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An Ecological Dynamics Approach to Promote Physical Literacy and Well-being of Primary School Children: A Cluster Randomized Controlled Trial Study Protocol

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An ecological dynamics approach to promote physical literacy and well-being of primary school children: A cluster randomized controlled trial study protocol

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Abstract

Background Little is known about the impact of an Ecological Dynamics (ED) intervention on primary school children's physical literacy and well-being in the Hong Kong context. The aim of this project is to introduce a physical literacy and well-being framework through an ED intervention that allows primary school children to develop good physical activity (PA) and daily behavioral habits.

Methods and analysis A four arm (cluster) randomized controlled trial will be conducted to examine the effect of EDI on physical literacy and well-being in primary schools located in each of the 18 administrative districts of Hong Kong. Four classes in senior primary students (grade 4) at each school will be randomly assigned to the four different conditions. These participating schools will be equipped with sit-stand desks, PA recess facility and equipment, and sleep pillows. The research team will adopt both objective measures (aerobic fitness, fundamental movement skills, daily behavior - physical activity, and cognitive function) and self-reported measures (perceived physical literacy, quality of life, sleep quality) covering the elements and domains of physical literacy and well-being to examine the effects of ED interventions at four time points, including baseline assessment, 3-month after intervention, post intervention and 3-month follow-up assessment. One-way analyses of variance (ANOVAs) will be used to test for differences in the baseline characteristics of participants between groups. Repeated measure ANOVAs and MANCOVA, with time (baseline, after intervention, and follow-up) as within-subjects factor, and intervention group as between-subjects factors, will be used to evaluate the effects of different interventions on the students' physical literacy and well-being. A Bonferonni correction to the p value will be calculated to adjust for multiple tests.

Ethics and dissemination Ethical approval was sought from the Joint CUHK-NTEC Clinical Research Ethics Committee in Hong Kong (CREC Ref.No.:2024.027).

Trial registration number ISRCTN84025914

Strengths and Limitations of this study

- Serve as first study to incorporate sit-stand desks into Hong Kong classrooms, with a combination of PA recess, and daytime sleepiness to promote a long-term influence on students' physical literacy and well-being among Hong Kong primary school children.

- This study provides evidence-based benefits of active classroom intervention for more Hong Kong children and promote sit-stand desks and active classroom strategies for more primary schools.
- Emphasize the concept of physical literacy, which has been adopted as the new standard to evaluate PE outcomes in many other countries, when implementing ecological dynamics intervention in Hong Kong primary school children.
- The generalizability of our findings may be limited to the specific context of Hong Kong primary schools.

1. Introduction

Sedentary behavior (SB) is defined as any low levels of energy expenditure including sitting, lying, and reclining and expending < 1.5 metabolic equivalents (Tremblay et al., 2017), which became a prevalent issue in modern society due to advances in technology and environmental changes over the last few decades. For children attending schools, sitting is a more prevalent behavior as they tend to sit in class for almost the whole day except for PE lessons and break. Clemes et al. (2016) revealed that children spent up to 65% of their waking time sitting, with some children having reported sitting time of over 10h/day. Particularly during the COVID-19 outbreak, younger generations in Hong Kong had a significant decline in PA with a corresponding increase in sedentary lifestyle (Zheng et al., 2020). High levels of SB showed positive associations with cardio-metabolic health risk such as obesity, blood pressure, cholesterol, and insulin in the child population (Marshall et al.,2004). A systematic review and meta-analysis synthesised that there were positive relationships between PA and night's sleep duration in children and youth (Huang, Ho, Tremblay & Wong, 2021). More importantly, sedentary lifestyle could be tracked throughout childhood into adolescence and adulthood (Biddle, Pearson, Ross, & Braithwaite, 2010). Therefore, breaking up prolonged sitting patterns and fostering an active lifestyle during childhood can be crucial for promoting a healthy life journey in adulthood. Physical literacy, described as the motivation, confidence, physical competence, knowledge and understanding to value and take responsibility for engaging in physical activities for life (Whitehead, 2019, p. 8), a novel perspective for addressing the prevalent sedentary behavior (SB) and declining levels of physical activity (PA) observed among primary school children in Hong Kong, given its established positive correlation with PA levels among adolescents in the region (Choi & Sum et al., 2018). A physically literate individual tends to be motivated to regularly participate in PA, holds positive attitudes towards PA, and

includes it in their daily living (Durden-Meyers et al. 2018; Whitehead 2010). The development of physical literacy is therefore critical to long-term health (McKean, 2013) and mitigate the adverse consequences of SB.

The school environment is an ideal setting for conducting PA interventions. A review of 26 studies found that school-based PA interventions have positive effects for the duration of PA, television viewing time, cardiorespiratory fitness, and blood cholesterol levels (Dobbins, De Corby, Robeson, Husson, & Tirilis, 2009). It has been suggested that schools should provide children with >30 min of moderate to vigorous PA accumulated within the school day (Carlson et al., 2015; Castelli et al., 2014).The application of sit-stand desk in school setting is an ideal approach to increase PA level and decrease SB, as studies have shown the acceptability and feasibility of applying sit-stand desks for primary school classrooms in less than 12 weeks (Blake, Benden, & Wendel, 2012; Clemes et al., 2016; Hinckson et al., 2013). Specifically, studies have reported that there are benefits to children in reducing their sitting time and increasing PA engagement and academic achievement (Dornhecker, Blake, Benden, Zhao, & Wendel, 2015; Koskelo et al., 2007). Other research has demonstrated that sit-stand desks in classrooms are effective in improving energy expenditure (Benden, Blake, Wendel, & Huber, 2011; Benden, Zhao, Jeffrey, Wendel, & Blake, 2014), standing time (Aminian, Hinckson, & Stewart, 2015), and musculoskeletal comfort for using the desks was also acceptable for children (Benden, Pickens, Shipp, Perry, & Schneider, 2013; Koskelo, Vuorikari, & Hänninen, 2007). However, to provide an active environment for children, such as combining PA recess with sit-stand desks in classroom would be a better approach to increase children's engagement in PA. Unfortunately, neither sit-stand desks nor PA recess together with daytime sleepiness large-scale intervention studies have been conducted in Hong Kong primary schools.

Therefore, this proposed study seeks to fill this research gap by implementing an ecological dynamics intervention (EDI) that incorporates sit-stand desks in classrooms, physical activity recess, and daytime sleepiness to reduce sedentary behavior and promote physical literacy and well-being among primary school children in Hong Kong.

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 PA 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.

