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An ecological dynamics approach to promote physical literacy and well-being of primary school children

Submission date 05/09/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 07/09/2023	**Overall study status** Ongoing	
Last Edited 11/06/2024	**Condition category** Other	

Plain English summary of protocol

Background and study aims
There isn't much information available about how a program called Ecological Dynamics (ED) affects the fitness and health of kids in primary school in Hong Kong. So, this project aims to use ED to help these kids get better at being physically active and making healthy choices every day. In Hong Kong and some other advanced countries, kids aren't getting enough exercise to stay healthy. This project will give primary school kids a cool way to learn how to be active and set them up for a healthy life as they grow up. It's all about helping them on their fitness journey and making sure they stay active throughout their lives.

Who can participate?
Senior primary students in grades 4 to 6 in primary schools across all 18 districts of Hong Kong.

What does the study involve?
We'll randomly put the schools into four different groups. The schools will get special things like sit-stand desks, a place to be active during breaks, and comfy pillows for better sleep. We'll use both scientific tests (checking things like how fit they are, how well they move, how active they are, and how well they think) and questions they answer themselves (about how they feel, their quality of life, and how well they sleep). All of this will help us understand how ED interventions affect their physical fitness and well-being.

What are the possible benefits and risks of participating?
Project participants are expected to demonstrate enhancements in physical literacy and overall well-being.

Where is the study run from?
The Research Grant Council (RGC) of Hong Kong SAR

When is the study starting and how long is it expected to run for?
August 2023 to June 2026

Who is funding the study?
The Research Grant Council (RGC) of Hong Kong SAR

Who is the main contact?
Professor Kim Wai Raymond Sum, kwsum@cuhk.edu.hk

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
14609123

Study information

Scientific Title
An ecological dynamics approach to promote physical literacy and well-being of primary school children: a cluster randomized controlled trial

Study objectives
We hypothesize that after the intervention and follow up:
1. The increase of physical competence including aerobic fitness and motor skills of participants in the intervention group will be greater than their counterparts in the control group.

2. The increase of physical activity engagement levels of participants in the intervention group will be greater than their counterparts in the control group.
3. The increase of cognitive functions of participants in the intervention group will be greater than their counterparts in the control group.
4. The increase of self-reported sleep quality, physical literacy, and quality of life of participants in the intervention group will be greater than their counterparts in the control group.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 14/03/2024, Joint CUHK-NTEC Clinical Research Ethics Committee (8/F, Lui Che Woo Clinical Sciences Building, Prince of Wales Hospital Shatin, Hong Kong, -, Hong Kong; +852 3505 3935; crec@cuhk.edu.hk), ref: 2024.027

Study design
Four-arm (cluster) randomized controlled trial

Primary study design
Interventional

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Primary school students in Hong Kong without any disability that prevents periods of standing nor an injury/illness that limits performing normal daily tasks.

Interventions
We will employ a computer-generated randomization sequence (GraphPad Software) to send email messages and invitation letters to primary schools based on their respective districts. Subsequently, participants from these schools will be allocated to different interventions.

1. Ecological Dynamics Intervention – A (EDI-A): 30 sit-stand tables will replace the traditional desks for all students to use during the school day. All children in this class are exposed to the sit-stand desks for at least 1h/day on average across the week. Students who are exposed to sit-stand desks will be encouraged to break up their classroom sitting every 15 minutes with standing for at least 2 minutes. Traditional chairs will be left for children to feel free to sit whenever they want to. During recess each day PA, including a series of mobility, stretching and pulse-raising exercises, will be provided to students. There will also be a 20-minute afternoon nap immediately after lunch in each school day.

2. Ecological Dynamics Intervention – B (EDI-B): In this condition, the focus will be on incorporating physical activity recess with mobility exercises, stretching, and pulse-raising activities during the school day. The implementation of sit-stand desks in classrooms will be deferred in this group, allowing for a comparative assessment of the independent effects of the physical activity component.

3. Ecological Dynamics Intervention – C (EDI-C): This condition will only incorporate the afternoon nap component into the school day. An uninterrupted 20-minute nap will be provided in classrooms after lunch, promoting a restorative environment and enhancing overall well-

being. The introduction of sit-stand desks and physical activity recess will be deferred, enabling an isolated evaluation of the nap intervention.

