establishment of transformative, community-driven, integrated approaches to WASH-related disease control. Exploring these relationships across contrasting contexts helps ensure findings will be of relevance to settings outside Kenya where similar housing, WASH infrastructure and disease risk are found. Results from this trial will help guide global and national environmental health priorities, at a time when the WHO is re-evaluating global targets for NTD control and elimination beyond 2020.

Beyond evaluating the intervention's effects on health outcomes there is a need to understand how practical the intervention is, and in particular to assess its feasibility and acceptability among target communities, as these factors will affect how relevant the findings are to control programmes. Results from the formative research indicate that there may be high levels of heterogeneity in how household members interact with the floor and adapt their behaviours such as cooking, animal husbandry and sleeping, all of which may play an important role in mitigating the success of the intervention. As such a dedicated process evaluation will take place alongside the RCT to explore implementation fidelity, intervention acceptability, and how the intervention is integrated into households' daily routines.

8. Study objectives

8.1. To evaluate the effectiveness of an improved flooring intervention in reducing the burden of enteric infections, STH and tungiasis in participating households through implementation of a RCT in two distinct settings in rural Kenya.

8.2. To determine the fidelity, durability, and acceptability of an improved flooring intervention in two distinct settings in rural Kenya through delivery of a process evaluation.

9. Intervention design and delivery

Our theory of change is that installation and ongoing maintenance of improved, low-cost flooring will reduce the transmission of enteric and parasitic infections, especially amongst children, by both preventing direct exposure and through an intermediate effect of improved domestic hygiene. Therefore, the proposed intervention consists of two linked components: (1) provision of a low-cost, sealed, washable floor throughout all existing rooms in the dwelling, and (2) a behaviour change component to support keeping these floors clean and well maintained. The intervention is targeted to households with children under five years, where the existing floor throughout the dwelling is exclusively constructed from unimproved materials.

9.1. Conceptual principles

The design of the intervention has been shaped by findings from formative research conducted in the study communities, and direct feedback from community members. Overall, design of the intervention has been guided by three principles:

1. **Ownership**: a body of evidence from the WASH sector highlights the pivotal role that ownership plays in promoting infrastructure use, maintenance and longevity [47]. That is, if recipients see the value of new infrastructure, and are afforded responsibility and accountability from the outset, they will be inspired to take ownership and engage with, use and/or maintain it. As such, the project will work to engender ownership through group

workshops and requiring some limited household investment such as asking households to procure their own cleaning supplies.

2. **Community norms and standards:** Community norms have been repeatedly shown to be an important determinant of routine behaviours [48-51]. The intervention will therefore aim to foster a sense of mutually accepted community standards around floor cleaning and maintenance practices. As the intervention is taking place at the household-level, community-wide activities such as mass-mobilisation events are not viable for this project due to the risk of contamination bias across study arms. Instead, the project will borrow practices from the community health club approach which has been previously implemented in Kenya [52] and that seeks to allow community members to find solutions for health and development challenges through establishing peer-support networks. For the trial, these group meetings (Floor Clubs) will act to engender reinforcement of norms around floor maintenance and cleaning and provide a platform for intervention households to share solutions to emerging challenges.

3. **Awareness of existing routines:** to ensure impact, it is important that household members do not feel they have to change their routines drastically, for example by changing how rooms in their homes are used. For this reason, the improved floor will be installed throughout all rooms in the home and not restricted to certain areas. Formative research conducted in both sites also identified that most households cook on an open fire or stove either inside their main building or in purpose-built kitchens and would wish to continue doing so once a new floor is installed. To deter households from building a new kitchen with unimproved floor for cooking, we will ensure an appropriate area of flooring within their existing kitchen remains heatproof by leaving it uncemented. Poultry ownership is high in both settings, with owners usually bringing their chickens inside to roost at night primary for security reasons. Changing this behaviour is not feasible, and therefore households should be supported to develop strategies to house their poultry safely whilst limiting contamination of the new floors.

9.2. Technical specifications of the floor

A low-cost, cement-based floor shall be installed in each room of the dwelling (including 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 sub-base layer made from compacted murram, a thin concrete layer and a final cement mortar finish.

The following stages are involved in construction:

1. Sub-base layer

- The weight that the floor imposes on the subsoil can easily compress the soil and cause the floor to sink.
- To prevent this, the subsoil is levelled-off and compacted and a 50mm murrum base (ie laterite soil, typically used for building homes in the study areas) is added to bring back to ground level.

2. Damp proofing

- A membrane material is added at ground level to prevent dampness rising up through the stabilized floor through capillary action.

3. Cement stabilized layer (150mm)

- A cement stabilized murram mix (1:9) is prepared and then added and compacted in layers over the murramdamp-proof membrane using a levelling board.

4. Screeding and Cement slurry finish

- Screed mix (1 parts of cement: 3 parts of sand) with adequate water will be prepared and applied on cured concrete slab.
- The depth of screed shall be 25mm
- A smooth cement and water slurry will be smeared on the screed to give a smooth finish of the floor.

All materials required to build the floor will be provided by the study. Floors will be installed by trained masons supervised by *icipe*, 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 whist 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.

9.3. Behaviour change and intervention delivery cascade

The flooring and behaviour change components of the intervention will be delivered in intervention households according to a structed cascade of pre-installation, installation, and post-installation activities (figure 2).

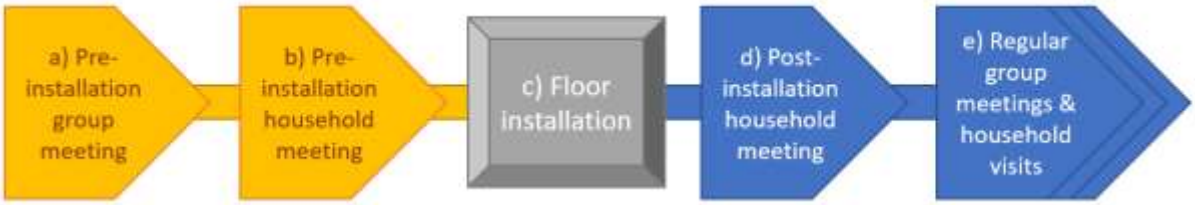


Figure 2 – intervention cascade

a. ***Pre-installation group meeting –*** Intervention households will be grouped with neighbouring intervention households to create "floor clubs". These groups will be comprised of 10-15 households and will meet regularly throughout the intervention period. The initial pre-installation meeting will be facilitated by a SABABU field officer and will cover the practicalities associated with installing and maintaining the floor. In addition to this they will cover responsibilities that households will be encouraged to take on – including procuring cleaning supplies such as soap, developing a plan for raised storage of belongings (to facilitate access to the floor for cleaning) and developing a plan for where poultry and livestock will be housed post-installation, especially at night.

b. ***Pre-installation household meeting*** – Following the initial group meeting, members of the study team will visit intervention households individually to confirm (i) the date of the floor installation, (ii) the household's plan for temporary accommodation during installation, and (iii) the household's plan for poultry and livestock housing post-installation. During this

meeting, household members and the study team will identify small areas of the dwelling to be left unfloored to prevent fires and cookstoves damaging the installed floor.

c. ***Floor installation*** – Households will receive a retrofitted cement-based floor in all buildings and rooms within their dwelling (as identified at the time of the baseline assessment). Existing unimproved pit-latrines will not have a slab retrofitted. If the household currently has a cooking area inside where stoves or fires are lit, this area will either be left unfloored around where the fire is normally lit or a semi-permanent clay stove will be installed by the household (based on household preference). Rooms or sheds where animals are housed that serve no other purpose beyond storing animals will not be floored. Household members will need to move all furniture and belongings from their property and temporarily relocate to another dwelling for duration of the floor installation process (up to 7 days). In situations where households are willing but unable to relocate for this period, the study team will work with community leaders to facilitate their relocation for this period. Installation will be performed by masons recruited locally and trained and overseen by engineers in the study team. Household members will be requested to provide the water needed for installation, and will be encouraged to contribute labour to the construction of the floor when practical.

d. ***Post-installation household meeting*** – Immediately following installation of the floor (and before households move back into their dwelling), SABABU field officers will visit households individually to address questions or concerns from household members, and to provide instruction and advice on how to care for the floor. Staff will use a double-sided, laminated visual aid to demonstrate the "dos" and "don'ts" of floor maintenance, which will be left with the household, tied in a visible space.

e. ***Regular "floor club" meetings and individual household meetings*** – Group meetings facilitated by SABABU field officers (using the same groups set-up during the pre-installation meetings) will be held at 2 weeks, 6 weeks and 14 weeks post intervention, with the meeting frequency to be re-examined after this. The purpose of these meetings will be 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 complimented 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.