2. Methods

2.1 Study Design

A four-arm (cluster) randomized controlled trial to investigate the effectiveness of an ecological dynamic intervention (EDI) on physical literacy and well-being among primary school children in Hong Kong. A total of 1,800 senior primary school children (grade 4) across all 18 administrative districts in Hong Kong will be recruited in this study and randomly assigned to one of the following groups (EDI-A: 30 sit-stand tables + physical activity(PA) recess+ 20 minutes afternoon nap; EDI-B: PA recess+ afternoon nap; EDI-C: afternoon nap only, and a Wait-list Controlled (WC) group: this group of participants will receive the same intervention as those in the experimental group at a later time). The intervention will be carried out for 6 months with a 3 months follow-up, and data measurements will be taken at four time points (pre-test, halfway after 3 months, post-test, 3 months follow-up) with a 3-month intervention. The flow diagram of the study is shown in Appendix (Figure 1). This protocol adheres to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines (Chan et al., 2013) and has been registered on the ISRCTN Registry (ISRCTN 84025914, summarized in Table 1).

Table 1. Registration information

Category	Information
Trail registry	ISRCTN Registry, ISRCTN 84025914
Registration date	07/09/2023
Source of support	General Research Fund: CUHK 1460913
Primary sponsor	Research Grants Council of Hong Kong
Public/scientific queries	Professor Kim Wai Raymond Sum, kwsum@cuhk.edu.hk
Public title	An ecological dynamics approach to promote physical literacy and

	well-being of primary school children: A cluster randomized controlled trial study protocol
Scientific title	An ecological dynamics approach to promote physical literacy and well-being of primary school children: A cluster randomized controlled trial study protocol
Country of recruitment	Hong Kong SAP, China
Health problem studied	Physical literacy and overall well-being
Intervention	Ecological Dynamics Intervention – A (EDI-A), sit-stand desk, PA recess and after lunch nap Ecological Dynamics Intervention – B (EDI-B),PA recess and after lunch nap Ecological Dynamics Intervention - C (EDI-C), after lunch nap Wait-list Controlled (WC):no treatment, obtain in the intervention at a later date
Inclusion/exclusion criteria	Inclusion criteria: Without any disability that prevents periods of standing nor an injury/illness that limits performing normal daily tasks. Students in grade 4 within 18 districts in 3 different regions (Hong Kong Island, Kowloon, and the New Territories) in Hong Kong
Study type	Interventional Allocation: randomized; intervention model: four-arm; masking: double blinded; Primary purpose: prevention
First enrolment date	01/08/2024
Target sample size	1,800
Recruitment status	Not started
Primary outcome	Physical Competence; Daily behavior (physical activity)l;

	Cognitive function;
Key secondary outcome	Physical literacy; Quality of life; Sleep quality

2.2 Participants

2.2.1 Sample size calculation

The required sample size is calculated based on the hypothesized effect sizes, and the likely rates of participant drop-out for the outcomes. The estimated sample size in each group is 20 concerning the effect size of 0.25, α of 0.05 and power of 0.80 (Faul et al., 2007). With the anticipation of a 20% participant drop-out rate, this leads to a required number of 25 participants per group. Since this is a four-armed randomized controlled trial with at least 18 primary schools representing different administrative districts in Hong Kong, there will be in total (18x4x25) 1,800 primary school children participating in this proposed study.

2.2.2 Eligibility criteria and recruitment

Eligibility criteria for participation in the intervention include students without any disability that prevents periods of standing nor an injury/illness that limits performing normal daily tasks. Students must in grade 4 within 18 districts in 3 different regions (Hong Kong Island, Kowloon, and the New Territories) in Hong Kong. The research team will randomly send a series of email messages and invitation letters to primary schools in accordance with their district via a computer-generated randomization sequence (GraphPad Software, Inc.) by a statistician who is blinded to the allocation of participating schools. After the primary school principals agree to participate, a leaflet package, which describes the theoretical background, timeframe, main objectives/learning goals, will be delivered to the school staff. The parents or guardians will also receive a package of leaflets with consent forms (Supplementary material 1) to be signed to approve their child's participation. Then an introductory meeting with teachers or teaching staff will be held to illustrate practical details related to the intervention. A further workshop will be provided to the teachers with instructions for using sit-stand desks and guidelines for instructing physical activities.

2.2.3 Randomization, blinding

The research team will randomly send a series of email messages and invitation letters to primary schools in accordance with their district via a computer-generated randomization sequence (GraphPad Software, Inc.) by a statistician who is blinded to the allocation of participating schools. Outcome assessors

will employ predetermined procedures to evaluate outcomes without prior knowledge of the intervention received by participants. They will not be involved in the implementation process, ensuring their natural blinding throughout the study. However, emergency unblinding will be permitted under specific circumstances crucial for participant safety, such as the occurrence of sudden cardiovascular or muscular diseases requiring knowledge of the participant's past physical activity history for immediate clinical management. The decision to unblind will be at the discretion of the principal investigator or an authorized individual not directly engaged in outcome assessments.

2.3 Intervention

Participants from different cluster will be randomly assigned to one of the following 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.

To ensure the successful implementation of the intervention, the principal of each participating school will be the key contact person responsible for approving the project and procuring the sit-stand desks. Subject teachers and PE teachers from each class will actively participate in the intervention progress, as they will be responsible for planning the sitting and standing patterns, as well as facilitating daytime sleepiness among the students. Therefore, a detailed instructional meeting will be held for all the teachers to instruct them on how to use the sit-stand desks and sleep pillows, as well as the setup of the PA recess facility and equipment. Additionally, subject teachers will play a vital role in encouraging students to use the sit-stand desks to break up their classroom sitting with standing intervals, while PE teachers will lead the PA recess exercises. Meanwhile, regular contact with the school teachers and parents (e.g., once a week) via email will be used to improve adherence. An excel file will be used to record the adherence of the participants every month.

2.4 Data collection

In this proposal, we will adopt both objective measures and self-reported measures to cover the elements and domains of physical literacy and well-being. Participants will be evaluated at Pre-test, halfway after 3 months, post-test, 3 months follow-up. All of them will be conducted at the participants' primary school in Hong Kong. The self-reported measurements will be administered by research assistants while the objective measurements will be performed by certified physical fitness instructors and health professionals.

2.4.1 Objective measures

Physical Competence

Cardiorespiratory fitness (CF) will be measured using the Progressive Aerobic Cardiovascular Endurance Run (PACER). The PACER comprise a multistage progressive 15-meter shuttle run requiring participants to run laps between 2 markers in time (decreases each minute) with prerecorded audible beeps. Participants run laps until they are unable to finish before the beep on 2 separate occasions. Participants' CF status are based on the number of laps completed. PACER has a strong correlation with maximum oxygen consumption (r = 0.83) (Varness et al, 2009).

Fundamental movement skills (FMS) The Canadian Agility and Movement Skill Assessment (CAMSA) will be adopted to measure children's FMS. Catching, throwing, skipping, hopping, and kicking will be assessed children's FMS. The score of the CAMSA test is composed of time score (14 points) and skill score (14 points), resulting in a total of 28 points (Longmuir et al., 2015).

Daily behavior (physical activity)

Accelerometer (Actigraph GT3X+) will be used to measure the PA engagement levels of participants, and are categorized as sedentary, light, moderate and vigorous. Participants will wear accelerometers to measure their PA engagement levels for at least 8 hours per day, for seven consecutive days.

