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Helping Sri Lankan adolescents build healthier habits: a school-based study to prevent obesity and non-communicable diseases

Submission date
27/08/2025

Recruitment status
Stopped

Registration date
29/08/2025

Overall study status
Stopped

Last Edited
28/08/2025

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Sri Lanka has made progress in reducing poverty and controlling infectious diseases. However, malnutrition, including both undernutrition and unhealthy eating habits, remains a serious public health issue. Most previous studies have focused on short-term changes in diet among younger children in wealthier countries, often looking only at things like fruit and vegetable intake. This study aims to take a broader approach by testing a school-based programme designed to help adolescents aged 11–14 years make long-term, healthier dietary choices. The goal is to help prevent obesity, type 2 diabetes, and heart disease later in life.

Who can participate?
Adolescents aged 11–14 years who attend public schools in the Colombo and Gampaha districts of Sri Lanka were intended to be invited to take part. One class from each school would have been selected.

What does the study involve?
The study was designed to include 244 schools, randomly assigned to one of three groups. All participants, including those in the control group, would receive pre-intervention education on healthier diets. Group A would receive a non-financial reward. Group B would receive both a non-financial reward and a “pre-commitment device” (a tool to help students stick to their goals). Group C would not receive any additional intervention beyond the educational component. Researchers planned to compare changes in diet and health across the groups over time, using statistical methods that account for differences like age, gender, and waist size.

What are the possible benefits and risks of participating?
The study aimed to help students develop healthier eating habits, which could reduce their risk of chronic diseases in the future. There were no known risks from participating, and the study would have followed procedures to protect students' privacy and wellbeing.

Where is the study run from?
The study was planned to be conducted in public schools located in the Colombo and Gampaha districts of Sri Lanka's Western Province.

When is the study starting and how long is it expected to run for?
The study was cancelled before participant recruitment began due to feasibility challenges caused by the COVID-19 pandemic, civil unrest, and economic crisis in Sri Lanka. These events disrupted school operations and made it impossible to launch the study within the available funding period. We plan to carry out the study when we are able to secure funding and when conditions make it possible to do so. If launched, the study is expected to last for 1 year.

Who is funding the study?
There is currently no active funder for the study. However, the development of the study protocol was supported by a grant from the National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Prof. Marisa Miraldo, m.miraldo@imperial.ac.uk

Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
NIHR grant 132960

Study information

Scientific Title
Effectiveness of a school-based behavioural change intervention to prevent obesity and non-communicable diseases among adolescents in Sri Lanka: a cluster-randomised controlled trial protocol

Study objectives
Evaluate the effectiveness of two school-based behavioural interventions in improving diet quality and diversity as the primary outcome and anthropometric measures (body mass index [BMI] and waist circumference) as secondary outcomes.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 25/09/2023, Imperial College Research Ethics Committee (Imperial College London, Room 221, Medical School Building, St Mary's Campus, London, W2 1PG, United Kingdom; +44 (0) 207 594 1862; researchethicscommittee@imperial.ac.uk), ref: 6696130

2. approved 04/04/2024, Ethics Review Committee (Faculty of Medicine, University of Kelaniya, PO Box 06, Thalagolla Road, Ragama, 11600, Sri Lanka; +94 (0)112961267; ercmed@kln.ac.lk), ref: P/12/01/2024

Study design
Multi-school three-arm cluster-randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of obesity and non-communicable diseases

Interventions
A difference-in-differences (DiD) approach will be used to estimate the average treatment effect of two behavioral interventions on nutritional outcomes.

Treatment A: Participants receive non-financial rewards.
Treatment B: Participants receive non-financial rewards plus a “pre-commitment device” (a tool to help students stick to their goals)
Control Group: Participants receive neither intervention.

All groups receive a pre-intervention nutritional education program.

Sample size: 2,442 participants per group (total: 7,326).Treatment duration: 6 weeks. Follow-up measurements: Week 7 (post-treatment), Month 6, Month 9, and Month 12. Baseline data: Collected immediately before the intervention begins.

Treatment is assigned at the class level, and the analysis will adjust for clustering at that level, as well as individual fixed effects and baseline covariates, including but not limited to age, gender, and waist circumference.

Intervention Type
Behavioural

Primary outcome(s)
1. Dietary quality measured using 24-hr dietary recall at Baseline + follow-up measurements: Week 7 (post-treatment), Month 6, Month 9, and Month 12
2. Dietary diversity measured using dietary diversity tool at Baseline and weekly between Weeks 1-9

Key secondary outcome(s))
1. BMI calculated using weight and height measurements, which are measured as follows. Height will be measured in a standing position, barefoot, using a Shorr Board portable stadiometer, recorded to the nearest 0.1 cm. Weight will be measured using a digital scale, recorded to the nearest 0.1 kg; participants will wear light clothing and no shoes. Measured at baseline, Week 7 (post-treatment), Month 6, Month 9, and Month 12.
2. Waist circumference measured using an inelastic tape measure, recorded to the nearest 0.1 cm. Measured at baseline, Week 7 (post-treatment), Month 6, Month 9, and Month 12.
3. Urinary biomarkers. Global metabolite profiling, sodium, potassium and nitrogen profiles will be obtained through the urine samples. The samples will be used for whole spectra analysis using NMR spectroscopy. Measured at baseline, Week 7 (post-treatment), Month 6, Month 9, and Month 12.
4. Nutritional literacy measured using the Healthy Diet Knowledge Assessment questionnaire at baseline, Week 7 (post-treatment), Month 6, Month 9, and Month 12.

Completion date
31/08/2025

Reason abandoned (if study stopped)
The study was cancelled before participant recruitment began due to feasibility challenges caused by the COVID-19 pandemic, civil unrest, and economic crisis in Sri Lanka. These events

disrupted school operations and made it impossible to launch the study within the available funding period. We plan to carry out the study when we are able to secure funding and when conditions make it possible to do so. If launched, the study is expected to last for 1 year.

Eligibility

Key inclusion criteria
School inclusion criteria:
1. Public institutions within Colombo or Gampaha
2. Have classes with adolescents aged 11–14 years
3. Have children with South Asian ancestry

Class/participant inclusion criteria:
Aged 11-14 years

Participant type(s)
Learner/student

Healthy volunteers allowed
No

Age group
Child

Lower age limit
11 years

Upper age limit
14 years

Sex
All

Key exclusion criteria
School exclusion criteria:
1. Located within a 3 km buffer zone of ongoing or planned community intervention sites, to prevent potential overlap of intervention impacts
2. Do not provide institutional consent

Participant exclusion criteria:
1. Have cancer or another serious illness expected to reduce life expectancy to less than 12 months
2. Have parents who are unable or unwilling to give consent
3. Are themselves unable or unwilling to give assent
4. Are unable to provide answers

Date of first enrolment
01/01/2024

Date of final enrolment

31/01/2024

Locations

Countries of recruitment
Sri Lanka

Study participating centre
Full list to be uploaded at a later date
Sri Lanka
tbd

Sponsor information

Organisation
Imperial College London

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Other

Funder Name
To be determined. Trial was cancelled due to feasibility challenges arising from the COVID-19 pandemic, civil unrest, and economic crisis in Sri Lanka. These circumstances led to school closures and logistical barriers that prevented us from initiating recruitment and intervention delivery within the current funding cycle. We are searching for a new funder.

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Marisa Miraldo (m.miraldo@imperial.ac.uk)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes