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A school-based, smartphone application-assisted, multi-component childhood obesity intervention: protocol of a cluster-randomized controlled trial (the DECIDE-children study)

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Abstract

Introduction Pediatric obesity has been an increasingly serious public health concern in China. There is an urgent need to develop an effective, feasible and scalable intervention to prevent this rising trend.

Methods and analysis DECIDE-Children is a cluster-randomized controlled trial (cluster-RCT) that aims to assess the effectiveness of a school-based, smartphone application-assisted, multi-component intervention to prevent obesity among the 4th grade primary school students. Twenty-four schools (approximately 1200 students) from eastern (Beijing), middle (Changzhi) and western (Urumchi) regions in China were randomized to the one-academic-year multi-component intervention group (intervention, n=12) or the usual care group (control, n=12). The intervention will be delivered through the schools, consisting of student-, parent- and school-elements as well as a smartphone application helping to promote the professional-teacher-parent interaction. The primary outcome is the change of students' body mass index (BMI) and BMI-Z score at the end of the one-academic-year intervention. Data of other anthropometric indicators (waist and hip circumferences, blood pressure, body fat percentage), physical fitness indicators, mediators and/or moderators of intervention effects including students' knowledge-attitude-practice, family and school environment related to obesity prevention are also collected. Study participants will be followed up to collect the data of those indicators at 4 months, 9 months and 21 months following baseline investigation.

Ethics and dissemination This study was granted ethical approval by Peking

University Health Science Center. Results will be disseminated through publication in peer-reviewed journals, presentation at conferences and in lay summaries provided to school staff and participants.

Trial registration ClinicalTrials.gov: NCT03665857.

Strengths and limitations of this study

1. Smartphone application employed to promote the professional-teacher-parent interaction and collaboration.

2. Involvement of three centers located in eastern, middle and western part of China with diversely geographical characteristics.

3. A theory-driven and systematic development during its formative phase.

4. A follow-up investigation conducted to determine the sustainability of the intervention.

5. This study is limited by a relatively short duration.

Introduction

Trends of obesity epidemic are rapidly increasing in China and worldwide [1, 2]. Based on data from the Chinese National Survey on Students Constitution and Health from 1985 to 2014, the prevalence of overweight and obesity among 7-18 y Chinese children increased continuously, reaching 19.4% in 2014, with the annual increasing rate of obesity during 2010-2014 greater than any other periods from 1985 to 2010 [2].

Recent studies showed that childhood obesity not only has adverse consequences on physical and mental health of children in the short term [3, 4], but also increases cardiovascular mortality in adulthood [5, 6]. Attempts to curb the epidemic are urgently needed.

Among obesity interventions worldwide, those conducted in the school settings have been assessed as "holding promise". More than 80% of the school-based RCTs reported statistically significant and favorable effects for at least one adiposity-related outcomes [7]. These findings support recommendations that the school be a focal point of obesity prevention effects.

Childhood obesity, in most cases, results from unhealthy diets and physical inactivity. Recent meta-analyses of behavior change interventions supports that goal-setting and self-monitoring, coupled with other behavior change strategies, promote physical activity, healthy eating as well as weight loss [8, 9]. However, traditional behavior change techniques (e.g., using diary to recording food and activity) can be too time-consuming to maintain. Interventions that utilize mobile health technologies have been shown potential for success [10]. With an increasing number of smartphone users in

China, there is promise for mobile technology-assisted childhood obesity prevention programs. Smartphone application (app) has been particularly promising due to its individualized and interactive characteristics, which might be greatly helpful in timely monitoring and feedback of children's nutritional status, diet and physical activity behaviors.

In September 2018, we started to conduct the cluster-RCT that aims to develop an innovative, effective and scalable programme to prevent childhood obesity among primary school students.

Methods and analysis

This protocol has been prepared in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement [11, 12].

Study design

The study is embedded in "Diet, ExerCIse and carDiovascular hEalth" (DECIDE) project. The primary purpose of the DECIDE project was to design a comprehensive intervention package for preventing cerebrovascular-related diseases (e.g., obesity) for Chinese population. Our DECIDE-children study was designed specifically for the children population. The study will be lasting until June 2020. Figure 1 shows the study flow. A total of 24 primary schools (clusters) were selected, 8 of which were from each of three regions in China, respectively: Beijing (eastern region), Changzhi in Shanxi Province (middle region) and Urumchi in Xinjiang Province (western region).

Following baseline investigation, schools were randomly assigned with 1:1 ratio to either the multi-component intervention or usual-care control group. The duration of intervention is one academic year (approximately 9 months). This study was approved by the Ethics Committee of Peking University Health Science Center (IRB00001052-18021).

Recruitment

Recruitment of schools

In primary schools in China, there are six grades in total, with age ranging from 6 to 11 years. The present study will be carried out in the grade 4 students (approximately 9 years old), for they can better understand health education knowledge and remain in

their schools at follow-up visits.

The inclusion criteria included that the school principal agreed to take part in the study, and the number of students recruited from grade 4 was no less than 50. If schools were located at different administrative districts, the number of schools in each administrative district should be even. Boarding schools, schools for children with special skills or minor ethnic groups were excluded. Schools that had conducted or would conduct other programme to prevent or treat childhood obesity during the study period were excluded. Schools were also not included if they had a definite plan for relocation or cancellation in the next two years.

One or two classes of grade 4 were recruited. If the number of eligible students in each class was predicted to be no less than 40, one class was selected; otherwise, two classes were recruited.

Recruitment of students

After recruiting schools, the research staff asked the class teachers to send informed consent forms to all students and their parents in the selected classes. All students and their parents who provided written informed consent participated in this study. But students with one of the following conditions were excluded: ① medical history of heart disease, hypertension, diabetes, tuberculosis, asthma, hepatitis or nephritis; or ② obesity caused by endocrine diseases or side effects of drugs; or ③ abnormal physical development like dwarfism or gigantism; or ④ being physically incomplete and deformed such as severe scoliosis, chicken breasts, limp, obvious O-leg or X-leg; or ⑤ inability to participate in school sports activities; or ⑥ having been losing weight by

vomiting or taking drugs during the past three months.

Baseline and follow-up data collection

The primary outcomes are the differences between the intervention and control group in the change of students' BMI and BMI-Z score after one academic year (9 months after baseline). The secondary outcomes include the differences between two groups in the changes of 1) students' BMI and BMI-Z score at 4 and 21 months after baseline, 2) students' waist and hip circumferences at 4, 9 and 21 months after baseline, 3) students' systolic and diastolic blood pressures at 4, 9 and 21 months after baseline, 4) students' body fat percentage at 9 months after baseline, 5) students' physical fitness measures (one-minute rope jumping, one-minute sit-up, standing jump and 50m*8 shuttle run) at 9 months after baseline, and 6) mediators and/or moderators of intervention effects including students' knowledge-attitude-practice, family and school environment related to obesity prevention at 9 months after baseline.

According to the standard procedure, baseline data were collected by the trained project personnel or physical education teachers (only for physical fitness measures). Follow-up investigations will be undertaken according to the same standard procedures at 4 months after baseline (i.e. in the middle of intervention for the intervention group), 9-month (i.e. immediately after intervention for the intervention group) and 21 months after baseline (i.e. 12 months after 9-month intervention for the intervention group). The assessors measuring students' height and weight at follow-up investigations will be blind for group allocation, i.e. they will not be told which schools were allocated to

the intervention or control group. Descriptions of the outcome measures are shown in Table 1.

Questionnaires were developed based on previous studies, pilot study of the project and found to be feasible and acceptable to students and parents [13-15]. Questions related to dietary intake were designed based on the validated Block Kids Food Screener [13], and those related to duration of moderate-to-vigorous physical activity were based on a validated 7-day physical activity questionnaire [14]. Other possible variables moderating or mediating students' nutritional status (e.g. children's eating behaviors [15]) were also included in the questionnaires.

Randomization procedures

Randomization was stratified by administrative districts that the schools belong to. For practical reasons, four schools were selected from each of the two districts (Dongcheng and Mentougou District) of Beijing, respectively; four schools were recruited from each of the two districts (Shayiba and Shuimogou District) of Urumchi, respectively; all of eight schools were selected from urban Changzhi (only one administrative district). Randomization was carried out using a computer-generated random number system by a researcher in the third-party organization who was not involved in the study.

Intervention description

Twelve schools in the intervention group will be implemented the multi-component intervention. Schools in the control group will carry on their usual care. After the study is completed, participants in the control group will receive health education materials delivered to the intervention group.

Theoretical framework of the intervention

Childhood obesity is a complex public health problem. Social Ecological Model, which captures the influencing factors of a specific health behavior at multiple levels, provides a framework that may be helpful for obesity prevention [16]. Based on the theoretical framework, the DECIDE-children study will be implemented at student-, family- and school-levels, which are likely to influence knowledge, attitude and behaviors of school children. Intervention components delivered at these levels are shown in Figure 2.

To strengthen collaboration between research staff, schools and families, a smartphone app ("Eat Wisely Move Happily") was designed to assist the implementation of this intervention. For instance, health education knowledge and monitoring data will be regularly input into computer management system of the app by research staff. Class teachers and primary caregivers can not only receive health education knowledge such as "Eat and Move Reasonably, a Healthy Weight", they will also be provided an assessment and feedback about children's nutritional status and behaviors related to obesity prevention/management by the app.

Description of the intervention components

Details of the intervention components are described in Table 2, including 1) school policies related to obesity prevention, 2) the smartphone app, 3) monthly monitoring of students' weight and height, 4) reinforcement of students' physical activity within and outside school as well as 5) health education activities towards students, parents (or other primary caregivers) and teachers.

Quality control of the intervention

Before implementation of the intervention, all of the participating school personnel have been trained by the project personnel. Two manuals ("An Implementation Manual for School Personnel Involving in the Multi-component Obesity Intervention among Primary School Students" and "An Implementation Manual for Project Personnel Involving in the Multi-component Obesity Intervention among Primary School Students") have been developed for this complex intervention. They describe in details the duty of both project personnel and school personnel in intervention schools delivering the intervention (school principals, class teachers, physical education teachers, school doctors), respectively. The manuals also describe the detailed workflow of implementation for each intervention component, i.e., who, when, how and to what extent the specific intervention element should be delivered. All of the school personnel have been required to carry out the intervention in accordance with the implementation manual.

During implementation of the intervention, regular field observation and checking of smartphone app records will aid in strengthening quality of the intervention.

Process evaluation

The process evaluation will be conducted in intervention schools throughout the project period to monitor and document the level of implementation of the intervention. It also aimed to aid in understanding the relationship between specific intervention elements and outcomes. Based on the steps and principles described in the conceptual framework by Saunders et al.[17], we identified the process evaluation elements including fidelity (the extent to which the intervention will be implemented as initially planned), dose

delivered (the frequency and intensity of actual implementation of the program), dose received (the extent to which students/parents/teachers will be exposed to the intervention, as well as the degree of their satisfaction with intervention and materials), reach (the proportions and the characteristics of students/parents/teachers/schools completing or dropping out from the intervention) and context (family environment and school policies related to obesity prevention).

The methods of process data collection will include: (1) direct regular field observation and records collected to control quality of the intervention (e.g., quality and quantity of the intervention sessions, number of students attending the lectures); (2) the users logs (e.g., frequency and duration) collected by the smartphone app; and (3) student- and parent-based questionnaires reporting the demographic information, family environment as well as their satisfaction with the intervention; (4) school questionnaires recording school policies related to obesity prevention.

Health economic evaluation

A cost-effectiveness analysis will be employed in the health economic evaluation, and a societal perspective is used to examine whether the intervention is economically feasible. Intervention costs include times (research staff, participating school staff, and students' parents) for all the intervention activities and material expenses. Time costs are based on personal employment compensations if available or average compensations in the local areas for similar types of employees. Material expenses are based on real purchasing prices. An incremental cost-effectiveness ratio will be calculated and a sensitivity analysis will be used to vary key parameters to examine the

robustness of health economic results.

Sample size estimation

We aim to recruit a total of 1,200 students from 24 schools with an average cluster size of 50 students per school. This sample size will provide 88% power at 5% significance level (two-sided) to detect a between-group difference of 0.50 kg/m^2 in BMI after the one-school-year intervention, assuming a standard deviation (SD) of 1.40 kg/m^2, an intra-cluster correlation coefficient of 0.05 and the 10% rate of attrition.

Statistical analyses

Statistical analyses will be performed using SAS version 9.4 (SAS Institute Inc., Cary, NC, USA). All statistical tests will be two-sided at 5% level of significance. Baseline characteristics at both school- and individual-level will be reported by using descriptive statistics. Continuous variables will be presented as means and SDs, and categorical variables will be presented as percentages.

The primary analysis will be based on the intention-to-treat principle including all randomized schools and students recruited from each school. Generalized linear mixed models will be used to evaluate the intervention effect on primary and secondary outcomes measured at 4 and/or 9 and/or 21 months following baseline investigation, adjusting for baseline outcome value, age and sex. The cluster effect of school and repeated measures of the same participant will be taken into account in the multi-level modelling, and missing data will be treated in the maximum likelihood estimates assuming they are missing at random. The intra-cluster correlation coefficient will also be estimated. Sensitivity analysis will be considered on the primary outcome using the

last-value-carry-forward (LVCF) imputation on missing data. Model-adjusted mean group differences will be reported on continuous outcomes. Adjusted odds ratio (OR) will be reported on binary outcomes using a logit link. The 95% confidence interval (CI) and associated *P*-value were calculated.

Discussion

The DECIDE-children study is a school-based, smartphone app-assisted, multi-component cluster-RCT designed to prevent obesity among Chinese children with diversely geographical characteristics. Based on theory-driven and systematic development during its formative phase (e.g., systematic review [18], qualitative interviews, panel discussions and a pilot study [19]), this study aims to explore an effective, feasible and scalable intervention for preventing childhood obesity.

This study has several distinguishing features: 1) a smartphone app is employed to promote the professional-teacher-parent interaction and collaboration; 2) all the intervention components were developed and integrated into the regular academic schedule of each intervention school; 3) randomization by a researcher in the third-party organization, blinding of key outcome measures (the assessors measuring students' height and weight at follow-up investigations will be blind for group allocation), conducting a follow-up investigation at 21 months after baseline (i.e. 12 months after 9-month intervention for the intervention group) to determine the sustainability of the intervention, and a detailed process evaluation plan will help to provide study results with high quality.

Ethics and dissemination

Any amendments to the study protocol were submitted for ethical approval prior to implementation. Written informed consent were obtained from all students and their parents who participated in this study via consent forms. Findings of this study will be disseminated via publications in peer-reviewed journals, conference presentations and lay summary reports which will be provided to school staff and participants.

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Authors' contributions

HJW and YFW conceived the project. HJW, ZL, YFW, WYN and HJL were involved in design of the study and development of intervention materials. ZL wrote the first draft of the manuscript. XXF, YL, AYG and FZ contributed to implementation of the program. HF contributed to economic evaluation. PG contributed to statistical analysis plan. All authors approved the final manuscript.

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Changzhi: Changzhi Medical College (Xiang-Xian Feng, Jian-hui Yuan, Li-fen Duan).

Urumqi: Urumqi Primary and Secondary School Health Care Center, Xinjiang (Yi Lin, Chun-Xia Xu, Guo-Qin Yang, Zheng Zhang).

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Competing interests statement

None.

Table 1 Outcome measurements for the DECIDE-children

Outcomes	Time				Device	Method
	Baseline	4 months after baseline	9 months after baseline	21 months after baseline		
Anthropometric measures						
Height	√	√	√	√	Stadiometer (Huateng GMCS-1)	Measured to the nearest 0.1 cm for at least twice
Weight	√	√	√	√	Lever scale (Wujin RGT-140)	Measured to the nearest 0.1 kg for at least twice
Waist circumference	√	√	√	√	Tape (MyoTape)	Measured to the nearest 0.1 cm for at least twice
Hip circumference	√	√	√	√	Tape (MyoTape)	Measured to the nearest 0.1 cm for at least twice
Systolic and diastolic blood pressures	√	√	√	√	Electronic sphygmomanometer (Omron HBP-1300)	Measured to the nearest 1 mmHg for at least twice
Body fat percentage	√		√		Body component instrument (Tanita MC-780MA)	According to the standard procedure
Physical fitness measures						
One-minute rope jumping	√		√		Physical fitness measures should be assessed by physical education teachers or trained project personnel according to the standard procedure.	

One-minute sit-up	√	√	
Long standing jump	√	√	
Shuttle run (50m*8)	√	√	
Behavioral and other measures			
Student questionnaire	√	√	Students should finish the questionnaires in the classroom in the presence of the trained project personnel, who can provide guidance and help.
Parent questionnaire	√	√	The questionnaires should be self-reported by parents or other primary caregivers of students.
School questionnaire	√	√	The questionnaires should be filled in by the trained investigators after face-to-face interviews with school leaders, doctors and physical education teachers.