Cognitive function

Cognitive domains to be assessed contain sustained attention, distractibility, and working memory. The psychomotor vigilance task (PVT) test, AX Continuous Performance Task (AX-CPT), and N-back test will be used for evaluating children's cognitive functioning. These tests will be performed using Psych lab 101 App in the iPad platform. The PVT-type test (Thomann, Baumann, Landolt, & Werth, 2014) is a sustained-attention, reaction-timed task that measures the speed with which subjects respond to a visual stimulus. The participant needs to press a button as soon as the light appears. Reaction time will be calculated. AX-CPT (Marcora, Staiano, & Manning, 2009) is any of several kinds of neuropsychological test that measures a person's sustained and selective attention. This test asks participants to press a button when seeing a red "A" followed by "X". Reaction time and corrections will be calculated. The N-back test is a continuous performance task that is commonly used as an assessment in cognitive neuroscience to measure a part of working memory and working memory capacity (Jaeggi et al., 2010). The participant is presented with a sequence of stimuli, and the task consists of indicating when the current stimulus matches the one from n steps earlier in the sequence.

2.4.2 Self-report measures

Physical literacy

Perceived Physical Literacy Instrument (PPLI). It is a 9-item instrument consisting of subscales - "knowledge and understanding", "self-expression and communication with others", and "sense of self and self-confidence" were identified as key attributes of physical literacy (Whitehead, 2010). PPLI is used to measure the perceived physical literacy of different individuals (Sum et al., 2016). Participants responded to the instrument on a 1 to 5 Likert scale (1 = strongly disagree and 5 = strongly agree). Sum et al. (2018) confirmed that the three-factor validity (RMSEA = 0.08; CFI = 0.94; & SRMR = 0.04) and convergent validity (CR = 0.72-0.78; AVE = 0.43-0.54) of the PPLI-A was satisfactory.

Quality of life

Health-related quality of life will be assessed using the Child Health Utility 9-Dimensions (CHU9D) (Stevens & Ratcliffe 2012) which includes nine items (worried, sad, pain, tired, annoyed, schoolwork, sleep, daily routine, and activities), and each item is scored on a five-point scale. CHU9D is a generic preference-based measure of health-related quality of life developed for children aged 7 to 11 years.

Sleep quality

Pediatric Daytime Sleepiness Scale (PDSS) (Drake et al., 2003) is a parent-reported instrument consisting of 8 items, having > 0.40 acceptable factor loadings. Higher scores on PDSS were associated with reduced total sleep time, poorer school achievement, poorer anger control, and frequent illness. Internal consistency of the total 8-item scale (factor 1, PDSS) was $\alpha = 0.81/0.80$ for the split-half samples.

2.5 Data analysis

Descriptive statistics (means and standard deviations) for primary school children's physical competence, PA levels, cognitive function, physical literacy, quality of life and sleep quality will be calculated for all subscales across all instruments. One-way analyses of variance (ANOVAs) will be used to test for differences in the baseline characteristics of participants between groups. Repeated measure ANOVAs and MANCOVA, with time (baseline, after intervention, and follow-up) as within-subjects factor, and intervention group as between-subjects factors, will be used to evaluate the effects of different interventions on the students' physical literacy and well-being. A Bonferonni correction to the p value will be calculated to adjust for multiple tests. SPSS version 27 for Windows will be used for data analysis. Statistical significance will be set at a level of 0.05.

2.6 Confidentiality

During the study, personal data will be treated with the utmost confidentiality and privacy. Participants' informed consent will be obtained, and data will be anonymized using unique identifiers. Secure data collection methods, including encryption and limited access, will be implemented. Data will be retained for 5 years, and personal identifiers will be securely disposed of when no longer needed. Access to personal data during the study will be limited to authorized research team members, including the principal investigator, co-investigators, data managers, and other staff involved in data-related activities. For those outside the research team who wish to access the study data, permission must be sought from the Principal

Investigator. Following permission and the completion of signed confidential documentation, access to the data will be granted.

2.7 Data monitoring

Interim analyses will be conducted at predetermined intervals to assess the efficacy and safety of the trial interventions. These analyses will be performed by a statistician who is blinded to the data input, ensuring objectivity and minimizing bias. If the statistician identifies issues with the study efficacy (e.g., lack of efficiency) or potential safety concerns, they will promptly report these findings to the study Principal Investigator (PI). The PI will then carefully evaluate the situation and make the final decision regarding whether to terminate the trial or continue based on the interim analysis results and other relevant considerations (Ciolino et al., 2023).

2.7 Patient and Public Involvement

None

2.8 Protocol amendments

We will communicate any protocol modifications, such as changes to eligibility criteria, outcomes, or interventions, to the Joint CUHK-NTEC Clinical Research Ethics Committee in Hong Kong, trial participants, and trial registries via email after discussion with the PI.

2.9 Harms

To prioritize participant safety and maintain the trial's integrity, we have implemented a structured approach. Data collection will occur at three-month intervals, encompassing adverse events. Primary school teachers will assume responsibility for collecting, assessing, and reporting adverse events and unintended effects of trial interventions to the Principal Investigator (PI). Recorded events will be documented in a predetermined Excel file for future reference. In the event of such occurrences, healthcare professionals will be promptly summoned for assistance.

3. Ethics and Dissemination

This study will adhere to the ethical principles outlined in the Declaration of Helsinki (WMA, 2013) and the principles of Good Clinical Practice (GCP) as outlined in the International Conference on Harmonisation (ICH) guidelines, specifically ICH E6(R2) (ICH, 2016). Ethical approval has been sought from the Joint CUHK-NTEC Clinical Research Ethics Committee (CREC Ref.No.:2024.027). The finding of this study

will be disseminated via peer-reviewed journals, international conference presentations and academic lectures. For secondary analysis of the data, please contact the corresponding author for permission.

4. Research Timeline

The proposed study consists of 3 phases (staffing and programming, research arrangement and reporting), each phase comprises of several sequential steps, with detailed procedures and time allocations delineated in Appendix (Table 2)

Trial STATUS

We will initialize the study on 1 January 2024 and will be completed on 30 June 2026.

Authors' Contributions

SUM Kim-Wai Raymond led the conceptualization of the research idea, precisely defining the study's scope and objectives, and took the lead in drafting the research protocol. In additions, he assembled and coordinated the research team, assigning roles and responsibilities. Played a pivotal role in revising and enhancing the manuscript, ensuring clarity and coherence.

SIT Hui-Ping Cindy provided valuable expertise advice in the designated field.

RUDD James contributed expertise advice and played a crucial role in the design and methodology of interventions.

CHOW JiaYi Offered expertise advice and played integral roles in methodology, data analysis, and interventions.

Xiaofei ZHANG assisted in drafting the research protocol, outlining a comprehensive plan for the study under the first author's guidance. He also collaborated with first author on the ethical review, drafted the combined questionnaire, and facilitated the upload of the study protocol to the ISRCTN registry.

All authors have read and approved the final manuscript.

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Declare of Interests

None declared

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Appendix

Figure 1. Flow diagram of participants' progress through different phases of the (cluster) randomized controlled trial

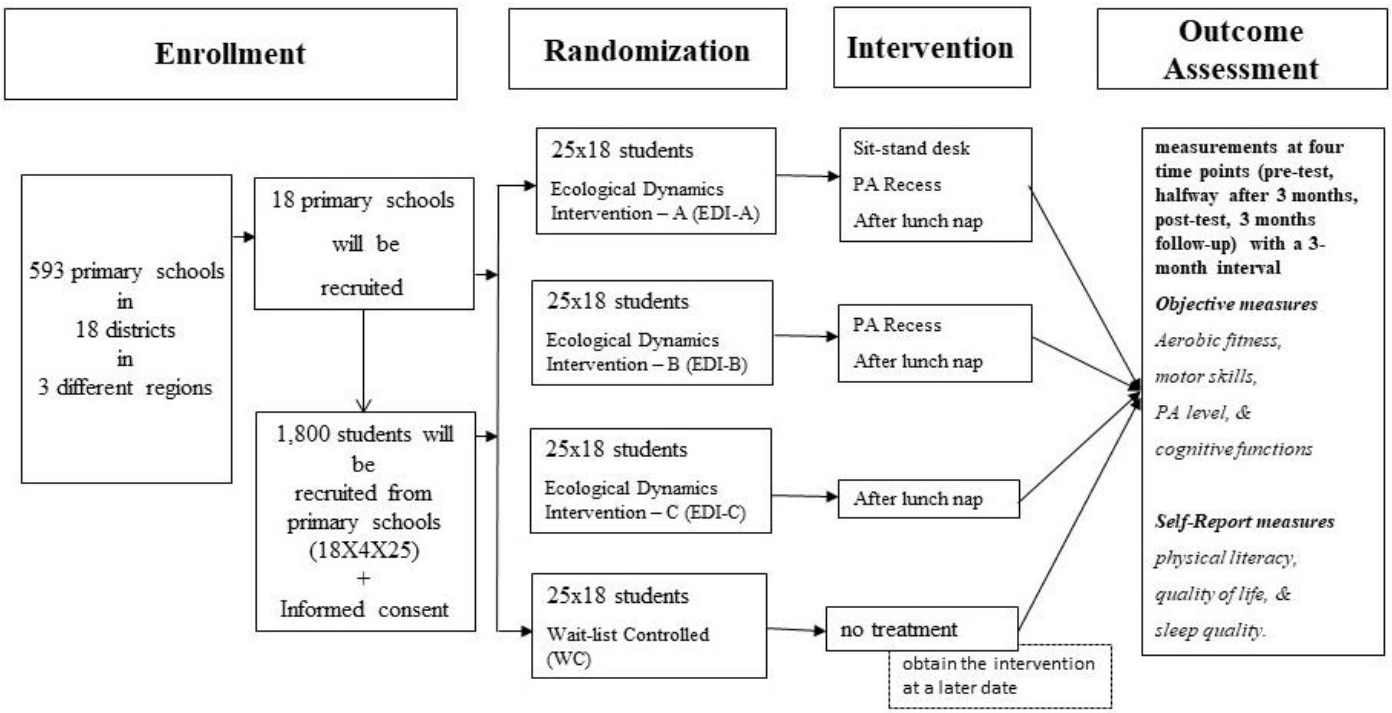

Table 2. Study Timeline of the cluster randomized controlled trial

	Tasks	2024												2025												2026					
	Time	JAN	FEB	MAR	APR	MAR	JUN	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAR	JUN	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAR	JUN
1	**Staffing and Programming**																														
1.1	Recruitment of staff																														
1.2	Planning for intervention																														
2	**Research Arrangement**																														
2.1	Preparation for research materials																														
2.2	Access primary schools																														
2.3	Workshop for teachers and helpers																														
2.4	Piloting the intervention & data collection																														
2.5	Randomization																														
2.6	Baseline data collection																														
2.7	Baseline data input and analyses																														
2.8	The intervention (6 months)																														
2.9	Wait list - intervention																														
2.10	Post-intervention data collection																														
2.11	Post-intervention data input and analyses																														
2.12	Follow-up data collection																														
2.13	Follow-up data input																														
2.14	Overall data editing and analyses																														
3	**Reporting**																														
3.1	Write-up of interim report																														
3.2	Write-up of manuscripts																														
3.3	Write-up of final report																														

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRITreporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin J, Dickersin K, Hróbjartsson A, Schulz KF, Parulekar WR, Krleža-Jerić K, Laupacis A, Moher D. SPIRIT 2013 Explanation and Elaboration: Guidance for protocols of clinical trials. BMJ. 2013;346:e7586

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	5-6
Protocol version	#3	Date and version identifier	1-21
Funding	#4	Sources and types of financial, material, and other support	14
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	12
Roles and	#5b	Name and contact information for the trial sponsor	1,14

responsibilities: sponsor contact information			
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	14
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	n/a
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3-5
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	8
Objectives	#7	Specific objectives or hypotheses	4-5
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	5
Methods: Participants, interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	7

Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8-9
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	8-9
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	9
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	9-11
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	21
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	7
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	7

Methods:

Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	7-8
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	7-8
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	8-9
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	7-8
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	8
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	9
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for	9

		participants who discontinue or deviate from intervention protocols	
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	11
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	11
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	11
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	11
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	n/a
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	12
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	12
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Ethics and dissemination			

Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	2
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	12
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	7
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	11
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	13
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	11
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	12
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	12
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	12

Appendices

Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	Supplementary material 1
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

Notes:

- 32: Supplementary material 1 The SPIRIT Explanation and Elaboration paper is distributed under the terms of the Creative Commons Attribution License CC-BY-NC. This checklist was completed on 28. April 2024 using https://www.goodreports.org/, a tool made by the EQUATOR Network in collaboration with Penelope.ai

BMJ Open

An Ecological Dynamics Approach to Promote Physical Literacy and Well-being of Primary School Children: A Cluster Randomized Controlled Trial Study Protocol

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An ecological dynamics approach to promote physical literacy and well-being of primary school children: A cluster randomized controlled trial study protocol

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Abstract

Background Little is known about the impact of an Ecological Dynamics (ED) intervention on primary school children's physical literacy and well-being in the Hong Kong context. The aim of this project is to introduce a physical literacy and well-being framework through an ED intervention that allows primary school children to develop good physical activity (PA) and daily behavioral habits.

