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

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

#### **ORCID ID**

http://orcid.org/0000-0003-0587-2505

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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

#### Sponsor details

21 Lower Kent Ridge Road Singapore Singapore 119077 +65 65166666 sshsph@nus.edu.sg

#### Sponsor type

University/education

#### Website

https://sph.nus.edu.sg/faculty-directory/chong-foong-fong-mary/

#### **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? |
|------------------|---------|--------------|------------|----------------|-----------------|
| Protocol article |         | 23/03/2024   | 25/03/2024 | Yes            | No              |