Trial protocol plain summary

Title:

A randomised controlled feasibility trial of a household play space intervention to reduce infant Campylobacter infection: The CAMPI trial

Abstract:

Globally, stunting is the most prevalent form of undernutrition. Poor water, sanitation and hygiene (WASH) facilities are associated with poor infant health (diarrhoea and undernutrition, including wasting and stunting) and so improved household WASH was recently incorporated into the malnutrition framework. Acting as a primary barrier to pathogenic bacteria, adequate WASH facilities should prevent infection for better infant health outcomes. However large randomised trials have not shown a consistent effect. In part, this might be because WASH interventions have focused on containing human excreta and have overlooked the large burden of pathogenic bacteria from animal faecal contamination. Within homes where occupants live closely with animals, infants are exposed to pathogens on contaminated floors, objects and hands. Further research is needed on potential solutions to block pathogen transmission and reduce infection. This is especially important in subsistence livelihood settings, where significantly changing traditional animal husbandry practices may be unfeasible. Furthermore concerns over antimicrobial resistance surround the use of preventative vaccinations, which also appear less effective due to the changes in gut function seen in undernourished children. The CAMPI trial (Campylobacter Associated Malnutrition Playspace Intervention trial) is a randomised, single site, feasibility control trial. It aims to evaluate the feasibility of a household play space to reduce infant infection. Based on outcomes it will make recommendations for scaling up into a full trial. Outcomes will provide further evidence for the exposure-infection pathway hypothesis and help fill the knowledge gap for alternative solutions to help reduce infant enteropathogen infection in rural subsistence settings.

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Name of Partner Institution:

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Intervention:

This trial is a single-centre, non-blinded, controlled randomised feasibility trial.

Trial timeline:

Start date: Approximately late January (with ethical approval).
Duration: 4-5 weeks

Study numbers and criteria

Total participants for the study will be 100 households across two study arms:

- Control: No intervention (HPS will be provided at the end of the trial) = 50
- Intervention with HPS (household will keep HPS at the end of the trial) = 50

Eligibility criteria:

- Infants aged 10−18 months at the start of the trial (proposed January 2020)
- Infants living in villages within PiN intervention areas (Sidama zone, SNNPR region)
- Households with free-roaming poultry OR cattle OR both
- Not involved in any other study

Exclusion criteria:

Pertaining to caregivers:

- Participating in other ongoing PIN studies
- Do not own domestic animals

Pertaining to infants:

- Outside the age range of 10-18 months at the trial start
- Participating in other ongoing PIN studies
- Known to have been low birth weight, pre-term or experienced other birth complications

Method details:

As a feasibility trial, the trial does not aim to formally test a hypothesis, or to test effectiveness, as it is underpowered to do so. This trial is designed to assess the feasibility of running a full RCT and to support its development if outcomes suggest to do so.

Primary aims:

1. Evaluate the feasibility of a play space as a public health intervention by measuring intervention fidelity, acceptance, adherence and attrition
2. Evaluate the appropriateness of the study design and research processes, including assessing their delivery against protocols (research fidelity)
3. Make recommendations for adjusting intervention and research design for future studies and on the feasibility of scaling up into a full trial, or alternative strategies
4. Contribute further evidence on the infection-exposure hypothesis

Secondary aims:

1. Estimate an effect side of the play space intervention on the infection parameter. This will be done by using prevalence rates of Campylobacter in the general population versus any reduction found in the trial at 14 days and/or at 4 weeks
2. Infant health outcomes, including growth data, diarrhoeal prevalence and infection prevalence at 3 time points and relationship to play space use

Outcome measures:

Outcome variable	**Measure**	**Control arm**	**HPS arm**	**Baseline measure**	**14 day measure**	**4 week measure**
Infant faecal *CB* prevalence	Culture-based	x	x	x	x	x
Fidelity and adherence: HPS use	• Current use of HPS (observation) • Hours using HPS in past 24hrs • Correct use of HPS		x		x	x
Fidelity and adherence: HPS cleanliness	• Visible dirtiness (Ngure et al. methods) • Animals inside HPS • Faeces inside HPS		x		x	x
Attrition: HPS use and non-use	Barrier analysis		x		x	x
Control variable	**Measure**	**Control arm**	**HPS arm**	**Baseline measure**	**14 day measure**	**4 week measure**
Infant anthropometry	• Height • Weigh • MUAC	x	x	x		x
Infant diarrhoeal prevalence	Caregiver 7-day recall	x	x	x	x	x
Household demographics / SES	Survey	x	x	x		
Household WASH facilities / use	Survey	x	x	x	x	x
Animal ownership and husbandry practices	Survey	x	x	x	x	x
Infant feeding practices, including food and serving	• Minimum meal frequency • Individual dietary diversity score • Feeding of fresh or reheated foods	x	x	x	x	x
Breastfeeding practices	• Breastfeeding at 1 year • Breastfeeding definition (full, partial, none)	x	x	x	x	x