10. Research questions – outcome evaluation (Objective 1)

Primary research question

10.1. What is the effect of the intervention on prevalence of enteric infections, STH and tungiasis, and the incidence of self-reported gastrointestinal illness in children?

Hypothesis: installation of an improved floor along with promotion of enhanced floor hygiene behaviours among household members will reduce exposure to enteric and parasitic pathogens

in the domestic setting, which will in turn result in lower rates of infection. Pre-school age children will see the greatest benefit from this intervention as they spend the largest proportion of their day in the dwelling and have greater levels of direct interaction with the floor.

Primary outcomes

10.1.1. The prevalence of enteric infections in children <5 years – assessed in both study arms by cross-sectional stool surveys conducted immediately prior to, and 12 months after delivery of the intervention

10.1.2. Prevalence of tungiasis infection in children <15 years – assessed in both study arms immediately prior and at 12 months after delivery of the intervention

10.1.3. The prevalence of at least one STH infection in all household members >1 year old – assessed in both study arms immediately prior and 12 months after delivery of the intervention (including hookworm, *A. lumbricoides* and *T. trichiura*)

Secondary outcomes

10.1.4. Prevalence of gastrointestinal illness in children <5 years – assessed in both study arms based on caregiver reported symptoms immediately prior to and 12 months after delivery of the intervention

10.1.5. Intensity of tungiasis and severity of acute and chronic tungiasis-associated pathology in children <15 years – assessed in both study arms immediately prior to and 12 months after delivery of the intervention using clinical severity scores.

10.1.6. Quality of Life using the modified dermatological quality of life index for tungiasis for children age 8 to 14 years – assessed in both study arms immediately prior to and 12 months after delivery of the intervention.

10.1.7. STH infection prevalence and intensity by species in all household members >1 year - assessed immediately prior and 12 months after delivery of the intervention (including hookworm, *A. lumbricoides* and *T. trichiura*)

Secondary research questions

10.2. **To what extent does the intervention reduce entero-pathogen and parasitic contamination of floors within the home?**

Hypothesis: Previous studies in settings with similar WASH and environmental profiles have shown that the domestic environment can be highly contaminated with enteric and parasitic pathogens [6, 14]. The intervention will reduce levels of contamination of STH species, T.penetrans off-host stages and enteric pathogens through facilitating the establishment of a hygienic environment in the home.

Primary outcomes

10.2.1. Environmental contamination for human-specific and animal faecal markers – assessed in both study arms at 12 months after delivery of the intervention from dust/soil samples from household cooking areas and living rooms.

10.2.2. Contamination of floors with eggs, larvae, pupae and adults of *T. penetrans* – assessed in both study arms through entomology soil surveys at 6 months post receiving the intervention

10.3. **What is the effect of the intervention on the subjective wellbeing of caregivers and children?**

Hypothesis: Housing quality has been linked to measures of psychological wellbeing in other settings [28]. In this setting the intervention will impact feelings of satisfaction, pride, and self-efficacy among caregivers and reduce the amount of time allocated to floor hygiene activities. Additionally, a reduced burden of disease on children will improve wellbeing of both children and caregivers.

Primary outcomes

10.3.1. Subjective wellbeing in caregivers and children aged 8-14 years – measured in both study arms immediately prior to delivery of the intervention and at month 12 using the WHO-5, WHOQOL-BREF, and CHU-9D wellbeing and quality of life tools

10.3.2. Task time allocation of caregivers - measured using self-reported usual daily allocation of time to tasks and direct structured observation of daily routines**.**

10.4. **How do the effects of the intervention differ across community and household contexts (including site, WASH infrastructure, animal husbandry, user adherence)?**

Hypothesis: The transmission pathways for STH species, enteric pathogens and tungiasis are heterogeneous and are influenced in different ways by environmental and socio-economic conditions. Variability in dwelling layout, access to WASH services, and ownership of animals will influence the degree to which the intervention is successful in reducing prevalence of enteric infections, STH and tungiasis

Secondary outcomes

10.1.1. Subgroup analysis of the prevalence of enteric infections in children <5 years – assessed in both study arms by cross-sectional stool surveys conducted immediately prior to and 12 months after delivery of the intervention stratified by study site and household contextual factors.

10.1.2. Subgroup analysis of the prevalence of tungiasis infection in children <15 years – immediately prior and 12 months after delivery of the intervention stratified by community and household contextual factors.

10.1.3. Subgroup analysis of the prevalence of at least one STH infection in all household members >1 year – assessed immediately prior and 12 months after receiving the intervention (including hookworm, *A. lumbricoides* and *T. trichiura*) stratified by community and household contextual factors.

11. Research questions – process evaluation (Objective 2)

11.1. To what extent is the intervention delivered consistently across both study sites and to the standards outlined in the standard operating procedures (SOPs)?

Hypothesis: the intervention is delivered consistently between and within study sites and according to the specifications outlined in the study SOPs, giving confidence in the internal validity of the study.

Primary outcomes

11.1.1. Internal project reporting on the delivery of i) training and equipping masons, and ii) retrofitting the flooring infrastructure – measured using pre and post-tests, direct semi-structured observations and installation quality checklists.

11.1.2. Internal project reporting on delivery of the behaviour change components of the study – measured using meeting attendance records and direct semi-structured observations and interviews.

11.2. To what extent is the intervention acceptable to participants?

Hypothesis: the intervention is designed collaboratively with stakeholder and community members and achieves a high degree of acceptability in both study sites, manifested in the sustained use of the floored areas within the dwelling for daily routines and the adherence of participants to promoted behaviours.

Primary outcomes

11.2.1. Use of space within the dwelling by household members and animals – measured in intervention households pre- and post-intervention through self-reported measures and post-intervention through direct semi-structured observations

11.2.2. Practicing of target behaviours by household members – measured in intervention households through structured spot-checks at bi-monthly intervals and direct semi-structured observations at endline

11.2.3. Caregiver satisfaction with the intervention – measured qualitatively in intervention households through semi-structured in-depth interviews immediately prior to and 12 months post intervention

11.3. What is the durability of the improved floor and how do environmental, installation, and use factors affect its longevity?

Hypothesis: the improved floor will demonstrate an overall high-degree of durability over the course of the study with adherence to promoted behaviours a key factor mitigating durability

11.3.1. Primary outcomes

Performance characteristics of the installed floors (hardness, abrasion, water resistance and visual observation) measured in intervention households through structured spot-checks at bi-monthly intervals.

11.4. Is implementation of the intervention practical, and what are the major cost drivers?

Hypothesis: the flooring intervention will be affordable and will be implementable by locally trained masons. Retrofitting of the improved floor is also achievable within a practical timescale for households.

Primary outcomes

11.4.1. Internal project reporting on procurement and training processes and implementation timelines

11.4.2. Cost breakdown for delivering each of the intervention components

12. Methods

12.1. Study sites

To improve the generalisability of this study's findings and examine how the intervention's impact varies across different environmental and cultural contexts, this study will take place in two study sites; one within Kwale county and the other in Bungoma county. During the formative research phase of this project seven contiguous or near contiguous villages were identified with favorable epidemiological profiles (reported STH and tungiasis endemicity) and housing conditions (high proportion of households with earthen floors) in each study site. The final study villages to be enrolled in the RCT and process evaluation described in this protocol will be drawn from among these pre-identified villages. Final selection of villages will be based on estimations of the number of eligible houses in each village – with the intention of selecting villages that allow the study to reach the declared sample size of 440 households per site using complete villages (i.e. all the households within a village).