Methods and analysis A four arm (cluster) randomized controlled trial will be conducted to examine the effect of EDI on physical literacy and well-being in primary schools located in each of the 18 administrative districts of Hong Kong. Four classes in senior primary students (grade 4) at each school will be randomly assigned to the four different conditions. These participating schools will be equipped with sit-stand desks, PA recess facility and equipment, and sleep pillows. The research team will adopt both objective measures (aerobic fitness, fundamental movement skills, daily behavior - physical activity, and cognitive function) and self-reported measures (perceived physical literacy, quality of life, sleep quality) covering the elements and domains of physical literacy and well-being to examine the effects of ED interventions at four time points, including baseline assessment, 3-month after intervention, post intervention and 3-month follow-up assessment. One-way analyses of variance (ANOVAs) will be used to test for differences in the baseline characteristics of participants between groups. Repeated measure ANOVAs and MANCOVA, with time (baseline, after intervention, and follow-up) as within-subjects factor, and intervention group as between-subjects factors, will be used to evaluate the effects of different interventions on the students' physical literacy and well-being. A Bonferonni correction to the p value will be calculated to adjust for multiple tests.

Ethics and dissemination Ethical approval was sought from the Joint CUHK-NTEC Clinical Research Ethics Committee in Hong Kong (CREC Ref.No.:2024.027). The finding of this study will be disseminated via peer-reviewed journals, international conference presentations and academic lectures. For secondary analysis of the data, please contact the corresponding author for permission.

Trial registration number ISRCTN84025914

Strengths and Limitations of this study

- This is a high-standard cluster randomized control trial (four-arm, double-blinded, control group).
- This study compares multiple interventions simultaneously within a real-world setting.
- There is a potential risk that we may not recruit enough participants.

- Participants in this study may be exposed to other conditions that will promote physical literacy and well-being aside from our intervention.

1. Introduction

Sedentary behavior (SB) is defined as any low levels of energy expenditure including sitting, lying, and reclining and expending < 1.5 metabolic equivalents[1] , which became a prevalent issue in modern society due to advances in technology and environmental changes over the last few decades. For children attending schools, sitting is a more prevalent behavior as they tend to sit in class for almost the whole day except for PE lessons and break. Clemes et al. (2016) revealed that children spent up to 65% of their waking time sitting, with some children having reported sitting time of over 10h/day[2]. Particularly during the COVID-19 outbreak, younger generations in Hong Kong had a significant decline in PA with a corresponding increase in sedentary lifestyle [3]. High levels of SB showed positive associations with cardio-metabolic health risk such as obesity, blood pressure, cholesterol, and insulin in the child population[4] . A systematic review and meta-analysis synthesized that there were positive relationships between PA and night's sleep duration in children and youth[5]. More importantly, sedentary lifestyle could be tracked throughout childhood into adolescence and adulthood[6]. Therefore, breaking up prolonged sitting patterns and fostering an active lifestyle during childhood can be crucial for promoting a healthy life journey in adulthood. Physical literacy, described as the motivation, confidence, physical competence, knowledge and understanding to value and take responsibility for engaging in physical activities for life[7], a novel perspective for addressing the prevalent sedentary behavior (SB) and declining levels of physical activity (PA) observed among primary school children in Hong Kong, given its established positive correlation with PA levels among adolescents in the region [8]. A physically literate individual tends to be motivated to regularly participate in PA, holds positive attitudes towards PA, and includes it in their daily living[7,9]. The development of physical literacy is therefore critical to long-term health and mitigate the adverse consequences of SB[10].

The school environment is an ideal setting for conducting PA interventions. A review of 26 studies found that school-based PA interventions have positive effects for the duration of PA, television viewing time, cardiorespiratory fitness, and blood cholesterol levels[11]. It has been suggested that schools should provide children with >30 min of moderate to vigorous PA accumulated within the school day[12,13].The application of sit-stand desk in school setting is an ideal approach to increase PA level and decrease SB, as

studies have shown the acceptability and feasibility of applying sit-stand desks for primary school classrooms in less than 12 weeks[2,14,15]. Specifically, studies have reported that there are benefits to children in reducing their sitting time and increasing PA engagement and academic achievement[16,17]. Other research has demonstrated that sit-stand desks in classrooms are effective in improving energy expenditure [18,19], standing time[15], and musculoskeletal comfort for using the desks was also acceptable for children[17,20]. However, to provide an active environment for children, such as combining PA recess with sit-stand desks in classroom would be a better approach to increase children's engagement in PA. Unfortunately, neither sit-stand desks nor PA recess together with daytime sleepiness large-scale intervention studies have been conducted in Hong Kong primary schools.

Therefore, this proposed study seeks to fill this research gap by implementing an ecological dynamics intervention (EDI) that incorporates sit-stand desks in classrooms, physical activity recess, and daytime sleepiness to reduce sedentary behavior and promote physical literacy and well-being among primary school children in Hong Kong.

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 PA 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.

2. Methods

2.1 Study Design

A four-arm (cluster) randomized controlled trial to investigate the effectiveness of an ecological dynamic intervention (EDI) on physical literacy and well-being among primary school children in Hong Kong. A total of 1,800 senior primary school children (grade 4) across all 18 administrative districts in Hong Kong will be recruited in this study and randomly assigned to one of the following groups (EDI-A: 30 sit-stand tables + physical activity(PA) recess+ 20 minutes afternoon nap; EDI-B: PA recess+ afternoon nap; EDI-C:

afternoon nap only, and a Wait-list Controlled (WC) group: this group of participants will receive the same intervention as those in the experimental group at a later time). The intervention will be carried out for 6 months with a 3-month follow-up, and data measurements will be taken at four time points (pre-test, halfway after 3 months, post-test, 3 months follow-up) with a 3-month intervention. The flow diagram of the study is shown Supplementary Material 1. This protocol adheres to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines[21] and has been registered on the ISRCTN Registry (ISRCTN 84025914, summarized in Table 1).

Table 1. Registration information

Category	Information
Trail registry	ISRCTN Registry, ISRCTN 84025914
Registration date	07/09/2023
Source of support	General Research Fund: CUHK 1460913
Primary sponsor	Research Grants Council of Hong Kong
Public/scientific queries	Professor Kim Wai Raymond Sum, kwsum@cuhk.edu.hk
Public title	An ecological dynamics approach to promote physical literacy and well-being of primary school children: A cluster randomized controlled trial study protocol
Scientific title	An ecological dynamics approach to promote physical literacy and well-being of primary school children: A cluster randomized controlled trial study protocol
Country of recruitment	Hong Kong SAP, China
Health problem studied	Physical literacy and overall well-being
Intervention	Ecological Dynamics Intervention – A (EDI-A), sit-stand desk, PA recess and after lunch nap Ecological Dynamics Intervention – B (EDI-B),PA recess and after lunch nap Ecological Dynamics Intervention - C (EDI-C), after lunch nap

Inclusion/exclusion criteria	Wait-list Controlled (WC):no treatment, obtain in the intervention at a later date Inclusion criteria: Without any disability that prevents periods of standing nor an injury/illness that limits performing normal daily tasks. Students in grade 4 within 18 districts in 3 different regions (Hong Kong Island, Kowloon, and the New Territories) in Hong Kong
Study type	Interventional Allocation: randomized; intervention model: four-arm; masking: double blinded; Primary purpose: prevention
First enrolment date	01/08/2024
Target sample size	1,800
Recruitment status	Not started
Primary outcome	Physical Competence; Daily behavior (physical activity) ; Cognitive function;
Key secondary outcome	Physical literacy; Quality of life; Sleep quality

2.2 Participants

2.2.1 Sample size calculation

The required sample size is calculated based on the hypothesized effect sizes, and the likely rates of participant drop-out for the outcomes. The estimated sample size in each group is 20 concerning the effect size of 0.25, α of 0.05 and power of 0.80[22]. With the anticipation of a 20% participant drop-out rate, this leads to a required number of 25 participants per group. Since this is a four-armed randomized controlled trial with at least 18 primary schools representing different administrative districts in Hong Kong, there will be in total (18x4x25) 1,800 primary school children participating in this proposed study.