Table 2 Description of the intervention components implemented in the DECIDE-children

Intervention components	Frequency, duration, contents	Implementation agents
School policies related to obesity prevention	The following school policies are suggested: **1. "Not selling":** Not selling unhealthy snack[1] or sugar-sweetened beverage within school; **2. "Not eating":** Telling students not to eat unhealthy snack or drink sugar-sweetened beverage within school; **3. "Not buying":** Students being educated by class teachers not to buy unhealthy snack or sugar-sweetened beverage around school.	Trained school principal; Trained class teachers
The smartphone app ("Eat Wisely Move Happily")	**1. Knowledge diffusion** The smartphone app provides knowledge to parents (or other primary caregivers) of the students, class teachers and project personnel (professionals) in accordance with health education activities. **2. Behavior monitoring** Parents (or other primary caregivers) together with their children are asked to fill in a weekly report about diet and physical activity behaviors of students, and then receive	The smartphone app (installed by parents, school teachers and research staff) and the computer management system (utilized by professionals)

[1] "Healthy snacks" refer to dairy products, fresh vegetables or fruits and natural unprocessed nuts which are eaten out of three meals per day. "Unhealthy snacks" refer to snacks other than the three kinds of healthy snacks.

	individualized feedback related to these behaviors. **3. Weight management** According to monthly monitoring of students' weight and height (described below), parents (or other primary caregivers of the students), school teachers and professionals could view the recent nutritional status (categorized according to the BMI percentile criteria [20, 21]), changes compared with previous records of the students as well as the individualized feedback related to weight management. **4. Assessment and feedback** In addition to the independent feedback of behaviors and nutritional status mentioned above, the smartphone app also provides a synthetic and individualized "assessment and feedback". This assessment combines changes of behaviors and nutritional status of students.	
Regular monitoring of students' weight and height	**1. Monthly monitoring** Students' weight and height will be monitored monthly, the data is then timely input into the computer management system and thus being shown in the smartphone app (described above); **2. Weekly monitoring** Students' weight is monitored weekly by the students themselves in the classroom.	The trained school doctors with the help of the trained professionals (for monthly monitoring); The trained professionals (for data input of monthly monitoring) Students (for weekly monitoring)

Reinforcement of students' physical activity within and outside school	**1. Reinforcement of students' physical activity within school** Students are organized by physical education teachers to do physical activity within school for at least one hour per school day (including physical education classes, class-break exercise, extracurricular activities), achieving moderate-to-vigorous intensity; Physical education teachers should teach students at least one sports game during each extracurricular activity. **2. Reinforcement of students' physical activity outside school** Parents (or other primary caregivers) will supervise and encourage students to do physical activity outside school, achieving 30 minutes per weekday and 1 hour per weekend day; Recommendations for physical activity outside school are given through the smartphone app once every two months; Students are encouraged to do sports games outside school that are taught by their physical education teachers during extracurricular activities.	The trained physical education teachers (for students' physical activity within school); Students' parents assisted by the smartphone app (for students' physical activity outside school)
Health education activities	**1. Health education activities towards parents (or other primary caregivers)** 1) Frequency and duration At least one activity (lasting for about 40-60 minutes) is held in each semester. During the first semester, one more activity is required. Another activity is held in the second semester if necessary. 2) Contents ➢ For the first activity Key messages are similar to health education activities towards students (described below). Parents (or other primary caregivers) are also taught to use the smartphone app. ➢ For other activities	The trained research staff (for health education activities towards parents/other primary caregivers and school teachers); The trained class teachers (for health education activities towards students)

	Project personnel will provide feedback about students' nutritional status and behaviors to parents. Face-to-face group discussions are needed between the project personnel and parents (or other primary caregivers). **2. Health education activities towards school teachers** 1) Frequency and duration The activity is held once (lasting for about 40 minutes) at beginning of the intervention. School teachers participating in this program in each school (school principal, class teachers, school doctors and physical education teachers) are required to attend the activity. 2) Contents Key messages are similar to health education activities towards students (described below). School teachers are also taught to use the smartphone app. **3. Health education activities towards students** 1) Frequency and duration A total of ten activities (lasting for 40 minutes per activity) are provided once every two to three weeks (six activities arranged in the first semester and four in the second semester). 2) Forms Seven health education lectures and three theme class meetings 3) Contents ① Knowledge diffusion Key messages include the benefits of healthy weight, measurement and assessment of weight, as well as skills to achieve a healthy weight (not eating excessively; not drinking sugar-sweetened beverage; eating less high-energy food; less sedentary behaviors; more physical activity). Health education books and "nutrition evaluation turnplate for Chinese	

	primary and middle school students" are delivered to students. Health education messages are also spread through posters in campus or classroom. ② Promotion for translating knowledge into action "Small hand in big hand" homework (e.g., "challenge of three days away from screen") is arranged in the end of each health education activity. ③ Feedback and encouragement for BMI and behavior change Feedback of regular monitoring results of students' BMI and behaviors is provided in each health education activity. The students with good performance are encouraged.	

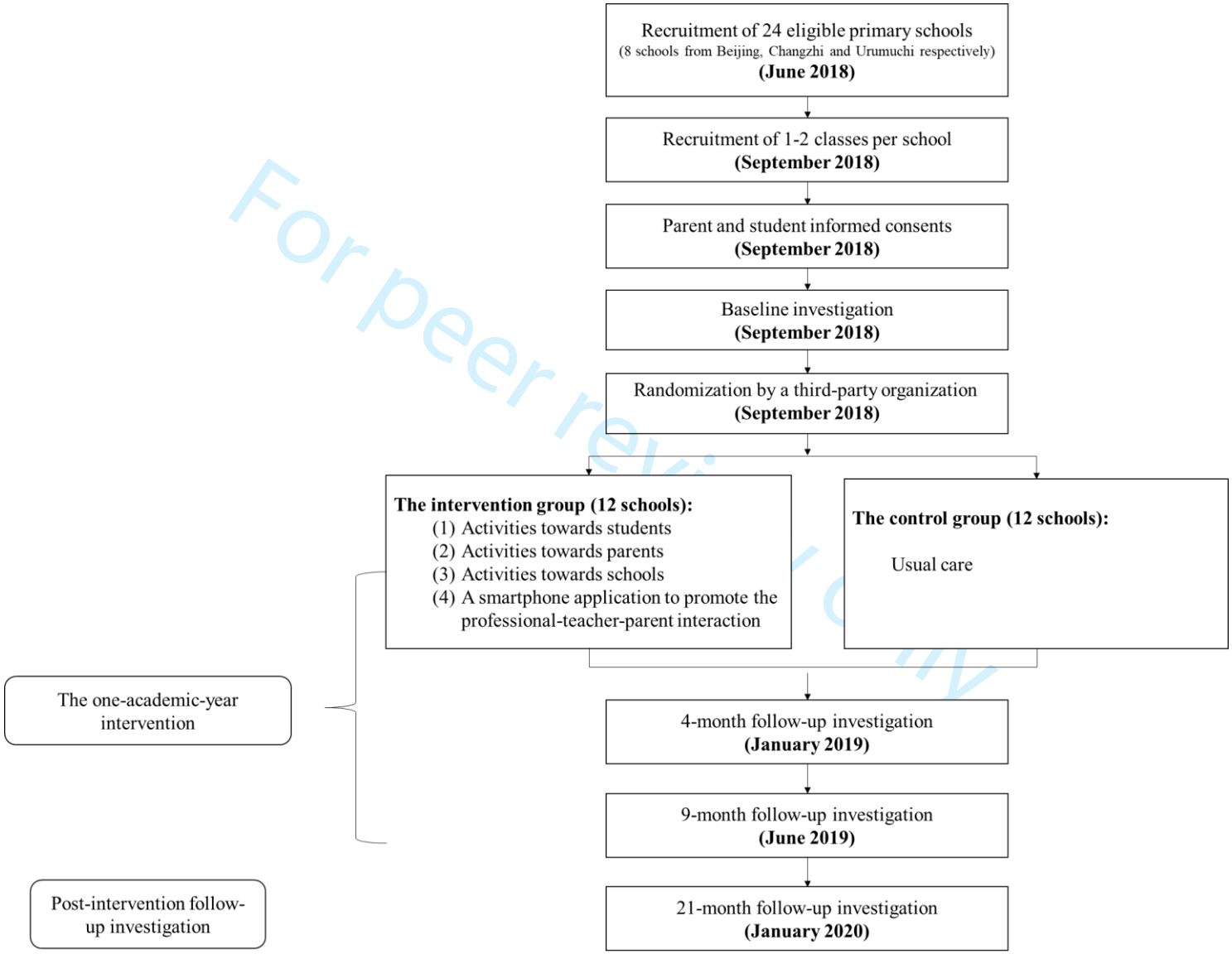

Figure 1 Study flow chart of the DECIDE-children

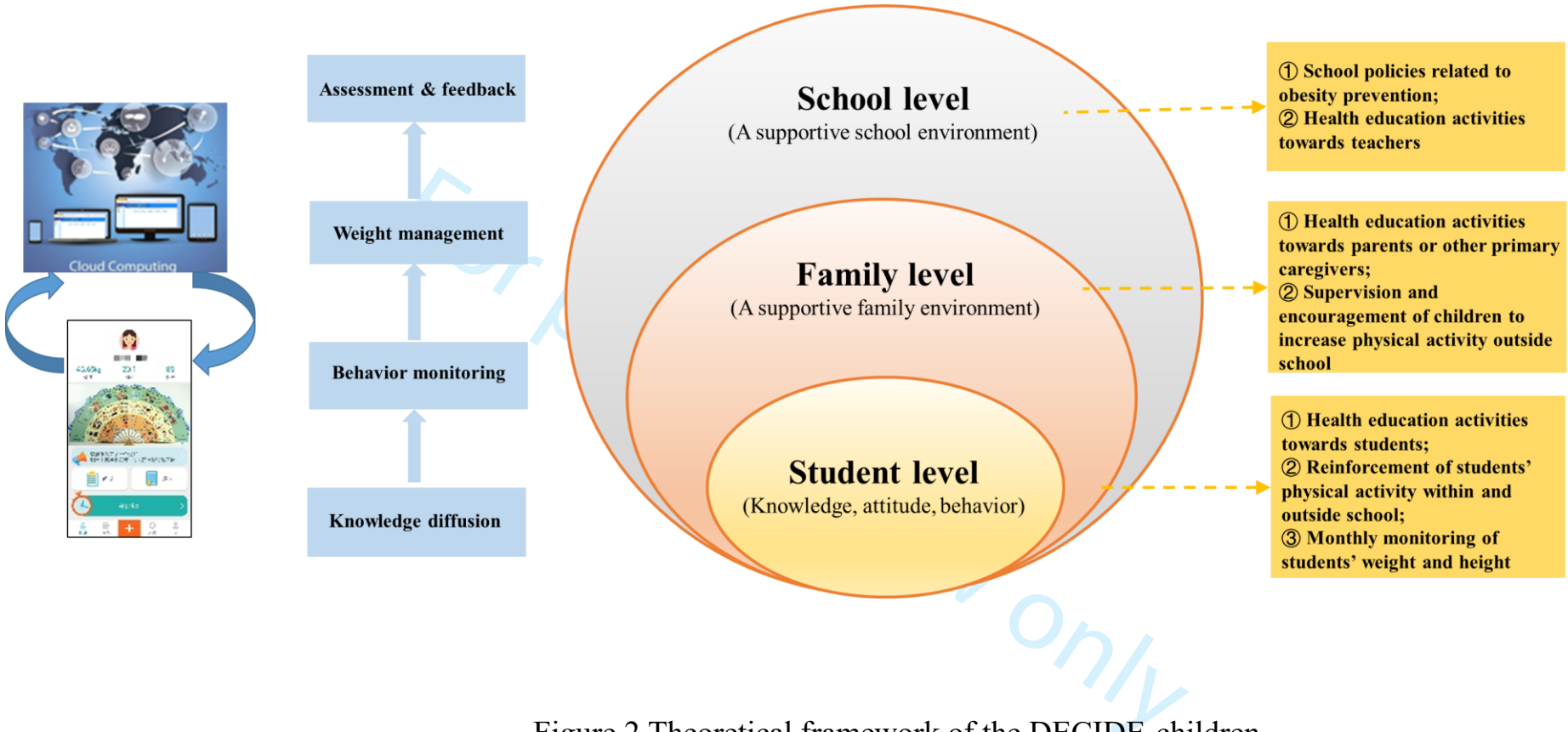

Figure 2 Theoretical framework of the DECIDE-children

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

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		Reporting Item	Page Number
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	3

Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	n/a
Protocol version	#3	Date and version identifier	n/a
Funding	#4	Sources and types of financial, material, and other support	22
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1,21,22
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	22
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	n/a
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)	22

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	5-6
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	n/a
Objectives	#7	Specific objectives or hypotheses	6
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)	7
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)	8-9
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	11-12, 25-29

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)	n/a
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	12-13
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	9-10 23-24
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)	7, Figure 1
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	14

Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	7-8
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	10
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	n/a (cluster-RCT)
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	10
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	9-10
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	n/a

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	9-10, 23-24
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	n/a
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	n/a
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	14-15
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	14-15

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)	14-15
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	n/a
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	n/a
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
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	7

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)	n/a
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	9
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	n/a
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	22
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	n/a
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	2-3
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	n/a
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n/a
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	n/a
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

BMJ Open

A school-based, multi-faceted health promotion programme to prevent obesity among children: protocol of a cluster-randomized controlled trial (the DECIDE-children study)

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A school-based, multi-faceted health promotion programme to prevent obesity among children: protocol of a cluster-randomized controlled trial (the DECIDE-children study)

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Abstract

Introduction Obesity is an increasingly serious public health concern globally. Effective and sustainable childhood obesity prevention strategies would have potential to help and may have impact on its lifelong health. However, few such strategies have been rigorously evaluated for Chinese children in different regions of China.

Methods and analysis DECIDE-Children is a cluster-randomized controlled trial that aims to assess the effectiveness and sustainability of a school-based, multi-faceted intervention to prevent obesity among Grade 4 primary school students (8 to 10 years old) in China. Twenty-four schools (approximately 1200 students) from the more than average, average and less than average developed regions in China will be randomized to intervention (12 schools) or usual practice (12 schools). The intervention will last for one year and consist of activities towards students, parents and school environment. A smartphone application will be used to assist in implementation of the intervention. Data will be collected at baseline, 4 months, 9 months and 21 months. The primary outcome is the difference between arms in the change of students' body mass index (BMI) at 9 months after the baseline investigation. The secondary outcomes include the differences between arms in the change of anthropometric measures, diet, physical activity and other measures at follow-up visits. A range of process evaluation methods will be used to determine implementation of the complex intervention.

Ethics and dissemination This study has been approved by the Peking University Institution Review Board (IRB00001052-18021). Results will be disseminated through publication in peer-reviewed journals, presentation at conferences and in lay summaries

provided to school staff and participants.

Trial registration ClinicalTrials.gov: NCT03665857.

Strengths and limitations of this study

1. This study will rigorously evaluate the effectiveness and scalability of a childhood obesity prevention programme in eastern, central and western regions with different levels of economic development in China.
2. We will employ a smartphone application to assist in implementation of the complex intervention, including information diffusion, behavior monitoring, weight management, assessment and feedback.
3. We will include an explicit process evaluation plan for both intervention and control groups, determining the implementation of the complex intervention.
4. A follow-up investigation will be conducted to evaluate the sustainability of the intervention.
5. This intervention is limited by a relatively short duration, but further funding will be sought for a potential longer-term intervention in future.

Introduction

Childhood obesity is a significant public health concern worldwide [1, 2]. China has seen a dramatic increase in childhood obesity with the economy fast growing over the past decades. The prevalence of obesity among 7-18 y Chinese children increased from 0.1% in 1985 to 7.3% in 2014 [2]. Childhood obesity is not only associated with adverse consequences on physical and mental health of children in the short term [3, 4], but also increases risk of developing cardiovascular diseases in the long term [5, 6]. Accordingly, effective strategies to curb and reduce childhood obesity prevalence would bear great long-term potential to prevent cardiovascular diseases in whole population.

Development of childhood obesity is complex and may involve multi-factorial mechanisms, but it basically results from an imbalance of energy intake and energy expenditure in most cases. Children spend half of their waking hours and consume at least one-third of their daily calories at school, and thus school-based interventions are promising in preventing childhood obesity [7]. Particularly, multi-faceted interventions combining diet, physical activity and a family component have shown the greatest effectiveness [7, 8]. However, there is a paucity of rigorously developed and evaluated prevention interventions for Chinese children [8, 9]. Moreover, not all school-based interventions were effective in preventing excessive weight gain of children [10, 11]. On one hand, it is crucial to increase our understanding of how and why these interventions work or do not work [12]. To achieve this, a thorough process evaluation of the intervention implementation is necessary. On the other hand, socioeconomic development is associated with patterns of childhood obesity [13] and may also affect

the effectiveness of a childhood obesity intervention. Yet previous studies have been largely conducted in a single region, which limits the generalizability of study findings to other populations. Another weakness is that most studies examined outcomes only at the end of the intervention. Thus, it remains unclear whether healthy behaviors and weight continue beyond the period of the intervention.

School system in China

In primary schools in China, there are six grades in total, with age of students ranging from 6 to 11 years. The usual size of a class is less than 45, but varies in different schools, ranging from 30 to 60. There are two school policies issued by Chinese government that are particularly relevant to prevention and management of childhood obesity. First, schools should have the school doctor or health care teachers who provide in-house school health care. Their routine practices include student health surveillance, health education for students, prevention and control of common diseases of students. Second, schools should implement 'One-Hour Physical Activity On Campus Every School Day'. That is, the total time of physical activity (i.e. physical education classes, class-break exercise and extracurricular activities) per school day should be no less than one hour. However, implementation of these policies in school system is varying in different regions in China [14].

Development of a childhood obesity intervention

To fill in the research gaps and in accordance with school system in China, we underwent four stages to develop the intervention: (1) we systematically reviewed previous literature to identify intervention elements related to intervention effectiveness;

(2) we conducted focus group discussions and interviews with key informants (children, parents, teachers, school principals, local health and education officials) to further revise and refine the intervention approaches; (3) to test feasibility of the proposed intervention, we also undertook a three-month, before-after, pilot study at two primary schools in Beijing (one in the urban area and the other in the rural area) among 58 Grade 4 students (mean age: 9.38±0.49 years)[15]; (4) we further discussed the proposed intervention with multiple experts. Based on all the work mentioned, we finally developed the intervention elements used for this study.

Aim and objectives

To develop effective lifestyle interventions for prevention and control of cardiovascular disease in China, the Diet, ExerCIse and CarDiovascular hEalth (DECIDE) project was initiated in 2016. As one of five independent DECIDE studies, the DECIDE-Children study is to develop a school-based, multi-faceted childhood obesity prevention programme targeting on school children aged 8-10 years in three different regions of China and rigorously test its effect in preventing excessive weight gain in Chinese primary school settings. The research objectives of the DECIDE-Children were: (1) to assess the effectiveness of the intervention compared with usual practice in preventing childhood overweight and obesity; (2) to determine the sustainability of the intervention in preventing overweight and obesity; (3) to undertake process evaluation and health economic evaluation of the intervention.

Methods and analysis

This protocol has been prepared in accordance with the Standard Protocol Items:

Recommendations for Interventional Trials (SPIRIT) statement [16, 17].

Study design

DECIDE-Children is a cluster-randomized, parallel-group controlled trial. To accommodate with the social and economic variations within the country and increase the scalability of our interventions, we will intentionally select study schools from three different regions of China, the more than average developed area in the east (Beijing), the average developed area in the central (Shanxi) and the less than average developed area in the west (Xinjiang). A total of 24 primary schools (clusters) equally distributed among three regions will be selected. In Beijing, 4 schools will be selected from Dongcheng district (located in the central city) and 4 from Mentougou district (located in a suburban rural area). In Xinjiang, all 8 schools will be selected in Urumchi, the capital city of the autonomous region; and half of the schools will be selected from Shayiba district (an urban district) and half from Shuimogou district (a rural district). In Shanxi, all 8 schools will be selected from only one urban district of Changzhi, a small to mediam size city in the province. The reason for excluding rural schools in Changzhi is that most of these schools were boarding schools. Thus, a total of 24 primary schools from five sites in three regions will be selected and randomized into two groups, one on the obesity prevention intervention and the other on usual practice. The intervention will be implemented for one school year from late September 2018 to June 2019, and the study will continue with a one-year follow-up investigation in June 2020. Figure 1 shows the study flow.

