

# Evaluation of complementary nutrition, water, sanitation and hygiene (WASH) and school garden interventions in Burkina Faso and Nepal

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| <b>Submission date</b><br>23/06/2015   | <b>Recruitment status</b><br>No longer recruiting        | <input type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>17/07/2015 | <b>Overall study status</b><br>Completed                 | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>18/08/2023       | <b>Condition category</b><br>Infections and Infestations | <input type="checkbox"/> Individual participant data  |

## Plain English summary of protocol

### Background and study aims

Complementary nutrition, WASH and school garden interventions can play an important role in improving health outcomes of children in developing countries. They consist in the improvement of water and sanitary environments at school and household level, education to promote dietary and hygienic behaviour, and the improvement of school-feeding programmes. However, we are not sure whether these complementary and integrated interventions help improve health outcomes of children in developing countries and the aim of this study is to find out more about it.

### Who can participate?

School children aged 8 to 14 in selected schools in Burkina Faso and Nepal.

### What does the study involve?

In Burkina Faso, school are randomly allocated to one of two groups: no intervention (control) or the whole package (nutrition, WASH and school garden). In Nepal, schools are randomly allocated to one of four groups: no intervention (control) or school gardens (but no nutrition and WASH) or nutrition and WASH (but no school gardens) or the whole package (nutrition, WASH and school garden).

### What are the possible benefits and risks of participating?

The possible benefits for the participants will occur at several levels:

1. At the level of schools, the study will increase the knowledge of teachers and children about WASH and nutrition interlinkage for better health.
2. At the level of households and communities, the study will increase alike the knowledge of mothers and children care takers about WASH and nutrition interlinkage for better health.
3. After the baseline surveys, participants will benefit from free drug administration for parasitic infections and specific treatment on anaemia (both) or any other clinical signs that may indicate a nutritional deficiency (e.g. Bitots spot, dry and infected cornea, dermatitis in Nepal).
4. Furthermore, after the surveys, the project will design and implement locally appropriate complementary nutrition and health interventions based on the results of the baseline study

with the support of the school principals, teachers, the research team, and implementing partners.

To prevent any risks, participants are informed in detail about the study processes at each step and either oral or written consent is collected both from the respondent and the legal representative.

Where is the study run from?

Selected schools in Burkina Faso and Nepal

When is the study starting and how long is it expected to run for?

February 2014 to December 2016

Who is funding the study?

Swiss Agency for Development and Cooperation (SDC)

Who is the main contact?

Mr Guéladio Cissé

## Contact information

**Type(s)**

Public

**Contact name**

Mr Guéladio Cissé

**ORCID ID**

<http://orcid.org/0000-0002-6286-976X>

**Contact details**

Department of Epidemiology and Public Health

Swiss Tropical and Public Health Institute

Socinstrasse 57, PO Box

Basel

Switzerland

4054

+41 (0)61 285 83 04

[gueladio.cisse@unibas.ch](mailto:gueladio.cisse@unibas.ch)

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N/A

# Study information

## Scientific Title

Complementary nutrition, WASH and school garden interventions in Burkina Faso and Nepal: measuring school children's nutritional and health status at baseline and follow-up over a 1-year period.

## Study objectives

We assume that integrated nutrition, WASH and school gardening interventions have an effect on school children's dietary and hygienic knowledge, awareness and practices, eventually improving their nutritional and health status. Therefore, the following hypotheses are made: complementary nutrition, WASH and school garden interventions will have a positive impact on targeted school children's nutrition and health knowledge, attitudes, practices and finally, improve their nutritional status (anthropometrics, haemoglobin) and health (parasitic infections, clinical examination in Nepal only).

Additional hypothesis tested in Nepal only:

1. The combination of only nutrition and WASH interventions has fewer/equal effects on targeted school children's nutrition and health status than the combined nutrition, WASH, health and school vegetable garden intervention package.
2. The school gardens interventions only (without combinations or complementary interventions) have fewer/equal effects on targeted school children's nutrition and health status than (i) the combination of only nutrition and WASH interventions; and (ii) the combined nutrition, WASH, health and school vegetable garden intervention package.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

1. Burkina Faso : Comité d'éthique pour la recherche en santé, Ministère de la recherche scientifique et de l'innovation, Ministère de la santé, 20/05/2014, ref: 2014-5-058
2. Nepal: Institutional Review Committee of Kathmandu University School of Medical Sciences, Dhulikhel Hospital, 24/08/2014, ref: 86/14
3. Nepal: Institutional Review Committee, Nepal Health Research Council, 11/11/2014, ref: No 565
4. Burkina Faso: Ethikkommission beider Basel (EKBB, Switzerland), 19/01/2015, ref: 2014-161
5. Nepal: Ethikkommission beider Basel (EKBB, Switzerland, 12/01/2015, ref: EKBB, UBE-15/02

## Study design

Observational, cross-sectional survey, epidemiological survey, cluster sampling, 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 the contact details to request a patient information sheet

## **Health condition(s) or problem(s) studied**

Communicable diseases (soil-transmitted helminths, protozoa, Schistosomiasis) and Nutrition

## **Interventions**

With the results of the baseline assessments in Burkina Faso and Nepal, appropriate complementary nutrition-and health-sensitive interventions are designed to improve the nutritional and health status of school children. These complementary interventions include the improvement of water and sanitary environments in schools, communities and households, biannual deworming of school-aged children; and especially school, community and household sensitisation on improved hygiene and dietary behaviours.

