10 December 2019

Dear Miss Budge ,

Reference: CURES/9357/2019
Title: Feasibility study with a non-blinded, pilot, randomised baseline trial to evaluate the fidelity of a play space intervention model to reduce infant Campylobacter infection in rural households in Sidama Zone, Ethiopia

Thank you for your application to the Cranfield University Research Ethics System (CURES).

I have received your response to the question asked an this is satisfactory and well argued.

I will arrange for the panel notes to be sent to you for information purposes only. There is no need to respond but I would encourage you to reflect on some of the points raised about risk assessment.

We are pleased to inform you your CURES application, reference CURES/9357/2019 **has been reviewed. You may now proceed with the research activities you have sought approval for.**

If you have any queries, please contact CURES Support.

We wish you every success with your project.

Regards,

CURES Team

You are encouraged to upload a research protocol if this is common practice in your area of study. In addition, please upload any supporting documents you may have that will help reviewers understand your research design such as questionnaires, interview schedules, participant information sheets, consent forms, case for support etc. (dependent on study)
The protocol is thorough and well-written, and the researchers have clearly given a lot of thought to the ethical implications of this work. I have a few further considerations:

1) Product risk assessment - Obviously we are not tasked with conducting a risk assessment here, but given the sheer vulnerability of the study group, it warrants a bit of consideration here. The research team is providing a product for very young children to use, and if a child were injured as a result of that product the consequences would be devastating for all concerned. The research team has clearly considered relevant safety standards in the design of the play space. Even so, there are questions. Are they satisfied that the literacy of the caregivers would be sufficient to interpret the warnings? Would they be happy for children to be left unattended in the play space (the warnings suggest this is permissable)? The warnings state that the play space should not be left near any cords, and yet in the pictures, a cord appears to be used to secure the play space? A rigorous risk assessment of the play space, perhaps with some independent product safety testing (as would be required in this country), is vital here.

2) Data security - Again, this is vital given the vulnerability of the study group. I'm satisfied that they've carefully considered data management, but I would strongly question the use of Dropbox (mentioned in 6.2) given its well-known security vulnerabilities. GDPR must be adhered to regardless of where the data is collected, and the university would bear ultimate responsibility for any data breach. Surely the university's online repository would serve the same function and be better than Dropbox?

3) Caregivers - In considering the potential harm to research participants, the emphasis (naturally) is on the children. The protocol currently doesn't give much consideration to potential harm to the caregivers. The protocol states that the data will be anonymised, but surely the identities of the participating families will be known

to PiN and to others in the villages where they live? Could any harm result from this (e.g. stigma)? It seems unlikely but warrants consideration.

4) I agree with the need for the protocol to address what happens if a child tests positive for Campylobacter during the trial - not just in terms of health but potential emotional and social impacts. I don't know what the potential impacts of the illness are but it seems like it should be handled sensitively.

28/11/2019 9:55 Dr Heather Smith

Please click on 'Next' in left hand actions bar to move forward to Part 6

This protocol is well designed and thorough. There are a couple of points that could be worth mentioning to the research team:

- In the safety considerations noted by the field team should there be a point on proximity to electrical socket. One is shown in the picture (Section 3.3).
- Will there be guidance given as to the maximum number of children should be using the HPS simultaneously and what kind of supervision is appropriate. I am not entirely sure how likely it could be used by friends and neighbours?
- If the concept of HPS is new to these population should there be a visit planned within 24 to 48 hours (not coupled with data collection) to check that the intervention is well received and understood. I am a bit confused on the visit planning as there is a visit plan (Figure 1. Example of baseline trial data collection Gantt chart) which does not quite reflect the “Household play space design method” at section 3.1.
- Has the research team reflected on the detection of a child infected with pathogenic Campylobacter either at the time of Baseline collection or after 14 days? How will the team approach such event? Should there be a communication plan to reassure the rest of the participants?