4. Wait-list Controlled (WC): The wait-list control group will not receive any modifications to their study environment during the initial phase. However, they will receive the same comprehensive intervention as the experimental groups at a later time, allowing for a valid comparison of the intervention effects.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measures as of 18/03/2024:
1. Cardiorespiratory fitness (CF) will be measured using the Progressive Aerobic Cardiovascular Endurance Run (PACER) at four time points (pre-test, halfway after 3 months, post-test, 3 months follow-up) with a 3-month interval.
2. Fundamental movement skills will be measured using The Canadian Agility and Movement Skill Assessment (CAMSA) at four time points (pre-test, halfway after 3 months, post-test, 3 months follow-up) with a 3-month interval.
3. Physical activity engagement levels will be measured using Accelerometer (Actigraph GT3X+) at four time points (pre-test, halfway after 3 months, post-test, 3 months follow-up) with a 3-month interval.
4. Cognitive functioning will be measured using the psychomotor vigilance task (PVT) test, AX Continuous Performance Task (AX-CPT), and N-back test at four time points (pre-test, halfway after 3 months, post-test, 3 months follow-up) with a 3-month interval.

Previous primary outcome measures:
1. Cardiorespiratory fitness (CF) will be measured using the Progressive Aerobic Cardiovascular Endurance Run (PACER) at baseline, 7th and 10th month.
2. Fundamental movement skills will be measured using the Canadian Agility and Movement Skill Assessment (CAMSA) at baseline, 7th and 10th month.
3. Physical activity engagement levels will be measured using an accelerometer (Actigraph GT3X+) at baseline, 7th and 10th month.
4. Cognitive functioning will be measured using the psychomotor vigilance task (PVT) test, AX Continuous Performance Task (AX-CPT), and N-back test at baseline, 7th and 10th month.

Key secondary outcome(s))
Current secondary outcome measures as of 18/03/2024:
1. Physical literacy will be measured using the Perceived Physical Literacy Instrument (PPLI) at four time points (pre-test, halfway after 3 months, post-test, 3 months follow-up) with a 3-month interval.
2. Health-related quality of life will be assessed using the Child Health Utility 9-Dimensions (CHU9D) at four time points (pre-test, halfway after 3 months, post-test, 3 months follow-up) with a 3-month interval.
3. Sleep quality will be measured using Pediatric Daytime Sleepiness Scale (PDSS) at four time points (pre-test, halfway after 3 months, post-test, 3 months follow-up) with a 3-month interval.

Previous secondary outcome measures:
1. Physical literacy will be measured using the Perceived Physical Literacy Instrument (PPLI) at baseline, 7th and 10th month.
2. Health-related quality of life will be assessed using the Child Health Utility 9-Dimensions

(CHU9D) at baseline, 7th and 10th month.
3. Sleep quality will be measured using the Pediatric Daytime Sleepiness Scale (PDSS) at baseline, 7th and 10th month.

Completion date
30/06/2026

Eligibility

Key inclusion criteria
Current inclusion criteria as of 18/03/2024:
1. Students without any disability that prevents periods of standing nor an injury/illness that limits performing normal daily tasks.
2. Students with signed parental or guardian consent.
3. Students of grade 4 in Hong Kong primary school.

Previous inclusion criteria:
1. Students without any disability that prevents periods of standing nor an injury/illness that limits performing normal daily tasks.
2. Students with signed parental or guardian consent.
3. Students of grade 4 to 6 in Hong Kong primary school.

Participant type(s)
Learner/student

Healthy volunteers allowed
No

Age group
Child

Lower age limit
8 years

Upper age limit
12 years

Sex
All

Key exclusion criteria
1. Students with any disability that prevents periods of standing nor an injury/illness that limits performing normal daily tasks.
2. Signed parental or guardian consent can not be obtained before the intervention starts.

Date of first enrolment
01/08/2024

Date of final enrolment
01/10/2024

Locations

Countries of recruitment
Hong Kong

Study participating centre
Schools in Hong Kong
Hong Kong
Hong Kong
Hong Kong
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Sponsor information

Organisation
Research Grant Council (RGC), Hong Kong SAR

Funder(s)

Funder type
Government

Funder Name
Research Grant Council (RGC), Hong Kong SAR

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 Professor Kim Wai Raymond Sum (Email: kwsum@cuhk.edu.hk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		05/06/2024	11/06/2024	Yes	No