2.2.2 Eligibility criteria and recruitment

Eligibility criteria for participation in the intervention include students without any disability that prevents periods of standing nor an injury/illness that limits performing normal daily tasks. Students must in grade 4 within 18 districts in 3 different regions (Hong Kong Island, Kowloon, and the New Territories) in Hong

Kong. The research team will randomly send a series of email messages and invitation letters to primary schools in accordance with their district via a computer-generated randomization sequence (GraphPad Software, Inc.) by a statistician who is blinded to the allocation of participating schools. After the primary school principals agree to participate, a leaflet package, which describes the theoretical background, timeframe, main objectives/learning goals, will be delivered to the school staff. The parents or guardians will also receive a package of leaflets with consent forms (Supplementary Material 2) to be signed to approve their child's participation. Then an introductory meeting with teachers or teaching staff will be held to illustrate practical details related to the intervention. A further workshop will be provided to the teachers with instructions for using sit-stand desks and guidelines for instructing physical activities.

2.2.3 Randomization, blinding

The research team will randomly send a series of email messages and invitation letters to primary schools in accordance with their district via a computer-generated randomization sequence (GraphPad Software, Inc.) by a statistician who is blinded to the allocation of participating schools. Outcome assessors will employ predetermined procedures to evaluate outcomes without prior knowledge of the intervention received by participants. They will not be involved in the implementation process, ensuring their natural blinding throughout the study. However, emergency unblinding will be permitted under specific circumstances crucial for participant safety, such as the occurrence of sudden cardiovascular or muscular diseases requiring knowledge of the participant's past physical activity history for immediate clinical management. The decision to unblind will be at the discretion of the principal investigator or an authorized individual not directly engaged in outcome assessments.

2.3 Intervention

Participants from different cluster will be randomly assigned to one of the following 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 later, allowing for a valid comparison of the intervention effects.

Participants may withdraw from the intervention or modify the allocated intervention if they meet specific criteria, such as personal scheduling conflicts, physical discomfort, musculoskeletal disease, cardiovascular disease, or inability to adhere to the intervention protocol. To ensure the successful implementation of the intervention, the principal of each participating school will be the key contact person responsible for approving the project and procuring the sit-stand desks. Subject teachers and PE teachers from each class will actively participate in the intervention progress, as they will be responsible for planning the sitting and standing patterns, as well as facilitating daytime sleepiness among the students. Therefore, a detailed instructional meeting will be held for all the teachers to instruct them on how to use the sit-stand desks and sleep pillows, as well as the setup of the PA recess facility and equipment. Additionally, subject teachers will play a vital role in encouraging students to use the sit-stand desks to break up their classroom sitting with standing intervals, while PE teachers will lead the PA recess exercises. Meanwhile, regular contact with the schoolteachers and parents (e.g., once a week) via email will be used to improve adherence. An excel file will be used to record the adherence of the participants every month.

2.4 Data collection

In this proposal, we will adopt both objective measures and self-reported measures to cover the elements and domains of physical literacy and well-being. Participants will be evaluated at Pre-test, halfway after 3 months, post-test, 3 months follow-up. All of them will be conducted at the participants' primary school in

Hong Kong. The self-reported measurements will be administered by research assistants while the objective measurements will be performed by certified physical fitness instructors and health professionals.

2.4.1 Objective measures

Physical Competence

Cardiorespiratory fitness (CF) will be measured using the Progressive Aerobic Cardiovascular Endurance Run (PACER). The PACER comprise a multistage progressive 15-meter shuttle run requiring participants to run laps between 2 markers in time (decreases each minute) with prerecorded audible beeps. Participants run laps until they are unable to finish before the beep on 2 separate occasions. Participants' CF status are based on the number of laps completed. PACER has a strong correlation with maximum oxygen consumption (r = 0.83) [23].

Fundamental movement skills (FMS) The Canadian Agility and Movement Skill Assessment (CAMSA) will be adopted to measure children's FMS. Catching, throwing, skipping, hopping, and kicking will be assessed children's FMS. The score of the CAMSA test is composed of time score (14 points) and skill score (14 points), resulting in a total of 28 points[24].

Daily behavior (physical activity)

Accelerometer (Actigraph GT3X+) will be used to measure the PA engagement levels of participants, and are categorized as sedentary, light, moderate and vigorous. Participants will wear accelerometers to measure their PA engagement levels for at least 8 hours per day, for seven consecutive days.

Cognitive function

Cognitive domains to be assessed contain sustained attention, distractibility, and working memory. The psychomotor vigilance task (PVT) test, AX Continuous Performance Task (AX-CPT), and N-back test will be used for evaluating children's cognitive functioning. These tests will be performed using Psych lab 101 App in the iPad platform. The PVT-type test[25] is a sustained-attention, reaction-timed task that measures the speed with which subjects respond to a visual stimulus. The participant needs to press a button as soon as the light appears. Reaction time will be calculated. AX-CPT [26] is any of several kinds of neuropsychological test that measures a person's sustained and selective attention. This test asks participants to press a button when seeing a red "A" followed by "X". Reaction time and corrections will be calculated. The N-back test is a continuous performance task that is commonly used as an assessment in cognitive neuroscience to measure a part of working memory and working memory capacity[27]. The participant is

presented with a sequence of stimuli, and the task consists of indicating when the current stimulus matches the one from n steps earlier in the sequence.

2.4.2 Self-report measures

Physical literacy

Perceived Physical Literacy Instrument (PPLI). It is a 9-item instrument consisting of subscales - "knowledge and understanding", "self-expression and communication with others", and "sense of self and self-confidence" were identified as key attributes of physical literacy ([7]. PPLI is used to measure the perceived physical literacy of different individuals[28]. Participants responded to the instrument on a 1 to 5 Likert scale (1 = strongly disagree and 5 = strongly agree). Sum et al. (2018) confirmed that the three-factor validity (RMSEA = 0.08; CFI = 0.94; & SRMR = 0.04) and convergent validity (CR = 0.72-0.78; AVE = 0.43-0.54) of the PPLI-A was satisfactory[29].