Recruitment

Recruitment of schools

The present study will be carried out in Grade 4 students (8 to 10 years old), as they are old enough to understand health education information and able to remain in the same school to complete the two-year study before they graduate. To be eligible, the school principal should agree with randomization procedure and compliance with the study protocol. The total number of Grade 4 students must be more than 50 in the school, and the school have not implemented or are not going to implement an obesity prevention or similar intervention program. Boarding schools, special schools for children with talent skills or minority ethnic groups will be excluded. Schools will also not be included if they have a definite plan for relocation or cancellation in the next two years. For schools participating the program, the size of a class varies from less than 30 to approximately 60 children a class. To meet the sample size requirement, we will recruit two classes of the school if the number of students in each class is less than 50 and one class otherwise. If the number of classes in one school is more than needed, the school principal will recommend which classes to be selected.

Three steps will be undertaken for the recruitment of schools. First, project staff will contact the local education authority to gain their opinion, support, approval and basic information of the schools (type of schools, number of students and teachers). Second, project staff will approach the schools by a phone call or a visit to understand the eligibility of the potential schools for participation. Third, the final list of eligible schools and classes will be made by the principal investigator and schools will be invited by local research partners.

Recruitment of students

After recruiting schools and before the baseline examination, written informed consent will be provided to all students and their primary caregivers (parents in most cases) in the selected classes. Then parents with informed consent will be required to fill in a self-administrative questionnaire about health status of their children. The project staff will collect the questionnaires and if find one or more of the following conditions reported by parents, their children will be excluded: 1) medical history of heart disease, hypertension, diabetes, tuberculosis, asthma, hepatitis or nephritis; 2) obesity caused by endocrine diseases or side effects of drugs; 3) abnormal physical development like dwarfism or gigantism; 4) being physically incomplete and deformed such as severe scoliosis, pectus carinatum, limp, obvious O-leg or X-leg; 5) inability to participate in school sports activities; 6) having been losing weight by vomiting or taking drugs during the past three months.

Randomization procedures

The random sequence of allocation of schools (clusters) to intervention or control will be stratified by the study sites. Schools in the same study site will be randomly allocated in 1:1 ratio to either the intervention or control group using a computer-generated random number system (the simple random sampling method). Randomization will be performed by an independent person at the central coordinating center at Peking University Clinical Research Institute. The randomization will take place only after the baseline assessments complete to ensure the allocation concealment.

Intervention

We used Social Ecological Model to identify intervention elements in this multi-faceted health promotion programme [18]. As shown in Figure 2, the programme will target the influencing factors of childhood obesity at both individual (student-focused activities) and environmental levels (providing a supportive family and school environment), with the intent to influence knowledge, attitude and behaviors of school children.

Description of the intervention components

The intervention components are described in Table 1 and 2.

Student-focused activities: These will include health education activities for students, reinforcement of students' physical activity within school and regular monitoring of students' weight and height.

Activities towards parents: These will include health education activities for parents, supervision and encouragement of children to increase physical activity outside school.

Activities towards schools: These will include school policies related to obesity prevention and health education activities for teachers.

The smartphone app: Project staff, school teachers and parents will be suggested to install the app--"Eat Wisely, Move Happily". The app, developed based on behavior change techniques [19], will be assisted in implementation of the intervention, including information diffusion, behavior monitoring, weight management, assessment and feedback.

Quality control of the intervention

Two manuals ("An Operation Manual for Project Staff Involving in the Multi-

component Obesity Intervention among Primary School Students" and "An Operation Manual for School Team Members Involving in the Multi-component Obesity Intervention among Primary School Students") have been developed for implementing and managing this complex intervention. They describe in detail the duties of project staff and school team members (school principals, class teachers, physical education teachers, school doctors/health care teachers) in delivering the intervention, respectively. The manuals also describe the detailed workflow of implementation for each intervention component, i.e., who, when, how and to what extent the specific intervention element should be delivered. All of the project staff and school team members will be required to carry out the intervention in accordance with the operation manuals.

During implementation of the intervention, regular field observation and checking of smartphone app records will also be applied. To improve fidelity, if it is found that schools are not complying with the study protocol, project staff will timely communicate with school team members and continue with follow-up supervision.

Control group

The twelve schools in the control group will not carry out any interventions delivered by the study and will continue usual practice according to their own teaching curriculum during the study period (from September 2018 to June 2020). Participants in the control group will receive the health education materials that will have been delivered to those in the intervention group as soon as the 21-month follow-up investigation be completed in June 2020.

Outcome evaluation

Table 3 describes what, when and how the study outcomes will be evaluated. Baseline measurements will be conducted in September 2018 for both intervention and control groups. Follow-up measurements will be undertaken at 4 months after baseline measurements in January (one school semester and in the half of the intervention), 9 months after baseline measurements in June 2019 (one school year and immediately whole intervention program completed) and 21 months after baseline measurements in June 2020 (two school years and 12 months after the intervention completion).

At the baseline and all follow-up visits, anthropometric measures (height, weight, waist and hip circumference, systolic and diastolic blood pressures, body fat percentage) and physical fitness measures (one-minute rope jumping, one-minute sit-up, long standing jump, shuttle run (50 m×8)) will be collected by the trained outcome assessors using uniform device and/or forms according to the standard methods and procedures. The assessors measuring students' height and weight will be blinded to group allocation of the schools. We will use questionnaires to measure students' behaviors (duration of moderate-to-vigorous physical activity, eating behavior, sedentary behavior), school policies for prevention and management of childhood obesity, and other potential moderators/mediators of the intervention (e.g. stage of change related to weight reduction behavior). Questionnaires were developed based on previous studies and the pilot study. They were found to be feasible and acceptable to students and their parents [20-22].

Outcomes

The primary outcome is the difference between arms in the change of students' body mass index (BMI=weight (kg)/(height (m))^2) immediately after the intervention completion (9 months after the baseline examination). The secondary outcomes include the change of BMI in one year after the intervention completion. In addition, we will also compare the following indices between arms at follow-up visits: 1) change in students' BMI-Z (standard deviation score will be calculated based on World Health Organization criteria [23]); 2) change in prevalence and incidence of childhood overweight/obesity defined according to the criteria for Chinese children and adolescents [24]; 3) change in students' waist circumference, waist-to-hip circumference ratio and systolic and diastolic blood pressures; and 4) change in students' body fat percentage, physical fitness measures, behavioral and other outcomes.

Sample size estimation

We assumed the difference between two groups in change in BMI (effect size) would be 0.50 kg/m^2, a standard deviation (SD) of BMI would be 1.40 kg/m^2, an intra-cluster correlation coefficient would be 0.05 and the rate of attrition would be 10% for sample size calculation in our study. We aimed to recruit a total of 1,200 students from 24 schools with an average cluster size of 50 students per school. This sample size will provide 88% power with a=0.05 to detect a mean difference of 0.50 kg/m^2 in change of BMI between groups after the one-school-year intervention.

Statistical analyses

Statistical analyses will be performed using SAS version 9.4 (SAS Institute Inc., Cary, NC, USA). All statistical tests will be two-sided at 5% level of significance. Baseline

characteristics at both school- and individual-level will be reported by using descriptive statistics.

The primary analysis will be based on the intention-to-treat principle including all students recruited with the baseline BMI measured. Generalized linear mixed models will be used to compare the primary and secondary outcomes at 4 and/or 9 and/or 21 months after the baseline, adjusting for the clustering effect and baseline outcome values. The missing data will be treated in the maximum likelihood estimates assuming they are missing at random. The intra-cluster correlation coefficient will also be estimated. Sensitivity analysis will be considered on the primary outcome using the last-value-carry-forward imputation if missing data exceeds 5%. For continuous outcomes, we will report pre-, post-intervention means for intervention and control groups, respectively, and model-adjusted mean differences between groups. For binary outcomes, we will report pre-, post-intervention percentages for intervention and control groups, respectively, and adjusted odds ratio (OR) between groups. The 95% confidence interval (CI) and associated *P*-value will be calculated. We will also examine whether any difference in outcomes between control and intervention arms varies by children sex, socioeconomic factor (mother's education), BMI status at baseline and primary caregivers of children (parents as compared with non-parents).

Process evaluation

The process evaluation will be conducted in intervention schools throughout the project period to monitor and document the implementation of the intervention. It also aims to aid in understanding the relationship between specific intervention elements and

outcomes. The control schools will also be monitored for "treatment as usual".

Based on the steps and principles described in the conceptual framework by Saunders et al.[25], we will identify the process evaluation elements including fidelity (the extent to which the intervention will be implemented as initially planned), dose delivered (the frequency and intensity of actual implementation of the program), dose received (the extent to which students/primary caregivers (parents in most cases)/teachers will be exposed to the intervention, as well as the degree of their satisfaction with intervention and materials), reach (the proportions and the characteristics of students/primary caregivers/teachers completing or dropping out of the intervention) and context (family environment and school policies related to obesity prevention and management).

The methods of process data collection will include: (1) direct regular field observation and records collected for quality control of the intervention (e.g., quality and quantity of the intervention sessions, number of students attending the lectures); (2) the user logs (e.g., frequency and duration) collected by the smartphone app; and (3) student and parent questionnaires (Table 3) on students' behaviors and family environment in both intervention and control schools; (4) school questionnaires on school policies related to obesity prevention and management in both intervention and control schools; (5) interviews with participants (6~8 students per school) conducted in follow-up investigations in both intervention and control schools.

Health economic evaluation

A cost-effectiveness analysis will be employed in the health economic evaluation, and a societal perspective is used to examine whether the intervention is economically

feasible. Intervention costs include times (project staff, school staff, and students' primary caregivers (parents in most cases)) for all the intervention activities and material expenses. Only time of project staff spent in implementing the intervention will be included. Time costs are based on personal employment compensations if available or average compensations in the local areas for similar types of employees. Material expenses are based on real purchasing prices. An incremental cost-effectiveness ratio will be calculated and a sensitivity analysis will be used to vary key parameters to examine the robustness of health economic results.

Patient and Public involvement

We conducted focus group discussions and interviews with key stakeholders (children, parents, teachers, school principals, local health, and education officials) refining the intervention approaches. We do not involve any of them in other research work in the study including the idea development, design, implementation, data collection, analysis and interpretation. Results of the study will be disseminated through publication in peer-reviewed journals, presentation at conferences and in lay summaries provided to school staff, students and parents. The benefits and burden of the intervention will be assessed by children and their primary caregivers through self-reported questionnaires at the end of intervention.

Trial status

The trial started and completed recruitment of schools and children in September 2018. Baseline measures commenced in late September 2018 and completed by the end of September in 2018. The one-school-year intervention started at the end of September

in 2018 and completed in June 2019. The 4-month follow-up measurements started and completed in January 2019. The 9-month follow-up measurements started and completed in June 2019. The 21-month follow-up measurements will start and complete in June 2020.

Ethics and dissemination

This study was reviewed and has been approved by the Peking University Institution Review Board (IRB00001052-18021). Any amendments to the study protocol will be submitted for IRB approval prior to implementation. Written informed consent will be obtained from all students and their parents. All data collected will be entered into electronic database with personal identification information de-identified. The database will be accessed only by designated staff with password. Results will be disseminated through publication in peer-reviewed journals, presentation at conferences and in lay summaries provided to school staff and participants. On completion of the trial, and after publication of these results, data would be available on request by contacting the corresponding author of this protocol.

Discussion

Non-communicable diseases, especially cardiovascular diseases, have been the public health burden among the whole population. Preventing childhood obesity in early life could have the greatest long-term potential to curb this epidemic burden. Although several childhood obesity intervention studies have been conducted in China, research gaps existed in terms of methodological flaws, process measures, scalability and sustainability of the intervention. Based on a theory-driven and systematic development

during its formative phase (e.g., systematic review [8], qualitative interviews, panel discussions and a piloted study [15]), the DECIDE-Children study provides one of the first examples of rigorous development and evaluation of a childhood obesity prevention programme implemented in eastern, central and western regions of China. This study has several distinguishing features: 1) randomization by an independent person not involved in the study, blinding of key outcome measures, and a detailed process evaluation plan will help to provide study results with high quality; 2) a follow-up investigation one year after the intervention completion will be conducted to determine the sustainability of the intervention; 3) a smartphone app with functions of information diffusion, behavior monitoring, weight management, assessment and feedback is employed to assist in implementation of the intervention; 4) three centers located in eastern, central and western regions of China will be involved to reflect different levels of economic development in China; 5) most of the intervention components (school polices, regular monitoring of students' weight and height, reinforcement of students' physical activity within school, health education activities for students) will be integrated into the regular academic schedule of each intervention school.

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Authors' contributions

HJW and YFW conceived the project. HJW, ZL, YFW, WYN and HJL were involved in design of the study and development of intervention materials. ZL wrote the first draft of the manuscript. XXF, YL, AYG and FZ contributed to implementation of the program. HF contributed to economic evaluation. PG contributed to statistical analysis plan. All authors approved the final manuscript.

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Study team of the DECIDE-Children study:

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Changzhi: Changzhi Medical College (Xiang-Xian Feng, Jian-hui Yuan, Li-fen Duan).

Urumqi: Urumqi Primary and Secondary School Health Care Center, Xinjiang (Yi Lin, Chun-Xia Xu, Guo-Qin Yang, Zheng Zhang).

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Competing interests statement

None.

Table 1 Description of the intervention components implemented in the DECIDE-children

Intervention components	Descriptions on contents, frequency, and duration	Responsible person
1. Student-focused activities		
Health education activities for students	1) Frequency and duration A total of ten activities (lasting for 40 minutes per activity) will be provided once every two to three weeks (six activities arranged in the first semester and four in the second semester). 2) Different kinds of activities Ten activities will include seven health education lectures and three theme class meetings. The focus of health education lectures will be on information diffusion, while the focus of theme class meetings will be on consolidation of the key messages learned in health education lectures through interactive and interesting group work (e.g., "Let me guess"). 3) Contents ① Information diffusion Key messages will include the benefits of healthy weight, measurement and assessment of weight, as well as skills to achieve healthy weight (not eating excessively; not drinking sugar-sweetened beverage; eating less high-energy food; less sedentary behaviors; doing more physical activity). Health education books and "nutrition evaluation turnplate for Chinese primary and middle school students" will be delivered to students. Health education messages will be also spread through posters in campus or classroom. ② Promotion for translating knowledge into action "Small hand in big hand" homework (e.g., "challenge of three days away from screen") will	The trained class teachers

	be arranged at the end of each health education activity. ③ Feedback and encouragement for BMI and behavior change Feedback of regular monitoring results of students' BMI and behaviors will be provided in each health education activity. The students with good performance will be encouraged.	
Reinforcement of students' physical activity within school	1) Students will be organized by physical education teachers to do physical activity within school for at least one hour per school day (including physical education classes, class-break exercise, extracurricular activities), achieving moderate-to-vigorous intensity. The aim of this component will be to improve the implementation of the Chinese national requirement for 'One-Hour Physical Activity On Campus Every School Day'. If schools have met this requirement, no extra physical activities will be added within school; if not, extra physical activities (i.e. physical education classes, class-break exercise or extracurricular activities) will be additionally added to the school schedule. Monitoring of implementation of these extra physical activities will be continuous within the intervention period for these intervention schools; 2) Physical education teachers will be advised to teach students at least one sports game during each extracurricular activity.	The trained physical education teachers
Regular monitoring of students' weight and height	<u>1) Monthly monitoring</u> Students' weight and height will be monitored monthly, the data will be then timely input into the computer management system and thus being shown in the smartphone app (described below); <u>2) Weekly monitoring</u> Students' weight will be monitored weekly by the students themselves in the classroom.	The trained school doctors/health care teachers with the assistance of the trained project staff (for monthly monitoring); The trained project staff (for data input of monthly monitoring) Students (for weekly monitoring)

2. Activities towards parents (providing a supportive family environment)		
Health education activities for parents	1) Frequency and duration At least one activity (lasting for about 40-60 minutes) will be held at the beginning of each semester. One more activity will be held in the middle of the first semester. Another activity will also be held in the middle of the second semester if necessary (such as fidelity is unsatisfactory). 2) Contents ➢ For the first activity Key messages will be similar to health education activities for students (described above). Parents will also be taught to use the smartphone app. ➢ For other activities Project staff will provide feedback about students' weight status and behaviors to parents. Face-to-face group discussions will be established between project staff and parents.	The trained project staff
Reinforcement of students' physical activity outside school	1) Parents will be instructed to supervise and encourage students to do physical activity outside school, achieving 30 minutes per weekday and 1 hour per weekend day; 2) Recommendations for physical activity outside school will be provided through the smartphone app once every two months; 3) Students will be encouraged to do sports games outside school that will be taught by their physical education teachers during extracurricular activities.	Students' parents
3. Activities towards schools (providing a supportive school environment)		
School policies related to obesity prevention	The following school policies will be suggested: 1) "Not selling":	Trained school principal; Trained class teachers

	Not selling unhealthy snacks[1] or sugar-sweetened beverages within school; 2) "Not eating": Telling students not to eat unhealthy snacks or drink sugar-sweetened beverages within school; 3) "Not buying": Students being educated by class teachers not to buy unhealthy snacks or sugar-sweetened beverages around school.	
Health education activities for school teachers	1) Frequency and duration The activity will be held once (lasting for about 40 minutes) in the first month of the intervention. School teachers participating in this program in each school (school principal, class teachers, school doctors/health care teachers and physical education teachers) will be required to attend the activity. 2) Contents Key messages will be similar to health education activities for students (described above). School teachers will also be taught to use the smartphone app.	The trained project staff
4. A smartphone app assisted in implementation of the intervention		
The smartphone app ("Eat Wisely, Move Happily")	1) Information diffusion (the behavior change technique (BCT) used: providing information on consequences of behavior) The smartphone app will provide information to parents, class teachers and project staff in	The smartphone app (installed by parents, school teachers and project staff) and the computer management

[1] "Healthy snacks" refer to dairy products, fresh vegetables or fruits and natural unprocessed nuts which are eaten at times other than at main meals. "Unhealthy snacks" refer to snacks other than the three kinds of healthy snacks.

	accordance with health education activities. 2) Behavior monitoring (the BCT used: prompting self-monitoring of behavior) Parents together with their children will be asked to weekly record diet and physical activity behaviors of students in the app, and then they will receive individualized feedback related to these behaviors (described in Table 2). 3) Weight management (the BCT used: prompting self-monitoring) According to monthly monitoring of students' weight and height (described above), parents, school teachers and project staff will view the recent weight status (categorized according to the BMI percentile criteria [24]), changes compared with previous records of the students as well as the individualized feedback related to weight management (described in Table 2). 4) Assessment and feedback (the BCT used: providing feedback on performance) The smartphone app will also provide a synthetic and individualized assessment that will combine changes of behaviors and weight status of students. Four kinds of feedback are provided in Table 2.	system (utilized by project staff)

Table 2 The four kinds of regular evaluation messages feedback to all stakeholders by the smartphone mobile app on the basis of data from regular monitoring of children's weight, height and behaviors

		Results automatically judged according to height and weight measured at regular monitoring	
		Positive results (BMI decreases in students who are overweight or obese, or BMI increases in students who are underweight)	Negative results (BMI increases in students who are overweight or obese, or BMI decreases in who are underweight)
Results automatically judged according to diet and physical activity behaviors recorded regularly	Full marks/ getting better	**Feedback 1**: "Your child is doing a great job. The weight changes are consistent with changes in diet and physical activity behavior. Keep it up!"	**Feedback 2**: "Your child's weight has not improved, but diet and physical activity behavior is good. It is might be that weight improvement requires a long-term adherence to a reasonable diet and physical activity, or that behavior records are inaccurate. Please continue to improve!"
	Unchanged/ getting worse	**Feedback 3**: "Your child has improved or maintained a healthy body weight, but there is still room for improvement in diet and physical activity behavior. Keep working!"	**Feedback 4**: "Your child's weight has not improved, and diet and physical activity also need improvement. Please continue to work hard!"