Dzombo Ward, Kwale county: Located within the Lunga Lunga sub-county, Dzombo ward has a population of around 50,000 inhabitants living across 54 villages. Prevalence of any STH (predominantly hookworm) was 20% in 2017[1] and tungiasis prevalence is reported to be as high as 52% in some village clusters[2]. Census data from the seven villages included in the formative research phase of this project (Mkuduru A, B, and C, Macjamungo, Bumbuni, Dzuni, and Mrindiro) showed a total of 5241 individuals living across 812 households. Eighty-percent of household floors were earthen and most households occupied multi-building dwellings with cooking areas often located in separate structures to those that were used for sleeping. Access to improved[3] sanitation was high at 89%, but almost half (42%) of those were facilities shared with multiple households. The median time reported for a round trip to primary water sources was 15 minutes. 85% of households owned at least one type of livestock, with chickens being the most common animal (71% ownership), followed by goats (50% ownership), and then cattle (42% ownership).

South Bukusu ward and Kabula ward (Remwa A and B), Bungoma county: South Bukusu has a population of approximately 24,000 individuals and is located in Bumula sub-county in the Western region of Kenya. Prevalence of any STH is 7.6%[4] and tungiasis has been reported as being present across the sub-location. Among the seven villages censused during formative research (Kibachenje A and B, Nakholo A and B, Remwa A and B, and Burangasi A) a total of 4560 individuals were recorded living across 906 households. Access to at least limited sanitation was very high with only 3% of households reporting no access to a facility. The majority of households had earthen floors (77%) and

[1] Data provided by the TUMIKIA project

[2] Data provided through personal communication with the Kwale Ministry of Health

[3] Defined by the Joint Monitoring Programme as "facilities are those designed to hygienically separate excreta from human contact, and include: flush/pour flush toilets connected to piped sewer systems, septic tanks or pit latrines; pit latrines with slabs (including ventilated pit latrines), and composting toilets"

[4] Data provided through personal communication with the Ministry of Health

the median number of buildings in a household dwelling was two. Food preparation and cooking were observed to either take place within dedicated kitchen out buildings, in shared-purpose rooms or in outside in the dwelling courtyard. The median amount of time for a round trip to households' primary water source was 20 minutes, and the majority of households had access to an improved water source (81%). Eighty-percent of households owned at least one type of livestock and the most common was chickens (71% ownership), followed by cattle (48% ownership), and then goats (17% ownership).

12.2. Trial description

This is a household cluster randomised trial comparing health outcomes in children and their caregivers living in homes with sealed, washable floors to those of children and their caregivers living in homes with rudimentary (earthen) floors.

Table 1. Trial Summary

Study design:	**Household cluster randomised controlled trial**
Intervention:	• Replacement of rudimentary floors with an improved floor, • Support for behaviour change through 'floor clubs'. • Annual mass treatment for STH infections (400 mg albendazole) • Treatment of tungiasis in those affected by heavy infections (at 0 and 12 months) according to county DoH recommendations
Control:	• Annual mass treatment for STH infections (400 mg albendazole) • Treatment of tungiasis in those affected by heavy infections (at 0 and 12 months) according to county DoH recommendations
Primary outcome:	Reduced prevalence of enteric infections, STH and tungiasis in children 12 months after installation of improved floors.
Household inclusion criteria:	Household with a child under 5 years of age that meets structural criteria (unimproved earthen flooring throughout, structurally sound), with members willing to temporarily relocate and provide water for installation. Provide consent.
Household exclusion criteria:	Households that are intending to move within the next 12 months, or that have improved flooring in any rooms or are not structurally sound. Refusal to consent.
Sampling inclusion criteria:	Those living in participating households i) aged under 5 years (for assessment of enteric infections), ii) aged under 15 years (for tungiasis), and iii) aged over 1 year (for STH). Provide consent/assent
Sampling exclusion criteria:	Refusal to consent/assent.
Sampling schedule:	Sampling of all eligible participants will take place at baseline (pre-installation) and at 12 months. Longitudinal monitoring of

	secondary outcomes will be conducted periodically from 0 to 12 months post-installation.

This study will be a two-arm parallel, open-label household cluster randomised trial design to measure the effect of the intervention 12 months post delivery. In each site, 220 households that meet the inclusion criteria with children aged under 5 years will be randomised (1:1) to either arm:

- **Intervention:** Replacement of rudimentary floors with an improved floor, accompanied by a tailored behaviour change intervention ('floor clubs'). At baseline, all household residents over 1 year will also be offered treatment for STH (400 mg albendazole). During assessments (at 0 and 12 months), those found to be affected by heavy-intensity tungiasis will be treated according to County DoH recommendations.
- **Control:** At baseline, all residents over 1 year will be offered treatment for STH (400 mg albendazole). During assessments (at 0 and 12 months), those found to be affected by heavy-intensity tungiasis will be treated according to County DoH recommendations.

In each cluster (i.e., household) all residents will be sampled immediately before and twelve months post-installation of floors. Faecal samples will be collected from the sampled population and will be assessed via multiplex PCR for enteric infections (in those aged under 5 years) and via Kato Katz for STH infections (for those aged >1 year old). Additional clinical examinations will be performed for tungiasis on all children aged under 15 years immediately prior to installation of floors, and then at 12-months post installation.

In addition to these primary outcomes, quality of life measures in enrolled children and their caregivers will be recorded immediately before and twelve months post-installation of floors, and environmental sampling will be conducted on floors and surfaces of all enrolled households 12 months post-installation of floors. Alongside the trial, a process evaluation will be undertaken to investigate intervention fidelity, acceptability, durability and practicality. After the endline assessments, all control households will be offered an improved floor.

The trial design is summarized below in Figure 1.

