Promoting hEatlhy Diet and Active Lifestyle (PEDAL): a multi-component pilot programme to increase healthy eating and decrease sedentary behaviours in children

Submission date 09/10/2022	Recruitment status No longer recruiting	Prospectively registered[X] Protocol
Registration date 16/10/2022	Overall study status Completed	 Statistical analysis plan Results
Last Edited 20/09/2024	Condition category Other	 Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims

Setting lifestyle habits on the right track during the formative years of childhood and early adolescence is critical as lifestyle habits can track to adulthood and help prevent chronic disease risks in later life. However, increasing evidence indicates that children and adolescents, both globally and locally, do not meet dietary and movement behaviour (comprising physical activity, sedentary behaviour, and sleep) guidelines. Guided by the UK MRC framework for complex intervention, we aim to develop and pilot test a multi-component programme to increase healthy eating and decrease sedentary behaviours in primary school children. This programme will be developed under the guidance of an advisory committee comprising experienced health and education professionals (from MOE, HPB [Health Promotion Board, Singapore], and schools), and underpinned by behavioural change theories and techniques.

Who can participate?

Primary 5 students who are attending one of the two selected public primary schools in Singapore.

What does the study involve?

Five lessons on healthy eating and lifestyle behaviour and forming healthy habits will be conducted by Physical Education teachers to the Primary 5 students during the typical Healthy Education sessions during school time. They will also be given a take-home activity consisting of dietary and physically active activities to support habit formation to complete in their own time. Some of the activities will require the involvement of students' parents. To incentivise students to complete the activities, badges will be awarded to students when they accumulate a certain number of points from completing the activities. School-level-wide activities will also be conducted during recess to create social norms around healthy eating and lifestyle behaviours.

What are the possible benefits and risks of participating?

As this is an educational intervention study, the participants will benefit from the knowledge

and skills gained from the lessons and activities. No physical or psychological injury or harm is expected in participating in the study.

Where is the study run from? The PEDAL study is being run by the Saw Swee Hock School of Public Health, National University of Singapore.

When is the study starting and how long is it expected to run for? November 2021 to December 2023

Who is funding the study? National Institute of Education (Singapore)

Who is the main contact? Dr. Mary Foong-Fong Chong mary_chong@nus.edu.sg

Contact information

Type(s) Principal Investigator

Contact name Dr Mary Chong

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Additional identifiers

EudraCT/CTIS number Nil known

IRAS number

ClinicalTrials.gov number Nil known

Secondary identifying numbers DEV 02/21 MCFF

Study information

Scientific Title

Development, implementation, and evaluation of a multi-component program to increase healthy eating and decrease sedentary behaviours in primary school children: a pilot study

Acronym

PEDAL

Study objectives

Current hypothesis as of 09/05/2023:

To develop, implement and pilot-test a multi-component program to increase healthy eating and decrease sedentary behaviours in primary school children

Previous hypothesis:

To develop, implement and evaluate a multi-component program to increase healthy eating and decrease sedentary behaviours in primary school children

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 22/11/2021, National University of Singapore Institutional Review Board (Blk MD11 Clinical Research Centre, 10 Medical Drive, #05-09, Singapore 117597; +65 6516 4311; irb@nus. edu.sg), ref: NUS-IRB-2021-640, amendment approval on 08/11/2023

Study design Multicenter interventional quasi-experimental pilot study

Primary study design Interventional

Secondary study design Non randomised study

Study setting(s) School

Study type(s) Prevention

Participant information sheet

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

Health condition(s) or problem(s) studied

Diet and sedentary behaviours

Interventions

This programme will consist of four core components:

1. A teaching curriculum on healthy eating and lifestyle behaviours, and forming healthy habits, to be conducted during the typical 30-minute Health Education sessions

2. Take-home activity consisting of dietary and physically active activities to support habit formation,

3. Involvement of parents in take-home activity, and

4. Conducting of school-level-wide activities during recess to create social norms around healthy eating and lifestyle behaviours.

Lesson plans, activities and the relevant materials will be developed and pre-tested with the relevant stakeholders (e.g., teachers and students). Feedback from the stakeholders will also be collected using quantitative and/or qualitative means. Refinement of the programme activities and materials will be done, if needed, after pre-testing.

The programme will then be implemented in two public, co-educational primary schools, to the Primary 5 cohort, over approximately one term (10 weeks). Process evaluation will be conducted to assess the programme's reach, usage, implementation, and acceptability. Outcome evaluation will be conducted to assess changes in dietary and movement behaviours using a pretest-posttest design.

Intervention Type

Behavioural

Primary outcome measure

Diet and sedentary behaviours are measured using an online time-use diary at baseline, 3, and 6 months.

Secondary outcome measures

1. Knowledge and skills on healthy eating and lifestyle behaviours measured using an online survey at baseline and 3 months.

2. Moderating factors that influence healthy eating and lifestyle behaviours (e.g., attitudes, perceived benefits/risks, self-efficacy, social support) using an online survey at baseline, 3, and 6 months.

3. Observations of school environment and canteen at baseline, 3 and 6 months.

4. Programme reach using class attendance for each lesson.

5. Feedback and acceptability of the PEDAL programme through online surveys with teachers after each lesson, students and parents post-intervention (3 months).

5. Feasibility of the PEDAL programme through focus group discussions with students and teachers, and interviews with canteen stall vendors.

Overall study start date

01/11/2021

Completion date 31/12/2023

Eligibility

Key inclusion criteria

For teachers:

1. Teacher teaching the Primary 5 Physical Health and Fitness (PHF) syllabus in the public schools

approved for this study. 2. Able to understand and converse in English

For students:

1. Primary 5 students (10-13 years old) who are studying in the MOE (Ministry of Education) schools approved for this study

2. Able to understand and converse in English

For canteen vendors:

1. Canteen vendors of schools that are participating in the intervention program

2. Able to understand and converse in English or Mandarin

For parents:

1. Parents of children who attended the intervention program

2. Able to understand and converse in English

Participant type(s) Mixed

Age group

All

Sex Both

Target number of participants 1000

Total final enrolment 270

Key exclusion criteria For teachers, canteen vendors, and parents:

Those who refused to participate in the study.

For students: Those whose parent, guardian or themselves refused to participate in this study.

Date of first enrolment 02/01/2022

Date of final enrolment 31/05/2023

Locations

Countries of recruitment Singapore **Study participating centre Alexandra Primary School** 2A Prince Charles Crescent Singapore 159016

Study participating centre Punggol Green Primary School 98 Punggol Walk Singapore 828772

Sponsor information

Organisation National University of Singapore

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Sponsor type University/education

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ROR https://ror.org/01tgyzw49

Funder(s)

Funder type University/education

Funder Name National Institute of Education, Nanyang Technological University Alternative Name(s) , National Institute of Education, NIE, NTU, NIE/NTU, NIE

Funding Body Type Government organisation

Funding Body Subtype Research institutes and centers

Location Singapore

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

01/09/2024

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Dr Mary Chong (mary_chong@nus.edu.sg) after publication.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Protocol article</u>		23/03/2024	25/03/2024	Yes	No