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Mikono Safi Study - Hand hygiene intervention to optimise helminthic infections control: a cluster-randomised controlled trial in NW Tanzania

Submission date
09/06/2017

Recruitment status
No longer recruiting

Registration date
21/06/2017

Overall study status
Completed

Last Edited
10/10/2022

Condition category
Infections and Infestations

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims:
Parasitic worms (helmiths) are organisms that live in the intestine and feed off their living hosts. They are among the most common type of infections worldwide, especially in poor and deprived communities. They are spread by eggs present in human faeces which in turn contaminate soil in areas where sanitation is poor. An infection can cause malnutrition, physical and mental retardation, and reduced work performance in older age. Previous surveys undertaking in the Kagera Region of Tanzania have found that more than 70% of primary school children aged 6 – 12 years in some schools suffer from parasitic worm infections. This is also the case in other parts of Tanzania (and other resource-limited countries) in spite of annual deworming campaigns that are conducted in schools by the national control programme for neglected tropical diseases. Deworming campaigns remain a cost-effective way to treat these infections, but they do not target the route cause and so many experience repeated infections. An integrated approach that combines deworming with sustainable hygiene behaviour change could prove an effective way to control parasitic worm infections. The aim of this study is to find out whether the effects of routine deworming campaigns in primary schools in Africa can be enhanced and sustained by combining it with an appropriate Water, Sanitation and Hygiene (WASH) behaviour change program to improve hand-washing practices.

Who can participate?
Primary school aged children attending participating primary schools.

What does the study involve?
Participating schools are randomly allocated to one of two groups. At the start of the study, children attending schools in both groups undergo annual deworming using deworming medication. Schools in the first group then continue as normal. Schools in the second group take part in the behaviour change program. This involves teacher-led health education in primary schools, low-cost structural improvements of water supply and sanitation (e.g. soap dispensers), nudges to increase students intention to wash hands after defecation (e.g. painted footpaths

that connect toilets with hand-wash stations), and a one-off screening of students for current worm infection combined with feedback of results to parents and health information given to students' parents (with the intention to increase parents' awareness and concern). One year after enrolment, all students complete a follow-up survey to see if they are infected with worms.

What are the possible benefits and risks of participating?
Participants may benefit from increased knowledge and skills on hand-washnig behaviour, preventing them from bacterial infections. Treatment with albendazole may improve the general health status of children, reduce potential aneaemia and improve their cognitive (mental) capacity. There are no notable risks however, treatment with albendazole may cause temporary nausea and questions on hygiene may be perceived as sensitive or embarrassing.

Where is the study run from?
The study is run from Mwanza Intervention Trials Unit and takes place in 16 primary schools in the Kagera Region (Tanzania)

When is study starting and how long is it expected to run for?
October 2016 to December 2018

Who is funding the study?
Department for International Development (UK)

Who is the main contact?
1. Professor Heiner Grosskurth (scientific)
2. Professor Saidi Kapiga (scientific)

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
Version 2

Study information

Scientific Title
Cluster-randomised controlled trial to evaluate the effectiveness of an intervention for improving handwashing behaviour on the prevalence of soil transmitted helminth infections among primary school children in NW Tanzania

Acronym
Mikono Safi Study

Study objectives
Among children with a high prevalence of soil transmitted helminth infections in-spite of annual deworming, a hand washing intervention will be effective in reducing the prevalence and intensity of Ascaris lumbricoides and Trichuris trichiura infections.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Medical Research Coordinating Committee (MRCC), National Institute for Medical Research,18 /05/2017, ref: Nu NIMR/HQ/R.8a/Vol. IX/2497
2. Ethics Committee of the London School of Hygiene and Tropical Medicine, ref: 11868

Study design
Open-label single-centre cluster randomised controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
1. Soil transmitted helminth infections
2. Water, sanitation and hygiene (WASH) related behaviour

Interventions
Participanting schools are randomised within geographical strata (districts). There are three districts (Bukoba Urban District, Bukoba Rural District and Muleeba District). Randomisation to either the intervention or control arm is done through a computer generator.
Both intervention and control arm schools participate in an annual deworming campaign, timed to start just before the intervention. Deworming is done with single dose Albendazole (400 mg orally). Following deworming with Albendazole in both arms of the study, students will participate in a baseline survey involving a stool examination to determine whether they have a helminth infection. Those still infected will be immediately re-treated with Albendazole

Intervention arm: Schools participants in a combination intervention with 4 components:
1. Teacher-led health education delivered in 3 sessions of about 2 hours each, over a period of 9 months
2. Low-cost structural improvements with respect to water supply and sanitation (e.g. continuous provision of hand wash stations and soap dispensers)
3. Nudges to increase students intention to wash hands after defecation (colour painted footpaths)
4. One-time screening of students for current worm infection at beginning of intervention, combined with feedback of results to parents and health information given to students' parents. Participants in this arm receive a behavioural intervention after this to improve their hand washing behaviour.

Control arm: Schools continue with business as usual.

One year after enrollment, participants in both arms complete a follow-up survey to determine whether they are infected or reinfected. Reinfected students are treated again.

Intervention Type
Behavioural

Primary outcome(s)
Combined prevalence of ascariasis and trichuriasis in students' stool samples is measured by microscopy using the formol-ether concentration method to identify helminth ova, at baseline and about 12 months after initial deworming.

Key secondary outcome(s))
1. Hand-washing behaviour in schools (reported and observed) and at home (reported only) by administering structured questionnaires and records respectively at baseline and 12 months after deworming
2. Intensity (worm egg count) of ascariasis and trichuriasis infections is measured by microscopy, counting helminth ova in samples of about 2 grams, at baseline and 12 months after deworming
3. Levels of hand contamination with worm eggs and E. coli bacteria is measured by a previously validated concentration procedure and microscopy, applied to hand-rinse samples, obtained at 12 months after deworming
4. Prevalence and intensity of hookworm infection is measured by microscopy at baseline and 12 months after deworming

Completion date
17/05/2019

Eligibility

Key inclusion criteria
1. Primary school students
2. Male and female
3. Attending classes 1 - 6
4. aged 6 - 12 years

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 years

Upper age limit
12 years

Sex
All

Total final enrolment
3163

Key exclusion criteria
1. Student not giving assent
2. Parent or guardian refusing consent

Date of first enrolment
01/08/2017

Date of final enrolment
30/11/2017

Locations

Countries of recruitment
Tanzania

Study participating centre
Mwanza Intervention Trials Unit (MITU)
National Institute for Medical Research Tanzania
Mwanza Centre

Isamilo Road
Mwanza
Tanzania
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Sponsor information

Organisation
London School of Hygiene and Tropical Medicine (LSHTM)

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Government

Funder Name
Department for International Development, UK Government

Alternative Name(s)
DFID

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be made available upon request from the PI Prof Saidi Kapiga (saidi.kapiga@lshtm.ac.uk), following approval from the Trial Steering Committee (TSC) and after the MITU research team has had an opportunity to publish the results of the trial, but latest within 2 years of the end of data collection (which is expected for December 2018 at the latest).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Qualitative results on facilitators and barriers to hand hygiene	28/11/2019	26/11/2020	Yes	No
Results article		21/05/2021	24/05/2021	Yes	No
Other publications	design and baseline characteristics	09/12/2020	23/04/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 2	26/05/2017	10/10/2022	No	No