Table 3 Outcome measurements for the DECIDE-Children

Outcomes	Time				Device (Manufacturer, model)	Method
	Baseline	4 months after baseline	9 months after baseline	21 months after baseline		
Anthropometric measures						
Height	√	√	√	√	Stadiometer (Huateng GMCS-1)	Measured to the nearest 0.1 cm at least twice
Weight	√	√	√	√	Lever scale (Wujin RGT-140)	Measured to the nearest 0.1 kg at least twice
Waist circumference	√	√	√	√	Tape (MyoTape)	Measured to the nearest 0.1 cm at least twice
Hip circumference	√	√	√	√	Tape (MyoTape)	Measured to the nearest 0.1 cm at least twice
Systolic and diastolic blood pressures	√	√	√	√	Electronic sphygmomanometer (Omron HBP-1300)	Measured to the nearest 1 mmHg at least twice
Body fat percentage	√		√		Body component instrument (Tanita MC-780MA)	According to the standard procedure
Physical fitness measures						
One-minute rope jumping	√		√		Physical fitness measures will be assessed by trained outcome assessors according to the standard procedure.	

One-minute sit-up	√	√	
Long standing jump	√	√	
Shuttle run (50m×8)	√	√	
Behavioral and other measures			
Students' knowledge related to energy balance	√	√	We will use 8 items to assess the change of students' knowledge related to energy balance. For example, we will ask students, "Is it right that drinking sugar-sweetened beverage cannot substitute drinking water." Three choices will be provided (Right; Wrong; Not clear). Students should finish the questionnaires in the classroom in the presence of the trained outcome assessors, who can provide guidance and help.
Students' duration of moderate-to-vigorous physical activity	√	√	Questions were designed based on a validated 7-day physical activity questionnaire (PAQ; kappa values for test-retest results: 0.46~0.79 (different measures of activity); face validity and content validity were good by experts' evaluation; correlations between PAQ and Caltrac motion sensor ranging from 0.38 to 0.46 (different measures of activity) for boys) [21]. Students should finish the questionnaires in the classroom in the presence of the trained outcome assessors, who can provide guidance and help.
Students' eating behavior	√	√	We will use a "Children Eating Behavior Questionnaire" (CEBQ) to assess students' eating behaviors, including responsiveness to food, enjoyment of food etc. This 35-item instrument has been shown relatively good reliability [22].

Students' sedentary behavior	√	√	The questionnaires should be self-reported by parents or other primary caregivers of students. We will use a self-designed questionnaire to ask the average duration of doing homework, watching television and playing electronic devices per day during the last week, respectively. Students should finish the questionnaires in the classroom in the presence of the trained outcome assessors, who can provide guidance and help.
School policies for prevention and management of childhood obesity)	√	√	The questionnaires should be filled in by the trained investigators after face-to-face interviews with school principals, doctors/health care teachers and physical education teachers.
Stage of change related to weight reduction behavior	√	√	We will use two items to assess it. First, we will ask "Have you taken action to reduce your weight during the last three months?" Yes/no choices will be provided. And then, we will ask "Do you intend to reduce your weight currently?" This item will be provided 5 choices from "completely not intend" to "intend very much". Students should finish the questionnaires in the classroom in the presence of the trained outcome assessors, who can provide guidance and help.

Figure 1 Study flow chart of the DECIDE-children

Figure 2 Social Ecological Model of the DECIDE-children

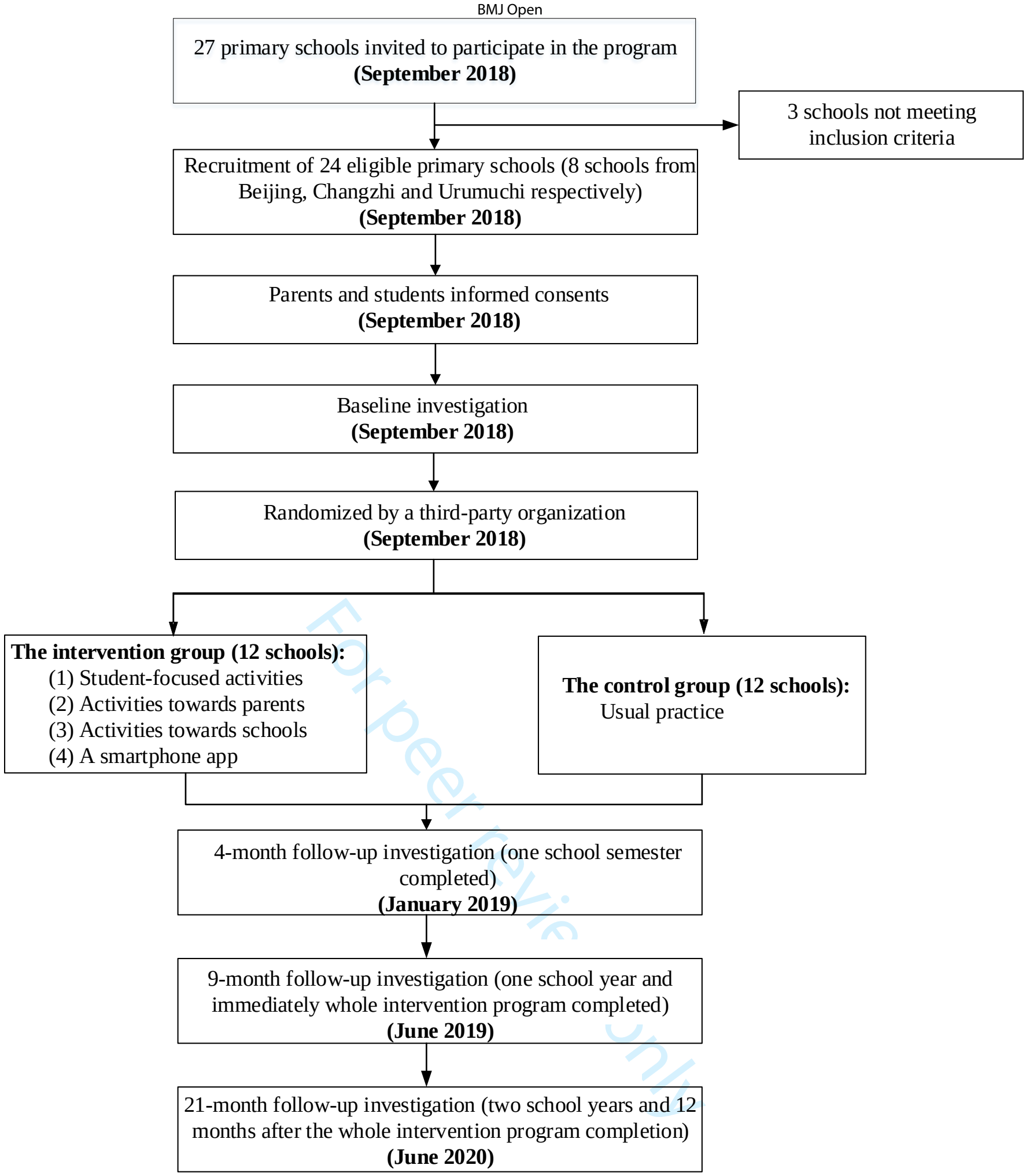

Figure 1 Study flow chart of the DECIDE-children

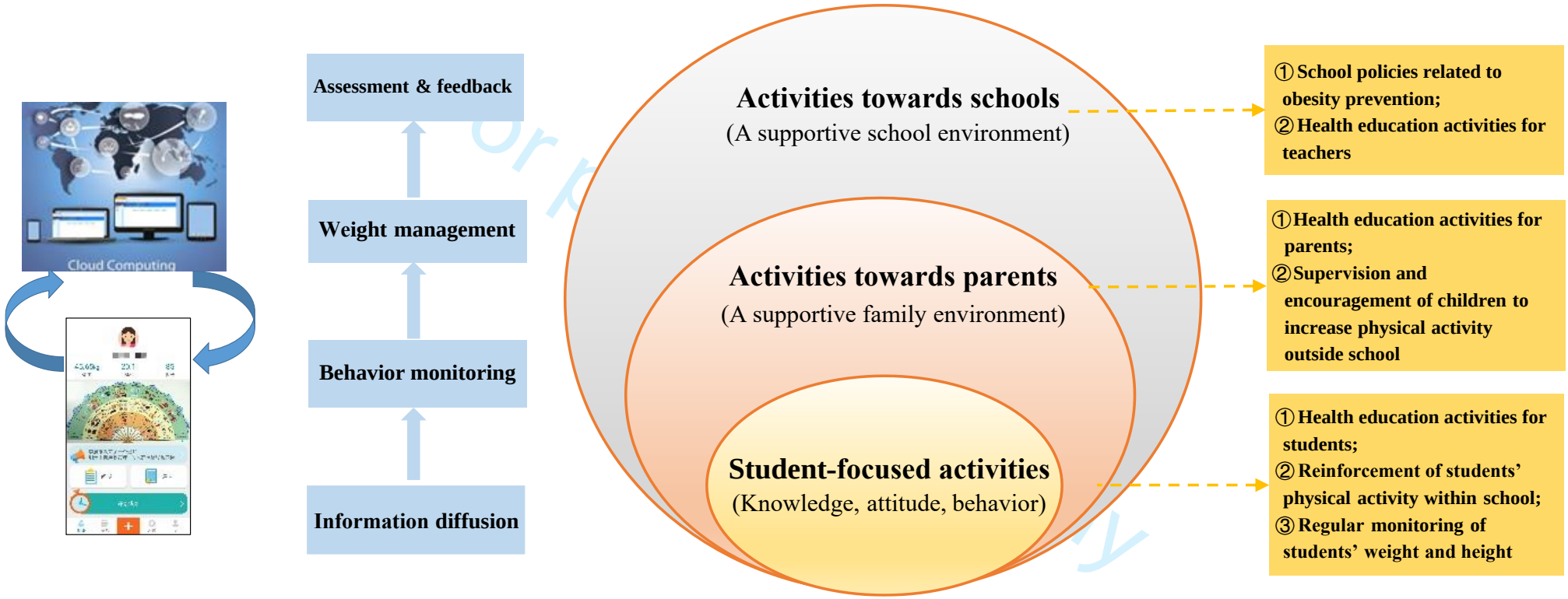

Figure 2 Social Ecological Model of the DECIDE-children

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 SPIRIT reporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. Ann Intern Med. 2013;158(3):200-207

		Reporting Item	Page Number
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	3

Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	This information is provided in the trial registration website.
Protocol version	#3	Date and version identifier	This information will be provided as soon as the manuscript revision is finally completed.
Funding	#4	Sources and types of financial, material, and other support	25
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	24-25
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	n/a. This study was not sponsored by any individuals or companies. The funder name and number has been provided in Page 25.
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	26

		report for publication, including whether they will have ultimate authority over any of these activities	
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)	25
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	5-7
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	6
Objectives	#7	Specific objectives or hypotheses	7
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)	8

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	8
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)	9-10
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	11, Table 1-2
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)	n/a. This is a childhood obesity prevention intervention. Based on our previous experiences, it is less likely that discontinuing or modifying allocated interventions for a given trial participant will take place.

Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	11-12
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a. This is a childhood obesity prevention intervention. Based on our previous experiences, it is less likely that concomitant care and interventions will take place.
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	13-14, Table 3
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and	Figure 1

		washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	
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	14
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	9-10
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	10
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing	10

		any steps to conceal the sequence until interventions are assigned	
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	9-10
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	13
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	n/a. The assessors measuring students' height and weight will be blinded to group allocation of the schools. We did not anticipate any necessary circumstances when unblinding is permissible.
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	13

		collection forms can be found, if not in the protocol	
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	15
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	3
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	15
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	15

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)	15
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	18
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	n/a. This is a childhood obesity prevention intervention. Based on our previous experiences, it is less likely that discontinuing interventions will take place.
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events	16 (we will use questionnaires to collect and

		and other unintended effects of trial interventions or trial conduct	assess any adverse events or other process data)
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	7 (This study is one of the five independent studies of the overall DECIDE project. This overall project is audited by the funder (National Key R&D Program of China).
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	2-3
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)	2-3
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	10
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data	n/a. This study will not collect biological specimens.

		and biological specimens in ancillary studies, if applicable	
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	3
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	26
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	3
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. This is a childhood obesity prevention intervention. Based on our experiences, it is less likely that ancillary and post-trial care will take place.
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public,	3

		and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	n/a
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n/a
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	10
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 This study will not collect biological specimens.

BMJ Open

A school-based, multi-faceted health promotion programme to prevent obesity among children: protocol of a cluster-randomized controlled trial (the DECIDE-Children study)

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Manuscript ID	bmjopen-2018-027902.R2
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A school-based, multi-faceted health promotion programme to prevent obesity among children: protocol of a cluster-randomized controlled trial (the DECIDE-Children study)

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Abstract

Introduction Obesity is a public health concern that is becoming increasingly more serious worldwide. Effective and sustainable childhood obesity prevention strategies may help to reduce the prevalence of obesity and may have an impact on lifelong health. However, few such strategies have been rigorously evaluated for Chinese children in different regions of China.

Methods and analysis DECIDE-Children is a cluster-randomized controlled trial that aims to assess the effectiveness and sustainability of a school-based, multi-faceted intervention to prevent obesity among Grade 4 primary school students (8 to 10 years old) in China. Twenty-four schools (approximately 1200 students) from above average, average and below average developed regions in China will be randomized to an intervention (12 schools) or usual practice (12 schools) group. The intervention will last for one year and consist of activities towards students, parents and school environment. A smartphone application will be used to assist in providing information on, monitoring and providing feedback on the behaviours and body weight of the students. Data will be collected at baseline, 4 months, 9 months and 21 months. The primary outcome will be the difference between groups in the change in students' body mass index (BMI) at 9 months after the baseline investigation. The secondary outcomes will include the differences between groups in the changes in anthropometric measures, diet, physical activity levels and other measures at the follow-up visits. A variety of process evaluation methods will be used to evaluate the implementation process of the complex intervention.

Ethics and dissemination This study was approved by the Peking University Institution Review Board (IRB00001052-18021). The results will be disseminated through publication in peer-reviewed journals, presentations at conferences and in lay summaries provided to school staff and participants.

Trial registration ClinicalTrials.gov: NCT03665857.

Strengths and limitations of this study

1. This study will rigorously evaluate the effectiveness of a childhood obesity prevention programme in eastern, central and western regions with different levels of economic development in China.
2. We will employ a smartphone application to assist in providing information on, monitoring and providing feedback on the behaviours and body weight of the students.
3. We will include an explicit process evaluation plan for both the intervention and the control groups, which will evaluate the implementation process of the complex intervention.
4. A follow-up investigation will be conducted to evaluate the sustainability of the intervention.
5. This intervention is limited by a relatively short duration, but additional funding will be sought for the implementation of a long-term intervention in the future.

Introduction

Childhood obesity is a significant public health concern worldwide [1, 2]. In China, childhood obesity has dramatically increased as the economy has grown quickly over the past decades. The prevalence of obesity among 7- to 18-year-old Chinese children increased from 0.1% in 1985 to 7.3% in 2014 [2]. Childhood obesity is associated with not only adverse consequences on the physical and mental health of children in the short term [3, 4], but also increases the risk of developing cardiovascular diseases in the long term [5, 6]. Accordingly, effective strategies to curb and reduce childhood obesity prevalence may help to prevent cardiovascular diseases in the whole population in the long term.

The development of childhood obesity is complex and may involve multi-factorial mechanisms, but in most cases, it essentially results from an imbalance between energy intake and energy expenditure. Children spend half of their waking hours at school and consume at least one-third of their daily calories at school; thus, school-based interventions are promising in preventing childhood obesity [7]. In particular, multi-faceted interventions combining diet, physical activity and a family component have shown the highest effectiveness [7, 8]. However, there is a paucity of rigorously developed and evaluated prevention interventions for Chinese children [8, 9]. Moreover, not all school-based interventions have been effective in preventing excessive weight gain in children [10, 11]. One potential interpretation of this finding is that adherence to the intervention components was not guaranteed [11]. It is thus crucial to increase our understanding of how and why these interventions work or do not work [12]. To

achieve this, a thorough process evaluation of the intervention implementation is necessary. Furthermore, socioeconomic development is associated with patterns of childhood obesity [13] and may also affect the effectiveness of a childhood obesity intervention. Social disparities in the patterns of obesity differ between China and Western countries. In China, socioeconomic development has been positively associated with overweight and obesity prevalence in children [13]. However, previous studies have been largely conducted in a single region, which limits the generalizability of study findings to other populations. Another weakness is that most studies examined outcomes only at the end of the intervention. Thus, it remains unclear whether healthy behaviours and a healthy weight are maintained beyond the period of the intervention.

School system in China

In primary schools in China, there are six grades in total, and the age of the students ranges from 6 to 11 years. The typical size of a Chinese class is fewer than 45 students, but varies in different schools, ranging from 30 to 60 students. There are two school policies that have been issued by the Chinese government that are particularly relevant to the prevention and management of childhood obesity. First, schools should have school doctors or health care teachers who provide in-house school health care. The routine practices include student health surveillance, health education for students, and the prevention and control of common diseases in students. Second, schools should implement 'One-Hour Physical Activity On Campus Every School Day'. That is, the total duration of physical activity (i.e., physical education classes, exercises during breaks from class and extracurricular activities) per school day should be no less than

one hour. However, the implementation of these policies in the school systems in China varies by region [14].

Development of a childhood obesity intervention

To fill in research gaps, in accordance with the school systems in China, we underwent four stages to develop the intervention: (1) we systematically reviewed previous literature to identify intervention elements related to intervention effectiveness; (2) we conducted focus group discussions and interviews with key informants (children, parents, teachers, school principals, local health and education officials) to further revise and refine the intervention approaches; (3) we conducted a three-month, before-after, pilot study at two primary schools in Beijing (one in an urban area and the other in a rural area) involving 58 Grade 4 students (mean age: 9.38±0.49 years) to test the feasibility of the proposed intervention [15]; and (4) we further discussed the proposed intervention with multiple experts. Based on all the work mentioned, we finally developed the intervention elements used for this study.

