

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	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 21/06/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/10/2022	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims:

Parasitic worms (helminths) 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 undertaken 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 aneemia 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

Prof Heiner Grosskurth

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Cluster randomised trial

Study setting(s)

School

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

1. Soil transmitted helminth infections
2. Water, sanitation and hygiene (WASH) related behaviour

Interventions

Participating 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 measure

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.

Secondary outcome measures

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

Overall study start date

01/10/2016

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

Age group

Child

Lower age limit

6 Years

Upper age limit

12 Years

Sex

Both

Target number of participants

16 clusters (primary schools) with 200 participants per school; 3200 children in total

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)

Sponsor details

Keppel Street

London

England

United Kingdom

WC1E 7HT

Sponsor type

University/education

Website

<https://www.lshtm.ac.uk/>

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

Publication and dissemination plan

Planned publication of the results of the trial in a high-impact peer-reviewed journal by or before December 2019. We also intend to issue policy briefs by about June 2019.

Intention to publish date

31/07/2020

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
Other publications	design and baseline characteristics	09/12/2020	23/04/2021	Yes	No
Results article		21/05/2021	24/05/2021	Yes	No
	version 2	26/05	10/10		

[Protocol file](#)

/2017	/2022	No	No
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