Two studies are conducted in 8 schools of Burkina Faso and in 16 schools of Nepal. The schools are randomly assigned to groups as follows:

Randomised intervention trial with two study arms and 2 schools per arm in Burkina Faso:

1. One arm without any intervention, the control schools;
2. One arm with the whole intervention package, means school garden, nutrition and WASH interventions.

Randomised intervention trial with four study arms and 4 schools per arm in Nepal:

1. One arm with school gardens but no nutrition and WASH interventions;
2. One arm with nutrition and WASH interventions but no school gardens;
3. One arm with school gardens nutrition and WASH interventions;
4. One arm without school gardens, nutrition and WASH interventions (control schools)

## **Intervention Type**

Behavioural

## **Primary outcome measure**

1. In Burkina Faso, the primary outcome measure is the differences in the prevalence of parasitic infections between school children of the intervention and control groups.
2. In Nepal, the primary outcome measure is the difference in the nutritional and health status (especially focused on malnutrition) between school children of the intervention and control groups.

## **Secondary outcome measures**

1. Assessing school children's nutritional status (BMI for age, height for age), dietary diversity, haemoglobin level, and their nutrition- and WASH- related knowledge and practices.
2. Analysing water, sanitation, and hygiene conditions at the level of selected schools, households and communities at the baseline and end-line of the study.
3. Assessing household socio-economic determinants, food security situation and nutrition- and health-related KAP

In Burkina Faso, the follow-up study will take place in February 2016 to evaluate possible changes in primary and secondary outcomes. In Nepal, the follow-up study will take place in May 2016 to evaluate the possible changes in primary and secondary outcomes.

**Overall study start date**

01/02/2014

**Completion date**

31/12/2016

## Eligibility

**Key inclusion criteria**

1. School children, either male or female, aged 8-14 years in Burkina Faso and Nepal, attending the randomly selected schools and enrolled in grade 6 or 7.
2. Willing to sign a written informed consent by parents or legal guardians of the school children (Burkina Faso) and by school teachers (Nepal)
3. Oral consent from school children and willing to submit two stool samples, conduct a questionnaire interview, take anthropometric and haemoglobin measurements and clinical examination

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

8 Years

**Upper age limit**

14 Years

**Sex**

Both

**Target number of participants**

1164

**Key exclusion criteria**

1. Absence of written informed consent
2. Child is younger than 8 or older than 14 years of age

**Date of first enrolment**

01/01/2015

**Date of final enrolment**

31/03/2015

# Locations

## Countries of recruitment

Burkina Faso

Nepal

## Study participating centre

Institut de Recherches en Sciences de la Santé

Ouagadougou

Burkina Faso

-

## Study participating centre

Kirnetar Health Center

Nepal

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# Sponsor information

## Organisation

Swiss Tropical and Public Health Institute (Switzerland)

## Sponsor details

Socinstrasse 57

PO Box

Basel

Switzerland

4054

## Sponsor type

Research organisation

## Website

<http://www.swisstph.ch/>

## ROR

<https://ror.org/03adhka07>

# Funder(s)

**Funder type**

Government

**Funder Name**

Direktion für Entwicklung und Zusammenarbeit

**Alternative Name(s)**

Swiss Agency for Development and Cooperation, Direction du Développement et de la Coopération, Agencia Suiza para el Desarrollo y la Cooperación, Direzione dello Sviluppo e della Cooperazione, DEZA, SDC, DDC, COSUDE, DSC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Switzerland

## Results and Publications

**Publication and dissemination plan**

The publication timeline for Burkina Faso is divided in two parts:

1. First, clinical and questionnaire based results of the cross-sectional baseline assessment are intended to be published between September and December 2015.
2. Publication and dissemination of the results of the follow-up study is planned for June-September 2016.

In Nepal the baseline laboratory, clinical, anthropometry and questionnaire based knowledge, attitude and practice related findings of the cross sectional assessments are intended to be published by November 2015. The publication and dissemination of the results after interventions is planned for September-December 2016.

**Intention to publish date**

01/09/2015

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Data sharing statement to be made available at a later date

**Study outputs**

| Output type                      | Details  | Date created | Date added | Peer reviewed? | Patient-facing? |
|----------------------------------|----------|--------------|------------|----------------|-----------------|
| <a href="#">Protocol article</a> | protocol | 09/03/2016   |            | Yes            | No              |

|                                 |   |            |            |     |    |
|---------------------------------|---|------------|------------|-----|----|
| <a href="#">Results article</a> | intestinal parasitic infections results | 18/10/2016 |            | Yes | No |
| <a href="#">Results article</a> | undernutrition results                  | 19/01/2017 |            | Yes | No |
| <a href="#">Results article</a> |   | 03/02/2020 | 18/08/2023 | Yes | No |
| <a href="#">Results article</a> |   | 29/09/2018 | 18/08/2023 | Yes | No |