ISRCTN14390796 https://doi.org/10.1186/ISRCTN14390796

Evaluation of a community-level complementary-food safety and hygiene, and nutrition intervention - the MaaCiwara study

Submission date
10/12/2021

Recruitment status
No longer recruiting

Registration date
13/12/2021

Overall study status
Completed

Last Edited
17/07/2024

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
The researchers propose a low-cost, scalable, and adaptable community intervention to improve water and food safety and hygiene behaviour, reduce food and water contamination and reduce diarrhoea among children aged 6-36 months in urban poor and rural settings in Mali.
After adapting the intervention to the Malian context, the intervention aims to empower local families and communities to implement behaviour change. It will include campaign-like activities such as culturally relevant dramatic arts (drama, songs, stories), public meetings, certifications, and home visits.
This study is designed to explore whether the interventions work differently in rural and urban contexts and to examine other societal influences (e.g. household poverty, women's work, and education, etc). Using observations, interviews, discussion groups, surveys, and laboratory tests the researchers will compare how the intervention worked and key outcomes in urban and rural settings.

Who can participate?
Residents of the selected communities in Mali with children aged 6-36 months

What does the study involve?
Delivery will be by a small team over 4 or 5 days of community campaign visits dispersed over about 35 days or more and includes home visits by trained female volunteers, plus a reminder campaign day at about 9 months or more. The researchers will allocate by chance 120 urban and rural communities in Mali to receive the intervention, or not, and assess about 27 households in each community after 4 and 15 months or longer following the allocation. The days of intervention will all be dependent on the outcome of the formative research and the intervention adaptation.

What are the possible benefits and risks of participating?
This study will be able to inform a programme on behavioural change for mothers' food preparation and handling practices, and improvement of child play.
Participants will not get paid for participation but refreshments will be provided during the

discussion. The researchers will refund transport for the community leaders group who will have to travel to a centrally located community. No transport costs will be paid to the other groups because these discussions will be conducted in their own community so they will not need to travel. There is no harm or discomfort associated with this study. There is a time cost.

Where is the study run from?
University of Science Technical and Technologies de Bamako (Mali)

When is the study starting and how long is it expected to run for?
October 2020 to December 2024

Who is funding the study?
UK Research and Innovation - Global Challenge Research Fund through Medical Research Council (UKRI-GCRF-MRC) (UK)

Who is the main contact?
1. Dr Evans Asamane, e.a.asamane@bham.ac.uk
2. Dr Semira Manaseki-Holland, s.manasekiholland@bham.ac.uk

Study website
https://www.birmingham.ac.uk/research/applied-health/research/maaciwara-study/index.aspx

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Protocol for a parallel-group, two-arm, superiority cluster randomised trial to evaluate a community-level complementary-food safety and hygiene and nutrition intervention in Mali: The MaaCiwara study

Acronym
MaaCiwara

Study objectives
Current study hypothesis as of 24/11/2022:
1. The intervention is associated with a change in the food and water preparation behaviours of mothers of children aged 6-36 months in urban-poor and rural Mali.
2. The intervention is associated with a change in the contamination of food and water provided to children aged 6-36 months in urban-poor and rural Mali.
3. The intervention is associated with a change in the incidence of diarrhoea among children aged 6-36 months in urban-poor and rural Mali.

Previous study hypothesis:
1. The intervention is associated with a change in the food and water preparation behaviours of mothers of children aged 6-24 months in urban-poor and rural Mali.
2. The intervention is associated with a change in the contamination of food and water provided to children aged 6-24 months in urban-poor and rural Mali.
3. The intervention is associated with a change in the incidence of diarrhoea among children aged 6-24 months in urban-poor and rural Mali.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 16/11/2020, Ethics Board, Faculty of Medicine, Surgery, Odontostomatology and Pharmacology (University of Science, Techniques, and Technologies of Bamako, University of Bamako, Bamako, Mali; +223 (0)20225277; email: not available), ref: 2020/253/CE/FMOS/FAPH

Study design
Parallel cluster randomized controlled trial and qualitative/ethnographic research

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Prevention of symptomatic enteric infection in children 6-36 months

Interventions
After baseline data collection, clusters will be randomly allocated by an independent statistician in a 1:1 ratio to either the treatment or control arm stratified by urban/rural status (30 intervention and 30 control clusters from both urban and rural settings). Within strata the researchers will use a minimisation method to allocate clusters to the treatment or control arms to improve the efficiency of the design given large potential heterogeneity between the clusters.