Aim and objectives

To develop effective lifestyle interventions for the prevention and control of cardiovascular disease in China, the Diet, ExerCIse and CarDiovascular hEalth (DECIDE) project was initiated in 2016. As one of five independent DECIDE studies, the DECIDE-Children study aims to develop a school-based, multi-faceted childhood obesity prevention programme targeting school children aged 8-10 years in three different regions of China and rigorously test its effectiveness in preventing excessive weight gain in Chinese primary school settings. The research objectives of the

DECIDE-Children study were (1) to assess the effectiveness of the intervention compared with the usual practice in preventing childhood overweight and obesity; (2) to determine the sustainability of the intervention in preventing overweight and obesity; and (3) to evaluate the process and health economics of the intervention.

Methods and analysis

This protocol has been prepared in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement [16, 17].

Study design

DECIDE-Children is a cluster-randomized, parallel-group controlled trial. To accommodate the social and economic variations within the country, we will intentionally select schools from three different regions of China: the above average developed area in the east (Beijing), the average developed area in central China (Shanxi) and the below average developed area in the west (Xinjiang). A total of 24 primary schools (clusters) equally distributed among three regions will be selected. In Beijing, 4 schools will be selected from the Dongcheng district (located in the centre of the city), and 4 will be selected from the Mentougou district (located in a rural suburban area). In Xinjiang, all 8 schools will be selected from Urumchi, the capital city of the autonomous region; four of the schools will be selected from the Shayiba district (an urban district), and the other four schools will be selected from the Shuimogou district (a rural district). In Shanxi, all 8 schools will be selected from only one urban district, Changzhi, a small- to medium-sized city in the province. The reason for excluding rural schools in Changzhi is that most of the rural schools are boarding schools, and parents

are difficult to reach in boarding schools. Thus, a total of 24 primary schools from five sites in three regions will be selected and randomized into two groups, the obesity prevention intervention group and the usual practice group. The intervention will be implemented for one school year from late September 2018 to June 2019, and the study will continue with a one-year follow-up investigation in June 2020. Figure 1 shows the flow of the study.

Recruitment

Recruitment of the schools

The present study will be carried out in Grade 4 students (8 to 10 years old), as they are sufficiently mature to understand health education information and are able to remain in the same school to complete the two-year study before they graduate. For a school to be eligible, the school principal must agree with the randomization procedure and comply with the study protocol. The total number of Grade 4 students must be greater than 50 in the school, and schools that have implemented or are planning to implement an obesity prevention intervention or similar intervention programme will not be eligible. Boarding schools and specialty schools for children with talents or minority ethnic groups will be excluded. Schools will also not be included if they have a definite plan for relocation or cancellation in the next two years. For the schools participating in the programme, the size of a class will vary between fewer than 30 children and approximately 60 children per class. If the number of students in each class is less than 50, we will recruit two classes from the school, and if the number of students is greater than 50, we will recruit one class to meet the sample size requirement. If there are more

classes in one school than needed for the study, the school principal will recommend which classes we should select.

Three steps will be followed for the recruitment of the schools. First, project staff will contact the local education authorities to gain their opinion, support, and approval of the study and basic information of the schools (type of schools and the number of students and teachers). Second, project staff will contact the schools by phone or visit the schools to determine the eligibility of the selected schools for the study. Third, the final list of eligible schools and classes will be made by the principal investigator and schools will be invited to participate in the study by local research partners.

Recruitment of the students

After recruiting the schools and before conducting the baseline measurements, written informed consent will be provided by all students and their primary caregivers (parents in most cases) in the selected classes. Then, the parents who provide informed consent will be required to complete a self-administrative questionnaire about the health status of their children. The project staff will collect the questionnaires and if a parent reports one of the following conditions, his or her children will be excluded: 1) medical history of heart disease, hypertension, diabetes, tuberculosis, asthma, hepatitis or nephritis; 2) obesity caused by endocrine diseases or side effects of drugs; 3) abnormal physical development like dwarfism or gigantism; 4) physical deformity such as severe scoliosis, pectus carinatum, limp, obvious O-leg or X-leg; 5) inability to participate in school sport activities; 6) a loss in weight by vomiting or taking drugs during the past three months.

Randomization procedures

The random sequence of allocation of the schools (clusters) to the intervention or control group will be stratified by the study sites. Schools in the same study site will be randomly allocated in a 1:1 ratio to either the intervention or control group using a computer-generated random number system (the simple random sampling method). Randomization will be performed by an independent person at the central coordinating centre at Peking University Clinical Research Institute. The randomization will take place only after the baseline measurements are completed to ensure allocation concealment.

Intervention

We used the Social Ecological Model to identify intervention elements in this multi-faceted health promotion programme [18]. As shown in Figure 2, the programme will target the influencing factors of childhood obesity at both individual (student-focused activities) and environmental levels (a supportive family and school environment), with the intent to influence the knowledge, attitude and behaviours of school children.

Description of the intervention components

The intervention components are described in Tables 1 and 2.

Student-focused activities: These activities will include health education activities for students, the reinforcement of students' physical activity at school and the regular monitoring of students' weight and height.

Activities towards parents: These activities will include health education activities for parents and the supervision and encouragement of children to increase their physical

activity level outside of school.

Activities towards schools: These activities will include school policies related to obesity prevention and health education activities for teachers.

The smartphone app: Project staff, school teachers and parents will be suggested to install the app titled "Eat Wisely, Move Happily". The app, which was developed based on behaviour change techniques [19], will aid in information diffusion, behaviour monitoring, weight management, assessment and feedback.

Quality control of the intervention

Two manuals ("An Operation Manual for Project Staff Involved in the Multi-component Obesity Intervention among Primary School Students" and "An Operation Manual for School Team Members Involved in the Multi-component Obesity Intervention among Primary School Students") have been developed for implementing and managing this complex intervention. The manuals describe in detail the duties of project staff and school team members (school principals, class teachers, physical education teachers, school doctors/health care teachers) in delivering the intervention. The manuals also describe the detailed workflow of the implementation of each intervention component, i.e., by whom, when, how and to what extent the specific intervention element should be delivered. All of the project staff and school team members will be required to conduct the intervention in accordance with the operation manuals.

During implementation of the intervention, regular field observations will be made and the smartphone app records will be checked. If it is found that schools are not complying

with the study protocol, project staff will communicate with school team members in a timely manner and conduct follow-ups to improve the fidelity of the study results.

Control group

The twelve schools in the control group will not carry out any of the DECIDE-Children intervention components and will continue their usual practice according to their own teaching curriculum during the study period (from September 2018 to June 2020). Participants in the control group will receive the same health education materials that will have been delivered to those in the intervention group immediately after the 21-month follow-up investigation is completed in June 2020.

Outcome evaluation

Table 3 describes the study outcomes, including when and how the study outcomes will be evaluated. Baseline measurements will be conducted in September 2018 for both the intervention and the control groups. Follow-up measurements will be conducted 4 months after the baseline measurements are conducted in January (after one school semester and half way through the intervention), 9 months after the baseline measurements are conducted in June 2019 (after one school year and immediately after the whole intervention programme is completed) and 21 months after the baseline measurements are conducted in June 2020 (after two school years and 12 months after the intervention is completed).

At the baseline and all follow-up visits, anthropometric measures (height, weight, waist and hip circumference, systolic and diastolic blood pressures, body fat percentage) and physical fitness measures (one-minute rope jumping, one-minute sit-up, long standing

jump, shuttle run (50 m×8)) will be collected by the trained outcome assessors using the same device and/or forms according to the standard methods and procedures. The assessors measuring students' height and weight will be blinded to the group allocation of the schools. We will use questionnaires to measure students' behaviours (duration of moderate-to-vigorous physical activity, eating behaviour, sedentary behaviour), school policies for prevention and management of childhood obesity, and other potential moderators/mediators of the intervention (e.g., stage of readiness for behaviour change related to weight reduction). The questionnaires were developed based on previous studies and the pilot study. The questionnaires were found to be feasible for this study and acceptable to students and their parents [20-22].

Outcomes

The primary outcome is the difference between groups in the change in students' body mass index (BMI=weight (kg)/(height (m))^2) immediately after the intervention completion (9 months after the baseline measurements are conducted). The secondary outcomes include the change in BMI one year after the intervention is completed (21 months after the baseline measurements are conducted). In addition, we will compare the following indices between groups at the follow-up visits: 1) change in students' BMI z-score (standard deviation score will be calculated based on the World Health Organization criteria [23]); 2) change in prevalence and incidence of childhood overweight/obesity defined according to the criteria for Chinese children and adolescents [24]; 3) change in students' waist circumference, waist-to-hip circumference ratio and systolic and diastolic blood pressures; and 4) change in students'

body fat percentage, physical fitness measures, behavioural outcomes and other outcomes.

Sample size estimation

We assumed that the difference between the two groups in the change in BMI (effect size) would be 0.50 kg/m^2, the standard deviation (SD) of the BMI would be 1.40 kg/m^2, the intra-cluster correlation coefficient would be 0.05 and the rate of attrition would be 10% for the sample size calculation in our study. We aimed to recruit a total of 1,200 students from 24 schools with an average cluster size of 50 students per school. This sample size will provide 88% power with a=0.05 to detect a mean difference of 0.50 kg/m^2 in the change in BMI between groups after the intervention lasting one school year.

Statistical analyses

Statistical analyses will be performed using SAS version 9.4 (SAS Institute Inc., Cary, NC, USA). All statistical tests will be two-sided at the 5% level of significance. Baseline characteristics at both the school and individual levels will be reported by using descriptive statistics.

The primary analysis will be based on the intention-to-treat principle and include all students recruited with the baseline BMIs measured. Generalized linear mixed models will be used to compare the primary and secondary outcomes at 4, 9, and 21 months after the baseline measurements are conducted, and the models will adjust for the clustering effect and baseline outcome values. The missing data will be treated in the maximum likelihood estimates assuming they are missing at random. The intra-cluster

correlation coefficient will also be estimated. Sensitivity analysis will be performed on the primary outcome using the last-value-carry-forward imputation if the percentage of missing data exceeds 5%. For continuous outcomes, we will report pre-, and post-intervention means for the intervention and control groups and model-adjusted mean differences between groups. For binary outcomes, we will report pre- and post-intervention percentages for the intervention and control groups and adjusted odds ratios (ORs) between groups. The 95% confidence intervals (CIs) and associated *P*-values will be calculated. We will also examine whether the differences in the outcomes between the control and intervention groups vary by the three regions (Beijing, Shanxi, Xinjiang), the sex of children, socioeconomic status (mother's education), BMI status at baseline and primary caregivers of the children (parents compared with non-parents).

Process evaluation

Based on the steps and principles described in the conceptual framework by Saunders et al.[25], we will identify the process evaluation elements including fidelity (the extent to which the intervention will be implemented as initially planned), dose delivered (the frequency and intensity of the actual implementation of the programme), dose received (the extent to which students/primary caregivers (parents in most cases)/teachers will be exposed to the intervention, as well as the degree of their satisfaction with the intervention and materials), reach (the proportions and the characteristics of students/primary caregivers/teachers completing or dropping out of the intervention) and context (family environment and school policies related to obesity prevention and management).

The intervention process data collection procedure will include (1) direct regular field observation and records which will be collected for the quality control of the intervention (e.g., quality and quantity of the intervention sessions and number of students attending the lectures) and will be recorded by the trained project staff; (2) the user logs (e.g., frequency and duration) which will be collected by the smartphone app; (3) school policies related to obesity prevention and management, which will be collected by the questionnaires (Table 3) in both the intervention and the control groups; and (4) interviews with participants (6~8 students per school) which will be conducted in both the intervention and the control groups.

Health economics evaluation

A cost-effectiveness analysis will be employed in the health economics evaluation, and a societal perspective will be used to examine whether the intervention is economically feasible. Intervention costs will include hours spent by project staff, school staff, and students' primary caregivers (parents in most cases) for all the intervention activities and material expenses. Only the time spent by the project staff in implementing the intervention will be included. Time costs will be based on personal employment compensations if available or average compensations in the local areas for similar types of employees. Material expenses will be based on the actual purchasing prices. An incremental cost-effectiveness ratio will be calculated and a sensitivity analysis will be used to vary key parameters to examine the robustness of the health economics results.

Patient and Public involvement

We will conduct focus group discussions and interviews with key stakeholders

(children, parents, teachers, school principals, local health, and education officials) by refining the intervention approach. We will not involve any of the stakeholders in other aspects of the research study, including idea development, design of the study, implementation of the protocol, data collection, and analysis and interpretation of the results. The results of the study will be disseminated through publication in peer-reviewed journals, presentations at conferences and in lay summaries provided to school staff, students and parents. The benefits and burden of the intervention will be assessed by children and their primary caregivers through self-reported questionnaires at the end of the intervention.

Trial status

The trial started and the recruitment of schools and children was completed in September 2018. Baseline measurements were conducted in the last few weeks in September 2018. The intervention lasting one school year started at the end of September 2018 and was completed in June 2019. The 4-month follow-up measurements started and were completed in January 2019. The 9-month follow-up measurements started and were completed in June 2019. The 21-month follow-up measurements will start and will be completed in June 2020.

Ethics and dissemination

This study was reviewed and approved by the Peking University Institution Review Board (IRB00001052-18021). Any amendments to the study protocol will be submitted for IRB approval prior to implementation. Written informed consent will be obtained from all students and their parents. All data collected will be entered into an electronic

database with de-identified information. The database will be accessed only by designated staff with a password. The results will be disseminated through publication in peer-reviewed journals, presentation at conferences and in lay summaries provided to school staff and participants. Upon completion of the trial and after the publication of these results, the data will be made available upon request by contacting the corresponding author of this protocol.

Discussion

Non-communicable diseases, especially cardiovascular diseases, have contributed to the public health burden worldwide. Preventing childhood obesity in early life may have the greatest long-term effects in curbing this widespread burden. Although several childhood obesity intervention studies have been conducted in China, research gaps exist in terms of methodological flaws, process measures, and sustainability of the intervention. The DECIDE-Children study is based on theory-driven and systematic developments (e.g., systematic review [8], qualitative interviews, panel discussions and a pilot study [15]) and serves as one of the first examples of a rigorously developed and evaluated childhood obesity prevention programme that will be implemented in eastern, central and western regions of China.

Our DECIDE-Children study can overcome poor adherence to the intervention components, which is a weakness of most previous studies, due to our favourable collaborations with local education authorities as well as the rigorous quality control of implementing the intervention. This study also has several other distinguishing features: 1) randomization by an independent person not involved in the study, blinding of key

outcome measures, and a detailed process evaluation plan will help to provide study results of high quality; 2) a follow-up investigation will be conducted one year after the intervention is completed to determine the sustainability of the effects of the intervention; 3) a smartphone app will be employed to assist in providing information on, monitoring and providing feedback on the behaviours and body weight of the children; 4) three centres located in eastern, central and western regions of China will be involved in the study to reflect the different levels of economic development in China; and 5) most of the intervention components (school polices, regular monitoring of students' weight and height, reinforcement of students' physical activity at school, health education activities for students) will be integrated into the regular academic schedule of each intervention school.

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Authors' contributions

HJW and YFW conceived the project. HJW, ZL, YFW, WYN and HJL were involved in design of the study and development of intervention materials. ZL wrote the first draft of the manuscript. XXF, YL, AYG and FZ contributed to implementation of the program. HF contributed to economic evaluation. PG contributed to statistical analysis plan. All authors approved the final manuscript.

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Competing interests statement

None.

Table 1 Description of the intervention components implemented in the DECIDE-Children study

Intervention components	Descriptions of the content, frequency, and duration	Person responsible
1. Student-focused activities		
Health education activities for students	(1) Frequency and duration A total of ten activities (each lasting 40 minutes) will be provided once every two to three weeks (six activities will be arranged in the first semester, and four will be arranged in the second semester). (2) Different kinds of activities The ten activities will include seven health education lectures and three theme class meetings. The focus of the health education lectures will be on information diffusion, while the focus of theme class meetings will be on consolidation of the key messages learned in health education lectures through interactive and interesting group work (e.g., "Let me guess"). (3) Content 1) Information diffusion Key messages will include the benefits of healthy weight, measurements and assessments of weight, and methods of achieving a healthy weight (not eating excessively; not drinking sugar-sweetened beverage; eating less high-energy food; less sedentary behaviours; performing more physical activity). Health education books and "nutrition evaluation turnplate for Chinese primary and middle school students" will be delivered to students. Health education messages will also be spread through posters on campus or in the classroom.	The trained class teachers

	2) Promotion for translating knowledge into action "Small hand in big hand" homework (e.g., "challenge of three days away from screen") will be arranged at the end of each health education activity. 3) Feedback and encouragement for BMI and behaviour change Feedback of regular monitoring results of students' BMIs and behaviours will be provided in each health education activity. The students with good performance will be encouraged.	
Reinforcement of students' physical activity within school	1) Students will be instructed by physical education teachers to perform physical activities with moderate-to-vigorous intensity at school for at least one hour per school day (including physical education classes, class-break exercise, extracurricular activities). The aim of this component will be to improve the adherence to the Chinese national requirement for 'One-Hour Physical Activity On Campus Every School Day'. If a school has met this requirement, no extra physical activities will be added at the school; otherwise, extra physical activities (i.e. physical education classes, exercises during breaks in class or extracurricular activities) will be added to the school schedule. The monitoring of the implementation of these extra physical activities will be continuous within the intervention period for the intervention group; 2) Physical education teachers will be advised to teach students at least one sports game during each extracurricular activity.	The trained physical education teachers
Regular monitoring of students' weight and height	1) Monthly monitoring Students' weight and height will be monitored monthly, and the data will then be input into the computer management system in a timely manner and shown in the smartphone app (described below); 2) Weekly monitoring	The trained school doctors/health care teachers with the assistance of the trained project staff (for monthly monitoring); The trained project staff (for data input

	Students' weight will be monitored weekly by the students themselves in the classroom.	of monthly monitoring) Students (for weekly monitoring)
2. Activities towards parents (providing a supportive family environment)		
Health education activities for parents	1) Frequency and duration At least one activity (lasting for approximately 40-60 minutes) will be held at the beginning of each semester. One more activity will be held in the middle of the first semester. Another activity will also be held in the middle of the second semester if necessary (for example, if the fidelity of the data is unsatisfactory). 2) Contents ➢ For the first activity Key messages will be similar to those for the health education activities for students (described above). Parents will also be taught to use the smartphone app. ➢ For other activities Project staff will provide feedback about students' weight status and behaviours to parents. Face-to-face group discussions will be established between the project staff and parents.	The trained project staff
Reinforcement of students' physical activity outside school	1) Parents will be instructed to supervise and encourage students to perform physical activities outside of school for 30 minutes per weekday and 1 hour per weekend day; 2) Recommendations for physical activity outside of school will be provided through the smartphone app once every two months; 3) Students will be encouraged to participate in sports games outside of school that will be taught by their physical education teachers during extracurricular activities.	Students' parents
3. Activities towards schools (providing a supportive school environment)		

School policies related to obesity prevention	The following school policies will be suggested: 1) "Not selling": Not selling unhealthy snacks[1] or sugar-sweetened beverages within school; 2) "Not eating": Telling students not to eat unhealthy snacks or drink sugar-sweetened beverages at school; 3) "Not buying": Students being educated by class teachers not to buy unhealthy snacks or sugar-sweetened beverages around school.	The trained school principal; The trained class teachers
Health education activities for school teachers	<u>1) Frequency and duration</u> The activity will be held once (lasting for approximately 40 minutes) in the first month of the intervention. School teachers participating in this programme at each school (school principal, class teachers, school doctors/health care teachers and physical education teachers) will be required to attend the activity. <u>2) Content</u> Key messages will be similar to those for the health education activities for students (described above). School teachers will also be taught to use the smartphone app.	The trained project staff
4. A smartphone app assisted in implementation of the intervention		
The smartphone app ("Eat Wisely, Move	<u>1) Information diffusion (the behaviour change technique (BCT) used: providing information on consequences of behaviours)</u>	The smartphone app (installed by parents, school teachers and project

[1] "Healthy snacks" refer to dairy products, fresh vegetables or fruits and natural unprocessed nuts which are eaten at times other than at main meals. "Unhealthy snacks" refer to snacks other than the three kinds of healthy snacks.