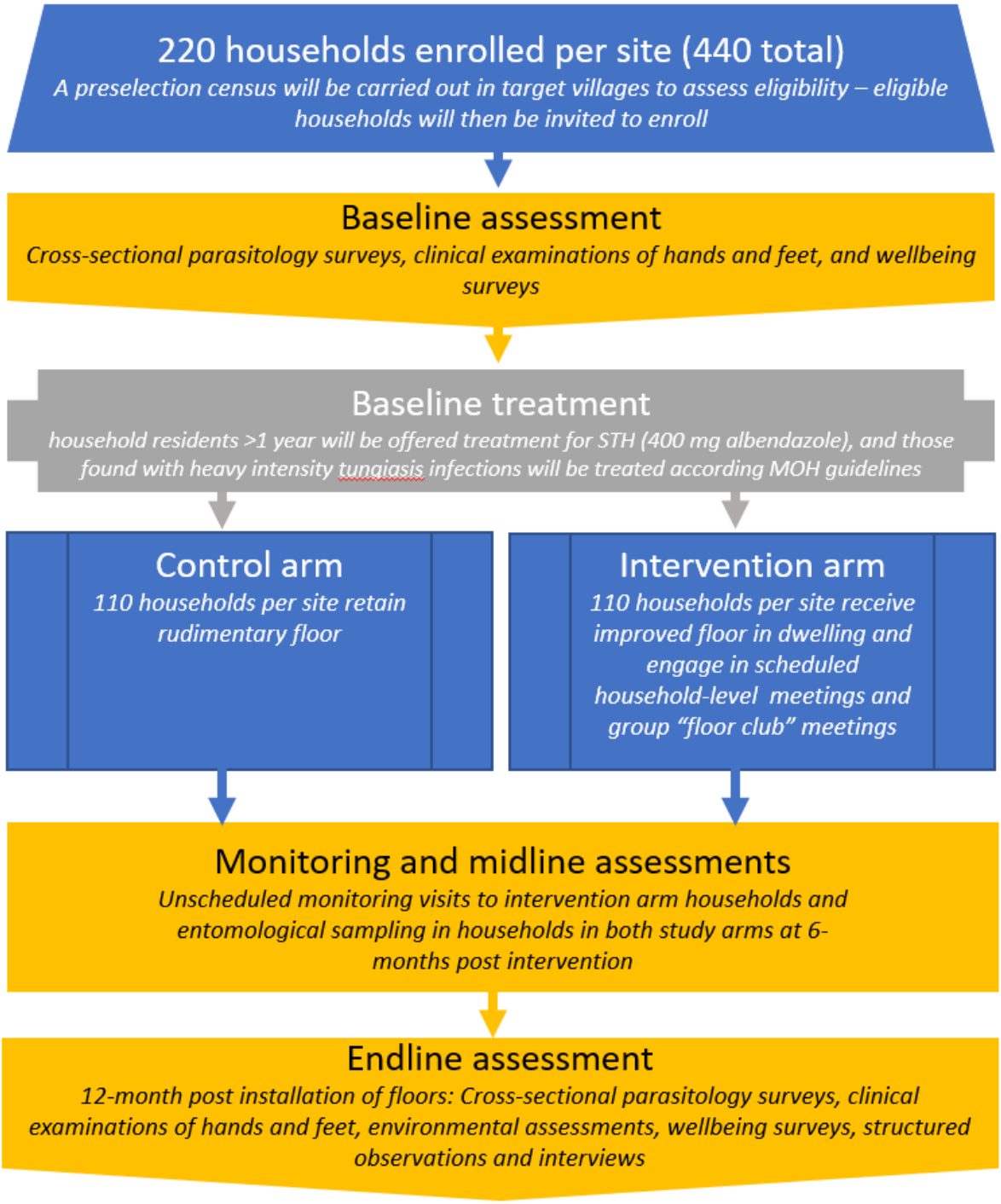


Figure 1. Study flow diagram

12.4. Household eligibility

Households located in the candidate villages will be assessed for eligibility using the following criteria:

Inclusion criteria

a. Household has a child under 5 years of age who is a resident at the household
b. Floor throughout the current household dwelling is exclusively made from unimproved materials (earth/sand/palm sticks/bamboo)

c. Dwellings are deemed by engineers to be structurally secure and suitable for retrofitting a new floor (for dwellings constructed with wood – timber posts must be embedded into the ground at a minimum depth of 50 cm and 30 cm interval, intact and undamaged by termites or fungal attack; for dwellings constructed of rammed earth or brick foundations should be reinforced and stability ascertained)[5].
d. Household members are willing to temporarily relocate to another dwelling for duration of the floor installation process (up to 7 days)
e. Household members are willing to provide water for installation of the floor

Exclusion criteria

a. Household head is unwilling to participate in the study
b. Household reports planning to move to different dwelling/location within 12 months
c. Floor of the current household dwelling is partly or entirely constructed from improved materials (cement/ceramic or vinyl tiles)
d. Household is deemed by engineers to be structurally insecure and unsuitable for retrofitting a new floor and cannot be fixed or household members are unwilling to fix.

12.5. Final site selection and eligibility assessment

To assess household eligibility and estimate village-level prevalence of tungiasis, a **pre-baseline rapid census and eligibility assessment** will be carried out in 2-4 candidate villages to record data on household rosters and dwelling structures *(See annex 10 for tool)*. Data collected as part of this study's preceding formative research phase will be used to pre-identify villages to include in the pre-baseline census to reach target number of 220 eligible households per site. This census will be conducted by trained field staff using a pretested and piloted questionnaire loaded on to an encrypted smartphone. The instrument will include questions on household members' sex, age and living arrangements, as well as a series of direct observations of the dwelling's building characteristics. Enumerators will also ask the respondent if anyone in the household has experienced tungiasis within the past two weeks. GPS coordinates of the dwelling location will also be recorded. Written informed consent will be obtained by an adult household member on behalf of the household. Data from this pre-baseline rapid census will be monitored daily. The trial will prioritise enrolling all eligible households in target village(s) with some provision to exceed the stated sample target if required.

12.6. Sample size calculation

Sample size and power calculations are based on the primary outcomes (prevalence of enteric infections in children under 5 years of age; prevalence of at least STH infection in all household members over 1 year old; prevalence of tungiasis infection in children under fifteen years of age) and have been informed by existing data from Kenyan populations. These include data from the national school-based deworming programme [39], community-based tungiasis surveys [53] , and the Global Enteric Multicenter Study (GEMS) study, which was a large case-control study of moderate to severe diarrhoea in children younger than 5 study that included Nyanza Province, Kenya [54].

Enrolled individuals will be clustered within households and calculations are thus based on the principles of cluster randomised trials, assuming an ICC of 0.1 based on small cluster size. Effect sizes

[5] Households residing in dwellings considered unsuitable will be given the opportunity to complete repairs as needed if they wish to do so.

for tungiasis and STH are based on our team's expert opinion of the smallest meaningful public health effect. Effect sizes for enteric pathogens are based on earlier WASH efficiency studies. Tungiasis prevalence will be evaluated per-site while data on STH and enteric infections will be pooled across-sites.

The primary outcome for which we require the largest sample size is STH prevalence, measured in enrolled children and their caregivers. We would expect STH prevalence to be 15% in the control arm and 10% in the intervention arm. Assuming five enrolled participants per household and a 15% loss to follow up, **220 households per arm in total across two sites** would provide 80% power to observe this difference at 0.05 significance. This sample size is also sufficient to detect at 80% power and 0.05 significance: (i) the expected difference in enteric infection risk in children <5 years old - assuming one <5 year old child per household, and an expected prevalence post-intervention of 70% in the control arm and 56% in the intervention arm; and the expected difference in tungiasis prevalence in children <15 years at a site level - assuming two children <15 per household and an expected prevalence post-intervention of 30% in the control arm and 15% in the intervention arm.

Based on these estimates, we plan to enrol 220 clusters (households) per arm – thus ensuring 220 children (aged <5 years) and 440 children (aged <15 years) per arm in both sites.

Tables 2 – 4 further illustrate the **minimum number of clusters** (households) required per arm to detect a range of reductions with 80% power and 5% significance for enteric infection in children under five years (Table 2), STH infection in all household members over 1 year (Table 3) and tungiasis in children under 15 years of age (Table 4).

Outcome: Prevalence of enteric infection in children <5 years

		Relative reduction in prevalence after 12 months		
		10% less	**20% less**	**30% less**
baseline	**80%**	445	121	57
	70%	711	184	83
	60%	1066	268	119

Assumptions: mean cluster size of 1 child under 5 per household, number of clusters required per arm to detect a range of reductions with 80% power and 5% significance.

* based on observations from GEMS trial site in Nyanza Province; expected differences extrapolated from observational studies and other WASH intervention trials

Outcome: Prevalence of at least one STH infection in all household members over 1 year old:

		Predicted prevalence after 12 months		
		12%	**10%**	**7.5%**
ICC	**0.05**	489	165	67
	0.1	571	193	78
	0.12	603	204	83

Assumptions: a baseline prevalence of 15%* and mean cluster size of 5 individuals per household, table presents number of clusters required per arm assuming a range of ICC values with 80% power and 5% significance.

* based on observations from TUMIKIA trial in Kwale and the National School-Based Deworming programme data; expected differences extrapolated from observational studies

Outcome: Prevalence of tungiasis infection in children under 15 years of age (assessed per site):

Predicted prevalence after 12 months

		20%	15%	10%
ICC	**0.05**	154	63	32
	0.1	161	66	34
	0.12	164	67	34

Assumptions: a baseline prevalence of **30%*** and mean cluster size of 2 individuals per household, table presents the number of clusters required per arm assuming a range of ICC values with 80% power and 5% significance.

* based on observations from prevalence surveys conducted in similar populations in Kenya and Uganda; expected differences extrapolated from observational studies

12.7. Enrollment and consent

Following final identification of study villages and potential eligible households, meetings will be held between the study team and ward and village level leadership to discuss which village(s) have been selected and the plans for enrollment and intervention roll-out. Households in selected study villages will then be visited by study staff and village guides and, if eligible, offered the opportunity to enroll in the study and have baseline assessments undertaken. If ineligible, the household will be informed of why they did not meet the eligibility criteria (and where appropriate, provided with opportunity to address minor structural concerns affecting eligibility, such as repairing timber posts).

For households that agree to participate in the study, written informed consent will be obtained from the head of household and all other adult household members. Written informed consent will be obtained from the household head on behalf of all children under the age of 18. In addition to this, written informed assent will be provided by children aged 12-17 and verbal assent will be provided by children aged 7-12. If the head of household is not present, then the study team will revisit at a later date before undertaking the consent process and baseline assessment. If other resident adult or child household members are not present but the head of household is present, then the consent process and baseline assessments will proceed, and consent will be obtained from missing household members during a revisit at a later date. No component of the intervention will be delivered before the relevant consent or assent has been provided by all resident household members.

12.8. Baseline assessments

Baseline assessments will be undertaken with all households immediately prior (within one month) of installation of floors by trained field staff using pre-tested and piloted survey instruments loaded on to an encrypted mobile device. The different components of the baseline assessments may take up to 90 minutes in total per household and are as follows:

Household questionnaire *(See annex 11 for tool)* **–** this will be administered to the primary caregiver or any adult household member and will include questions on household members' demographics, ownership of assets, ownership and husbandry practices for poultry and livestock, WASH arrangements, and building and room uses. Direct observations by field staff will be made of WASH facilities and building conditions. GPS coordinates of the dwelling location will also be collected.

Caregiver questionnaire *(See annex 12 for tool)* **–** this will be conducted with the primary caregiver and will include a pre-validated question module based on the WHO-5 and WHOQOL-BREF to evaluate respondent psychological wellbeing. If the primary caregiver is not present the field officers will return later to complete the questionnaire.

Child questionnaire *(See annex 13 for tool)* **–** Children aged between 8-14 will be asked to participate in a short set of questions about their psychological wellbeing and perceived quality of life. Questions will be drawn from the WHO-5 and the EQ-5D-Y. If children are not present field officers will return later to complete the questionnaire.

Stool survey for enteric and STH infections – all household members will be invited to provide a stool sample for screening for enteric infections (in children under five years) and STH infections (for all residents over 1 year). Participants will be provided with sample collection kits and will be instructed how to collect an early morning sample for collection by the study team the following day. Samples will be collected from households by the study team to maintain confidentiality and will be transported on ice to the field laboratory and processed for examination the same day.

Tungiasis assessment *(See annexes 14-15 for tools)* – all children aged under the age of 15 will have their feet washed and dried and examined by trained field workers for presence and severity of tungiasis, supported by a parent/guardian if appropriate. Field workers will wear latex gloves during examinations. The skin of study participants' feet and hands will be examined for the presence of embedded fleas, with diagnosis of tungiasis made on the basis of the presence of embedded fleas; either a red-brown itching spot with a diameter of 1–2 mm; a yellow-white watchglass-like patch with a diameter of 3–10 mm with a central dark spot; or a brown-black crust with or without surrounding necrosis. Sand flea lesions with evidence of manipulation with needles or thorns by the patient or a caretaker will be documented. The stage and number of lesions will be recorded.

Associated morbidity will be assessed semi-quantitatively. The feet are divided into 9 zones each and the number of zones with each pathology are recorded. For acute pathology the signs are thermographic hot spots, desquamation, fissures, ulcers, abscess. For chronic pathology the signs are hyperkeratosis, deformed nails, lost nails, deformed toes. These are then summed into an All-Pathology score. The hands are rarely infected without the feet also being infected and so will not be assessed for pathology.

To safeguard the study team and participants during clinical and wellbeing assessments, examinations and interviews will only be conducted by fully trained team members, with a second field team members trained in all procedures acting as a chaperone. We will ensure that examinations are conducted in private locations that will maintain the dignity of the patient. All tungiasis cases will be treated according to the County DOH recommendations.

12.9. Randomisation

Randomisation of households to either the control or intervention arm of the study will take place once baseline assessments have been completed for all participating households. A member of the study team in London not familiar with study communities or the day-to-day operation of the trial will randomly generate a list allocating household IDs to either the control or intervention arm along with the documentation describing how the randomisation was conducted. This list will be stored on a password protected spreadsheet that will then be shared with the wider study team. The password for the spreadsheet will be shared with the study coordinator in the lead up to the randomization ceremony that will be held to publicly announce which households have been allocated to which arm.

12.10. Midline assessments and ongoing monitoring

Ongoing monitoring of intervention durability, acceptability and user adherence to target behaviours will be undertaken through regular random spot checks of intervention households *(See annex 16 for*

tool). These will be performed by field officers using a structured checklist of items that will assess the structural condition of the floor, levels of debris and clutter on the floor, and the location of different daily activities. Spot checks will take place at regular intervals during the 12 months between intervention delivery and endline assessments with the aim for each intervention household to be visited at least four times. They will not be arranged in advance with households to minimize reactivity and response bias.

A standalone midline assessment involving **entomological sampling** will also be undertaken at 6 months post-intervention delivery in both control and intervention households *(See annex 17 for tool)*. This will include the collection of sand, dust and fine debris in three or more locations: 1) in food preparation areas, 2) in food storage areas, and 3) all child sleeping areas, that will be swept and gathered into well-sealed zip-lock bags to be shipped to the laboratory in Muhaka, Kwale County or Mbita, Homa Bay County for heat extraction of soil arthropods from samples. Samples will be double bagged and shipped in a sealed cool box.

12.11. Endline assessments

Endline assessments will be undertaken in all study households twelve months post-intervention delivery and will include the household questionnaire, caregiver questionnaire, child questionnaire, tungiasis assessment, and parasitological sampling that are listed in section 12.8. In addition to this the following activities will be undertaken:

***Environmental sampling for enteric pathogens*:** Floor dust samples will be collected in 2 locations within dwellings: 1) the floor 50cm inside from the exterior entrance to the primary household building, and 2) the floor 50cm from the cooking fire/stove in the direction of the entrance to the cooking area. The level of visible debris on the sampled area will be be recorded at the time of sampling. Following protocols developed by the evaluation of EarthEnable floors in Uganda [55] study personnel will demarcate surface areas of 100 cm^2 sweeping surfaces with an ethanol cleaned paintbrush in horizontal, vertical, and diagonal directions. Collected dust will be transferred into sterile Whirl-Pak bags and transported on ice to the field laboratory, where they will be stored at 4^0C refrigeration.

In-depth interviews *(See annex 19 for tool)* – IDIs will be conducted with caregivers from a random sample of 9 intervention households and 3 control households in each study site (total n=24) that will cover topics on user satisfaction with the floor, cleaning regimens, animal husbandry practices, cooking, food preparation, relaxation, school-work, leisure activities, child caregiving, and perceptions on social status and the economic value of the floor. Interviews will take between 30-60 minutes and will be conducted by trained interviewers using pre-piloted question guides. Interviews will be audio recorded using an encrypted mobile device, transcribed, and translated before being analysed.

Household structured-observations *(See annex 20 for tool)* – Household observations will be undertaken in intervention households at endline. The purpose of this activity will be to quantify time spent by children, caregivers, and animals in different parts of the dwelling and to identify where different activities are undertaken within the dwelling. Observations will be undertaken by two field officers over a two-day period, using a pre-piloted form for quantifying animal and household member location. Observers will be positioned so as to be able to observe different areas of the dwelling.

888 Table 2 – Summary of sampling approach for data collection activities

Table x – Summary of sampling approach for data collection activities				
Activity	Frequency	Sampling unit	Sampling method	Estimated sample size per site (total sample size)
Pre-baseline rapid census	Once: pre-baseline	Adult household member (on behalf of household)	Exhaustive (in candidate villages)	300 (600)
Household questionnaire	Twice: baseline and endline (12 months post-intervention)	Adult household member (on behalf of household)	Exhaustive (among enrolled households)	220 (440)
Caregiver questionnaire	Twice: baseline and endline (12 months post-intervention)	Primary caregiver	Exhaustive (among enrolled households)	220 (440)
Child questionnaire	Twice: baseline and endline (12 months post-intervention)	Children aged 8-14 years of age	Exhaustive (among enrolled households)	300 (600)
Tungiasis assessment	Twice: baseline and endline (12 months post-intervention)	Children <15 years of age	Exhaustive (among enrolled households)	600 (1200)
Parasitological (stool) survey	Twice: baseline and endline (12 months post intervention)	Household members (all ages)	Exhaustive (among enrolled households)	1300 (2600)
Household spot checks	Four times between baseline and endline (12 months post intervention)	Household dwelling	Exhaustive (among intervention households)	440 (880)
Entomology sampling	Once 6-month post intervention	Household dwelling areas (All bedrooms, cooking area, animal sleeping areas)	Exhaustive (among enrolled households) – max 4 areas per household	880 (1760)
Environmental sampling	Once: endline (12 months post-intervention)	Household dwelling areas (living rooms, cooking areas)	Stratified random sample of households by study arm (max 2 areas per household)	240 (480)
In-depth interviews	Once: Endline	Primary caregiver	Purposive sample (stratified 3:1 intervention VS control)	12 (24)
Household observations	Once: Endline	All present household members	Purposive sample (stratified 3:1 intervention VS control)	12 (24)

12.12. Lab procedures

Enteric infections

Stool samples will be examined for enteric infections by polymerase chair reaction (PCR) using the Luminex xTAG® Gastrointestinal Pathogen Panel (GPP) (Luminex Corporation, Toronto, ON, Canada), a multiplex gastrointestinal syndromic panel that includes targets for *Campylobacter, Clostridium difficile* (Toxin A/B), *E. coli, Salmonella, Shigella, Vibrio cholerae, Yersinia enterocolitica,* adenovirus 40/41, norovirus GI/GII, rotavirus A, *Cryptosporidum, Entamoeba histolytica* and *Giardia.* After collection, stool samples will be aliquoted into cryovials for storage in 95% ethanol at -80^{o}C. Assays will be run as per manufacturer's instructions at central KEMRI laboratory facilities. In brief, the assay involves PCR amplification and hybridization of biotinylated amplicons to cDNA probes bound to beads with unique fluorescence spectral patterns and to phycoerythrin (PE)-labelled streptavidin. The beads are then passed through a flow cytometer, identified via unique UV light fluorescence patterns, and analyzed for the presence and quantity of bound amplicons (MFI values). The identified beads are matched to each pathogen on the panel, and the associated MFI values are compared to predetermined thresholds to determine presence or absence.

Soil transmitted helminths

The stool samples will be examined in duplicate (41.7mg template) for presence of STH eggs by two independent technicians using the Kato-Katz method and the intensity of infection expressed as eggs per gram of faeces [56].

Tungiasis

Floor soil samples will be extracted using Berlese-Tullgren funnels which rely on heat to drive small soil arthropods downwards out of the soil, through a sieve and into a collection container. Arthropods will then be examined under a stereo microscope for presence and counting of eggs, larvae, pupae and adults of *T. penetrans* and other flea species as well as other arthropods such a bedbugs Morphological identification will be supported by molecular tools for the identification of flea species (subset of samples to confirm morphological identification).

Environmental sampling

Soil/dust samples will be examined for enteric pathogens by PCR also using the Luminex xTAG® GPP. DNA will be extracted from soil samples according to specifications outlined in the QIAGEN® DNeasy® PowerSoil® Pro documentation [57].

13. Data management

13.1. Quantitative data

In general, data will be stored electronically. The majority of quantitative survey data will be collected via SurveyCTO using smartphones and downloaded daily. Quantitative data collected as part of household surveys, including the participant signature collected as part of the informed consent process, will be encrypted at the point of collection on encrypted mobile phones locked with a study-specific password. After collection, data will be downloaded and automatically transferred via an encrypted connection to a secure server if there is a mobile network available in the area. If a mobile network is not available, the data is stored on the phone until it can be transmitted via a Wi-Fi connection to the same secure server. Access to the secure server will be limited to essential research personnel within specified user roles.

Data from the server will be downloaded and stored on institutional servers for access by the PIs and members of the core research team for analysis and preparation of reports. Records will be stored in .csv format. Files containing sensitive information will be encrypted and password protected before any transfer between collaborators. No names or other direct identifiers will appear in typed documents, transcripts, or recordings.

Data will be stored electronically in the file formats specified above on a Microsoft OneDrive folder with access restricted to a select group of study collaborators. Any paper copies of data will not be retained after a 10-year period from the end of the study in accordance with LSHTM, KEMRI, and *icipe* data management policies. Following publication of the principal papers and reports, we will add fully anonymised data to LSHTM's internal research data repository.

13.2. Qualitative data

Fieldworkers, transcribers, and translators will be trained to record, transcribe, translate, and store qualitative data, before starting data collection. Interviews will be conducted in person and audio-recorded on encrypted audio devices. Audio files will be digitally transcribed and they will be destroyed once transcriptions are complete.

Audio files from in-depth interviews will be transcribed, fully verbatim, into Microsoft Word by a transcriber. The transcription will be proof-read against the audio file by both the transcriber and a supervising member of the research team to check for accuracy, and any areas of confusion or unclear terminology. Sections of text (10%) will be double-checked for accuracy by other members of the research team.

Names of study participants will only be recorded during the information and consent procedure. After that, names will be substituted with a unique coded identifier. All personal identifying information will be removed when transcribing audio-recordings or inputting qualitative data electronically. In published outputs, anonymized identifiers, such as numbered codes for individuals will be used for participants. The names of some organisations, departments and health facilities may, however, be used when necessary to accurately describe the context of the study site.

Paper and soft copies of field notes and consent forms will be kept on the person of the fieldworkers or in a locked cabinet or room and only shared within the study team. All electronic field notes, interview audio-recordings and transcripts will be stored a secure OneDrive folder with limited access by a selected number of team members.

13.3. Lab data management

The stool samples will be examined in duplicate (41.7mg template) for presence of STH eggs by two independent technicians using the Kato-Katz method and the intensity of infection expressed as eggs per gram of faeces [56, 58]. PCR will be performed on pathogen DNA extracted from floor dust samples.

A combination of stool culture, Luminex® Gastrointestinal Pathogen Panel (GPP), parasitological microscopic examinations, and rapid antigen detection tests will be used to diagnose enteric infection using protocols that have been previously developed and manufacturers instruction [59].

14. Data analysis

14.1. Quantitative data

Data management and analysis will be conducted using STATA 16 (STATA Corporation, College Station, TX, USA) and R (r-project.org).

Pre-baseline rapid census & household eligibility

Upon completion of the pre-baseline rapid census, structures, households and individuals will be allocated numerical unique identifiers within the dataset. Pre-specified criteria on eligibility will be applied to surveyed households and lists of eligible and ineligible households will be produced.

Effect of the intervention on prevalence of enteric infections, STH, tungiasis and self-reported gastro-intestinal illness in children (RQ 10.1)

Analysis of the primary and secondary outcomes for this research question will be carried out on groups as randomised (intention-to-treat). Results will be presented as appropriate effects sizes with a measure of precision (95% CIs), using generalised estimating equations to account for clustering by household. Incidence of caregiver-reported gastrointestinal illness will be analysed using interrupted time series methods.

To what extent does the intervention reduce entero-pathogen and parasitic contamination of floors within the home? (RQ 10.2)

Pre-specified faecal indicator bacteria and specific pathogens of interest will be quantified in each study arm. Generalised linear models with robust standard errors will be used to estimate differences in overall pathogen prevalence in the dwelling environment at endline.

What is the effect of the intervention on the subjective wellbeing of caregivers and children? (RQ 10.3)

Data from the caregiver questionnaire will be used to quantify scores on the WHO-5 wellbeing index, the WHOQOL-BREF (caregivers only), and the EQ-5D-Y (children only). Generalised linear models with robust standard errors will be used to estimate differences in wellbeing scores between study arms at endline.

How do the effects of the intervention differ across community and household contexts (including site, WASH infrastructure, animal husbandry, user adherence)? (RQ 10.4)

Pre-specified analyses of impact heterogeneity will be conducted to explore the influence of context, through the inclusion of interaction terms for household WASH access, ownership of livestock, and socio-economic status. This will be complemented by structural equation modelling and causal analysis to further explore the role of flooring in disease transmission.

14.2. Qualitative data

Analysis of qualitative data will be conducted using Nvivo 12.0 (QSR International) and Microsoft Word (Microsoft Cooperation).

What is the effect of the intervention on the subjective wellbeing of caregivers and children? (RQ 10.3)

Data from midline in-depth interviews with caregivers will be used to explore different pathways through which the intervention has changed caregiver and child daily routines and if these changes have wrought any impact on wellbeing. Pre-identified themes to explore include caregiver self-efficacy, social status, pride, and availability of free time. Following transcription and translation, data will be coded and analysed thematically using a case-memo approach. Results will be triangulated with data from the quantitative caregiver wellbeing questionnaire.

15. Ethical considerations

All study data will be handled in compliance with the existing guiding principles for ethical research of partner institutions, the Scientific Ethics Review Unit (SERU) of the Kenya Medical Research Institute (KEMRI) and the LSHTM ethics review committee, as well as MRC Guidelines for Good Clinical Practice

(GCP) in Clinical Trials. The participant will be informed that his/her personal study-related data will be used, shared, and stored by the research team in accordance with Kenyan data protection law and General Data Protection Regulation (GDPR). Study participants will be treated equally and barriers to research involvement based on any discrimination - on the basis of gender, age, ethnicity, socio-economic status, disability, language, among others - will be challenged. Attention to research ethics will be ongoing throughout the study and, if necessary, revisited.

15.1. Training

All members of the study teams- including research assistants, field officers, laboratory technicians, interviewers, interpreters, translators - will participate in training which will cover the purpose of the study, the importance of consent and how to administer consent and assent forms, the ethical and practical aspects of using the study tools, including explicit instructions on building rapport and ensuring confidentiality, and guidelines will also be given around the management of sensitive data. Before starting the research, guidance will be provided to researchers related to working with vulnerable participants, such as children and people with disabilities. Support mechanisms will be put in place for the research team to help guide and inform their research practice, such as supervision arrangements. While in the field, fieldworkers will have continuous contact with a mobile phone with the research supervisors in case of any queries. Members involved in conducting clinical examinations for tungiasis will receive extensive training on safeguarding and respectful examination.

15.2. Informed consent

Written informed consent and where appropriate written or verbal assent will be sought for all participants directly involved in research activities and from the household head for activities pertaining to the overall household (table 3) (Annexes 1-9, 20). For activities involving adults written informed consent will be sought; for activities involving children caregiver written informed consent will be sought in addition to written assent for children aged 13-17, or verbal assent for children aged 7-12.

Table 3. Summary table of activity informed consent requirements

Activity	Individuals to provide consent	When collected	Form(s) used
Pre-baseline census	Present adult household member provides consent on behalf of household	Pre-baseline	Pre-baseline census household consent form (annex 1)
Household questionnaire	Head of household provides consent on behalf of household	Baseline	Study household consent form (annex 2)
Entomology sampling	Head of household provides consent on behalf of household	midline	Study household consent form (annex 2)
Environmental sampling	Head of household provides consent on behalf of household	Baseline	Study household consent form (annex 2)
Household spot checks	Head of household provides consent on behalf of household	Baseline	Study household consent form (annex 2)
Household observations	Head of household provides consent on behalf of household	Baseline	Study household consent form (annex 2)

	All present household members provide written consent and written or verbal assent when appropriate	Endline	Individual observation consent form (annexes 3-4)
Child questionnaire	Child provides assent (verbal or written) and adult provides written consent	Baseline & endline	Child tungiasis and wellbeing consent and assent form (annex 5-6)
Tungiasis assessment	Child provides assent (verbal or written) and adult provides written consent	Baseline & endline	Child tungiasis and wellbeing consent and assent form (annex 5-6)
Stool collection	Individuals provide written consent and written or verbal assent when appropriate	Baseline & endline	Individual stool survey consent and assent form (annexes 7-8)
Caregiver questionnaire	Caregiver provides consent	Baseline	Caregiver wellbeing consent form (annex 9)
Caregiver in-depth interviews	Caregiver provides written consent	Baseline	Caregiver interview consent form (annex 20)

Prior to starting any research activities an information sheet (Annexes 1-9, 20) describing the research will be provided to the participant. The research officer will explain to participants the purpose of the study, the methods, the risks and benefits, the expected taken time and the use of data. They will then respond to any questions asked by the participant.

Research officers will ensure that information sheet and consent form are fully understood by study participants (and impartial witness if applicable). All forms will be translated into the local languages spoken by participants (Bukusu, Swahili). The informed consent discussion will be conducted in a language that participants are comfortable with, using a translator if necessary. Participants will identify a witness of their choice if they cannot read. Researchers will inform study participants that their participation is fully voluntary: they have the right to refuse to answer a question, not to have their pictures taken or filmed and to withdraw from the research at any point. Written consent and assent will be recorded on a paper form in duplicate, with one copy retained by the study and one copy retained by the household.

They will ensure that it is made clear to participants that any refusal will not obstruct their access to any health and welfare-related services (patients) nor will have any impact on their work (health staff, etc.).

15.3. Photography

Throughout the project photographs may be taken of dwellings to support implementation fidelity, intervention performance, and intervention acceptability. These could include photographs of dwellings before, during, and after intervention delivery. Photographs will only ever be taken of dwellings with the explicit verbal consent of present adults. Photographs will be stored on a secure OneDrive folder for a period of up to five years before being deleted. In some instances the study may use photographs of dwellings to support research dissemination – for example in study reports, academic papers, or presentations. Published photos will not include research participants, except in scenarios where specific written consent has been provided (detailed in below paragraph). As part of

study enrolment, heads of household will be made aware of the study's procedures relating to photography.

In instances where photographs are taken that include research participants, for example if domestic routines or interactions with the floor are being documented, participants will be invited to sign photograph release forms before any of these photos are used in reports or publications (Annex 21).

15.4. Community engagement

The research will be presented to county-level stakeholders, including health management and the local administration. During this meeting with local stakeholders, study villages (meeting the study inclusion criteria) for the study will be selected. A sensitization cascade from sub-county to ward level with focus being at ward and village level will be implemented. Meetings with chiefs and ward administrators to inform them about the study will be conducted. The chiefs will then invite the sub location chiefs and the village elders, who will then hold village baraza where the community will be invited to a sensitization meeting together with a member of the study team the study procedures will be explained in ways that enable them to understand the project aims and objectives. During these meetings information sheets will be provided for their review.

15.5. Privacy and confidentiality

All research team members will be committed to keeping all personal information obtained during the research process confidential. Participants will be informed that participation in a research study may involve a loss of privacy, but that all records will be kept as confidential as possible. Researchers will ensure participants that collected information will be securely stored and accessible only to those are authorized throughout the research process. No personal and medical information about patients will be disclosed. Strategies will be used to help maintain anonymity in transcriptions, research reports, presentations, and other means of disseminating findings (webpages, public events, etc.), such as changing the names of communities, attributing an ID to participants and using pseudonyms. Select quotations from field notes, interviews or any other material, such as photos, will be included in published material only if sufficiently anonymized. Contributions from stakeholders may also be attributed to the institutions they represent.

15.6. Benefits

The study participants will individually benefit from having a new sealed, washable floor installed in their house at no monetary cost. Those in the control group will receive the same floor at the end of the study. Data collected during this research will be used to further the understanding of an important and under-explored aspect of environmental health. These findings could have a considerable impact on the health and well-being of study participants through providing a better understanding of the relationship between household flooring and poor health. This in turn could lead to greater resources being made available for improved flooring as well as better designed interventions. Local masons and *fundis* will benefit from being taught new construction methods and having the opportunity to practice and refine these skills under the stewardship of trained engineers.

15.7. Safeguarding and risks

The study project will adhere to KEMRI, *icipe* and LSHTM safeguarding policies and procedures and staff codes of conduct. Researchers will be trained and supervised to be able to anticipate, mitigate and address potential and actual risks for participants. Researchers will inform participants how they can raise safeguarding concerns related to the research and will provide them with contact details, when seeking their consent for research participation.

Maintaining privacy and confidentiality will be emphasized among researchers and other participants. Participants in data collection activities will be required to allocate time to the activities, which could cause some inconvenience. However, these activities will take place either at the home or within the study village so travel time will be minimised. Participants in the trial will be required to vacate their dwelling for the duration of the floor installation which may take up to (7 days). In situations where households are not able to do this, the study team will work with the household and local leadership structures to make arrangements for their temporary relocation.