Quality of life

Health-related quality of life will be assessed using the Child Health Utility 9-Dimensions (CHU9D) [30] which includes nine items (worried, sad, pain, tired, annoyed, schoolwork, sleep, daily routine, and activities), and each item is scored on a five-point scale. CHU9D is a generic preference-based measure of health-related quality of life developed for children aged 7 to 11 years.

Sleep quality

Pediatric Daytime Sleepiness Scale (PDSS) [31] is a parent-reported instrument consisting of 8 items, having > 0.40 acceptable factor loadings. Higher scores on PDSS were associated with reduced total sleep time, poorer school achievement, poorer anger control, and frequent illness. Internal consistency of the total 8-item scale (factor 1, PDSS) was $\alpha = 0.81/0.80$ for the split-half samples.

2.5 Data analysis

Descriptive statistics (means and standard deviations) for primary school children's physical competence, PA levels, cognitive function, physical literacy, quality of life and sleep quality will be calculated for all subscales across all instruments. One-way analyses of variance (ANOVAs) will be used to test for differences in the baseline characteristics of participants between groups. Repeated measure ANOVAs and MANCOVA, with time (baseline, after intervention, and follow-up) as within-subjects factor, and intervention group as between-subjects factors, will be used to evaluate the effects of different interventions on the students' physical literacy and well-being. A Bonferonni correction to the p value will be calculated

to adjust for multiple tests. SPSS version 27 for Windows will be used for data analysis. Statistical significance will be set at a level of 0.05.

2.6 Confidentiality

During the study, personal data will be treated with the utmost confidentiality and privacy. Participants' informed consent will be obtained, and data will be anonymized using unique identifiers. Secure data collection methods, including encryption and limited access, will be implemented. Data will be retained for 5 years, and personal identifiers will be securely disposed of when no longer needed. Access to personal data during the study will be limited to authorized research team members, including the principal investigator, co-investigators, data managers, and other staff involved in data-related activities. For those outside the research team who wish to access the study data, permission must be sought from the Principal Investigator. Following permission and the completion of signed confidential documentation, access to the data will be granted.

2.7 Data monitoring

Interim analyses will be conducted at predetermined intervals to assess the efficacy and safety of the trial interventions. These analyses will be performed by a statistician who is blinded to the data input, ensuring objectivity and minimizing bias. If the statistician identifies issues with the study efficacy (e.g., lack of efficiency) or potential safety concerns, they will promptly report these findings to the study Principal Investigator (PI). The PI will then carefully evaluate the situation and make the final decision regarding whether to terminate the trial or continue based on the interim analysis results and other relevant considerations [32].

2.7 Patient and Public Involvement

Patients or the public WERE involved in the design, or conduct, or reporting, or dissemination plans of our research.

2.8 Protocol amendments

We will communicate any protocol modifications, such as changes to eligibility criteria, outcomes, or interventions, to the Joint CUHK-NTEC Clinical Research Ethics Committee in Hong Kong, trial participants, and trial registries via email after discussion with the PI.

2.9 Harms

To prioritize participant safety and maintain the trial's integrity, we have implemented a structured approach. Data collection will occur at three-month intervals, encompassing adverse events. Primary school teachers will assume responsibility for collecting, assessing, and reporting adverse events and unintended effects of trial interventions to the Principal Investigator (PI). Recorded events will be documented in a predetermined Excel file for future reference. In the event of such occurrences, healthcare professionals will be promptly summoned for assistance.

3. Ethics and Dissemination

This study will adhere to the ethical principles outlined in the Declaration of Helsinki [33] and the principles of Good Clinical Practice (GCP) as outlined in the International Conference on Harmonisation (ICH) guidelines, specifically ICH E6(R2) [34]. Ethical approval has been sought from the Joint CUHK-NTEC Clinical Research Ethics Committee (CREC Ref.No.:2024.027). The finding of this study will be disseminated via peer-reviewed journals, international conference presentations and academic lectures. For secondary analysis of the data, please contact the corresponding author for permission.

4. Research Timeline

The proposed study consists of three phases (staffing and programming, research arrangement and reporting), each phase comprises of several sequential steps, with detailed procedures and time allocations delineated in Supplementary Material 3.

Trial STATUS

We will initialize the study on 1 January 2024 and will be completed on 30 June 2026.

Authors' Contributions

SUM Kim-Wai Raymond led the conceptualization of the research idea, precisely defining the study's scope and objectives, and took the lead in drafting the research protocol. In additions, he assembled and coordinated the research team, assigning roles and responsibilities. Played a pivotal role in revising and enhancing the manuscript, ensuring clarity and coherence.

SIT Hui-Ping Cindy provided valuable expertise advice in the designated field.

RUDD James contributed expertise advice and played a crucial role in the design and methodology of interventions.

CHOW JiaYi Offered expertise advice and played integral roles in methodology, data analysis, and interventions.

Xiaofei ZHANG assisted in drafting the research protocol, outlining a comprehensive plan for the study under the first author's guidance. He also collaborated with first author on the ethical review, drafted the combined questionnaire, and facilitated the upload of the study protocol to the ISRCTN registry.

All authors have read and approved the final manuscript.

