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A randomized-controlled intervention and evaluation of an innovative school health education (ISHE) project for primary schools in rural Bangladesh

Submission date
15/11/2023

Recruitment status
No longer recruiting

Registration date
17/11/2023

Overall study status
Completed

Last Edited
14/07/2025

Condition category
Other

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

Plain English summary of protocol
Background and study aims
This research evaluates the effect and cost-effectiveness of skill-based health education (SBHE) in inducing healthier and hygienic practices among schools and pupils, and additionally improved health in pupils through a randomised-controlled trial (RCT) in primary schools in rural Bangladesh. In Bangladesh, despite efforts by the government and international community, children are still suffering from preventable diseases. The SBHE aims to improve the health-related school environment, and children's health and health-related knowledge, attitudes, practices, and behaviour (KAPB).

Who can participate?
The participants are randomly selected schools and school pupils in Moheshpur and Kodchandpur, Jehnaidah District in Bangladesh.

What does the study involve?
The project delivers a once-a-week SBHE session to children, delivered by a trained para-teachers for a year.

What are the possible benefits and risks of participating?
Possible benefits of one-year SBHE school intervention are a healthier/cleaner school environment, improved health-related KAPB and health among the pupils. No risk for participants is expected.

Where is the study run from?
The intervention is run in Moheshpur and Kodchandpur, Jehnaidah District in Bangladesh.

When is the study starting and how long is it expected to run for?
April 2011 to March 2014

Who is funding the study?
This study was enabled by the research grants from the Japan Society for the Promotion of Science — Japanese Grant-in-Aid for Scientific Research (No. 23402033) and the Nomura Foundation, and by in-kind contribution and collaboration with Save the Children (SC), Inc. (originally SC, USA), Dhaka Office (Bangladesh)

Who is the main contact?
Makiko Omura, Meiji Gakuin University (makiko@eco.meijigakuin.ac.jp)

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
AEARCTR-0004265

Study information

Scientific Title
The effects of cluster Randomised-Controlled Intervention of Skill-Based Health Education (SBHE) on health and hygiene practice and behaviour among primary schools and pupils in rural Bangladesh

Acronym
RCT-SBHE

Study objectives
The skill-based health education (SBHE) provided to schools have positive effects on healthy practice and behavioural change at both school and child levels.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 15/06/2011, Meiji Gakuin University Research Integrity Review Board (1-2-37 Shirokanedai, Minato-ku, Tokyo, 108-8636, Japan; +81-3-5421-5111; kenkyu@mguad.meijigakuin.ac.jp), ref: None provided

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Healthy and hygiene behaviour: cold-related symptoms; other infectious disease (diarrhoea; scabbies); other health symptoms (stomachache; dizziness; fatigue; appetite loss)

Interventions
The proposed project applied a treatment-control pre-post evaluation based on a cross-cutting randomisation design of SBHE (HE) and a soap-provision (SP) intervention. The unit of intervention was school, and 180 randomly chosen schools out of total of 204 primary schools were stratified according to the school type—government primary school (GPS) and registered non-government primary school (RNGPS). A cross-cutting HE- SP treatments were then randomly assigned to 180 schools stratified by two school-type stratified. Thus, four groups (HE, SP, HESP, and control) with 45 school each were randomly chosen using Excel random classification formula by the author who was also the principal investigator. The process was repeated until statistical nondifference of baseline school characteristics between the groups was ensured. Children surveyed were chosen randomly using seat placement based on the pre-determined randomly selected seat numbers prescribed by the author. Surveyors were masked about the treatment status in both baseline and endline surveys.

The baseline survey was conducted before the intervention in September–December 2011, and the endline data were collected in April–August 2013, after the completion of the intervention (March 2012–March 2013). The randomisation was done in January 2012 after the beginning of academic year in Bangladesh, thus the treatment status should not have affected the choice of school by the children and their families. Treatment randomisation ensured statistical nondifference between treatment and control schools at school level variables. We collected data from 180 schools, with 45 each randomly assigned for a cross-cutting HE-SP treatments. Data collection was done by the Dhaka based survey institute SURCH who received intensive training on the questionnaires, measurement and interview methods, subject random selection method by the author and conducted a pilot survey with the author. For school data, interviews were conducted to headteachers, and observational data were collected with photographs. For child level data, interviews and observational data were collected. All interviews and data

collection used structured questionnaires. Data were collected from the interviewees upon informed consent

The skill-based health education session consisted of 26 modules. An additional cross-cutting soap provision provided six small soap bars to soap-treatment schools and three small soap bars to randomly selected children in the soap-treatment schools.

Intervention Type
Behavioural

Primary outcome(s)
1. Handwashing practice: handwashing habit index (frequency and used materials before eating, after defecation, and after playing), frequency of handwashing with soap on each occasion, washing under running water, and correct handwashing procedure.
2. Dental-care practice: dentalcare index (frequency); tooth-brushing frequency using brush /branch; combination of used materials such as fingers, branch to brush, with ash, coal, powder and/or paste.
3. Oher hygiene practice: shoe-wearing habits at school; shoe-wearing habits at home (inside latrine and in courtyard).
4. Hand cleanliness: clean hands, trimmed nails, and clean nails; adenosine triphosphate (ATP): ATP improvement rate comparing before and after handwashing.
5. Nutrition practice: breakfast taken, and food taken for the past three days, ordered by the richness of the nutrition score and categorised into three categories (none; carbohydrate and vitamins; carbohydrate, protein and plus).
6. Health/hygiene knowledge: handwashing procedure; breakfast important; putting water in latrine before defecating (endline only), oral rehydration solution (ORS) making (endline only), food pyramid (endline only).

Key secondary outcome(s))
1. nthropometry: height-, weight- (net of clothes) and BMI-for-age-z-score.
* Given the fact that WHO Growth Chart for weight is only available for 5-10 years, while that for height and BMI is available for 5-19 years, the British 1990 Growth Charts available for 0-20 years were utilised to calculate the z-scores.
2. Cold-related symptoms: cough, breathing difficulty, sore throat, fever, running nose, and congested nose at present and in the past two-weeks.
3. Other illness: diarrhoea, stomachache, scabies in the past two-weeks, fatigue, dizziness, and appetite loss.

Completion date
31/03/2014

Eligibility

Key inclusion criteria
School children attending the selected schools

Participant type(s)
Learner/student

Healthy volunteers allowed
No

Age group
Child

Lower age limit
5 years

Upper age limit
17 years

Sex
All

Total final enrolment
180

Key exclusion criteria
Declined to take part in the survey

Date of first enrolment
11/10/2011

Date of final enrolment
08/07/2013

Locations

Countries of recruitment
Bangladesh

Study participating centre
Primary schools in Jhenaidah, Bangladesh
Jhenahidah
Bangladesh
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Sponsor information

Organisation
Meiji Gakuin University

ROR
https://ror.org/01zwcys39

Funder(s)

Funder type
Research organisation

Funder Name
Japan Society for the Promotion of Science

Alternative Name(s)
KAKENHI, JSPS KAKEN, JSPS Grants-in-Aid for Scientific Research, Gakushin, , Nihon Gakujutsu Shinkō Kai, JSPS

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Japan

Funder Name
Nomura Foundation

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Japan

Funder Name
Save the Children

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 form the principal investigator (Makiko Omura, makiko@eco.meijigakuin.ac.jp)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		11/07/2025	14/07/2025	Yes	No
Participant information sheet	Child assent form		20/11/2023	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes