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Evaluating the health benefits of community-led total sanitation in Kenya

Submission date	Recruitment status	[X] Prospectively registered
24/01/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/02/2020	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
29/07/2020	Infections and Infestations	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Diarrhoea is a major killer of children aged under five, remaining the fourth-leading cause of disability-adjusted life-years (DALYs) among children in 2017. Sanitation coverage is still exceedingly below target and lack of sanitation causes a large disease burden in many developing countries. Community-led total sanitation (CLTS) approaches started in 2000. CLTS interventions have been implemented in more than 60 countries and adopted as sanitation policy in more than 30 countries. However, as few studies have investigated the effect of CLTS on reducing diarrhoea in children under five, we do not know how much benefit CLTS would bring, especially for reducing child morbidity and mortality. More evidence is required for appropriate resource allocation and also for formulating evidence-based health policy.

We aim to find evidence of the impact of CLTS on diarrhoea in children under five.

Who can participate?
Caregivers with a child(ren) aged under 5 years

What does the study involve?
Community-led total sanitation (CLTS) would take place in the intervention community. Participating caregivers would be required to keep a diary record of diarrhea in their child(ren) aged under 5 years over the 6 month study period.

What are the possible benefits and risks of participating?
No material or financial subsidies will be provided to participants. However, we expect that the participants will gain health and economic benefits such as a reduction in diarrhea, saving on health care expenses and etc. To our understanding, there is no risk of participating in CLTS activities.

Where is the study run from?
The UNICEF Kenya Country office, the UNICEF Turkana office and the KOICA Kenya office (Kenya)

When is the study starting and how long is it expected to run for?
August 2019 to December 2021

Who is funding the study?
Korea International Cooperation Agency, KOICA (South Korea)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
N/A

Study information

Scientific Title
Effects of community-led total sanitation on the diarrhoeal incidence and prevalence in children under five in rural areas of Kenya

Study objectives

Community-led total sanitation will reduce the diarrhoeal incidence of under-five children in Turkana county of Kenya by 29%

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/05/2020, KEMRI Scientific and Ethics Review Unit (SERU) (Kenya Medical Research Institute, PO Box 54840-00200, Nairobi, Kenya; +254 2722541; info@kemri.org), ref: KEMRI/RES /7/3/1

Study design
Cluster-randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a participant information sheet

Health condition(s) or problem(s) studied
Diarrhoea

Interventions
The cluster-randomized trial takes the community as the randomization unit since it is expected to be a cluster in which improved sanitation will bring impact on diarrhea transmission across households. All the interventions will be applied on a community-wide basis. Since the purpose of the intervention is to reduce diarrhea, the community would be an appropriate dimension of transmission zone, where humans, vectors, and intermediate hosts are interacting and sharing a common pool of parasites.

Of the 1950 communities, 720 communities will be selected for project implementation of clean water supply, and hygiene and sanitation improvement by the selection criteria on the basis of the degree of needs. The 720 communities will be stratified by water and sanitation coverage, accessibility to the main road, and socioeconomic status.

Of the 720 communities, 60 will be selected for trial arms. These 60 communities will be stratified into blocks having similar underlying, pre-intervention, risks of diarrhea. Then they will

be randomized within each block by a restricted, stratified randomization process such that 30 comparable communities will each be randomly assigned to either the intervention arm or the control arm.

For improved sanitation and hygiene, the project is to roll out only in the intervention arm for the first phase and then the control arm will receive the intervention after the first phase trial is completed. In addition, improved water will be supplied to the intervention arm for the second phase and the control will have access to improved water supply after the second phase trial is completed.

A baseline survey will be conducted in the 60 participating communities at enrolment and at the end of the first phase to assess child diarrhoeal incidence and longitudinal prevalence and latrine coverage.

The participating households will be required to take up household latrines using locally available and affordable materials in intervention arms. The households in control arms will not be involved in any activities for the first phase; however, they will be required to take up household latrines during the second phase of the trial.

Participating caregivers would be required to keep a daily diary record of diarrhea incidence in their child(ren) aged under 5 years over the study period.

The total duration of the study and follow-up for all study arms is 12 months

Intervention Type
Behavioural

Primary outcome measure
Child diarrheal incidence and longitudinal prevalence measured by diary methods on the daily diarrheal incidence of the youngest under-five child in intervention and control villages at baseline and at every single day of 6 months of follow-up

Secondary outcome measures
Latrine coverage measured by direct observation on latrine presence at the household level in intervention and control villages at baseline and at 1, 2, 3, 4, 5, and 6 months of follow-up

Overall study start date
25/08/2019

Completion date
31/12/2021

Eligibility

Key inclusion criteria
Households with a child(ren) aged under 5 years

Participant type(s)
Mixed

Age group

Mixed

Sex
Both

Target number of participants
Caregivers of 900 households with at least one under-five child in 60 communities

Key exclusion criteria
1. Households who reject the registration
2. Households who do not provide informed consent

Date of first enrolment
01/03/2020

Date of final enrolment
15/03/2020

Locations

Countries of recruitment
Kenya

Study participating centre
UNICEF Turkana office
Lodwar
Turkana County
Lodwar
Kenya
N/A

Sponsor information

Organisation
Korea International Cooperation Agency

Sponsor details
825 Daewangpangyo-ro
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Korea, South
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Sponsor type
Government

Website
http://www.koica.go.kr/english/main.html

ROR
https://ror.org/0106d7657

Funder(s)

Funder type
Government

Funder Name
Korea International Cooperation Agency

Alternative Name(s)
KOICA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Korea, South

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/12/2021

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date