Happily")	The smartphone app will provide information to parents, class teachers and project staff in accordance with the health education activities. 2) Behaviour monitoring (the BCT used: prompting the self-monitoring of behaviours) Parents together with their children will be asked to record the diet and physical activity behaviours of students in the app weekly, and then they will receive individualized feedback related to these behaviours (described in Table 2). 3) Weight management (the BCT used: prompting self-monitoring) According to the monthly monitoring of students' weight and height (described above), parents, school teachers and project staff will view the recent weight status (categorized according to the BMI percentile criteria [24]), changes compared with previous records of the students and the individualized feedback related to weight management (described in Table 2). 4) Assessment and feedback (the BCT used: providing feedback on performance) The smartphone app will also provide a synthetic and individualized assessment that will combine changes in the behaviours and weight status of the students. The four kinds of feedback are shown in Table 2.	staff) and the computer management system (utilized by project staff)

Table 2 The four kinds of regular evaluation feedback messages provided to all stakeholders by the smartphone mobile app on the basis of data from the regular monitoring of children's weight, height and behaviours

		Results automatically judged according to the heights and weights measured at the regular monitoring intervals	
		Positive results (BMI decreases in students who are overweight or obese, or BMI increases in students who are underweight)	Negative results (BMI increases in students who are overweight or obese, or BMI decreases in students who are underweight)
Results automatically judged according to the diet and physical activity behaviours recorded regularly	Full marks/ getting better	**Feedback 1**: "Your child is doing a great job. The weight changes are consistent with the changes in the diet and physical activity behaviours. Keep it up!"	**Feedback 2**: "Your child's weight has not improved, but the diet and physical activity behaviours are good. It might be that weight improvement requires long-term adherence to a reasonable diet and physical activity behaviour, or that the behaviour records are inaccurate. Please continue to improve!"
	Unchanged/ getting worse	**Feedback 3**: "Your child has improved or maintained a healthy body weight, but there is still room for improvement in the diet and physical activity behaviours. Keep working!"	**Feedback 4**: "Your child's weight has not improved, and the diet and physical activity behaviours also need improvement. Please continue to work hard!"

Table 3 Outcome measurements for the DECIDE-Children study

Outcomes	Time				Device (Manufacturer, model)	Method
	Baseline	4 months after baseline	9 months after baseline	21 months after baseline		
Anthropometric measures						
Height	√	√	√	√	Stadiometer (Huateng GMCS-1)	Measured to the nearest 0.1 cm at least twice
Weight	√	√	√	√	Lever scale (Wujin RGT-140)	Measured to the nearest 0.1 kg at least twice
Waist circumference	√	√	√	√	Tape (MyoTape)	Measured to the nearest 0.1 cm at least twice
Hip circumference	√	√	√	√	Tape (MyoTape)	Measured to the nearest 0.1 cm at least twice
Systolic and diastolic blood pressures	√	√	√	√	Electronic sphygmomanometer (Omron HBP-1300)	Measured to the nearest 1 mmHg at least twice
Body fat percentage	√		√		Body component instrument (Tanita MC-780 MA)	According to the standard procedure
Physical fitness measures						
One-minute rope jumping	√		√		Physical fitness measures will be assessed by trained outcome assessors according to the standard procedure.	

One-minute sit-up	√	√	
Long standing jump	√	√	
Shuttle run (50 m×8)	√	√	
Behavioural measures and other measures			
Students' knowledge related to energy balance	√	√	We will use 8 items to assess the change in students' knowledge related to energy balance. For example, we will ask students, "Is it correct that drinking sugar-sweetened beverage cannot substitute drinking water ?" Three choices will be provided (right; wrong; not clear). Students should finish the questionnaires in the classroom in the presence of the trained outcome assessors, who can provide guidance and help.
Students' duration of moderate-to-vigorous physical activity	√	√	The questions were designed based on a validated 7-day physical activity questionnaire (PAQ; kappa values for test-retest results were 0.46~0.79 (different measures of activity), face validity and content validity were good based on experts' evaluations, and the correlations between the PAQ and Caltrac motion sensor data ranged from 0.38 to 0.46 (different measures of activity) for boys) [21]. Students should finish the questionnaires in the classroom in the presence of the trained outcome assessors, who can provide guidance and help.
Students' eating behaviour	√	√	We will use the "Children Eating Behaviour Questionnaire" (CEBQ) to assess students' eating behaviours, including their responsiveness to food and enjoyment of food. This 35-item instrument has been shown to have relatively

			good reliability [22]. The questionnaires should be self-reported by parents or other primary caregivers of the students.
Students' sedentary behaviour	√	√	We will use a self-designed questionnaire to determine the average duration of completing homework, watching television and playing electronic devices per day during the last week. Students should finish the questionnaires in the classroom in the presence of the trained outcome assessors, who can provide guidance and help.
School policies for the prevention and management of childhood obesity	√	√	The questionnaires should be filled by the trained investigators after face-to-face interviews with school principals, doctors/health care teachers and physical education teachers.
Stage of readiness for behaviour change related to weight reduction	√	√	We will use two items for the assessment. First, we will ask "Have you taken action to reduce your weight during the last three months?" Yes/no choices will be provided. In addition, we will ask "Do you currently intend to reduce your weight?" Five choices ranging from "completely do not intend" to "intend to very much" will be provided. Students should finish the questionnaires in the classroom in the presence of the trained outcome assessors, who can provide guidance and help.

Figure 1 Flow of the DECIDE-Children study

Figure 2 The Social Ecological Model as applied to the DECIDE-Children study

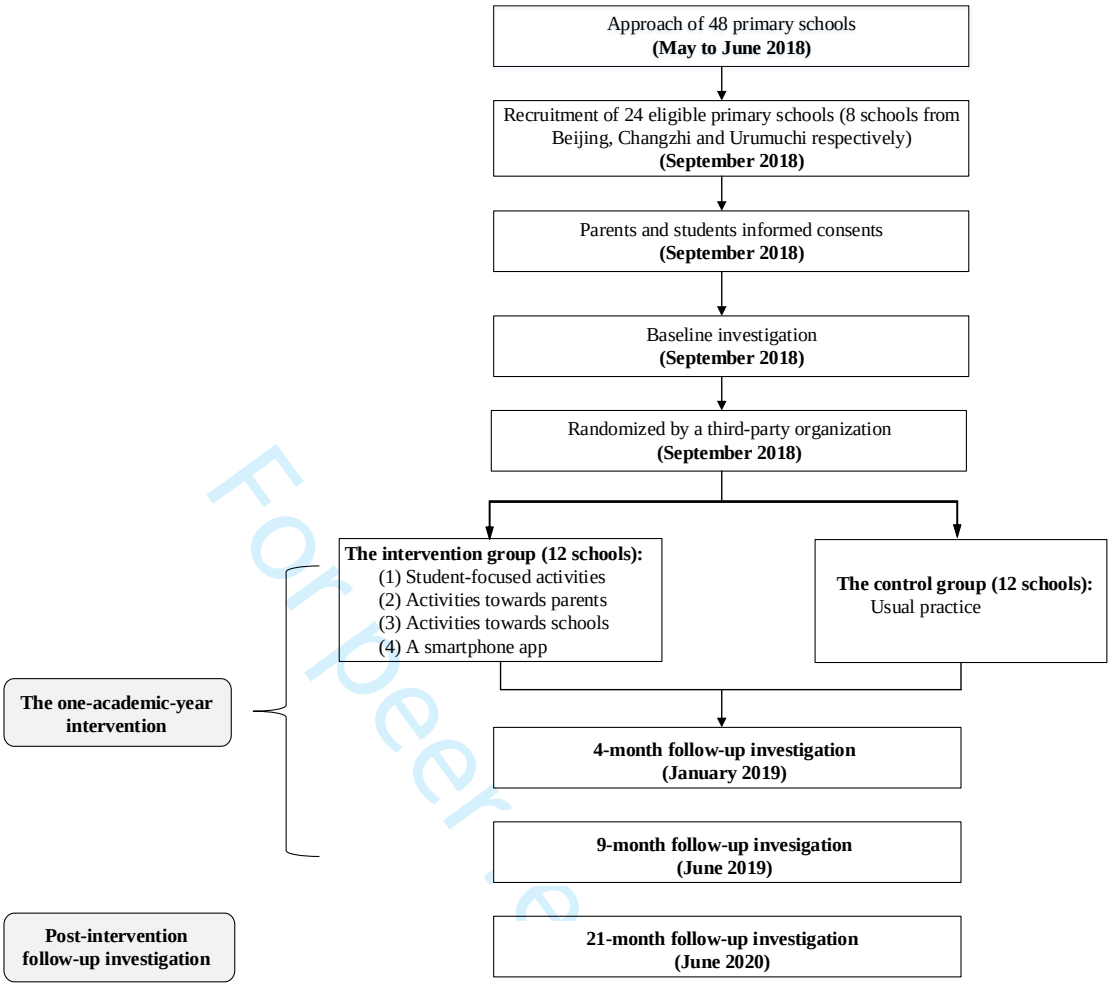

Figure 1 Flow of the DECIDE-Children study

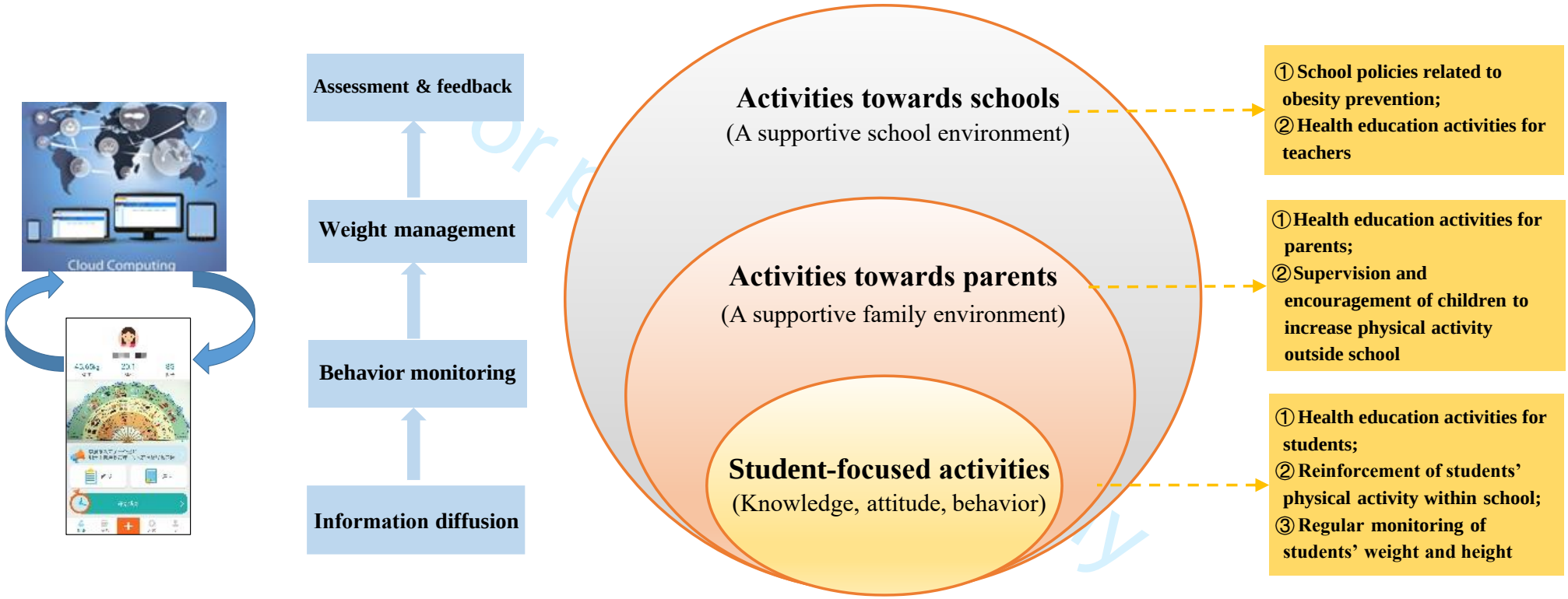

Figure 2 The Social Ecological Model as applied to the DECIDE-Children study

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 SPIRIT reporting guidelines, and cite them as:

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		Reporting Item	Page Number
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	3

Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	This information is provided in the trial registration website.
Protocol version	#3	Date and version identifier	This information will be provided as soon as the manuscript revision is finally completed.
Funding	#4	Sources and types of financial, material, and other support	25
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	24-25
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	n/a. This study was not sponsored by any individuals or companies. The funder name and number has been provided in Page 25.
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	26

		report for publication, including whether they will have ultimate authority over any of these activities	
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)	25
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	5-7
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	6
Objectives	#7	Specific objectives or hypotheses	7
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)	8

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	8
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)	9-10
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	11, Table 1-2
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)	n/a. This is a childhood obesity prevention intervention. Based on our previous experiences, it is less likely that discontinuing or modifying allocated interventions for a given trial participant will take place.

Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	11-12
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a. This is a childhood obesity prevention intervention. Based on our previous experiences, it is less likely that concomitant care and interventions will take place.
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	13-14, Table 3
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and	Figure 1

		washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	
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	14
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	9-10
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	10
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing	10

		any steps to conceal the sequence until interventions are assigned	
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	9-10
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	13
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	n/a. The assessors measuring students' height and weight will be blinded to group allocation of the schools. We did not anticipate any necessary circumstances when unblinding is permissible.
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	13

		collection forms can be found, if not in the protocol	
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	15
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	3
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	15
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	15

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)	15
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	18
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	n/a. This is a childhood obesity prevention intervention. Based on our previous experiences, it is less likely that discontinuing interventions will take place.
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events	16 (we will use questionnaires to collect and

		and other unintended effects of trial interventions or trial conduct	assess any adverse events or other process data)
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	7 (This study is one of the five independent studies of the overall DECIDE project. This overall project is audited by the funder (National Key R&D Program of China).
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	2-3
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)	2-3
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	10
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data	n/a. This study will not collect biological specimens.

		and biological specimens in ancillary studies, if applicable	
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	3
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	26
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	3
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. This is a childhood obesity prevention intervention. Based on our experiences, it is less likely that ancillary and post-trial care will take place.
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public,	3

		and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	n/a
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n/a
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	10
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 This study will not collect biological specimens.

BMJ Open

A school-based, multi-faceted health promotion programme to prevent obesity among children: protocol of a cluster-randomized controlled trial (the DECIDE-Children study)

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Primary Subject Heading:	Epidemiology
Secondary Subject Heading:	Paediatrics, Public health
Keywords:	pediatric obesity, cluster, prevention, randomized controlled trial

A school-based, multi-faceted health promotion programme to prevent obesity among children: protocol of a cluster-randomized controlled trial (the DECIDE-Children study)

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Abstract

Introduction Obesity is a public health concern that is becoming increasingly more serious worldwide. Effective and sustainable childhood obesity prevention strategies may help to reduce the prevalence of obesity and may have an impact on lifelong health. However, few such strategies have been rigorously evaluated for Chinese children in different regions of China.

Methods and analysis DECIDE-Children is a cluster-randomized controlled trial that aims to assess the effectiveness and sustainability of a school-based, multi-faceted intervention to prevent obesity among Grade 4 primary school students (8 to 10 years old) in China. Twenty-four schools (approximately 1200 students) from above average, average and below average developed regions in China will be randomized to an intervention (12 schools) or usual practice (12 schools) group. The intervention will last for one school year (9 months) and consist of activities towards students, parents and school environment. A smartphone application will be used to assist in providing information on, monitoring and providing feedback on the behaviours and body weight of the students. Data will be collected at baseline, 4 months, 9 months and 21 months. The primary outcome will be the difference between groups in the change in students' body mass index (BMI) at 9 months after the baseline investigation. The secondary outcomes will include the differences between groups in the changes in anthropometric measures, diet, physical activity levels and other measures at the follow-up visits. A variety of process evaluation methods will be used to evaluate the implementation process of the complex intervention.

Ethics and dissemination This study was approved by the Peking University Institution Review Board (IRB00001052-18021). The results will be disseminated through publication in peer-reviewed journals, presentations at conferences and in lay summaries provided to school staff and participants.

Trial registration ClinicalTrials.gov: NCT03665857.

Strengths and limitations of this study

1. This study will rigorously evaluate the effectiveness of a childhood obesity prevention programme in eastern, central and western regions with different levels of economic development in China.
2. We will employ a smartphone application to assist in providing information on, monitoring and providing feedback on the behaviours and body weight of the students.
3. We will include an explicit process evaluation plan for both the intervention and the control groups, which will evaluate the implementation process of the complex intervention.
4. A follow-up investigation will be conducted to evaluate the sustainability of the intervention.
5. This intervention is limited by a relatively short duration, but additional funding will be sought for the implementation of a long-term intervention in the future.

Introduction

Childhood obesity is a significant public health concern worldwide [1, 2]. In China, childhood obesity has dramatically increased as the economy has grown quickly over the past decades. The prevalence of obesity among 7- to 18-year-old Chinese children increased from 0.1% in 1985 to 7.3% in 2014 [2]. Childhood obesity is associated with not only adverse consequences on the physical and mental health of children in the short term [3, 4], but also increases the risk of developing cardiovascular diseases in the long term [5, 6]. Accordingly, effective strategies to curb and reduce childhood obesity prevalence may help to prevent cardiovascular diseases in the whole population in the long term.