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Declare of Interests

None declared

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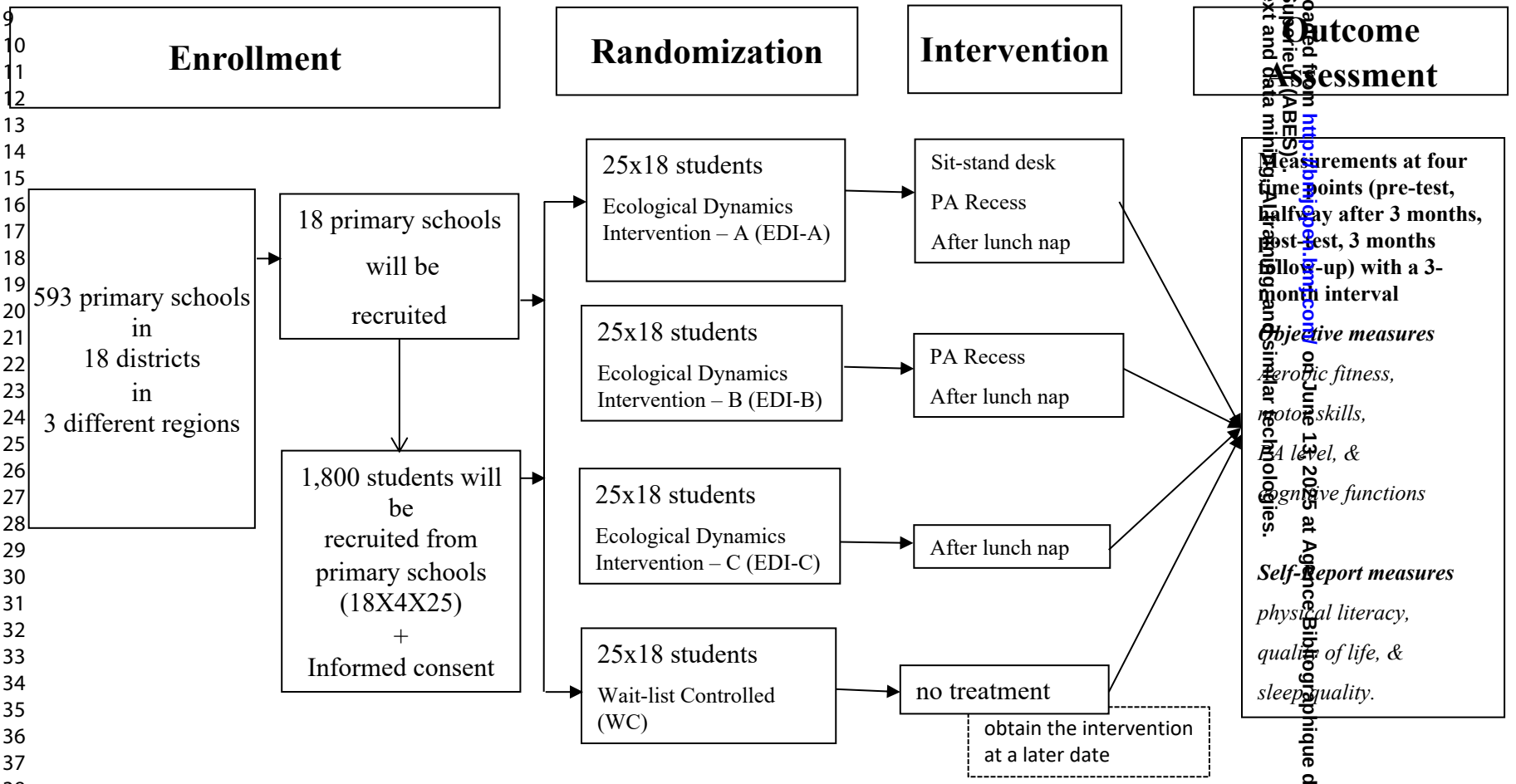
Figure 1

Flow diagram of participants' progress through different phases of the (cluster) randomized controlled trial



Informed consent materials

The Chinese University of Hong Kong

Consent Form

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

Investigator: Sum Kim Wai, Raymond
Department of Sports Science & Physical Education (SSPE)
The Chinese University of Hong Kong (CUHK)

Thank you for your interest in taking part in this project. Please take your time to review this consent form and discuss any questions you may have, or words you do not clearly understand, with the investigator or staff.

Purpose of the Study

The purpose of this study is to evaluate physical literacy and well-being of primary school children to achieve the goal of healthy lifestyles.

Voluntary Participation

Your participation is completely voluntary, and you may withdraw your participation at any time during the process, either temporarily or permanently.

Study Procedures

Upon receiving your consent, you will be contacted by phone and, or email according to your preferred contact. In this project, should you decide to participate, you will be allocated into one of the four groups – intervention (1, 2, or 3) and control group. You will be notified by e-mail and telephone about their randomization allocation. Before, halfway after three-month, after six-month intervention, and three-month follow-up, you will be requested to complete a set of questionnaires, together with a cognitive test and objective physical competence assessment. These measurements will be completed again by all the participants three months after the intervention period.

Your participation will be able to contribute valuable insights to the conceptual framework of promoting physical literacy and well-being of primary school children in Hong Kong

Confidentiality

Your participation in this study will be strictly confidential. Your real name will not be used at the intervention. No identifying information and name will be used and revealed in any written reports or publications. All findings in this study will be reported in aggregate form with no identifying information. All personal and study data will be kept for 5 years after the study. After this period, all identifiable information will be permanently anonymized or destroyed, and only de-identified data will be retained for potential future analysis or reference.

Should any questions arise at any point during the study, please do not hesitate to contact me at: 3943 6091 (office), or 9217 4388 (mobile).

---------Reply Slip---------

Parent/Guardian Consent Form

To the Department of Sports Science & Physical Education, The Chinese University of Hong Kong:

I, _____, am the parent/guardian of _____, who is in _____ class, _____ grade.

I have read and understood the purpose and content of the research titled " An ecological dynamics approach to promote physical literacy and well-being of primary school children: a cluster randomized controlled trial" I hereby give my consent for my child to participate in this project and understand the following:

- My child's participation in this project is entirely voluntary and without remuneration.
- I understand that all measurement data will be kept strictly confidential. My child's personal information will not appear in any research reports in a way that allows identification.
- If I wish to obtain individual measurement reports for my child, I can request them through the responsible teacher at the school, who will contact the Department of Sports Science, The Chinese University of Hong Kong.
- My child has the right to withdraw from the project at any time without providing reasons, and there will be no repercussions.

Parent/Guardian Signature: _____

Name: _____

Date: _____

Table 2. Study Timeline of the Cluster Randomized Controlled Trial

Tasks		2024												2025												2026					
Time		JAN	FEB	MAR	APR	MAR	JUN	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAR	JUN	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAR	
1	**Staffing and Programming**																														
1.1	Recruitment of staff																														
1.2	Planning for intervention																														
2	**Research Arrangement**																														
2.1	Preparation for research materials																														
2.2	Access primary schools																														
2.3	Workshop for teachers and helpers																														
2.4	Piloting the intervention & data collection																														
2.5	Randomization																														
2.6	Baseline data collection																														
2.7	Baseline data input and analyses																														
2.8	The intervention (6 months)																														
2.9	Wait list - intervention																														
2.10	Post-intervention data collection																														
2.11	Post-intervention data input and analyses																														
2.12	Follow-up data collection																														
2.13	Follow-up data input																														
2.14	Overall data editing and analyses																														
3	**Reporting**																														
3.1	Write-up of interim report																														
3.2	Write-up of manuscripts																														
3.3	Write-up of final report																														

Reporting checklist for protocol of a clinical trial

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	5, 6
Protocol version	#3	Date and version identifier	1, 4
Funding	#4	Sources and types of financial, material, and other support	2
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1, 2
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	1, 2
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	3
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team,	n/a

		and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3-4
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	2/a
Objectives	#7	Specific objectives or hypotheses	4
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	4-5
Methods: Participants, interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	4
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6-7
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7-8
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug	8

		dose change in response to harms, participant request, or improving / worsening disease)	
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	8
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	8-10
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	8
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	6
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	6-7
Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a	7

		separate document that is unavailable to those who enrol participants or assign interventions	
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	7
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	7
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	7
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	7
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	8-10
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	8-10
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data	11

		quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	10
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	10
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	10
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	11
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	11
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	11
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a

Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	2
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	11
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	7
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	8
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	3
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	11
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	12

Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	12
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	12
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	Supplementary material 2
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A