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Evaluating the effectiveness of a school-based salt reduction intervention in Malawi

Submission date
24/10/2019

Recruitment status
No longer recruiting

Registration date
20/11/2019

Overall study status
Completed

Last Edited
21/01/2025

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Background and study aims
The "Tackling cardiovascular risk in the adolescent life-course through a schools' salt-reduction intervention in rural (Karonga) and urban (Lilongwe) Malawi" trial aims to determine whether meaningful reductions in salt intake in Malawian adolescents and their parents can be achieved through a school-based education package on salt reduction.

Who can participate?
School children aged 11 -14 years and adult members of the household resident in the study areas

What does the study involve?
The study is a school-based cluster-randomised controlled trial. Clusters will consist of a single primary school, and there will be 13 clusters per arm. Schools will be sampled from those within Area 25 and adjacent administrative areas within Lilongwe City (urban site) and schools within the Karonga DSS (rural site). The study will will compare a 10-week interactive education package on salt reduction delivered to standard 6 school children (approximate age range 11-14) to the national school curriculum. The intervention will be delivered to all school children enrolled in standard 6, during routine school lesson hours.

What are the possible benefits and risks of participating?
Although there is no direct individual benefit to participating in this study, if you decide to take part you may find it useful and informative to have your blood pressure and weight checked. The data that will be collected at the end of the intervention will help researchers and policy-makers both in Malawi and abroad know how to design better public health interventions, and whether or not this programme should be scaled up in school in Malawi once the study has finished.
There are very few risks to participating. All the people who will be working in the study are well trained to handle any situations or procedures that you may find uncomfortable or sensitive as it relates to collection of urine, anthropometric measurements (height, weight and blood pressure), and the dietary recall questionnaire. Any data that is collected will remain confidential and will be limited to only the fieldworker at the time of collection and the data manager responsible for this study. Data that could be used to identify you will be removed (e.g. name or address) once it is submitted to the data manager, and the results of this study will only ever be

shared with other researchers and policy-makers at an aggregated (e.g. school or community) level

Where is the study run from?
Malawi Epidemiology & Intervention Research Unit (MEIRU), Malawi

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

Who is funding the study?
Medical Research Council (MRC), UK

Who is the main contact?
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Type(s)
Scientific

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Additional identifiers

Protocol serial number
Version 5 (20190228)

Study information

Scientific Title
Tackling cardiovascular risk in the adolescent life-course through a school salt reduction intervention in rural (Karonga) and urban (Lilongwe) Malawi

Acronym
N2N/NTN

Study objectives
A school-based health education intervention delivered as part of the routine school curriculum results in significantly decreased levels of dietary sodium in school children and their parents

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 18/04/2019, National Health Sciences Research Committee (NHSRC) of Malawi (Ministry of Health and Population: P.O. Box 30377, Lilongwe 3, Malawi; (no email address); +265 789 400), ref: #2206
2. Approved 20/06/2019, London School of Hygiene & Tropical Medicine (LSHTM) Research Ethics Committee, (Keppel Street, London, WC1E 7HT, UK; ethics@lshtm.ac.uk; +44 20 7636 8636.), ref: #17098

Study design
Open-label single-centre cluster-randomized trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
1. Dietary sodium intake
2. Hypertension and cardiovascular disease

Interventions
The intervention consists of a 10-week programme of classroom-based contextually-relevant lessons related to salt reduction delivered to all Standard 6 children in 13 primary schools in Lilongwe (Area 25 and surrounding administrative areas) and Chilumba (Karonga DSS site).

The intervention will be delivered by the standard 6 class teacher(s), who will receive training in the intervention through a training workshop, in addition to on-going support throughout implementation from officers from the Ministry of Education, Science & Technology; Ministry of Health; District Education (DEO) and District Health Offices (DHO); and MEIRU.

The content and pedagogy of the lessons will include lectures on the harmful effects of excess salt, salt reduction targets, and methods of reducing salt consumption; interactive classes to discuss the practical challenges of salt reduction; linked homework (e.g. food diaries); competitions, interactive dramas, and family quizzes; and provision of complementary printed materials including workbooks and posters.