Delivery of the intervention will involve making substantial changes to participant dwellings – namely through excavating existing floors and replacing them with cement-based floors. This process will not be reversible, so participants will be asked to think carefully before agreeing to participate. Every effort and precaution will be made to only enrol households that have dwellings suitable for the retrofitting of a new floor, however it is possible that dwellings could suffer cosmetic or structural damage as a result of the installation process. If this occurs as a clear and direct result of the installation process, the study will be responsible for repairing this damage. In the event that it is not clear whether the installation process was directly responsible for any perceived damage then an engineer will be consulted to assess the dwelling. Resolution to any disputes between participating households and the study will involve mediation by local stakeholders and will tend towards compromise. Participants will be made aware of dispute resolution options as part of the consent process and prior to making any decision about participation.

15.8. Ethical approval

Before commencement of the research ethical approval will be obtained from:

KEMRI SERU, Kenya

The London School of Hygiene & Tropical Medicine Ethics Review Committee, UK

15.9. Covid risks and precautions

There are currently no COVID-19-related restrictions pertaining to social gatherings, travel, or research within Kenya. All research conducted by this study will be undertaken according to current MoH and KEMRI COVID-19 guidelines. As a minimum the study will ensure that all field officers undergo training on how to minimize the risk of COVID-19 transmission while conducting study activities. All study staff will be equipped with hand sanitiser and will be required to sanitise their hands between visits to different households.

16. Sponsorship

London School of Hygiene & Tropical Medicine is the main research sponsor for this study. For further information regarding the sponsorship conditions, please contact the Research Governance and Integrity Office:

London School of Hygiene & Tropical Medicine
Keppel Street
London WC1E 7HT
Tel: +44 207 927 2626
Email: RGIO@lshtm.ac.uk

16.1. Indemnity

London School of Hygiene & Tropical Medicine holds Public Liability ("negligent harm") and Clinical Trial ("non-negligent harm") insurance policies which apply to this trial.

16.2. Sponsor

London School of Hygiene & Tropical Medicine will act as the main sponsor for this study. Delegated responsibilities will be assigned locally.

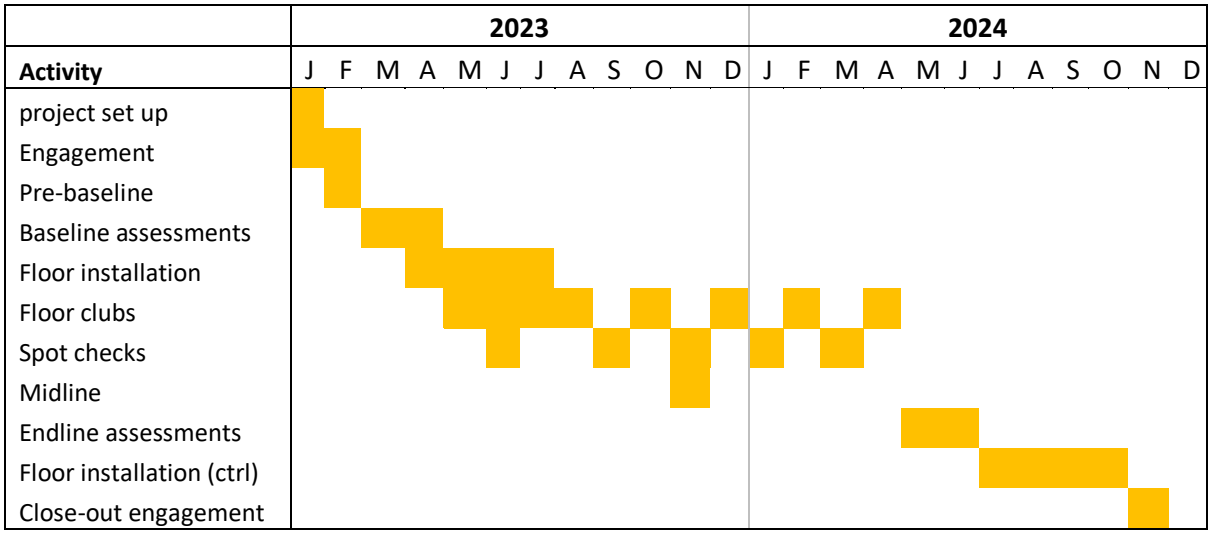
16.3. Audits and inspections

The study may be subject audit by the London School of Hygiene & Tropical Medicine under their remit as sponsor, the Study Coordination Centre and other regulatory bodies to ensure adherence to GCP.

17. Application of the results

Results from this trial will provide vitally needed evidence on the role of household floors as a residual pathway for transmission of enteric and parasitic infections among children. Results will be proactively disseminated to sub-county and county level leadership within Bungoma and Kwale, to the Ministries of Health at the county and national levels within Kenya and to the Ministry of Transport, Infrastructure Housing Urban Development and Public Works. It is intended that the results will inform development of future public health and housing policy within Kenya, specifically with regards to the control of STH and tungiasis. Further to this, findings relating to the feasibility and acceptability of the intervention will be of significant use to any programmes within the public health and housing sectors that are planning future interventions relating to household flooring. Dissemination will also take place beyond Kenya through presentations at academic conferences and publication of the results in peer reviewed journals, with the intention that other countries with similar housing and epidemiological profiles will be able benefit from these findings.

18. Workplan



19. Budget

Table 4. Budget summary for the SABABU study

Item	**Amount (GBP£)**	**Amount (Kshs)**
a) Personnel salaries and benefits Project coordinators and investigators Field officers	 471,308 169,175	
b) Patient Costs	3,322	
c) Equipment	57,991	
d) Supplies	244,669	
e) Travel and accommodation Flights Accommodation Meetings	 107,600 84,773 18,309	
f) Transportation Field car hire and fuelling	 71,633	
g) Operating expenses Office hire Insurance	 16,309 9,600	
h) Animals	Not applicable	
j) Contingency funds	Not applicable	
k) Institutional administrative overheads	124,216	
Total	**1,378,905**	**193,768,221**

20. Justification of the budget

Personal salaries and benefits

Project coordinators and investigators – Providing scientific and logistical oversight for the research.

Field officers – Conducting community sensitization, collecting informed consent from participants, delivering surveys, observations, spot checks, and interviews.

Equipment

Including laptops to conduct data cleaning and analysis, lab equipment for diagnostics, and data collection apparatus such as mobile devices and dictaphones.

Supplies

Supplies including building supplies for the intervention, office consumables, and lab consumables.

Travel and accommodation

The PIs and investigators will need to travel to and stay at the two sites during preparation and delivery of research activities and engage in meetings and workshops.

Transportation

During the study the field officers will leave and return to the field offices and so vehicles will be provided to transport them to the communities during research activities. All costs for travel and accommodation have been estimated using standard KEMRI mileage.

Operating expenses

Office hire – Field offices will need to be rented for the duration of the study period to serve as bases of operation for trainings and research activities

Trial insurance – Insurance for the trial

21. Role of investigators

Table 5. Investigator roles for the SABABU study

Name	**Duties and responsibilities**
Dr Charles Mwandawiro	SCD, PD, SG, SE, T
Dr Rachel Pullan	SCD, PD, SG, DA
Dr Ulrike Fillinger	SCD, PD, SG, T, DA, TD, RW
Dr Katherine Halliday	SCD, PD, TD, DA
Dr William Oswald	SCD, PD, TD, DA
Prof Elizabeth Allen	SCD, DA
Dr Doris Njomo	SG, SE, T, DA, RW, TD
Prof Sammy Njenga	SG, T, DA, RW
Dr Stella Kepha	SCD, SG, DC, SE, T, DA, RW, TD
Dr Lynne Elson	SCD, PD, SG, T, DA, TD, RW
Mr Hugo Legge	SCD, DC, T, DA, RW, TD
Dr Victoria Akoth	DC, SE, T, DA, TD
Dr Beatrice Kakoi	PD, SG, DA, TD
Prof James Wambua	PD, SG, DA, TD
Ms Jacinta Mwongeli	SG, T, DA, RW, TD

Abbreviations:

SCD: study conception and design

PD: proposal development

SG: scientific guidance

DC: data collection

SE: Stakeholder engagement

T: Training

DA: data analysis and synthesis

RW: report writing

TD: tool development

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