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An evaluation of the impact of water and sanitation interventions on the health of children in Nepal

Submission date
13/05/2021

Recruitment status
No longer recruiting

Registration date
25/05/2021

Overall study status
Completed

Last Edited
04/01/2022

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
One of the important factors to cause serious health impacts among children is the lack of access to clean water. Various types of pathogens can affect children in many different ways such as the ones causing water-borne diseases such as cholera, diarrhea, and intestinal parasitic infections. There are various ways of fecal contamination of drinking water. Moreover, adequate nutrition is also essential among children for ensuring healthy growth, proper organ formation and function, and neurological and cognitive development. However, nutrition as a cross-cutting theme is closely interlinked with multifactorial determinants. Hence the objective of this research is to analyse the impacts of water quality and hygiene interventions on water quality at the point-of collection as well as point of consumption; availability, condition, and use of WASH infrastructure; knowledge, attitude, and practice of water management and hygiene; and to determine the burden of water-borne diseases, malnutrition, nutritional deficiency, and anemia among children within the households before and after the intervention.

Who can participate?
Households with at least one child aged less than 10 years will be involved in the study.

What does the study involve?
A randomized controlled trial will be conducted following a repeated cross-sectional assessment in Western Nepal. Intervention packages will be developed. The study will deepen the understanding of the effectiveness of interventions aiming at improving WASH and nutrition status in rural households in Nepal and provide scientific evidence on the health impact of such interventions. The results of the study will provide scientific evidence for the adjustment or replication of programs for preventing water contamination and reducing the WASH-related health burden in Nepal.

What are the possible benefits and risks of participating?
There is no risk of participation however there are benefits associated with participation. All the participants will receive training on improved hygiene, sanitation, and household water treatment, including facilitated access to products required for water treatment. In control

areas, the information on water treatment and access to respective products will be provided after final collection. Participants will also be informed about the outcomes of the study and the results of their personal examination. Those found infected with parasites will be treated in accordance with their infection at recommended doses
following the standard treatment schemes of WHO.

Where is the study run from?
Selected communities in rural areas of Nepal such as Surkhet, Dailekh, and Accham.

When is the study starting and how long is it expected to run for?
March 2018 to December 2021

Who is funding the study?
Swiss Agency for Development and Cooperation (SDC)

Who is the main contact?
Ms Regula Meierhofer, Regula.Meierhofer@eawag.ch

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Evaluation of the impact of water and sanitation interventions on the health status of children in the project area of the Helvetas WARM-P Project in Nepal

Study objectives
The main assumption of the study is based on the idea that improved water management leading to safe water at the point of consumption either through system level chlorination or adequate household water treatment at the point of consumption and hygiene infrastructure such as hand washing infrastructure and improved sanitation will lead to a reduction of the water-borne diseases including intestinal parasitic infections.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 25/02/2018, Kantonale Ethikkommission Zurich (Stampfenbachstrasse 121, Postfach, 8090 Zurich, Switzerland; +41 43 259 79 70; peter.kleist@kek.zh.ch), ref: 2018–00089
2. Approved 07/06/2018, Institutional Review Committee, Nepal Health Research Council (Ramshah Path, Kathmandu, P.O.Box 7626, Nepal; +977-1-4254220; nhrc@nhrc.gov.np), ref: 2956

Study design
Interventional cluster randomized trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Water, sanitation and hygiene, Communicable diseases (soil-transmitted helminthes and protozoa) and Nutrition

Interventions
A randomized controlled trial (RCT) will be conducted in rural areas of Dailekh, Surkhet (A and B) and Acchham, following a cross-sectional baseline assessment on situational factors, water quality at the point of collection and point of use, WASH infrastructure, knowledge, attitude and practice as well as health indicators using standardized tools. The follow-up assessment will be conducted 2 years after the intervention. One to one matching with the intervention area will be done for the selection of the control area.

The study will comprise of the following intervention schemes:
Baseline scenario Intervention No of households
Area A PWS HHH + S-CHL 375
Area B PWS HHH + HWTS 375
Area C PWS HHH 375
Area D (Control) PWS - 375

PWS is an area with the availability of a piped water supply scheme, that has not yet received the WARM-P training intervention

HHH household hygiene intervention in accordance with the WARM-P training, but not establishing access to products for household water treatment
HWTS providing access to high quality products for household water treatment and safe storage, including training on adequate product operation and maintenance
S-CHL providing scheme-level chlorination

Intervention Type
Behavioural

Primary outcome(s)
Water quality examined using the membrane filtration technique and colony-forming units of total coliforms and Escherichia coli were counted at baseline (2018) and will be counted during follow-up study (2021)

Key secondary outcome(s))
1. Clinical signs of nutritional deficiencies measured by the certified medical assistants using a standard checklist at baseline (2018) and will be measured during follow-up (2021)
2. Anthropometric measurements (height, weight and length) of the children under 10 years was measured adhering to the standard procedures and calculated using AnthroPlus (WHO; Geneva, Switzerland) in accordance with the World Health Organization guidelines at baseline (2018) and will be repeated at follow-up (2021)
3. Presence of worm infection and intensity of helminths eggs per gram of stools was examined at baseline (2018) and will be repeated at follow-up (2021)
4. Knowledge, attitude and practice questions related to water, sanitation and hygiene and health were administered using a quantitative, structured questionnaire to the children's caregivers (mostly mothers) at baseline (2018) and will be repeated at follow-up (2021)

Completion date
12/12/2021

Eligibility

Key inclusion criteria
1. Households located in the project implemented areas
2. Households with at least one child in the age between 6 months to 10 years will be involved in the study. If a participating household has more than one child, the health of the youngest child will be examined as the vulnerability of young children for diarrheal infections is highest

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 months

Upper age limit
10 years

Sex
All

Key exclusion criteria
1. Households not providing written consents for the study
2. Household without children younger than 10 years

Date of first enrolment
15/03/2018

Date of final enrolment
12/12/2021

Locations

Countries of recruitment
Nepal

Study participating centre
Helvetas
Birendranagar
Surkhet
Nepal
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Sponsor information

Organisation
Swiss Federal Institute of Aquatic Science and Technology

ROR
https://ror.org/00pc48d59

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

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. The data collected are covering a sensitive topic and participants in the study provided informed consent under the condition that personal data will be kept confidential and will not be shared with anyone other than members of the survey team and only researchers involved in this study, public authorities and the members of the ethical review boards in Nepal and in Switzerland while keeping confidentiality can access original data. Any inquiries regarding reasonable requests for the data can be directed to the president of the Kantonale Ethikkommission Kanton Zürich, Dr. med. Peter Kleist: peter.kleist@kek.zh.ch

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?
Results article	baseline results	15/08/2020	13/05/2021	Yes	No
Protocol file	version v2	25/02/2018	01/06/2021	No	No