Intervention
The intervention will be an adapted version of a community level complementary-food hygiene and safety intervention previously carried out in Mali, Bangladesh and Nepal, and evaluated in the Gambia (Manjang et al., 2017; Nakahara et al., 2014). The intervention will also include hygienic play and dietary diversity and meal frequency promotion, which were not included in later studies, including the Gambia intervention (Manjang et al., 2017).
The intervention schedule and tools used in the MaaChampion Gambian study (Manjang et al., 2017; Nakahara et al., 2014) will be contextualised and adapted by applying the findings of a mixed-methods formative research study conducted in Mali in 2021 and developing a creative brief for a Mali creative team to design the community level intervention components. The full intervention, once adapted, will be described in a separate publication in compliance with the template for intervention description and replication (TIDieR) checklist and guide Hoffmann et al., 2014). The basic components and principles of the intervention will be the same as the MaaChampion intervention. (Manjang et al., 2017).
The adaptation will mainly influence the choice of behaviours, language and cultural aspects of

dramatic arts, and the focus on community hierarchies. The intervention will involve 5 days of campaign community visits dispersed across 35 days (days 1, 2, 15, 17, and 35), including home visits, community events, neighbourhood meetings, dramatic arts (songs, drama, stories, animation), and competitions based around achieving a model-mother status. Community volunteer home visits followed between each campaign day, and a reminder campaign day after nine months to embed the behaviours into social norms, and thereby enhancing sustainability. They will be paid minimally (comparable to local health system health volunteers) for the first year of the project.
Implementation will be through Intervention teams who will include district-level community health promotion or public health staff, community traditional communicators (traditional singers, drummers, and performing artists) and respected community members as assisted volunteers (often older mothers or traditional birth attendants). All community members (including fathers) will be involved as well as community leaders in promoting the intervention.

Control
The control communities will receive a 1-day community-based campaign on the use of water in homes and outdoors. The content is designed to be similar to the intervention in terms of being a community-based intervention delivered through a one-day campaign event, but does not contain equivalent content on food and water preparation, hygiene, child nutrition or hygienic play. It is designed to serve as a "placebo". The specific choice of topic for control communities will be finalised after the adaptation of the intervention to ensure minimal overlap. As with the intervention, a Public Health/Health Promotion Officer will provide the visit in each control community. The intervention and control village activities will be delivered in parallel.

Intervention Type
Behavioural

Primary outcome measure
1. Water and food safety and hygiene behaviour measured using a bespoke standard observation form (number of opportunities met (binomial)) at baseline, 4 months and 15 months
2. Food and water contamination measured through sample collection and field testing at baseline, 4 months and 15 months
3. Diarrhoea measured through observation of collected stool by field workers at baseline, 4 months and 15 months

Secondary outcome measures
Current secondary outcome measures as of 27/02/2024, with the trialist confirming they are correct as of 12/12/2022:
All data is collected by survey at baseline, 4 months and 15 months.
1. Water and food safety and hygiene behaviour (availability and use of soap in key areas for handwashing [kitchen and toilet])
2. Diarrhoea (7-day parental report of child diarrhoea episodes [3 or more watery stools in 24 h])
3. Uptake and fidelity of implementation of the intervention
4. Maternal knowledge
5. Maternal autonomy
6. Improved supervision and conditions of child play to reduce geophagy
7. Dietary diversity and frequency
8. Reported acute respiratory infection
9. Diarrhoea hospitalisation
10. Enteric infection
11. Growth and anthropometry

12. Cognitive development
13. Community trust, unity and social cohesion
14. Water and food safety and hygiene behaviour measured using a bespoke standard observation form (number of opportunities met [binomial]). This is for family foods and not child food which is captured as primary outcome.
15. Communal handwashing of the mother before eating herself measured through observation