The intervention will initially be drafted based on the materials developed for a previous trial and reviewed during a stakeholders workshop prior to piloting. Following piloting in 2 schools, the intervention will be further refined based on feedback from users and recipients, prior to full implementation in all 13 intervention schools.

Allocation to study group is by cluster (school). Randomisation is stratified by site (rural or urban) and location (rural vs. peri-urban in rural site, and Area 25 vs. Area 49 & 50 in urban site) in order to reduce the likelihood of chance imbalances. Randomisation occurs in two stages, whereby all clusters are first randomly assigned to a term 12:14 (term 1: term 2) within each strata. Clusters are then randomly assigned to a study group 1:1 (intervention: control). Clusters therefore remain balanced with respect to each strata in both term 1 and 2, but the number of clusters is not equal between terms due to different numbers of clusters within each strata. Half of the schools randomly assigned to intervention will implement during term 1 (September-December 2019) and the other half of schools randomly assigned to intervention implement during term 2 (January-March 2020). Assignment of the study arms therefore remains hidden until the completion of community sensitisation and baseline assessments, regardless of allocation to term 1 or term 2 to minimise participation bias.

First, an independent statistician will assign each cluster to term 1 or term 2 by random number allocation. Second, at a public ceremony a delegate from each school allocated to term 1 is invited to select a ball from a sealed bag containing equal numbers of two different coloured balls representing assignment to intervention or control arms. The same procedure will be repeated for schools assigned to term 2.

In each cluster, 30 children are randomly selected from an updated standard 6 class enrolment list. Two adults are subsequently sampled at a visit to the household of the sampled child. The mother or female PCG (primary caregiver), and father or male PCG are first sampled and invited to participate. If either adult is not eligible or declines to participate, they are systematically replaced with the adult(s) closest in age to them and of the same sex within the same household, followed by the adult(s) closest in age but of the opposite sex to the originally sampled adult

Intervention Type
Behavioural

Primary outcome(s)
Urinary sodium content as assessed by 24-hour urine using the crown ether membrane electrode method at baseline, 12-weeks and 52-weeks

Key secondary outcome(s))

1. Blood pressure at baseline, 12-weeks and 52-weeks
2. Individual dietary salt consumption as reported by 24-hour dietary recall questionnaire at baseline, 12-weeks and 52-weeks
3. Household per-capita salt consumption as assessed by 7-day household measurements at baseline, 12-weeks and 52-weeks

Completion date
31/01/2021

Eligibility

Key inclusion criteria
1. Child currently enrolled in standard 6 and aged 11-14 years OR an adult (16 years and above) in the household of a sampled and eligible child
2. Resident in study area (as defined as Area 25 and surrounding administrative areas in urban site; or Karonga DSS in rural site)
3. Both the sampled child and at least one adult member of the household willing to participate

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
11 years

Sex
All

Total final enrolment
1968

Key exclusion criteria
1. Not intending to stay in the same household for the following 18 months
2. Currently unwell
3. Mental incapacity such that they are unable to follow the instructions to collect a urine sample
4. More than one sampled child residing within the same household

Date of first enrolment
16/09/2019

Date of final enrolment
31/01/2020

Locations

Countries of recruitment
Malawi

Study participating centre
Malawi Epidemiology & Intervention Research Unit (MEIRU)
Community Health Sciences Unit (CHSU)
Area 3
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Sponsor information

Organisation
London School of Hygiene & Tropical Medicine (LSHTM)

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository. The data generated from this study, including de-identified individual participant data, in addition to the data collection tools and associated materials, will be deposited on completion of the study on the London School of Hygiene & Tropical Medicine (LSHTM) Data Compass (https://datacompass.lshtm.ac.uk/) or similar digital repository, through which requests for access can be made to the principal investigator

IPD sharing plan summary

Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	Formative work and process evaluation	30/08/2023	21/01/2025	Yes	No