The development of childhood obesity is complex and may involve multi-factorial mechanisms, but in most cases, it essentially results from an imbalance between energy intake and energy expenditure. Children spend half of their waking hours at school and consume at least one-third of their daily calories at school; thus, school-based interventions are promising in preventing childhood obesity [7]. In particular, multi-faceted interventions combining diet, physical activity and a family component have shown the highest effectiveness [7, 8]. However, there is a paucity of rigorously developed and evaluated prevention interventions for Chinese children [8, 9]. Moreover, not all school-based interventions have been effective in preventing excessive weight gain in children [10, 11]. One potential interpretation of this finding is that adherence to the intervention components was not guaranteed [11]. It is thus crucial to increase our understanding of how and why these interventions work or do not work [12]. To

achieve this, a thorough process evaluation of the intervention implementation is necessary. Furthermore, socioeconomic development is associated with patterns of childhood obesity [13] and may also affect the effectiveness of a childhood obesity intervention. Social disparities in the patterns of obesity differ between China and Western countries. In China, socioeconomic development has been positively associated with overweight and obesity prevalence in children [13]. However, previous studies have been largely conducted in a single region, which limits the generalizability of study findings to other populations. Another weakness is that most studies examined outcomes only at the end of the intervention. Thus, it remains unclear whether healthy behaviours and a healthy weight are maintained beyond the period of the intervention.

School system in China

In primary schools in China, there are six grades in total, and the age of the students ranges from 6 to 11 years. The typical size of a Chinese class is fewer than 45 students, but varies in different schools, ranging from 30 to 60 students. There are two school policies that have been issued by the Chinese government that are particularly relevant to the prevention and management of childhood obesity. First, schools should have school doctors or health care teachers who provide in-house school health care. The routine practices include student health surveillance, health education for students, and the prevention and control of common diseases in students. Second, schools should implement 'One-Hour Physical Activity On Campus Every School Day'. That is, the total duration of physical activity (i.e., physical education classes, exercises during breaks from class and extracurricular activities) per school day should be no less than

one hour. However, the implementation of these policies in the school systems in China varies by region [14].

Development of a childhood obesity intervention

To fill in research gaps, in accordance with the school systems in China, we underwent four stages to develop the intervention: (1) we systematically reviewed previous literature to identify intervention elements related to intervention effectiveness; (2) we conducted focus group discussions and interviews with key informants (children, parents, teachers, school principals, local health and education officials) to further revise and refine the intervention approaches; (3) we conducted a three-month, before-after, pilot study at two primary schools in Beijing (one in an urban area and the other in a rural area) involving 58 Grade 4 students (mean age: 9.38±0.49 years) to test the feasibility of the proposed intervention [15]; and (4) we further discussed the proposed intervention with multiple experts. Based on all the work mentioned, we finally developed the intervention elements used for this study.

Aim and objectives

To develop effective lifestyle interventions for the prevention and control of cardiovascular disease in China, the Diet, ExerCIse and CarDiovascular hEalth (DECIDE) project was initiated in 2016. As one of five independent DECIDE studies, the DECIDE-Children study aims to develop a school-based, multi-faceted childhood obesity prevention programme targeting school children aged 8-10 years in three different regions of China and rigorously test its effectiveness in preventing excessive weight gain in Chinese primary school settings. The research objectives of the

DECIDE-Children study were (1) to assess the effectiveness of the intervention compared with the usual practice in preventing childhood overweight and obesity; (2) to determine the sustainability of the intervention in preventing overweight and obesity; and (3) to evaluate the process and health economics of the intervention.

Methods and analysis

This protocol has been prepared in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement [16, 17].

Study design

DECIDE-Children is a cluster-randomized, parallel-group controlled trial. To accommodate the social and economic variations within the country, we will intentionally select schools from three different regions of China: the above average developed area in the east (Beijing), the average developed area in central China (Shanxi) and the below average developed area in the west (Xinjiang). A total of 24 primary schools (clusters) equally distributed among three regions will be selected. In Beijing, 4 schools will be selected from the Dongcheng district (located in the centre of the city), and 4 will be selected from the Mentougou district (located in a rural suburban area). In Xinjiang, all 8 schools will be selected from Urumchi, the capital city of the autonomous region; four of the schools will be selected from the Shayiba district (an urban district), and the other four schools will be selected from the Shuimogou district (a rural district). In Shanxi, all 8 schools will be selected from only one urban district, Changzhi, a small- to medium-sized city in the province. The reason for excluding rural schools in Changzhi is that most of the rural schools are boarding schools, and parents

are difficult to reach in boarding schools. Thus, a total of 24 primary schools from five sites in three regions will be selected and randomized into two groups, the obesity prevention intervention group and the usual practice group. The intervention will be implemented for one school year from late September 2018 to June 2019, and the study will continue with a one-year follow-up investigation in June 2020. Figure 1 shows the flow of the study.

Recruitment

Recruitment of the schools

The present study will be carried out in Grade 4 students (8 to 10 years old), as they are sufficiently mature to understand health education information and are able to remain in the same school to complete the two-year study before they graduate. For a school to be eligible, the school principal must agree with the randomization procedure and comply with the study protocol. The total number of Grade 4 students must be greater than 50 in the school, and schools that have implemented or are planning to implement an obesity prevention intervention or similar intervention programme will not be eligible. Boarding schools and specialty schools for children with talents or minority ethnic groups will be excluded. Schools will also not be included if they have a definite plan for relocation or cancellation in the next two years. For the schools participating in the programme, the size of a class will vary between fewer than 30 children and approximately 60 children per class. If the number of students in each class is less than 50, we will recruit two classes from the school, and if the number of students is greater than 50, we will recruit one class to meet the sample size requirement. If there are more

classes in one school than needed for the study, the school principal will recommend which classes we should select.

Three steps will be followed for the recruitment of the schools. First, project staff will contact the local education authorities to gain their opinion, support, and approval of the study and basic information of the schools (type of schools and the number of students and teachers). Second, project staff will contact the schools by phone or visit the schools to determine the eligibility of the selected schools for the study. Third, the final list of eligible schools and classes will be made by the principal investigator and schools will be invited to participate in the study by local research partners.

Recruitment of the students

After recruiting the schools and before conducting the baseline measurements, written informed consent will be provided by all students and their primary caregivers (parents in most cases) in the selected classes. Then, the parents who provide informed consent will be required to complete a questionnaire about the health status of their children. The project staff will collect the questionnaires and if a parent reports one of the following conditions, his or her children will be excluded: 1) medical history of heart disease, hypertension, diabetes, tuberculosis, asthma, hepatitis or nephritis; 2) obesity caused by endocrine diseases or side effects of drugs; 3) abnormal physical development like dwarfism or gigantism; 4) physical deformity such as severe scoliosis, pectus carinatum, limp, obvious O-leg or X-leg; 5) inability to participate in school sport activities; 6) a loss in weight by vomiting or taking drugs during the past three months.

Randomization procedures

The random sequence of allocation of the schools (clusters) to the intervention or control group will be stratified by the study sites. Schools in the same study site will be randomly allocated in a 1:1 ratio to either the intervention or control group using a computer-generated random number system (the simple random sampling method). Randomization will be performed by an independent person at the central coordinating centre at Peking University Clinical Research Institute. The randomization will take place only after the baseline measurements are completed to ensure allocation concealment.

Intervention

We used the Social Ecological Model to identify intervention elements in this multi-faceted health promotion programme [18]. As shown in Figure 2, the programme will target the influencing factors of childhood obesity at both individual (student-focused activities) and environmental levels (a supportive family and school environment), with the intent to influence the knowledge, attitude and behaviours of school children.

Description of the intervention components

The intervention components are described in Tables 1 and 2.

Student-focused activities: These activities will include health education activities for students, the reinforcement of students' physical activity at school and the regular monitoring of students' weight and height.

Activities towards parents: These activities will include health education activities for parents and the supervision and encouragement of children to increase their physical

activity level outside of school.

Activities towards schools: These activities will include school policies related to obesity prevention and health education activities for teachers.

The smartphone app: Project staff, school teachers and parents will be suggested to install the app titled "Eat Wisely, Move Happily". The app, which was developed based on behaviour change techniques [19], will aid in information diffusion, behaviour monitoring, weight management, assessment and feedback.

Quality control of the intervention

Two manuals ("An Operation Manual for Project Staff Involved in the Multi-component Obesity Intervention among Primary School Students" and "An Operation Manual for School Team Members Involved in the Multi-component Obesity Intervention among Primary School Students") have been developed for implementing and managing this complex intervention. The manuals describe in detail the duties of project staff and school team members (school principals, class teachers, physical education teachers, school doctors/health care teachers) in delivering the intervention. The manuals also describe the detailed workflow of the implementation of each intervention component, i.e., by whom, when, how and to what extent the specific intervention element should be delivered. All of the project staff and school team members will be required to conduct the intervention in accordance with the operation manuals.

During implementation of the intervention, regular field observations will be made and the smartphone app records will be checked. If it is found that schools are not complying

with the study protocol, project staff will communicate with school team members in a timely manner and conduct follow-ups to improve the fidelity of the study results.

Control group

The twelve schools in the control group will not carry out any of the DECIDE-Children intervention components and will continue their usual practice according to their own teaching curriculum during the study period (from September 2018 to June 2020). Participants in the control group will receive the same health education materials that will have been delivered to those in the intervention group immediately after the 21-month follow-up investigation is completed in June 2020.

Outcome evaluation

Table 3 describes the study outcomes, including when and how the study outcomes will be evaluated. Baseline measurements will be conducted in September 2018 for both the intervention and the control groups. Follow-up measurements will be conducted 4 months after the baseline measurements are conducted in January (after one school semester and half way through the intervention), 9 months after the baseline measurements are conducted in June 2019 (after one school year and immediately after the whole intervention programme is completed) and 21 months after the baseline measurements are conducted in June 2020 (after two school years and 12 months after the intervention is completed).

At the baseline and all follow-up visits, anthropometric measures (height, weight, waist and hip circumference, systolic and diastolic blood pressures, body fat percentage) and physical fitness measures (one-minute rope jumping, one-minute sit-up, long standing

jump, shuttle run (50 m×8)) will be collected by the trained outcome assessors using the same device and/or forms according to the standard methods and procedures. The assessors measuring students' height and weight will be blinded to the group allocation of the schools. We will use questionnaires to measure students' behaviours (duration of moderate-to-vigorous physical activity, eating behaviour, sedentary behaviour), school policies for prevention and management of childhood obesity, and other potential moderators/mediators of the intervention (e.g., stage of readiness for behaviour change related to weight reduction). The questionnaires were developed based on previous studies and the pilot study. The questionnaires were found to be feasible for this study and acceptable to students and their parents [20-22].

Outcomes

The primary outcome is the difference between groups in the change in students' body mass index (BMI=weight (kg)/(height (m))^2) immediately after the intervention completion (9 months after the baseline measurements are conducted). The secondary outcomes include the change in BMI one year after the intervention is completed (21 months after the baseline measurements are conducted). In addition, we will compare the following indices between groups at the follow-up visits: 1) change in students' BMI z-score (standard deviation score will be calculated based on the World Health Organization criteria [23]); 2) change in prevalence and incidence of childhood overweight/obesity defined according to the criteria for Chinese children and adolescents [24]; 3) change in students' waist circumference, waist-to-hip circumference ratio and systolic and diastolic blood pressures; and 4) change in students'

body fat percentage, physical fitness measures, behavioural outcomes (including students' duration of moderate-to-vigorous physical activity, students' eating behaviour and students' sedentary behaviour) and other outcomes (including students' knowledge related to energy balance, school policies for the prevention and management of childhood obesity and stage of readiness for behaviour change related to weight reduction).

Sample size estimation

We assumed that the difference between the two groups in the change in BMI (effect size) would be 0.50 kg/m^2, the standard deviation (SD) of the BMI would be 1.40 kg/m^2, the intra-cluster correlation coefficient would be 0.05 and the rate of attrition would be 10% for the sample size calculation in our study. We aimed to recruit a total of 1,200 students from 24 schools with an average cluster size of 50 students per school. This sample size will provide 88% power with a=0.05 to detect a mean difference of 0.50 kg/m^2 in the change in BMI between groups after the intervention lasting one school year.

Statistical analyses

Statistical analyses will be performed using SAS version 9.4 (SAS Institute Inc., Cary, NC, USA). All statistical tests will be two-sided at the 5% level of significance. Baseline characteristics at both the school and individual levels will be reported by using descriptive statistics.

The primary analysis will be based on the intention-to-treat principle and include all students recruited with the baseline BMIs measured. Generalized linear mixed models

will be used to compare the primary and secondary outcomes at 4, 9, and 21 months after the baseline measurements are conducted, and the models will adjust for the clustering effect and baseline outcome values. The missing data will be treated in the maximum likelihood estimates assuming they are missing at random. The intra-cluster correlation coefficient will also be estimated. Sensitivity analysis will be performed on the primary outcome using the last-value-carry-forward imputation if the percentage of missing data exceeds 5%. For continuous outcomes, we will report pre-, and post-intervention means for the intervention and control groups and model-adjusted mean differences between groups. For binary outcomes, we will report pre- and post-intervention percentages for the intervention and control groups and adjusted odds ratios (ORs) between groups. The 95% confidence intervals (CIs) and associated *P*-values will be calculated. We will also examine whether the differences in the outcomes between the control and intervention groups vary by the three regions (Beijing, Shanxi, Xinjiang), the sex of children, socioeconomic status (mother's education), BMI status at baseline and primary caregivers of the children (parents compared with non-parents).

Process evaluation

Based on the steps and principles described in the conceptual framework by Saunders et al.[25], we will identify the process evaluation elements including fidelity (the extent to which the intervention will be implemented as initially planned), dose delivered (the frequency and intensity of the actual implementation of the programme), dose received (the extent to which students/primary caregivers (parents in most cases)/teachers will be exposed to the intervention, as well as the degree of their satisfaction with the

intervention and materials), reach (the proportions and the characteristics of students/primary caregivers/teachers completing or dropping out of the intervention) and context (family environment and school policies related to obesity prevention and management).

The implementation process data collection procedure will include (1) direct regular field observation and records which will be collected for the quality control of the intervention (e.g., quality and quantity of the intervention sessions and number of students attending the lectures) and will be recorded by the trained project staff; (2) the user logs (e.g., frequency and duration) which will be collected by the smartphone app; (3) school policies related to obesity prevention and management, which will be collected by the questionnaires (Table 3) in both the intervention and the control groups; and (4) interviews with participants (6~8 students per school) which will be conducted in both the intervention and the control groups.

Health economics evaluation

A cost-effectiveness analysis will be employed in the health economics evaluation, and a societal perspective will be used to examine whether the intervention is economically feasible. Intervention costs will include hours spent by project staff, school staff, and students' primary caregivers (parents in most cases) for all the intervention activities and material expenses. Only the time spent by the project staff in implementing the intervention will be included. Time costs will be based on personal employment compensations if available or average compensations in the local areas for similar types of employees. Material expenses will be based on the actual purchasing prices. An

incremental cost-effectiveness ratio will be calculated and a sensitivity analysis will be used to vary key parameters to examine the robustness of the health economics results.

Patient and Public involvement

We will conduct focus group discussions and interviews with key stakeholders (children, parents, teachers, school principals, local health, and education officials) by refining the intervention approach. We will not involve any of the stakeholders in other aspects of the research study, including idea development, design of the study, implementation of the protocol, data collection, and analysis and interpretation of the results. The results of the study will be disseminated through publication in peer-reviewed journals, presentations at conferences and in lay summaries provided to school staff, students and parents. The benefits and burden of the intervention will be assessed by children and their primary caregivers through self-reported questionnaires at the end of the intervention.

Trial status

The trial started and the recruitment of schools and children was completed in September 2018. Baseline measurements were conducted in the last few weeks in September 2018. The intervention lasting one school year started at the end of September 2018 and was completed in June 2019. The 4-month follow-up measurements started and were completed in January 2019. The 9-month follow-up measurements started and were completed in June 2019. The 21-month follow-up measurements will be completed in June 2020.

Ethics and dissemination

This study was reviewed and approved by the Peking University Institution Review Board (IRB00001052-18021). Any amendments to the study protocol will be submitted for IRB approval prior to implementation. Written informed consent will be obtained from all students and their parents. All data collected will be entered into an electronic database with de-identified information. The database will be accessed only by designated staff with a password. The results will be disseminated through publication in peer-reviewed journals, presentation at conferences and in lay summaries provided to school staff and participants. Upon completion of the trial and after the publication of these results, the data will be made available upon request by contacting the corresponding author of this protocol.

Discussion

Non-communicable diseases, especially cardiovascular diseases, have contributed to the public health burden worldwide. Preventing childhood obesity in early life may have the greatest long-term effects in curbing this widespread burden. Although several childhood obesity intervention studies have been conducted in China, research gaps exist in terms of methodological flaws, process measures, and sustainability of the intervention. The DECIDE-Children study is based on theory-driven and systematic developments (e.g., systematic review [8], qualitative interviews, panel discussions and a pilot study [15]) and serves as one of the first examples of a rigorously developed and evaluated childhood obesity prevention programme that will be implemented in eastern, central and western regions of China.

Our DECIDE-Children study can overcome poor adherence to the intervention

components, which is a weakness of most previous studies, due to our favourable collaborations with local education authorities as well as the rigorous quality control of implementing the intervention. This study also has several other distinguishing features: 1) randomization by an independent person not involved in the study, blinding of key outcome measures, and a detailed process evaluation plan will help to provide study results of high quality; 2) a follow-up investigation will be conducted one year after the intervention is completed to determine the sustainability of the effects of the intervention; 3) a smartphone app will be employed to assist in providing information on, monitoring and providing feedback on the behaviours and body weight of the children; 4) three centres located in eastern, central and western regions of China will be involved in the study to reflect the different levels of economic development in China; and 5) most of the intervention components (school polices, regular monitoring of students' weight and height, reinforcement of students' physical activity at school, health education activities for students) will be integrated into the regular academic schedule of each intervention school.

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Authors' contributions

HJW and YFW conceived the project. HJW, ZL, YFW, WYN and HJL were involved in design of the study and development of intervention materials. ZL wrote the first draft of the manuscript. XXF, YL, AYG and FZ contributed to implementation of the program. HF contributed to economic evaluation. PG contributed to statistical analysis plan. All authors approved the final manuscript.

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Competing interests statement

None.