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Previous secondary outcome measures :
1. Uptake and fidelity of implementation of the intervention measured using an investigator report and survey at baseline, 4 months and 15 months
2. Maternal knowledge measured using a survey at baseline, 4 months and 15 months
3. Maternal autonomy measured using a survey questionnaire at baseline, 4 months and 15 months
4. Improved supervision and conditions of child play to reduce geophagy measured using bespoke standard observation form (number of opportunities met (binomial)) at baseline, 4 months and 15 months
5. Dietary diversity and frequency measured using a survey questionnaire (developed from DHS) at baseline, 4 months and 15 months
6. Reported acute respiratory infection measured using a survey questionnaire at baseline, 4 months and 15 months
7. Diarrhoea hospitalisation measured using a survey questionnaire at baseline, 4 months and 15 months
8. Enteric infection measured through sample collection and lab testing (presence/absence (of each) at baseline, 4 months and 15 months
9. Growth and anthropometry measured using standard measuring procedures (height for age (z-score [WHO International Growth Tables]) captured on-site at baseline, 4 months and 15 months
10. Cognitive development measured through survey/observation at baseline, 4 months and 15 months

Overall study start date
01/10/2020

Completion date
31/12/2024

Eligibility

Key inclusion criteria
Current inclusion criteria as of 12/12/2022:
Cluster inclusion criteria:
1. Permission from community leaders
2. In urban areas, clusters/communities will include predominantly poor communities to be approximately comparable to the rural clusters. The clusters in both urban and rural communities must be areas of 500 to 2,000 people (approximately 200 to 500 households).
3. These clusters are bounded by obvious environmental features including roads and rivers.
4. The clusters are also designed to have a relatively central community area. As much space as possible between cluster areas will be included to reduce the risk of contamination, either from individuals in one cluster visiting the intervention in another site, or knowledge produced by the intervention being communicated over larger areas.

Participant inclusion criteria:
1. Resident within selected communities (not a visitor)
2. Has child aged 6-36 months
3. Regular child carer available for 9 hours to be observed

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Previous inclusion criteria:
Cluster inclusion criteria:
1. Permission from community leaders
2. In urban areas, clusters/communities will include predominantly poor communities to be approximately comparable to the rural clusters. The clusters in both urban and rural communities must be areas of 500 to 2,000 people (approximately 200 to 500 households).
3. These clusters are bounded by obvious environmental features including roads and rivers.
4. The clusters are also designed to have a relatively central community area. As much space as possible between cluster areas will be included to reduce the risk of contamination, either from individuals in one cluster visiting the intervention in another site, or knowledge produced by the intervention being communicated over larger areas.

Participant inclusion criteria:
1. Resident within selected communities (not a visitor)
2. Has child aged 6-24 months
3. Regular child carer available for 9 hours to be observed

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
60 intervention clusters (communities) and 60 control clusters (communities). In each cluster, 27 mother-child pairs randomly sampled to participate at each of evaluation time point) Total =3240.

Key exclusion criteria
For clusters:
1. Involved in the Formative Research or the piloting of the intervention or questionnaires

For participants
1. Mother or child’s main regular daytime carer not available to consent or be observed all day or the child him/herself not available the next day

Date of first enrolment
21/01/2022

Date of final enrolment
28/01/2022

Locations

Countries of recruitment
Mali

Study participating centre
University of Science, Techniques, and Technology Bamako
Bamako
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1805

Sponsor information

Organisation
Université des Sciences, des Techniques et des Technologies de Bamako

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Sponsor type
University/education

Website
http://www.usttb.edu.ml/

ROR
https://ror.org/023rbaw78

Funder(s)

Funder type
Government

Funder Name

UK Research and Innovation - Global Challenge Research Fund through Medical Research Council (UKRI-GCRF-MRC)

Alternative Name(s)
UKRI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
1. Publication in a high-impact journal
2. Conference presentation
3. Stakeholder workshops
4. The protocol will soon be published after getting the trial registered

Intention to publish date
01/02/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request and only anonymised data will be shared. Consent has been obtained from participants indicating that anonymised data will be made public for a period of 10 years. This follows the data storage requirements of the University. A bespoke data-sharing request form will be made publicly available at the end of the study for the public to make a request. In this form, the type of data, format and preferred mode of transferring the data should be included to help us process any request. All completed data request forms should be sent to the chief investigator, Dr. Semira Manaseki-Holland on s.manasekiholland@bham.ac.uk. It is anticipated that a request for data can be made after 01/12/2027.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		30/01/2023	02/02/2023	Yes	No
Statistical Analysis Plan		16/07/2024	17/07/2024	No	No