

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

<b>Submission date</b> 09/06/2017	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 21/06/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 10/10/2022	<b>Condition category</b> 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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### Type(s)

Scientific

### Contact name

Prof Saidi Kapiga

### Contact details

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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?
<a href="#">Results article</a>	Qualitative results on facilitators and barriers to hand hygiene	28/11/2019	26/11/2020	Yes	No
<a href="#">Other publications</a>	design and baseline characteristics	09/12/2020	23/04/2021	Yes	No
<a href="#">Results article</a>		21/05/2021	24/05/2021	Yes	No
	version 2	26/05	10/10		

[Protocol file](#)

/2017      /2022      No      No