Table 1 Description of the intervention components implemented in the DECIDE-Children study

Intervention components	Descriptions of the content, frequency, and duration	Person responsible
1. Student-focused activities		
Health education activities for students	(1) Frequency and duration A total of ten activities (each lasting 40 minutes) will be provided once every two to three weeks (six activities will be arranged in the first semester, and four will be arranged in the second semester). (2) Different kinds of activities The ten activities will include seven health education lectures and three theme class meetings. The focus of the health education lectures will be on information diffusion, while the focus of theme class meetings will be on consolidation of the key messages learned in health education lectures through interactive and interesting group work (e.g., "Let me guess"). (3) Content 1) Information diffusion Key messages will include the benefits of healthy weight, measurements and assessments of weight, and methods of achieving a healthy weight (not eating excessively; not drinking sugar-sweetened beverage; eating less high-energy food; less sedentary behaviours; performing more physical activity). Health education books and "nutrition evaluation turnplate for Chinese primary and middle school students" will be delivered to students. Health education messages will also be spread through posters on campus or in the classroom.	The trained class teachers

	2) Promotion for translating knowledge into action "Small hand in big hand" homework (e.g., "challenge of three days away from screen") will be arranged at the end of each health education activity. 3) Feedback and encouragement for BMI and behaviour change Feedback of regular monitoring results of students' BMIs and behaviours will be provided in each health education activity. The students with good performance will be encouraged.	
Reinforcement of students' physical activity within school	1) Students will be instructed by physical education teachers to perform physical activities with moderate-to-vigorous intensity at school for at least one hour per school day (including physical education classes, class-break exercise, extracurricular activities). The aim of this component will be to improve the adherence to the Chinese national requirement for 'One-Hour Physical Activity On Campus Every School Day'. If a school has met this requirement, no extra physical activities will be added at the school; otherwise, extra physical activities (i.e. physical education classes, exercises during breaks in class or extracurricular activities) will be added to the school schedule. The monitoring of the implementation of these extra physical activities will be continuous within the intervention period for the intervention group; 2) Physical education teachers will be advised to teach students at least one sports game during each extracurricular activity.	The trained physical education teachers
Regular monitoring of students' weight and height	1) Monthly monitoring Students' weight and height will be monitored monthly, and the data will then be input into the computer management system in a timely manner and shown in the smartphone app (described below); 2) Weekly monitoring	The trained school doctors/health care teachers with the assistance of the trained project staff (for monthly monitoring); The trained project staff (for data input

	Students' weight will be monitored weekly by the students themselves in the classroom.	of monthly monitoring) Students (for weekly monitoring)
2. Activities towards parents (providing a supportive family environment)		
Health education activities for parents	1) Frequency and duration At least one activity (lasting for approximately 40-60 minutes) will be held at the beginning of each semester. One more activity will be held in the middle of the first semester. Another activity will also be held in the middle of the second semester if necessary (for example, if the fidelity of the data is unsatisfactory). 2) Contents ➢ For the first activity Key messages will be similar to those for the health education activities for students (described above). Parents will also be taught to use the smartphone app. ➢ For other activities Project staff will provide feedback about students' weight status and behaviours to parents. Face-to-face group discussions will be established between the project staff and parents.	The trained project staff
Reinforcement of students' physical activity outside school	1) Parents will be instructed to supervise and encourage students to perform physical activities outside of school for 30 minutes per weekday and 1 hour per weekend day; 2) Recommendations for physical activity outside of school will be provided through the smartphone app once every two months; 3) Students will be encouraged to participate in sports games outside of school that will be taught by their physical education teachers during extracurricular activities.	Students' parents
3. Activities towards schools (providing a supportive school environment)		

School policies related to obesity prevention	The following school policies will be suggested: 1) "Not selling": Not selling unhealthy snacks[1] or sugar-sweetened beverages within school; 2) "Not eating": Telling students not to eat unhealthy snacks or drink sugar-sweetened beverages at school; 3) "Not buying": Students being educated by class teachers not to buy unhealthy snacks or sugar-sweetened beverages around school.	The trained school principal; The trained class teachers
Health education activities for school teachers	<u>1) Frequency and duration</u> The activity will be held once (lasting for approximately 40 minutes) in the first month of the intervention. School teachers participating in this programme at each school (school principal, class teachers, school doctors/health care teachers and physical education teachers) will be required to attend the activity. <u>2) Content</u> Key messages will be similar to those for the health education activities for students (described above). School teachers will also be taught to use the smartphone app.	The trained project staff
4. A smartphone app assisted in implementation of the intervention		
The smartphone app ("Eat Wisely, Move	<u>1) Information diffusion (the behaviour change technique (BCT) used: providing information on consequences of behaviours)</u>	The smartphone app (installed by parents, school teachers and project

[1] "Healthy snacks" refer to dairy products, fresh vegetables or fruits and natural unprocessed nuts which are eaten at times other than at main meals. "Unhealthy snacks" refer to snacks other than the three kinds of healthy snacks.

Happily")	The smartphone app will provide information to parents, class teachers and project staff in accordance with the health education activities. 2) Behaviour monitoring (the BCT used: prompting the self-monitoring of behaviours) Parents together with their children will be asked to record the diet and physical activity behaviours of students in the app weekly, and then they will receive individualized feedback related to these behaviours (described in Table 2). 3) Weight management (the BCT used: prompting self-monitoring) According to the monthly monitoring of students' weight and height (described above), parents, school teachers and project staff will view the recent weight status (categorized according to the BMI percentile criteria [24]), changes compared with previous records of the students and the individualized feedback related to weight management (described in Table 2). 4) Assessment and feedback (the BCT used: providing feedback on performance) The smartphone app will also provide a synthetic and individualized assessment that will combine changes in the behaviours and weight status of the students. The four kinds of feedback are shown in Table 2.	staff) and the computer management system (utilized by project staff)

Table 2 The four kinds of regular evaluation feedback messages provided to all stakeholders by the smartphone mobile app on the basis of data from the regular monitoring of children's weight, height and behaviours

		Results automatically judged according to the heights and weights measured at the regular monitoring intervals	
		Positive results (BMI decreases in students who are overweight or obese, or BMI increases in students who are underweight)	Negative results (BMI increases in students who are overweight or obese, or BMI decreases in students who are underweight)
Results automatically judged according to the diet and physical activity behaviours recorded regularly	Full marks/ getting better	**Feedback 1**: "Your child is doing a great job. The weight changes are consistent with the changes in the diet and physical activity behaviours. Keep it up!"	**Feedback 2**: "Your child's weight has not improved, but the diet and physical activity behaviours are good. It might be that weight improvement requires long-term adherence to a reasonable diet and physical activity behaviour, or that the behaviour records are inaccurate. Please continue to improve!"
	Unchanged/ getting worse	**Feedback 3**: "Your child has improved or maintained a healthy body weight, but there is still room for improvement in the diet and physical activity behaviours. Keep working!"	**Feedback 4**: "Your child's weight has not improved, and the diet and physical activity behaviours also need improvement. Please continue to work hard!"

Table 3 Outcome measurements for the DECIDE-Children study

Outcomes	Time				Device (Manufacturer, model)	Method
	Baseline	4 months after baseline	9 months after baseline	21 months after baseline		
Anthropometric measures						
Height	√	√	√	√	Stadiometer (Huateng GMCS-1)	Measured to the nearest 0.1 cm at least twice
Weight	√	√	√	√	Lever scale (Wujin RGT-140)	Measured to the nearest 0.1 kg at least twice
Waist circumference	√	√	√	√	Tape (MyoTape)	Measured to the nearest 0.1 cm at least twice
Hip circumference	√	√	√	√	Tape (MyoTape)	Measured to the nearest 0.1 cm at least twice
Systolic and diastolic blood pressures	√	√	√	√	Electronic sphygmomanometer (Omron HBP-1300)	Measured to the nearest 1 mmHg at least twice
Body fat percentage	√		√		Body component instrument (Tanita MC-780 MA)	According to the standard procedure
Physical fitness measures						
One-minute rope jumping	√		√		Physical fitness measures will be assessed by trained outcome assessors according to the standard procedure.	

One-minute sit-up	√	√	
Long standing jump	√	√	
Shuttle run (50 m×8)	√	√	
Behavioural measures and other measures			
Students' knowledge related to energy balance	√	√	We will use 8 items to assess the change in students' knowledge related to energy balance. For example, we will ask students, "Is it correct that drinking sugar-sweetened beverage cannot substitute drinking water ?" Three choices will be provided (right; wrong; not clear). Students should finish the questionnaires in the classroom in the presence of the trained outcome assessors, who can provide guidance and help.
Students' duration of moderate-to-vigorous physical activity	√	√	The questions were designed based on a validated 7-day physical activity questionnaire (PAQ; kappa values for test-retest results were 0.46~0.79 (different measures of activity), face validity and content validity were good based on experts' evaluations, and the correlations between the PAQ and Caltrac motion sensor data ranged from 0.38 to 0.46 (different measures of activity) for boys) [21]. Students should finish the questionnaires in the classroom in the presence of the trained outcome assessors, who can provide guidance and help.
Students' eating behaviour	√	√	We will use the "Children Eating Behaviour Questionnaire" (CEBQ) to assess students' eating behaviours, including their responsiveness to food and enjoyment of food. This 35-item instrument has been shown to have relatively

			good reliability [22]. The questionnaires should be self-reported by parents or other primary caregivers of the students.
Students' sedentary behaviour	√	√	We will use a self-designed questionnaire to determine the average duration of completing homework, watching television and playing electronic devices per day during the last week. Students should finish the questionnaires in the classroom in the presence of the trained outcome assessors, who can provide guidance and help.
School policies for the prevention and management of childhood obesity	√	√	The questionnaires should be filled by the trained investigators after face-to-face interviews with school principals, doctors/health care teachers and physical education teachers.
Stage of readiness for behaviour change related to weight reduction	√	√	We will use two items for the assessment. First, we will ask "Have you taken action to reduce your weight during the last three months?" Yes/no choices will be provided. In addition, we will ask "Do you currently intend to reduce your weight?" Five choices ranging from "completely do not intend" to "intend to very much" will be provided. Students should finish the questionnaires in the classroom in the presence of the trained outcome assessors, who can provide guidance and help.

Figure 1 Flow of the DECIDE-Children study

Figure 2 The Social Ecological Model as applied to the DECIDE-Children study

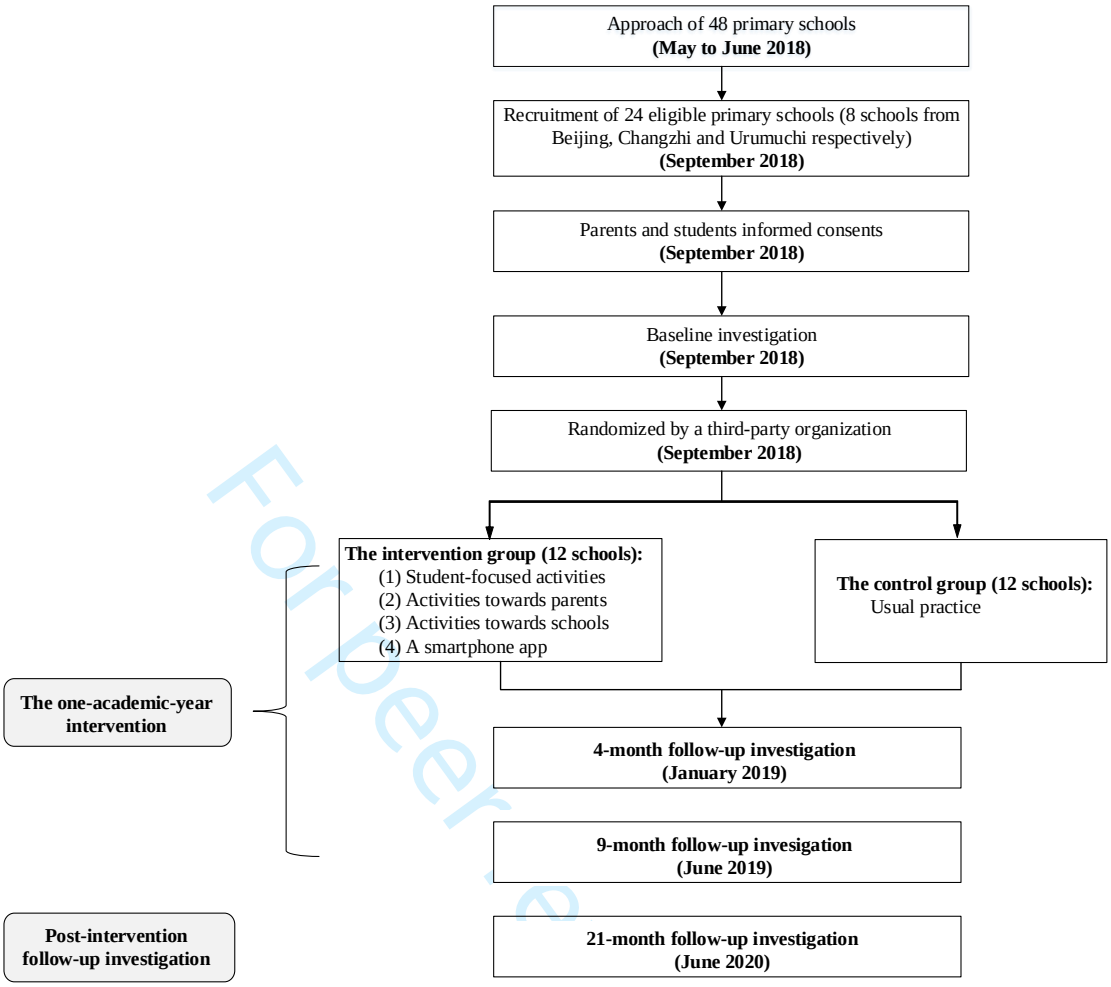

Figure 1 Flow of the DECIDE-Children study

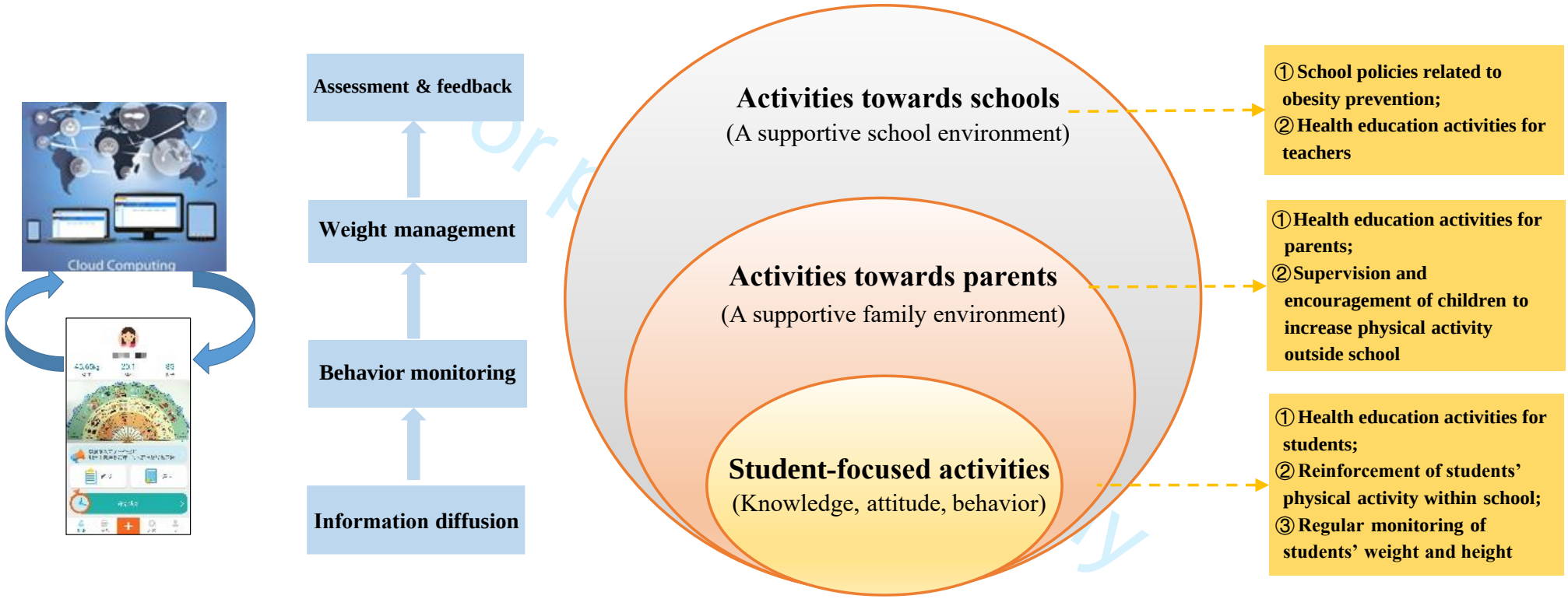

Figure 2 The Social Ecological Model as applied to the DECIDE-Children study

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 SPIRIT reporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. Ann Intern Med. 2013;158(3):200-207

		Reporting Item	Page Number
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	3

Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	This information is provided in the trial registration website.
Protocol version	#3	Date and version identifier	This information will be provided as soon as the manuscript revision is finally completed.
Funding	#4	Sources and types of financial, material, and other support	25
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	24-25
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	n/a. This study was not sponsored by any individuals or companies. The funder name and number has been provided in Page 25.
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	26

		report for publication, including whether they will have ultimate authority over any of these activities	
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)	25
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	5-7
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	6
Objectives	#7	Specific objectives or hypotheses	7
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)	8

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	8
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)	9-10
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	11, Table 1-2
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)	n/a. This is a childhood obesity prevention intervention. Based on our previous experiences, it is less likely that discontinuing or modifying allocated interventions for a given trial participant will take place.

Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	11-12
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a. This is a childhood obesity prevention intervention. Based on our previous experiences, it is less likely that concomitant care and interventions will take place.
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	13-14, Table 3
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and	Figure 1

		washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	
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	14
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	9-10
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	10
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing	10

		any steps to conceal the sequence until interventions are assigned	
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	9-10
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	13
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	n/a. The assessors measuring students' height and weight will be blinded to group allocation of the schools. We did not anticipate any necessary circumstances when unblinding is permissible.
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	13

		collection forms can be found, if not in the protocol	
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	15
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	3
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	15
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	15

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)	15
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	18
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	n/a. This is a childhood obesity prevention intervention. Based on our previous experiences, it is less likely that discontinuing interventions will take place.
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events	16 (we will use questionnaires to collect and

		and other unintended effects of trial interventions or trial conduct	assess any adverse events or other process data)
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	7 (This study is one of the five independent studies of the overall DECIDE project. This overall project is audited by the funder (National Key R&D Program of China).
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	2-3
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)	2-3
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	10
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data	n/a. This study will not collect biological specimens.

		and biological specimens in ancillary studies, if applicable	
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	3
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	26
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	3
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. This is a childhood obesity prevention intervention. Based on our experiences, it is less likely that ancillary and post-trial care will take place.
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public,	3

		and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	n/a
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n/a
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	10
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 This study will not collect biological specimens.